Above reproach: Developing a comprehensive ethics and compliance program / Commentaries / Reply
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ABOVE REPROACH: DEVELOPING A COMPREHENSIVE ETHICS AND COMPLIANCE PROGRAM

Executive Summary

How can a healthcare organization improve the public's confidence in the conduct of its business operations? What can it do to ensure that it can thrive despite being the subject of public and governmental scrutiny and doubt? Healthcare providers must establish standards of conduct that are above reproach and ensure that those standards are clearly articulated and strictly adhered to.

This article descibes the merits of a comprehensive ethics and compliance program, suggests five basic elements of such a program—organizational support/structure, setting standards, creating awareness, establishing a mechanism for reporting exceptions, and monitoring and auditing—and then demonstrates how those elements should be applied in several high-risk areas.

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Fundamentally, an ethics and compliance program has two purposes: to ensure that all individuals in an organization observe pertinent laws and regulations in their work; and to articulate a broader set of aspirational ethical standards that are well-understood within the organization and become a practical guideline for organization members making decisions that raise ethical concerns. Every ethics and compliance program should contain certain fundamental aspects. First, the effort must have the active support of the most senior management in the organization. To instill a commitment to ethics and compliance absent a clear and outspoken commitment to such purposes by organization leaders is simply impossible. Second, an ethics and compliance program is fundamentally about organizational culture—about instilling a commitment to observe the law and, more generally, to do the right thing. Third, ethics and compliance are responsibilities of operating management (sometimes called line management). Although staff such as compliance officers are obligated to provide the necessary resources for a successful program and to design the program, such staff officers cannot achieve implementation and execution. Only operating managers can do that. Fourth, an ethics and compliance effort should be about the conduct of individuals, not about "checking the boxes" in a model plan or generating attractive written or educational materials. Such an effort is about individuals on a day-to-day basis knowing what is expected of them and doing it and about never compromising integrity, regardless of pressures faced.

A great deal of progress has been made in healthcare organizations in the development of increasingly sophisticated ethics and compliance programs. A particularly energetic focus has been placed on these programs since formal government guidance regarding compliance programs was first issued in the laboratory area about two years ago and as more sophisticated automated monitoring tools have been developed.

As ethics and compliance programs have become more sophisticated, certain best practices have been established. This discussion will set forth approaches to ethics and compliance in the context of what are believed to be illustrative best practices. Much of what is described here is descriptive of the efforts of Columbia/HCA Healthcare Corporation from October 1997 to the present[1]; however, this article has been presented not as a mere descriptive piece but rather as a set of normative guidelines. We hope that other healthcare providers will find this to be of practical use. Provider settings pose certain unique challenges that are specifically addressed in this discussion; however, many of the issues raised can be adapted to other healthcare organizations. For simplicity's sake, because the authors of

this article all work on a daily basis primarily with hospitals, the article is written from a hospital perspective.

OBJECTIVES

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) issued *Compliance Program Guidance for Hospitals* (OIG 1998b) in February 1998 (hereafter termed "the model guidance"). In the model guidance, the OIG identified its rationale for why a hospital should establish a compliance program:

> *Fundamentally, compliance efforts are designed to establish a culture within a hospital that promotes prevention, detection and resolution of instances of conduct that do not conform to federal and state law, and federal, state and private payor healthcare program requirements, as well as the hospital's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process. The existence of benchmarks that demonstrate implementation and achievements are essential to any effective compliance program. Eventually, a compliance program should become part of the fabric of routine hospital operations. (OIG 1998b, 2)*

The model guidance is a beginning point; however, each healthcare organization must determine its objectives with respect to its particular ethics and compliance program, tailoring the program to its own needs and aims.

ELEMENTS

The model guidance articulates seven elements that a comprehensive compliance program should include:

1. The development and distribution of written standards of conduct, including policies and procedures "that promote the hospital's commitment to compliance . . . and that address specific areas of potential fraud" (OIG 1998b, 7);
2. Designation of a chief compliance officer and other appropriate bodies;

3. Development and implementation of education and training;
4. Maintenance of a process for reporting exceptions;
5. Development of a system to respond to allegations of improper activities, accompanied by appropriate discipline;
6. Development of an audit and monitoring system; and
7. "The investigation and remediation of identified systemic problems and the development of policies addressing the nonemployment or retention of sanctioned individuals" (OIG 1998b, 5).

A healthcare organization should assess these elements and determine whether additional elements are necessary, and then determine how the elements chosen can best be accomplished within the organization's structure. One method of organizing the elements is by identifying organizational structure/supports; setting standards; creating awareness; identifying exceptions; and monitoring program performance and auditing.

Identifying Organizational Structure and Supports

Within its particular structure, the organization should determine how to assign responsibility throughout the organization for elements of the compliance program. Figure 1 illustrates how a compliance program can be implemented through the organizational structure. At a minimum, a healthcare organization should:

1. Establish an ethics and compliance committee of its board of directors or board of trustees ("board committee");
2. Establish an ethics and compliance committee comprised of organization senior managers ("organization committee");
3. Appoint an ethics and compliance officer (ECO) ("organization ECO") who should be a senior executive with accountability to the chief executive officer (CEO) and/or board of directors;
4. Identify "responsible executives" throughout the organization who are the subject matter experts in compliance risk areas and whose responsibilities should include developing policies and procedures, developing

Figure 1.
Organizational Structure and Supports
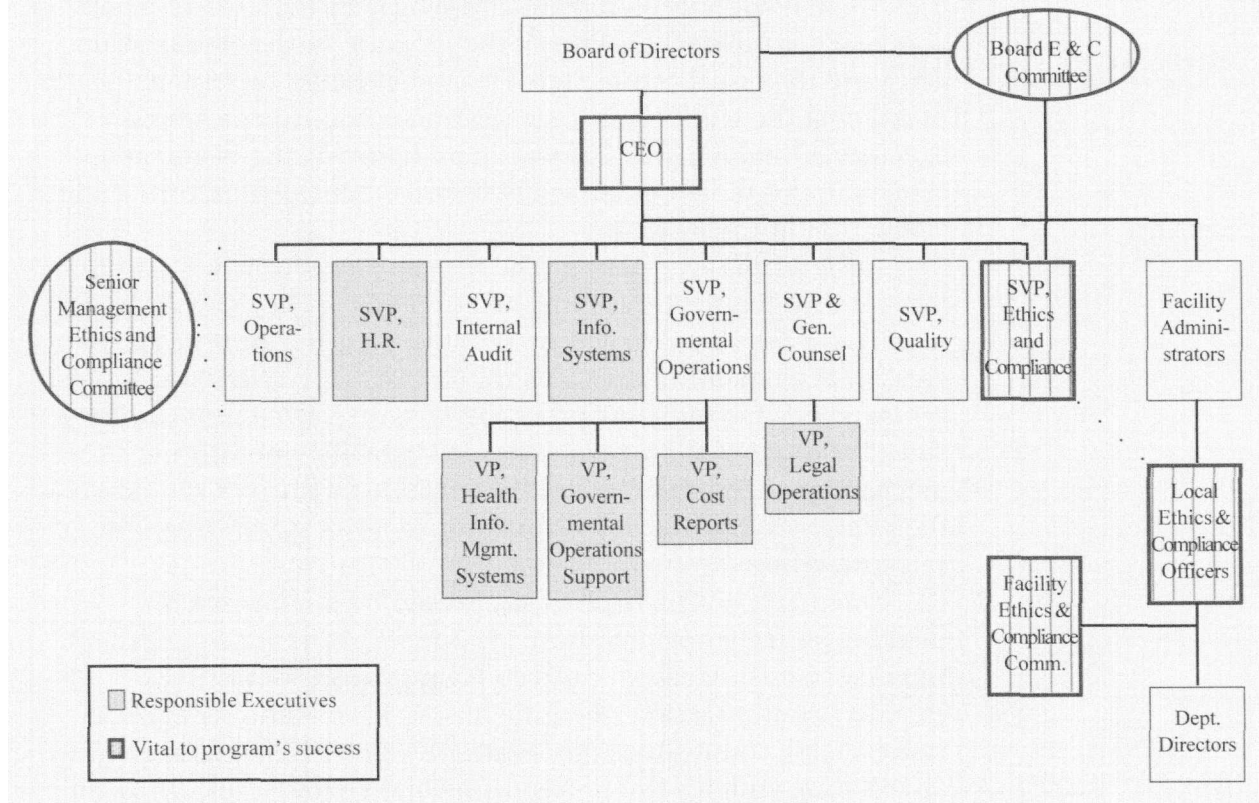
and delivering compliance education and training, and monitoring compliance activities; and

5. If the organization is a multihospital organization, identify local ethics and compliance officers ("local ECOs") to oversee the implementation of the program at the local level.

Each organizational component must be given distinct objectives and clear instruction as to how to achieve them.

Committees. For instance, the board and organization committees should have charters that specify their activities and duties, and should keep minutes of their meetings. Additionally, the committees should periodically report their activities to the entity or individual to which they report, and such entities or individuals should monitor the activities of the committees and provide leadership and direction where necessary.

Organization ECO. The organization ECO should be responsible for the overall development and implementation of the ethics and compliance program and should be required to report regularly regarding the status of the program to the organization CEO and the board committee. He or she should be responsible for overseeing the work of the organization committee, responsible executives, and local ECOs, and should provide the vision and leadership for the program and be involved in the monitoring and evaluation of the program.

Responsible Executives. The responsible executives should be led and coordinated by the organization ECO. They should be required to develop detailed compliance plans for their respective areas of responsibility that, at a minimum, address the basic risks, set standards (policies and procedures), create awareness (training and education) of those standards, and establish monitoring mechanisms. To be successful, responsible executives should view the relationship with the organization ECO as an additional line of accountability.[2]

Local ECOs. The local ECOs should be responsible for carrying out the program at the local level. At a minimum, they should establish facility ethics and compliance committees ("facility committees") when the hospital is of sufficient size to make such a committee appropriate, develop mechanisms for distributing policies and procedures, conduct and track ethics and compliance training and education, assist in investigating and resolving exceptions that are reported to the organization's ethics line or that are otherwise brought to the local ECO's attention, monitor and evaluate ethics and compliance efforts at the hospital, and report to the organization ECO as to the ethics and compliance activities and issues at the hospital or other local unit of activity.[3]

Setting Standards

A vital element of an effective ethics and compliance program is the development and dissemination of consistent ethics and compliance standards. Formal standards usually take the form of a code of conduct and policies and procedures.

Code of Conduct. To be most effective, a code of conduct should be easy to understand and must be written in a simple, straightforward style. Many codes suffer from being overly legalistic in their approach. The code must reflect an assessment of the compliance risks that have been identified in the organization. It should include, at a minimum, a statement of the organization's

Figure 2.	Figure 3.
Topics for a Code of Conduct	**Topics for Policy and Procedure Development**
1. Regulatory compliance;	1. Billing;
2. Dealing with accrediting bodies;	2. Coding;
3. Confidentiality and preservation of business information (including medical records) and information systems;	3. Confidentiality of patient information;
4. Workplace conduct and employment practices, including conflicts of interest, diversity, harassment, health and safety, insider trading (if the organization involved is a publicly held corporation), and personal use of organization resources;	4. Medicare cost reports;
	5. Physician relationships;[4]
	6. Prohibiting employment, vendor, and billing relationships with sanctioned individuals or entities;
	7. Self-reporting;
5. Marketing practices;	8. Business courtesies;
6. Environmental compliance;	9. Records management;
7. Business courtesies; and	10. Environmental compliance;
8. Political activities.	11. Information security and related topics; and
	12. The Emergency Medical Treatment and Active Labor Act (EMTALA).

mission and values, a summary of the standards of conduct that are expected of the organization's employees, a statement that discipline will be imposed for failure to adhere to the code, and identification of the resources available to the organization's employees to ask questions and obtain additional information or clarification of the standards. Including some practical questions and answers is helpful. Suggested topics for a code of conduct are listed in Figure 2.

An organization that is developing a code should provide the opportunity for large segments of the organization to have input into the code. A draft could be circulated and comments incorporated where practical. That the organization's employees feel a sense of ownership of and pride in the code is most important. The process described is intended to get "buy-in" throughout the organization and prevent the appearance that the code has been imposed by a handful of senior managers. Employees will be more likely to be committed to the code if such is the case.

Policies and Procedures. Policies and procedures should be developed in each major area of compliance risk (see Figure 3), and each healthcare organization must assess its particular needs. An organization should consider developing policies that cover all the topics raised in the model guidance (OIG 1998b). Many policies will be based on pertinent laws and regulations, though some will be at the election of the organization and reflective of its values rather than an externally imposed legal obligation. Policies should

be written in a manner that is clear and concise, thereby creating more likelihood that they will be understood and followed. Most policies should be able to stand on their own, but in some instances it may be necessary to develop implementation guidelines, checklists, or other materials to assist in further explaining and operationalizing policies and procedures. Additionally, to the extent feasible, policies should include a mechanism for testing the employees' understanding of and adherence to them. A self-audit or monitoring tool for some policies is very helpful.

How the policies are developed will vary from organization to organization, but in any case the subject matter experts who are responsible for the given area of risk in the organization should have primary responsibility for drafting the policy and any accompanying materials, which should be circulated to affected individuals (or, for multihospital entities, to all facilities) for feedback and input. The organization committee should review the policy and determine whether to adopt it. Once adopted, the policy should be distributed or notice should be provided, letting employees know where the policy can be found. Brief explanatory material can be helpful when the policy is transmitted. If an organization has a number of policies, a short summary of each may be helpful for employees who are seeking guidance on a particular issue. Additionally, if employees are likely to access policies or related information on the organization's intranet, the policies should be included there as well.

Creating Awareness

Once an organization has adopted standards, it must ensure that each standard is communicated and understood by all who are affected by the standards. The organization must determine the best methods for articulating those standards and for educating employees regarding the expectations established by the standards, realizing that one method may not address every need. If the organization's compliance training needs are extensive, it may be helpful to develop a training architecture that identifies categories of employees and the training that each needs to receive. Figure 4 illustrates the training architecture used by Columbia/HCA. The architecture includes a learner taxonomy (the different levels of knowledge the employees will need—e.g., awareness training versus application training), the methods of delivery (e.g., in-person, video, CD-ROM, or Internet), the methods for testing employees' learning, and the mechanism for tracking the training.

Figure 4.
Compliance Training Architecture

	CEO	CFO	CNO	COO	ECO	Health Info. Mgmt. Director	Coder	Bus. Office Director	Bus. Office Staff	Operations Counsel
Physician relations										
Agreements/ contracts with physicians	*	*			*					*
Appropriate access										
Confidentiality of patient information	*	*	*	*	*	*	*	*	*	*
Billing										
Laboratory billing		*			*			*	*	*
General billing non-laboratory		*			*			*	*	*
Laboratory panels/ profiles/ orders		*	*	*	*	*	*	*	*	*
Medical necessity	*	*			*	*	*	*	*	*
Coding										
Coding (both inpatient and outpatient)	*	*	*	*	*	*	*			
Cost reports										
Reimbursement manual	*	*								
Settlement data	*	*						*		
Allowable costs	*	*								
Related party transactions		*								
Physician issues (e.g., time studies)	*	*								
Allocation basis (statistics used)	*	*								

Once the needs for the training and delivery method(s) are determined, the content for a particular session must be developed. In some instances, content may already exist and may be purchased. When the healthcare organization must develop its own content, it is best to rely on subject matter experts within the organization to do so. The organization may also find that the content does exist but is not in a format that works well with the training delivery systems in place (e.g., content is in a video format but the most effective or efficient delivery method for the

organization is the Internet) or that is affordable to the organization. In some instances, the vendor may be able to convert the content to another delivery mechanism. A final consideration in developing training materials is whether any special needs should be addressed—for example, does the organization need to develop closed-captioned videos, should it print the code of conduct in Braille or have it available audibly, or do any of its materials need to be available in a second language?

Beyond formal training programs, an organization should consider other methods of communication, both internal and external, that will advance the objectives and share the accomplishments of the organization's ethics and compliance program. Senior managers may communicate a consistent message at various opportunities, such as at regular meetings of managers and through written communications with organization staff. If an organization has an intranet system, a site that includes its code of conduct, compliance policies and procedures, and descriptions of other elements of its program could be established to ensure internal communication of the program.

To the extent that healthcare organizations have developed innovative or creative approaches to ethics and compliance, they fulfill an element of organizational social responsibility by making such materials available to others in healthcare, thereby promoting enhanced values and standards among all healthcare organizations.

Similarly, an organization with an Internet website should consider developing an ethics and compliance site that includes important program information to assist with external communication of its program. Participation in professional associations and other organizations can provide opportunities for public discussion of the organization's program (with the added benefit of having the opportunity to learn from others in such organizations). To the extent that healthcare organizations have developed innovative or creative approaches to ethics and compliance, they fulfill an element of organizational social responsibility by making such materials available to others in healthcare, thereby promoting enhanced values and standards among all healthcare organizations.

Identifying Exceptions

Even the most effective compliance training program will not prevent a small number of employees from engaging in activity that does not comply with the organization's policies and procedures or with the law. Every ethics and compliance program

needs a method for identifying and resolving this type of conduct. The need for this exception-reporting mechanism is reinforced by the OIG model guidance, which states:

> *The OIG encourages the use of hotlines (including anonymous hotlines), e-mails, written memoranda, newsletters, and other forms of information exchange to maintain these open lines of communication. If the hospital establishes a hotline, the telephone number should be made readily available to all employees and independent contractors, possibly by conspicuously posting the telephone number in common work areas. Employees should be permitted to report matters on an anonymous basis. Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies, regulations or statutes should be documented and investigated promptly to determine their veracity. A log should be maintained by the compliance officer that records such calls, including the nature of any investigation and its results.* (OIG 1998b, 33)

In addition to meeting the OIG's expectations by providing a formal method to report exceptions, other benefits result from operating a formal internal-reporting mechanism.

The mechanism reduces the frequency of litigation.

A formal internal-reporting mechanism provides an outlet for employee and other concerns. Some of these concerns are either remedied or addressed as part of the exception-reporting process. For those concerns that are remedied, pursuing litigation is unnecessary. For some of the concerns the explanation provided will sufficiently diminish the caller's concerns and eliminate the need for a lawsuit. In all instances an internal method for employees to raise concerns outside the employee's chain of supervision provides an additional alternative to litigation.

The mechanism promotes compliance and constructive resolution of complaints.

On occasion, supervisors take a shortcut or ignore an employee concern, possibly because they believe "nobody will ever know." An internal-reporting mechanism serves as a check on such behavior by providing the possibility that someone outside the

supervisor's organization might examine the issue and find the supervisor's conduct lacking.

The mechanism improves employee morale.

Establishing a credible internal-reporting mechanism sends a strong signal to employees that the organization is committed to ethical conduct and that it values employees' input.

Policy goals for an internal-reporting mechanism should include handling cases in a manner that protects the privacy of the caller; investigation in a timely manner by persons with a sufficient level of expertise and who are not implicated in any wrongdoing described in the initial call; and ensuring effective disciplinary or corrective action for all cases where misconduct or inappropriate activity occurred.

For an internal-reporting mechanism to be effective, employees and others must have an underlying confidence that reporters will not be subjected to retaliation if they make a good-faith report of potential misconduct. The prohibition on retaliation for good-faith reports of potential misconduct should be unequivocally stated in the organization's code of conduct and reinforced both by management statements and vigorous investigation and enforcement of reports of retaliation. However, callers may still perceive a necessity to protect their identity prior to expressing their concern. For those callers, the reporting mechanism must provide methods to protect their identity (see Figure 5).

> **Figure 5.**
> **Safeguards for the Internal-Reporting Mechanism**
>
> 1. A third-party vendor receives calls via a toll-free number,[5] which provides reassurance to individuals who are leery of speaking to an official of the organization.
> 2. A caller's permission is obtained before his or her name is supplied to investigators.[6] If the caller does not want the name forwarded, a redacted call summary is prepared and questions to the caller are routed through the internal-reporting mechanism staff.
> 3. Investigators are reminded of the obligation to protect the identity of the caller.
> 4. Internal-reporting mechanism files are secured at all times.
> 5. Memoranda summarizing the results of the investigations do not contain the caller's name.

As a rule of thumb, cases should be assigned to an investigator who is at least two levels of supervision above the alleged wrongdoer. Some allegations of a particularly serious nature or that present particular issues would be most appropriately investigated by someone from outside the hospital or someone with specialized expertise.

If an investigation determines that misconduct or wrongdoing occurred, the appropriate corrective or disciplinary action to

address the issue must be determined and a mechanism should exist to confirm that the corrective or disciplinary action occurred.

All of the above actions should be documented before a case is closed. As the case is closed, the caller who initiated the matter should be contacted with a summary of the results of the investigation and a brief description of the corrective action, if any. However, the internal-reporting mechanism is only one means to determine where exceptions may be occurring. An organization with a thorough ethics and compliance program will additionally focus energy and resources on monitoring and auditing to learn where additional exceptions may exist.

Monitoring and Auditing Program Performance

"Auditing" and "monitoring" are not the same concept. Monitoring uses the control systems, as designed and implemented by management, to direct and correct day-to-day operations. Monitoring systems should be real-time and broad in scope to facilitate appropriate management action. Auditing, in contrast, predominantly consists of retrospectively testing the established monitoring systems to ensure they are functioning as prescribed. Placing reliance upon the results of retrospective, sample-based audits is an unwarranted attempt to use the audit function as a monitoring tool.

This distinction between "monitoring" and "auditing" is consistent with that made by the Treadway Commission (1987) and within internal auditing standards (Institute of Internal Auditing 1995). Auditing should also include a periodic review and challenge of the designed monitoring systems, to ensure those systems continue to properly address the issues facing the organization. Finally, auditing should be proactive in attempting to identify new potential risks to the organization, for which monitoring systems may yet need to be developed.

Monitoring

Monitoring differs from organization to organization and, particularly in large organizations, may even differ within segments of the organization. The tools that will be used to measure a program's effectiveness should be well-defined. More detail is included below in the discussions of several particular risk areas, but basically an organization must establish processes that review how policy and legal requirements are being implemented. If monitoring mechanisms can

be built directly into systems and business processes, that is the most desirable approach. The organization should consider whether appropriate automated monitoring systems are available and, if available, are affordable for the organization. If automated monitoring systems are not available or cannot be developed, the organization should consider developing manual processes to check compliance rates and implementation effectiveness. The organization should also consider who would be responsible for ensuring that appropriate corrective action is taken when the monitoring reveals exceptions. Roles and responsibilities should be clearly defined to determine the root cause of the "problem," determine the method of correction, and communicate the appropriate standards more effectively.

Auditing

Even the best-planned monitoring processes will result in some exceptions, and thus those processes should be audited using the organization's internal auditing staff, assuming that the organization is of sufficient size to have such a capability. Just as the organization needs to consider the nature of various compliance risks to develop its code of conduct, the internal audit function independently should consider the risks and then determine what areas of concern demand audit priority. As part of this risk analysis, the internal audit function should consider existing control structures and the effectiveness of those controls in minimizing or eliminating the potential risks. An internal auditor's greatest contribution to an organization is identifying areas of risk exposure and helping to define appropriate corrective internal control and monitoring systems.

The federal government has provided assistance in this effort by publishing the DHHS OIG Work Plan (hereafter "work plan"), which is released each October 1 and details the government's areas of concern and audit focus for the next fiscal year. The applicability to the organization of each work plan clause should be thoroughly evaluated by the internal audit function and input should be solicited from external auditors, executive management, and other employees whose work is involved with compliance risk areas. This evaluation should identify applicable issues and concerns, potential risks, and any existing controls and monitoring systems relating to the particular work plan elements. All employees should be encouraged to identify, on an ongoing basis, any potential compliance issues and share that information so the organization can prepare a risk evaluation as to issues raised. All available input and data elements should be used; however, the

final proposal as to the nature, timing, and extent of testing must result from the internal auditor's exercise of independence and due professional care considering all the facts and circumstances.

All organizations must deal with the reality of limited resources, and internal audit functions are not exempt from this constraint. Generally, resources will not be available to test all risk areas and existing monitoring systems annually. Thus, the internal audit function's work priorities must be set according to risk. This ranking or proposed audit plan, based on information from various sources, should be presented to the organization's management, including the compliance officer, chief operating officer, and CEO or administrator. After this process, the audit committee of the board of directors or board of trustees should review the audit plan and approve it. The approved audit plan is then executed. However, the audit plan should allow some flexibility or be subject to approved modifications to permit reallocating resources for any new issues identified during the year to be of more significant risk.

> **An internal auditor's greatest contribution to an organization is identifying areas of risk exposure and helping to define appropriate corrective internal control and monitoring systems.**

Internal audit functions are most effective when viewed as "team members" or a "helpful resource" within the organization, rather than as a "management police force." This perception can be accomplished by assuming a "customer relations posture" with the auditee. Throughout the audit process, open communications with the auditee and any other affected department(s) are required. An organization's internal audit staff would be wise to solicit the auditee's input during the audit engagement planning phase; explain organization policies and compliance risks; gather the concerns of the auditee; and work with the auditee to understand how any existing monitoring systems are used by management. The steps to be performed during a particular internal audit should be explained to the auditee. Periodic updates (daily, if necessary) on the progress of the audit should be provided to appropriate management personnel to communicate issues or control deficiencies, jointly consider possible corrective actions, or (in some instances) solicit management assistance for audit completion. A closing conference marks the conclusion of audit fieldwork and summarizes the work and results for management. Recommended monitoring systems or system enhancements are formally presented for management consideration at the closing conference, and exceptions necessitating rebilling or self-reporting are communicated. The auditee should be required to prepare a written action plan that addresses each audit finding—what will be done, when, and by whom.

This written action plan allows the internal auditor a final opportunity to ensure that the auditee understood the audit issues and will pursue appropriate corrective actions. Failure to document an appropriate course of action should be immediately addressed with the auditee and, if necessary, more senior management in that organization. Follow-up of compliance issues is critical, and written action plans can provide the basis for limited follow-up audits or, as is sometimes used, auditee management attestation statements (i.e., that the corrective actions have been implemented).

Overall summary reporting of audits and results must be communicated to executive management, including the ethics and compliance department and the audit committee of the board. The challenge in this process is summarizing diverse and often detailed information into a format that clearly depicts the status of the organization's ethics and compliance program. Again, open and frequent communication with the report users will facilitate their understanding of the outstanding risks to the organization and the effectiveness of the compliance monitoring systems currently in place.

SPECIFIC AREAS OF COMPLIANCE FOCUS

Once an organization determines the basic structure of its ethics and compliance program, it must determine its priorities in actually establishing the program. It would be wise to determine the areas of risk and focus on those that are most important. Although priorities will vary from organization to organization, providers should consider at least the following five areas as priorities: billing, coding, Medicare cost reports, patient confidentiality, and physician relationships. Another area of compliance risk an organization should not overlook is compliance with requirements of accrediting and certifying agencies. A suggested approach to each of these areas follows.

Billing Compliance

One of the significant areas of concern is billing, particularly billing to governmental payors. The complicated rules issued by government agencies have made it imperative that healthcare providers invest a considerable amount of time, resources, and systems to ensure appropriate billing. The development, implementation, and ongoing monitoring of these compliance programs assist providers in these efforts. A healthcare organization establishing a billing compliance program should include, at a minimum, the following areas of risk:

- Laboratory and other fee schedule–based services such as radiology and therapy services;
- Excluded services such as self-administered drugs;
- Inclusive services such as services rendered within three days of an inpatient admission ("three-day window") or bundled as indicated in Correct Coding Initiative (CCI) edits; and
- Medical necessity.

In addition to the model guidance mentioned previously, the OIG has issued model guidance for laboratories (hereafter "the model lab guidance") (OIG 1998a). Both model guidance documents should be used as guides in the development of organization policies, procedures, and processes. By using these model plans as a design template, the areas of risk identified may be developed into organization-wide standards, and monitoring efforts may become standardized to ensure appropriate implementation.

Once risk areas have been identified, specific policies and procedures should be developed. Several topics should be considered when identifying areas for policy and procedure development.

- Outpatient specimen collection;
- Hematology procedures;
- Organ and disease panels;
- Reflex orders;
- Marketing practices;
- Unlisted procedure codes;
- Handling charges;
- Calculated laboratory tests;
- Urinalysis procedures;
- Custom profiles;
- Standing orders;
- Referred laboratory testing; and
- Anatomical and surgical pathology services.

Each area identified above has either been mentioned in the model lab guidance or has been cited as a part of ongoing governmental investigations industry-wide. Additionally, laboratory services are reimbursed on a fee-schedule basis, which requires the astute attention of the provider as it relates to the CCI edits. Services should be billed in accordance with these established guidelines to ensure appropriate bundling of services and accurate reimbursement.

Further, at a minimum, the following other areas of billing risk should be considered:

- Test orders;
- Advance beneficiary notice;
- Patient records;
- Self-administered drugs;
- Medical necessity;
- Three-day window;
- Refunding overpayments; and
- Collection of financial information in the emergency department (EMTALA).

Again, each of the above topics has either been mentioned in the model lab guidance or has been cited as a part of an ongoing governmental investigation.

In the area of billing, an oversight committee should provide strategic direction to those individuals responsible for development of policies, procedures, and processes. This strategic committee should include individuals representing functions related to cost reporting, auditing, coding, information systems, ethics and compliance, and legal to ensure all affected areas are considered during the development process. A development team should use resources such as Health Care Financing Administration (HCFA) manuals, OIG opinions, fraud alerts, and the like to draft necessary policies and procedures. Multidisciplinary teams should be used to further develop such policies to ensure the policy may be operationalized at the appropriate levels within the organization. Teams should be comprised of ancillary services, health information management, the business office, administration, the audit team, information systems, and the physician community. By using this approach, the groundwork will be laid to ensure buy-in and effective implementation of the billing compliance plan. The individuals responsible for development can be used as champions to roll out the plan and get others on board.

One of the greatest challenges in training and education is ensuring that affiliated physicians understand the organization's policies and legal requirements, particularly regarding medical necessity and advance beneficiary notices (ABNs). Thus, an organization should consider developing materials or programs specifically for physicians, such as developing a videotape or a pamphlet that can be provided to the physicians and their office staffs explaining important requirements.[7]

For effective implementation, specific time frames must be established for adoption of policies and procedures. An audit or monitoring process should be established to identify potential billing errors once the policies have been implemented.[8] If resources are constrained, a self-audit process should prove practical and useful.

Finally, implementation of an effective compliance plan as it relates to billing should be viewed as a journey. You never quite reach the final destination. A continuous and ongoing effort is required to identify changes in the billing rules, monitor fraud alerts and OIG advisory opinions, and stay abreast of the ever-changing environment. Policies, procedures, and processes must be updated on a timely basis, and these changes must be communicated throughout the organization to ensure the effectiveness of the plan.

As with all other areas of compliance, an effective billing compliance plan requires a commitment expressed at the most senior management level of the organization. The standardized policies, procedures, and processes developed must be used on a continuing basis. One of the greatest concerns of any compliance program is that there will be execution or implementation shortfalls—that is, that the well-designed program will not become reality in the organization. Evidence of a successful plan is the organization's willingness to commit the necessary resources at each step in the process—standard-setting, awareness-building, and monitoring—to ensure successful implementation of a compliance program.

Coding Compliance

The coding function has received significant attention in the healthcare environment during the last several years. Complete, accurate, and consistent coding has always been a core business fundamental; therefore, a balanced and effective coding compliance program must be implemented. This program must minimize risk exposure and at the same time focus on managing potential financial impact by monitoring for appropriate reimbursement. A truly successful coding compliance program strives to improve the timeliness and quality of medical record documentation and reduce variations in health information management processes including coding, thereby resulting in improved data integrity.

A comprehensive coding compliance program must include a delineation of the standards of performance. These policies and procedures guide all personnel responsible for performing, supervising,

or monitoring the coding of inpatient and outpatient services. The following elements should be included in building a balanced and sound foundation for coding practices in an organization.

Commitment to Data Integrity. One of the important philosophies of an organization should be the commitment to conduct business with integrity and always to render services on a highly ethical level. An organization that has such a philosophy relative to coding practices should issue a statement of its commitment to data integrity (see Figure 6).

Coding Documentation for Inpatient and Outpatient Services. In addition to clearly stating the organization's commitment to data integrity and compliance with the official guidelines for coding and reporting of diagnoses and procedures, an entity must define its documentation standards. Minimal documentation requirements for coding purposes should be clearly delineated. In addition, methods for clarifying ambiguous or conflicting documentation—the query process—must be addressed to ensure that the medical record documentation supports the codes assigned.

Coding References and Tools. By defining and providing access to current and comprehensive national and organization-generated resources, the organization demonstrates its commitment to empowering the coding team members to be successful. Maintaining a coding help line also affords access to coding advice that is compliant with the organization's standards.

Coding Vendors. Providing an avenue for external coding support assists in reducing potential variations in the coding process. When outsourcing support is necessary, using certified vendors that have agreed to follow the organization standards will lead to more consistent results. Outsourcing arrangements should not base any part of the vendor's compensation on the results of the advice provided, because this may create a bias on the part of the vendor to rationalize codes with more favorable reimbursement. The purpose of any such vendor engagement should be to ensure accurate coding.

Orientation and Training. Everyone involved in documenting in the patient medical record as well as performing, supervising, or monitoring the coding process needs to be aware of the organization's policies and procedures related to coding. The commitment to data integrity statement should be the philosophy that guides all activities in the coding arena. An organization's orientation and training process should include a thorough review and understanding of the commitment to data integrity and all related policies and procedures. New employees must know how to access all of the tools and

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Figure 6.
Sample Philosophy of Coding Practice

1. We have great confidence in our employees and their commitment to collect, manage, and report data in an unbiased, honest, and ethical manner.

2. We believe that diagnosis and procedure coding should be governed by official coding guidelines and that all codes mandated by the guidelines should be assigned and reported. Adherence to guidelines will promote consistency and accuracy of coded data in organization databases. The organization policy is that ICD-9-CM diagnosis and procedure codes and CPT procedure codes must be correctly submitted and will not be modified or mischaracterized to be covered and paid. Diagnoses or procedures will not be misrepresented or mischaracterized by assigning codes for the purpose of obtaining inappropriate reimbursement.

3. We believe that the diagnosis reported by the physician as the reason for the encounter or visit and the codes reported must be consistent.

4. We believe that the procedural codes reported should accurately reflect the procedures performed during the encounter as documented by the physician.

5. We are committed to providing the support needed to effectively classify our patients. Support provided to the organization's facilities includes coding seminars, training tools, group purchases of products at discounted rates, publications, and nosology (coding advice) support.

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resources available to support them in completion of their job duties. A review and under-standing of these items should be documented and maintained in the employee's department education file.

Continuing Education and Training. All personnel involved in the performance of coding or formalized monitoring and auditing of coding processes need to be aware of coding guidelines and coding guideline changes that affect achievement of complete, accurate, and consistent coding. Ongoing requirements for continuing education hours need to be defined to ensure that the organization is committing the time and resources necessary to keep its personnel current. Professional development hours should be recorded and maintained on file for future monitoring and auditing functions.

Documentation Improvement Plan. Recognize that coding is an outcome, and monitor the clinical pertinence of the organization's medical record documentation. Recurring opportunities for improvement in completeness, accuracy, and timeliness should be addressed through a documentation improvement plan. Methods to improve the quality of documentation on a concurrent basis not only support information availability for ongoing quality patient care, but enhance data integrity for other concurrent and retrospective business uses.

Monitoring. In addition to prevention, the identification and correction of potential variations are important components of any program. Coding indicators should be monitored at a high level to

identify potential opportunities for improvement. This monitoring can include looking at diagnostic-related group (DRG) ratios, changes in the case-mix index, changes in the complication/comorbidity percentage, and other volume or severity shifts. These indicators should be used as triggers to initiate record-level investigation.

Record-level monitoring activities should be conducted on an ongoing basis to ensure complete, accurate, and consistent coding. These reviews should be completed internally as well as by external entities. Monitoring activity results should be used to develop action plans for success. These corrective action plans may include additional review of the standards and policies/procedures, additional training and education, access to additional resources, documentation improvement strategies, and ongoing monitoring activities to ensure resolution of the problem(s). Finally, as discussed previously, an audit process (both by internal auditors and external auditors) should always be in place to detect any weaknesses in the comprehensive control system.

A balanced coding compliance program that focuses on complete, accurate and consistent coding will ensure that an organization is able to respond to any changes in classification systems and reimbursement formulas. An organization that embraces the philosophy of data integrity will continue to be positioned for ongoing success in the ever-changing arena in which we work.

Medicare Cost Report Compliance

The Medicare cost report process[9] is complex and requires a provider to collect large amounts of data and to arrange this data in accordance with detailed rules as to the determination of allowable costs and the allocation of those costs. The challenge of performing all of these financial activities in an accurate fashion is an enormous one. Providers constantly struggle to meet the increasing and changing Medicare requirements as well as substantial administrative and paperwork burdens.

The tremendous challenge of properly completing a Medicare cost report requires extensive knowledge. The volumes of statutes, regulations, and guidelines, which undergo frequent change, complicate the cost report process. The cost report is based on a technical accounting process; therefore, oversight and completion requires personnel familiar not only with accounting principles and procedures, but with the complex technical Medicare rules as well. Many multihospital organizations have a centralized department

responsible for the cost reporting process and for developing, overseeing, and monitoring implementation of internal policies and guidelines. Although a centralized group provides many benefits, it also presents a challenge to keep hospital personnel up to date regarding Medicare rules and how to properly identify activities and financial or other business transactions that affect a cost report. Likewise, single-hospital organizations face the challenge of staying current with laws and regulations and appointing appropriate personnel to maintain the cost reporting process.

With respect to reimbursement claims, including Medicare cost reports, an organization's written policies and procedures should reflect and reinforce current governmental statutes, regulations, and instructions (hereafter collectively termed "rules"). Because of the ever-changing rules concerning the Medicare cost report, issuing new compliance policies to address the treatment of certain areas or a specific item may not be feasible. Rather, an overall policy requiring compliance with all applicable rules and a process to communicate the changes to appropriate personnel should be established. Moreover, an internal reimbursement manual or guidelines applying the rules to the organization's operations is likely to be useful.

In developing a compliance program, an organization should consider the model guidance and address basic cost report issues such as:

- Appropriate and accurate documentation that is auditable, current, and consistent for all costs and information claimed or included in the cost report;
- Identification of and appropriate treatment of costs including unallowable costs, related party costs, and indirect costs;
- Accurate and verifiable allocation statistics (i.e., statistics used to allocate overhead costs);
- Appropriate and accurate matching of revenues and expenses, for departments, payors, and in total; and
- Accurate and supportable third-party payor settlement data, including a process to use the most accurate data. (Medicare requires the use of its information unless a provider can demonstrate that the provider's information is more accurate. Providers that do not maintain accurate internal information must rely upon intermediary claim data. Fiscal intermediaries have acknowledged that their data is sometimes incorrect.

Within a multihospital organization, many people are involved in the preparation of a cost report: hospital personnel provide the information, personnel in a centralized reimbursement department compile the cost report, and a hospital officer must certify the report. A compliance program in a multihospital organization must address all areas of the organization to minimize any risks related to a cost report. In these types of organizations, the reimbursement department should maintain a "standard workpaper package" (including instructions) to be completed by hospitals. This package should be comprehensive in content and structure to document cost report claims; should address cost report risk areas, such as documentation, classification of expenses, statistics used to allocate indirect costs, and third-party settlement data; and should include workpapers designed to identify information such as unallowable cost and related party transactions. A standard workpaper package should be viewed as a critical step in ensuring compliance with applicable rules, because it is the foundation of the claims included in the cost report.

For cost reporting purposes, an organization should consider standardizing and expanding its chart of accounts used for accounting purposes and to segregate unallowable costs and related party transactions in separate accounts. One multihospital organization has implemented a standard chart of accounts (for all hospitals to use) to minimize cost report risks and to capture costs that are subject to special treatment under the cost report rules.

An organization should consider a policy regarding adequate documentation. The length of the cost report process, the timing of intermediary audits, and the final resolution of a cost report requires that appropriate documentation be maintained for an extensive period of time. An organization must address what constitutes appropriate documentation and the length of time the records must be retained. Frequently, the retention requirements for documentation needed to substantiate a claim in the cost report are not available in the statutes or regulations. Policies should address the fact that the documentation must be auditable and verifiable.

Additionally, an organization should consider a policy addressing the review of the cost report. Standard review checklists should be used to set minimum review procedures and potential risk areas. Someone in addition to the initial cost report preparer should be responsible for reviewing the report to ensure that the report is filed in compliance with applicable regulations and is an accurate presentation of the hospital's operations in Medicare format and that the hospital is using adequate documentation to

support the cost report. For example, within a multihospital organization, reimbursement department personnel would be responsible for the technical review. After this review, the cost report package and accompanying support should be reviewed with hospital personnel before filing.

When submitting a cost report to the fiscal intermediary, the person signing the report not only certifies that the cost report is accurate but also certifies that he or she is familiar with the laws and regulations regarding the provision of health services, and that services identified in the report were provided in compliance with such laws and regulations. This certification is a very broad statement. Considering the complexity of the Medicare rules and the frequency of changes to them, an organization should adopt a policy to ensure that the person signing the cost report understands the representations made in the report as well as all accompanying documentation and information. When the signer does not prepare the report, the policy should also address specific information and documents to be reviewed with the signer of the cost report prior to the cost report being submitted to the appropriate governmental agency. This policy should also address the process to follow in the event of a disagreement over the treatment of an issue in the cost report.

Organizations should determine if additional information should accompany the cost report when filing the report with the fiscal intermediary. A cost report "filing" also includes a provider questionnaire (HCFA Form 339) addressing changes in operations during the period; however, other pertinent information may be required that could be beneficial to the intermediary in reviewing and finalizing the cost report. The organization should develop a policy regarding disclosure in the cost report. Disclosures to be considered for inclusion in a "transmittal letter" should include:

- Changes in treatment of costs from prior year;
- New or complex transactions in current period;
- Financial statement contingent liability amount and issues; and
- Protest items claimed on the cost report for appeal purposes.

The transmittal letter should be discussed with provider personnel responsible for certifying the cost report. Although disclosure statements by a provider may reduce potential risks related to cost reports, management should also be aware that the cost report is subject to the Freedom of Information Act,[10] and

therefore certain confidential information may be released to the public as a result of those disclosures.

The Medicare rules are complex and the final adjudication of a particular cost report and of certain issues may span several years. Providers may not agree with program policy and/or an intermediary's past audit adjustments. The Medicare rules specify that any costs falling in these categories be included in the cost report on the protest line of the settlement worksheet. An organization should develop a policy regarding the use of the protest line of the cost report. The policy should address the requirements in the *Provider Reimbursement Manual* (HCFA Pub. 15-2). If a cost is not claimed in the cost report, a provider has little chance of ever being reimbursed for the cost. Any cost that the provider believes is reimbursable must be claimed and disclosed in the appropriate manner to have a denial of reimbursement to appeal.

A provider wishing to appeal intermediary audit adjustments must follow a defined process. However, prior to the appeal, a provider must have claimed the cost in the filed cost report to protect its appeal rights. An organization should develop guidelines to ensure that the appropriate actions and administrative steps are followed to protect appeal rights.

Ongoing training and education must be provided to all personnel involved with the Medicare cost reporting process. A variety of communications and other activities should be used to educate organization personnel about new compliance policies, risk areas, changes in rules promulgated by various governmental bodies, and any other pertinent issues.

Threshold levels of annual education and training requirements should be established and should include appropriate training opportunities both within the organization and those offered by external entities. A formal process of communicating changes in government rules should be established and should include personnel within all areas of the organization who have a responsibility for implementing or reporting such changes. Internal newsletters, frequently asked questions (FAQs), conference calls, and telecasts are all viable means to communicate information to hospitals and organization areas within a multihospital organization.

Significant changes in payment methodologies were mandated by the Balanced Budget Act of 1997.[11] These changes potentially affect the way information is reported in all areas. An organization should establish an interdisciplinary group to address the organization's preparation for and implementation of the changes in Medicare rules—including compliance issues. An interdisciplinary approach

ensures that the organization identifies potential risk issues in all areas of the organization and appropriately establishes policies and guidelines to minimize its risk.

As is true in each risk area, compliance with Medicare cost reporting standards must be monitored. Evaluation may be accomplished with a variety of methods, depending on the organization's structure and size. Automated monitoring (e.g., comparing one entity with national data or comparing one year's data with a prior year's data) is a tool to identify potential problem areas and requires timely and complete follow-up of data exceptions.

An internal audit department should implement a compliance review plan for cost reports. In an organization with a large reimbursement department, an internal peer review process can be developed to examine the department's adherence to compliance policies. The peer review process should identify areas needing improvement, further guidance, or changes to the cost report component of the organization's compliance program. A peer review process is particularly beneficial as it allows various elements of a large organization to learn from one another.

Finally, external entities should determine whether the organization is adhering to compliance policies designed to address Medicare statutes, regulations, and guidelines. These reviews may involve assessing the completeness and accuracy of the organization's policies in addition to performing procedures that indicate and validate compliance with the policies by organization personnel.

Confidentiality of Patient Information

Technological advances have presented new opportunities for managing patient information within a healthcare organization and between provider entities. The ability to access patient information electronically can facilitate the timeliness and quantity of information available to provide ongoing quality patient care. Coupled with this increased access level is the responsibility to protect the patient's right to confidentiality. A "need-to-know" approach should drive the patient information compliance program.

As organizations develop online longitudinal patient records, the standards related to the electronic collection, processing, maintenance, and storage of patient information should be clearly stated, particularly if the information is accessible from multiple locations (as is assumed for the purposes of this article). A patient information protection program should be driven by the following principles:

1. Users will collect, dispose, process, view, maintain, and store patients' clinical and financial information in an honest, ethical, and confidential manner.
2. The collection, processing, viewing, maintenance, and storage of patient information will be done in such a manner that, at a minimum, meets all applicable federal and state laws, regulations, and accreditation standards.
3. Support must be provided to effectively maintain patient information in a confidential manner.
4. Access to patient information will be limited to individuals with a legitimate need to know to effectively perform their specific job duties and responsibilities.
5. Access will be granted through the use of an Information Security Agreement.[12]

With these guiding principles delineated, it is important to have policies and procedures that define how these standards should be integrated into the day-to-day operations of the organization.[13] The following items highlight key operational success factors.

Security committee. A security committee should be established and be responsible for providing direction and oversight of the processes that affect confidentiality and the security of patient data. The activities of the committee should include implementing, monitoring, and maintaining compliance with all of the policies and procedures.

Examples of responsibilities include but are not limited to: determining access levels necessary to carry out job responsibilities; providing guidelines for implementation of the policies and procedures; establishing procedures, guidelines, and reports to monitor compliance with the policies and procedures; and reviewing and responding to violations and trends related to access.

Disclosure of patient data. Disclosure and redisclosure of any patient information must be in compliance with all federal and state laws and regulations. Policies and procedures should categorize requests for access. Examples of categories include access upon admission, access for inpatient consultation, and referrals. Standards should also outline the responsibilities of the health information management department and other members of the healthcare team to ensure the receipt and validity of patient authorization.

Protecting highly sensitive patient health information. Special consideration should be given to the management of highly sensitive patient health information. Higher-access restrictions should be used for confidential patient classifications including

behavioral health visits for the treatment of psychiatric or substance abuse conditions; employee health records; celebrities or other defined patient categories; and defined clinical test results, for example, tests for HIV.

Methods of access restriction include customizing computer menus by job responsibilities, restricting access to users based on the location of the patient in the hospital, and managing access by data sources with a need-to-know approach.

Physicians and physician office staff access. Organizations that have afforded physicians access to patient information in remote locations have the added responsibility of ensuring appropriate use by the physician and the physicians' office staff. Restrictions must allow the physician and his or her agents to access only information relative to patients who are assigned to the physician or physician group.

External entity access. Online patient information broadens the potential entities—authorized research reviewers, continuity of care providers, and fiscal reviewers—that can access the information. The compliance program must therefore clearly define which external entities are allowed access to patient information and the requirements that must be met.

Information security agreement. As a condition of employment or contract, an organization must require the review, understanding, and authentication of the information security agreement. This form acknowledges an awareness of specific responsibilities related to patient information access and use.

Enforcement and discipline. The enforcement and discipline standard should describe the requirements for discipline when breaches of confidentiality are identified. Suggested methods for determining the severity of the breach and subsequent action should be outlined.

Articulating standards. The need-to-know philosophy must be embraced at all levels of the organization and be entwined in the activities of the organization. Obviously, the code of conduct is the first vehicle for clearly stating the organization's commitment to protect the patient's right to confidentiality. Beyond the code and any related training, however, employees with access to patient-specific information must receive further education.

Education and awareness. The orientation and education plan for each employee, physician, physician office staff member, vendor, or other external entity needs to include discussion of the policies and procedures; review, understanding, and authentication of the information security agreement; and application-based training for specific access and usage rights.

Awareness should also be reinforced at the time of user log-on. Messages at the beginning of the session and during computer use should reinforce the organization's commitment to protect patient confidentiality and each user's obligation.

The patient must also be aware of the organization's approach to managing patient information. The conditions of admission and authorization for medical treatment should outline for patients how their information will be collected, maintained, used, and stored.

As technology solutions are installed and enhanced, training and education should be integrated into the implementation plan. Guidelines for success should be provided to give demonstrated best processes that can be applied within the organization.

Monitoring. Access to patient information must be continually monitored through the use of audit trails to ensure compliance with the policies and procedures. Standards for compliance monitoring should define, at a minimum, what reports should be generated. The security committee should determine the responsibility for review, sample size, and frequency of reviews. Examples of monitoring activities include a review of a sample of users to ensure there is a signed information security agreement on file; and a review of reports that identify access to patient information sorted by patient, user, or highly sensitive category.

Once these monitoring activities identify infractions, immediate attention should be focused on determining appropriate corrective and disciplinary actions. Results of the analysis should also be used to continue to refine the standards and ensure appropriate application throughout the organization. Monitoring activities should be audited both by internal auditors and external entities to ensure that appropriate controls are in place and are being effectively managed.

Balancing timely access and the patient's right to confidentiality are major challenges for the healthcare field. A comprehensive patient information compliance program is one mechanism for responding to this business imperative.

Physician Relationships

The relationship between a hospital and members of its medical staff is truly symbiotic. Physicians need hospitals to provide a wide range of primary, tertiary, and quantinary healthcare services, and hospitals need physicians to bring their patients to the hospital for treatment. To merely ask a physician to refer his or her patients to a hospital is not inappropriate; however, the federal government has firmly and clearly stated that hospitals cannot pay physicians for referrals.

Numerous federal as well as state statutes and regulations govern the relationship between hospitals and physicians, but two major federal statutes focus on the "payment for referrals" aspect of the hospital-physician relationship. The Anti-Kickback Statute[14] states that it is illegal to offer or to pay (or solicit or receive) remuneration with the *intent* to induce (or make) referrals in exchange for that remuneration. This criminal statute carries stiff financial penalties as well as the possibility of imprisonment. The other major statute, the "Stark II" legislation,[15] imposes civil money penalties only. Stark II fundamentally prohibits giving anything of value to someone making referrals to you absent an exception in the law or regulations. As a practical matter, Stark II places a burden on hospitals to prove affirmatively that each financial relationship with a physician fits within one of the exceptions to the general prohibition of the law. A detailed discussion of the Federal Anti-kickback Statute and the Stark II legislation is outside the scope of this article. Suffice it to say that the federal statutes and regulations are very broad and far-reaching. Thus, the appropriate compliance program must be carefully crafted, implemented, and monitored to avoid either purposefully or inadvertently failing to comply with federal requirements.

The relationship between a hospital and members of its medical staff is truly symbiotic.

First, a hospital needs to carefully review each and every aspect of its operations to see where it may have financial relationships with physicians. This includes such obvious matters as employment of physicians, medical directorships with physicians, medical office building leases (where either the hospital is the landlord or the tenant), and the provision of services from the hospital to the physician. However, more discreet subtle arrangements may come within the purview of the law, but may not automatically be recognized as financial relationships. These areas include free parking at the hospital, provision of free food in the medical staff lounge, provision of continuing medical education seminars for free or at a discount, and entertainment.

Second, the hospital should create a committee composed of legal representatives, compliance experts, hospital administrators, and representatives from any other area affected by the policies. The committee's goal should be to implement detailed policies setting forth the requirements of each financial relationship with the physician as well as the process that should be followed. These policy statements must comply with applicable federal statutes and regulations. Ideally, these policy statements should comport with the safe harbors within the anti-kickback statute and relevant advisory opinions issued by the OIG (as to the anti-kickback statute) and the

Figure 7.
Sample of a Portion of the Physician Relationship Checklist

Requirements	Answer* (Yes or True)
Professional Service Agreements	
Are services required/needed by the facility?	
Has the facility CEO documented and justified the need for the services?	
Does the agreement incorporate by reference all other separate arrangements with the physician?	
Is a written statement of services rendered required before each payment?	
Has the required facility CEO certification been obtained?	

*The answer to each question or requirement must be "yes" or "true" to proceed with a professional services agreement.

HCFA (as to Stark II). The policies should also reflect the hospital's business position on various issues. For example, although the hospital's attorneys may ultimately opine that it is legally appropriate to offer a loan to a physician at fair market value interest rates, the hospital must decide as a business issue whether it wants to be in the position of being a lender.

The policies should set forth who has the authority to enter into financial relationships with physicians. Consider mandating that all financial relationships with physicians must be in writing and approved by at least one reporting level higher than the individual desiring to enter into that financial relationship, as well as by legal counsel. Also consider requiring the individual desiring to enter into the financial relationship, and his or her superior, to execute a certificate certifying that the financial relationship complies with all legal requirements as well as with the organization's policy and was not entered into with the intent to induce referrals. Finally, these policies need to be approved by the governing body of the organization.

Once the polices have been adopted and implemented, they should be made available to all affected personnel. Education sessions should be scheduled and attended by all those individuals expected to abide by and implement the policies. The organization's employees must understand how the process works and what it takes to have a legally compliant relationship with a physician. Another particularly effective tool in this area is to develop a checklist (see Figure 7) that administrators can use as they contemplate entering into relationships with physicians.

After policies have been implemented, individuals have been trained, and processes are in place, the hospital should put in place a monitoring system that works for its type and size of operation. One way to monitor performance is to periodically run reports of the accounts payable and ascertain to which physicians the hospital is paying money. Then the existence of a written agreement between the hospital and that physician should be confirmed to be in compliance with the policies of the hospital, and the payment should be confirmed to be consistent with the terms of the agreement. If a written agreement does not exist or is not in compliance with the hospital's policies, or if payments are not consistent with the terms of the written agreement, then such noncompliance must be addressed.

In addition to real-time monitoring, an organization's policies regarding its relationships with physicians should be assessed periodically by internal auditors and external review entities.

Compliance with Accrediting and Certifying Agency Requirements

Of extreme importance to the establishment of a compliance program is adherence to standards, conditions, and regulations developed and disseminated by accreditation, certification, or licensure organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), the HCFA, and state licensure entities. To achieve compliance, providers must have continuous processes for receipt of new or revised requirements and dissemination of changes as well as processes to support the attainment and maintenance of accreditation, certification, and licensure.

In establishing accreditation, certification, and licensure compliance a healthcare organization should at a minimum:

1. Identify the departments and services of the facility and the voluntary or required accrediting, certification, or licensure entities applicable to each.
2. Aggregate data, information, and resources including the applicable standards, conditions of participation, or licensure regulations necessary for hospital and medical staff leadership reference.
3. Afford educational and other resources for managers to learn of their responsibilities and the actions that must be performed and documented for patient care services to comply with the agency requirements for clinical and organizational functions.

4. Articulate and demonstrate the commitment of management to continuous compliance and preparedness for survey by any accreditation, certification, or licensure agency, including the use of any agency recommendations as priorities to the provider's continuous quality improvement processes and mission.

Meeting the requirements of the healthcare accreditation, certification, and licensure agencies is crucial to even minimal compliance efforts; exceeding these requirements should be the goal of the entire organization.

ORGANIZATIONAL ETHICS

An effective ethics and compliance program is more than just compliance with laws, regulations, and policies. An important aspect of a successful program is the balance of compliance and ethics. Programs that seem to be focused only on legal compliance are inevitably less effective overall than programs that concentrate on organizational ethics as well. In part, such ineffectiveness results because the majority of the staff in a hospital is not involved in a direct fashion with many areas of legal compliance risk. If an ethics and compliance program is to resonate throughout the institution, it must speak to the needs, interests, and concerns of caregivers who may see a limited relevance to their work of issues such as Medicare reimbursement. An effective ethics and compliance program should balance regulatory compliance standards and education with an ethical decision-making structure that promotes the organization's value system as to both business and clinical decisions. The program should be part of an effort to build a culture that supports not only doing what is legally required, but also what is right in the broadest sense of that word. Promoting organizational ethics requires an articulation of expectations and some formal training, but most importantly it requires the reflection of such values in the daily leadership example set by management. An organization that is committed to operating ethically should adopt a values statement and should determine its commitments to its stakeholders. Emphatic leadership statements must be made to the effect that no operating pressures are ever an acceptable rationalization for failing to meet the ethical and compliance standards that have been set.

CLINICAL ETHICS

The entire area of clinical ethics, sometimes called biomedical ethics, is also critically important, but lies largely beyond the scope of this article. The value of clinical ethics committees in hospitals has long been recognized, and having an effective committee in a hospital to advise physicians on clinical ethics issues should be considered essential. Often employees in the hospital may become confused about the relationship between clinical and organizational ethics efforts, and an effort should be made to clarify the distinction. As a general rule, conducting parallel but separate organizational and clinical ethics efforts is not only appropriate, but also probably most effective. Structures to support clinical ethics have long existed, and the fact that greater weight is now put on organizational ethics is not a reason to reconfigure clinical ethics structures that are familiar to individuals and are operating well.[16]

CONCLUSION

Hospitals that devote the time, energy, and resources to implement the type of ethics and compliance program described in this article will benefit substantially from such an effort. The authors believe that such an effort will not only maximize the likelihood that complex legal rules will be observed, but will also establish an overall culture that will support the general mission of the healthcare provider. This type of program protects the organization and its members and, just as importantly, articulates aspirations of right conduct that inevitably cause individuals to be proud to be organization members.

Notes
1. Detailed information pertaining to Columbia/HCA's ethics and compliance efforts, including its code of conduct and all of its compliance policies and procedures, can be found at *http://www.columbia-hca.com/ethics.*
2. See a description of Columbia/HCA's Responsible Executive Program at *http://www.columbia-hca.com/ethics/OrgSupport/Respexec2.html.*
3. See *Columbia/HCA's Guide for Facility Ethics and Compliance Officers* at *http://www.columbia-hca.com/ethics/Guidebook/ecoguidefin2.html.*
4. Detailed information about the development of policies and procedures and other aspects of addressing these topics is included below.
5. If a healthcare organization decides to contract with a third party to answer its toll-free number, it should consider including the following in the contractual requirements: (1) The organization has the right to move the toll-free number to another vendor or answer it internally; (2) the outside vendor must check every name mentioned in a call against the DHHS-OIG's listing of sanctioned individuals; and (3) the security of the vendor's computer system

that stores the call information should be at least equivalent to the security the organization provides for the data within the organization's system. (This third requirement is best verified by an external audit of the security of the vendor's system.)

6. Some calls cannot be investigated appropriately without revealing the identity of the caller, for example, callers who complain about their own terminations or patients who complain about the care they received or their bill. These types of callers should be informed that effective investigation requires the use of the caller's name.

7. See, for example, Columbia/HCA's pamphlet explaining ABNs, attached to BOS.GEN.002 (Medical Necessity) available at Columbia/HCA's website identified in Note 1.

8. See, for example, Columbia/HCA's self-audit tool, attached to BOS.GEN.001 (Audit and Monitoring) available at Columbia/HCA's website identified in Note 1.

9. A cost report is a standardized Office of Management and Budget (OMB)–approved HCFA form that is prepared by or on behalf of a healthcare provider and is required to be certified by an officer of the provider detailing the activities of the provider for a specific time period, usually one year. The cost report process requires providers to gather information solely for cost reporting purposes and maintain such data for an extensive period of time. As Medicare implements other non–cost based prospective payment systems to compensate providers for services provided to Medicare beneficiaries, the importance of the cost report for current payment purposes diminishes. However, cost reports are also used to administer the Medicare program and are the basis for changes and updates to the Medicare prospective payment systems.

10. Freedom of Information Act, 5 U.S.C. § 552.

11. Balanced Budget Act of 1997, Public Law 105-33.

12. See, for example, Columbia/HCA's Information Security Agreement, attachment to IS.AA.013 (Information Security Agreement) available at Columbia/HCA's website identified in Note 1.

13. See Columbia/HCA's "appropriate access" policies for a comprehensive set of this type of standard—IS.AA.001 through IS.AA.015 available at Columbia/HCA's website identified in Note 1.

14. 42 U.S.C. § 1320a-7b.

15. 42 U.S.C. § 1395nn.

16. Although the subject of pastoral care is also beyond the scope of this article, the existence in many hospitals of professional clergy as members of the hospital staff offers a unique opportunity to use such individuals as a resource for both the organizational and clinical ethics efforts.

Acknowledgment

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THE COMMENTARIES: A SUMMARY

Although our lead article provides an excellent series of guidelines and principles for compliance programs, the commentaries provide the broader framework. Yuspeh et al. stress the importance of linking compliance with ethics; in the first commentary, John Abbott Worthley explores the organizational ethics context in detail.

As a managerial ethics consultant, Worthley welcomes the attention that the development of compliance programs has shed on organizational ethics. For him, the relationship between ethics and compliance is not one of balance, rather, ethics provides the framework within which an effective compliance program can operate. In the past, Worthley contends, "ethics prattle" tended to dominate, but in today's environment, good intentions are not enough. For Worthley, the increased attention that compliance programs are receiving has great value, and will serve to increase the performance and professionalism in healthcare organizations and ultimately improve healthcare delivery in the United States.

Worthley believes that organizational ethics is about pressures to behave in certain ways. The ethical climate should provide positive pressures toward compliance efforts and make non-compliant behavior difficult to sustain. The pressures are both structural and cultural, and Worthley provides workable guidelines that managers can use to exert these pressures at the corporate, group, and individual levels.

As lawyers and consultants with Davis Wright Tremaine, Charles Murdter and Peter Grant have a dramatically different view of compliance efforts. For Murdter and Grant, the real purpose of compliance programs is managing risk, and Medicare providers' first concern should be to make sure that the rules and regulations are strictly followed. They point out that so-called voluntary compliance programs are hardly voluntary, for the establishment of a compliance program has become a virtual condition for Medicare participation.

Murdter and Grant explore the dilemma an organization faces when it discovers an overpayment. The risks of non-disclosure are high, but the risk of additional penalties if a disclosure is made may be substantial.

Finally, Murdter and Grant find the lead article lacking one important element of a corporate compliance program. Organizations would be wise, they suggest, to have a strategy or plan in place in the event of a government investigation.

John E. Steiner, Jr., chief compliance officer with the Cleveland Clinic Health System, supplies this issue's final commentary. With the perspective of experience, Steiner affirms Yuspeh et al.'s key elements of an effective compliance program, and provides additional information on certain compliance techniques. He would add another key success factor for compliance programs—the ability to

easily consult with a cadre of subject matter experts for advice on specific issues.

Our readers will no doubt greatly appreciate the detailed inventory that Steiner has appended to his comments. It has been developed for use by the Cleveland Clinic, and relates the inventory of risk areas identified by the Office of Inspector General to the appropriate service delivery elements. As Steiner notes, the grid is quite effective in emphasizing the breadth of risk areas that compliance programs must address.

Healthcare compliance programs are in their first generation. Their sophistication and effectiveness will no doubt improve with time and experience. The guidelines and advice provided by this issue's lead authors and commentators will hopefully aid our readers in taking their organization's compliance programs to that next level.

JOHN ABBOTT WORTHLEY

Compliance in the Organizational Ethics Context

Do what I say, not necessarily what I do. Isn't that how an old saw goes? In the compliance context of today's healthcare management challenge, that guideline simply does not cut it. Owing to a stroke of brilliance within the Federal Sentencing Guidelines Commission, consistency between preaching and practice is the new saw: What we say had better be matched by what we do or we will be out millions of dollars in fines.

The Yuspeh et al. article reflects this development. In emphasizing "best practices" for managing compliance and ethics realities, the authors offer a useful perspective for assisting healthcare organizations in addressing this stark new dimension of healthcare management. As a management ethicist who has neither attended law school nor served as a compliance officer, I will highlight the organizational ethics context of the compliance phenomenon described by the Columbia/HCA team. Six observations are offered.

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Action Trumps Words

One, the compliance crusade has finally given teeth to what in the past often tended to be ethics prattle. When it comes to ethics it is relatively simple to talk a good line, generously spouting splendid sounding terms like "principles," "integrity," and "the highest standards." Historically, we in healthcare have written inspired codes and policies and spoken eloquently of our strong commitment to ethics. Our good intentions have been manifest. The difference today, in the compliance era, is that good intentions alone count for little. Rather, what we actually do with regard to ethics—good intentions aside as Laura Nash puts it in her important book (Nash 1990)—determines an organization's ethical posture. Action, behavior, and managerial measures are the hallmarks, and these are much more challenging and complicated than mere expressions of ethical intentions. Yuspeh et al. provide perspective on just how involved the effort can be.

Consistency Is the Key

Two, consistency is central to this development, and by "consistency" I mean much more than merely being consistent in our ethics and

Figure 1.
Areas for Structural Compliance Attention

Corporate	Group	Individual
Code of conduct	Unit policies	Training attendance
Compliance program	Group training	Compliance coordinator
Training program	Task force	Ethics officer
Reporting hotlines	Local compliance teams	Job descriptions
Ethics committee		
CEO involvement		
Board policies		
Monitoring procedures		
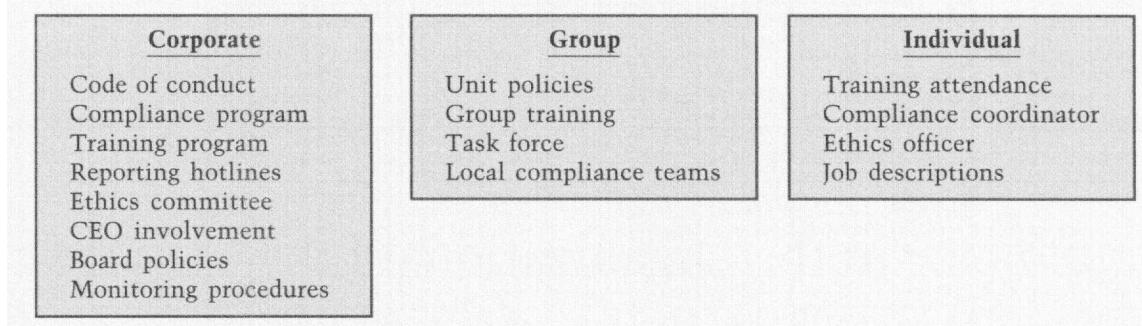
compliance standards. Actual practice and organization behavior must be consistent with touted organization standards, and rigorous managerial mechanisms must demonstrate that we are serious about making routine behavior consistent with the standards articulated in codes, policies, and training sessions. To make the point not merely manifest but mired, the Federal Sentencing Guidelines (U.S. Sentencing Commission 1994) provide harsh penalties when lofty organizational standards are unsupported by tough ethics procedures and mechanisms. On the other hand, tremendous leniency is granted when rigorous ethics and compliance systems are demonstrably in place. Consistency is the key that opens compliance solutions.

Pressures Must Be Positive

Three, organization ethics is fundamentally about pressures that affect not only compliance efforts, but all organizational behavior. Organizational ethics programs are supposed to establish and nurture an organizational climate that makes it easier for good healthcare workers to work ethically, and more difficult for them to work unethically. Going far beyond the lead article's contention that a compliance effort is about "individuals never compromising their own integrity, regardless of pressures they may face," the Federal Sentencing Guidelines Commission

as well as the Department of Health and Human Services focus compliance precisely on those "pressures," requiring that they be rigorously positive and supportive of compliance and ethical behavior. Lack of managerial attention to negative organizational pressures is grounds for significant fines and penalties. To paraphrase Norman Vincent Peale's famous sobriquet, organizational ethics and compliance recognizes the power of positive pressure.

Culture Must Support Structure

Four, that pressure must be not only structural but cultural. As the lead article pithily puts it, "an ethics and compliance program is fundamentally about organizational culture." In the organizational theory field we often distinguish the formal from the informal organization, the former being the structural and official realities, the latter being subtle realities like attitudes, beliefs, and patterns of behavior. Compliance programs tend to emphasize formal, structural mechanisms like those described in the Columbia/HCA piece and summarized in Figure 1.

But Federal Sentencing Guidelines require a direct link to organizational culture. For example, formal sexual harassment policies and structures are now standard in most healthcare organizations. Officially, all forms of sexual

Figure 2.
Areas for Organizational Culture Pressure

Corporate	Group	Individual
Attitudes	Peer pressure	Feelings
Norms	Referents	Loyalties
Rewards	Social mores	
Beliefs	Open dialogue	
Patterns		
Grapevines		
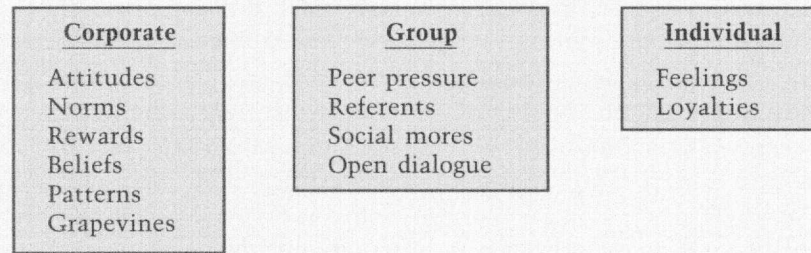
harassment are condemned and investigated. Nevertheless, according to numerous research reports, such as Pierce, Smolinski, and Rosen (1998), negative attitudes and patterns of harassing behavior continue to be a major problem in many healthcare organizations. There is an inconsistency between words and results, between promulgated policies and actual behavior. Federal compliance guidelines focus on results. Organizational ethics and compliance programs need to do likewise, and this usually requires serious measures to address negative organizational culture realities. Visible role modeling by senior executives, for example, is important in this regard. Figure 2 provides a lens for discerning areas of organizational culture that may benefit from managerial attention. As does Figure 1, it distinguishes individual, group, and corporate dimensions of organizations as a conceptual tool for facilitating analysis of organizational culture.

A lens like this can suggest several compliance-related questions. For example, despite words to the contrary, is there an organizational attitude that ethics can be put aside when it comes to corporate revenues? Despite stated policies, is it an organizational belief that economic efficiency is rewarded no matter how it is achieved? Despite a code of conduct requiring reporting of unethical behavior, does group peer pressure reward loyalty and punish whistle-blowing? Do senior executives or middle managers routinely make sexist comments notwithstanding strong sexual harassment policies? Do employees feel that ethics is only fluff that is not relevant in everyday practices? Does the organization's "grapevine" communicate ethics or is it silent? These are the kinds of analytical questions that increasingly are expected by compliance authorities.

Monitor and Evaluate

Five, as the authors suggest, comprehensive ethics and compliance programs can benefit from conscious application of the financial management paradigm of strategic planning (budgeting), operational monitoring (accounting), and program evaluation (auditing) to the ethics effort. I call it the "before-during-after" ethics management tool. Currently, compliance efforts in healthcare seem to be doing well at planning for ethics and compliance. *Before* things happen organizations are now developing codes, hiring compliance officers, designing compliance mechanisms and putting them in place, and providing ethics training. Less attention is being given to the *during* phase of organization behavior. How often is the code being used? Is it found to be relevant or unrealistic? Which mechanisms are being employed and how often? What reward systems are prevailing? What attitudes and

patterns are evident? Jansen and Von Glinow (1985) and Brien (1996) illustrate the kinds of questions that can be raised and managerial actions that can be taken. But, instruments to measure what is happening in the ethics/compliance domain—akin to the accounting tools commonly used in the financial domain—need to be better developed and employed. Surveys, as the lead article alludes to, exemplify one such tool available.

With regard to the *after* phase, ethics audits would do well to embrace the tools of the program evaluation field to systematically review the code, the standards, the training, the monitoring mechanisms, and so on, to determine what is working, what is not, and what modifications and adjustments are in order to make the ethics and compliance program tougher, more meaningful, and more effective. Solid efforts at all three phases—before, during and after—demonstrate that an organization is serious about compliance and ethics. Judicial and regulatory authorities are using indications of such efforts as paramount criteria for leniency in sentencing.

Make Ethics the Content

Finally, from an organizational ethics perspective, the notion of seeking a "balance" between compliance and ethics is troublesome. Rather, I would argue that organizational ethics is the overarching context within which compliance programs—as well as clinical ethics—unfold. If the organization as a whole does not continuously develop consistency between what it says and what it does, then those aspects at which compliance efforts are targeted (such as the Medicare matters discussed in the lead article) have weak foundational support. As Driscoll, Hoffman, and Murphy (1998) conclude from their compliance studies, inconsistency is then likely to thrive and compliance problems are inevitable. Bioethicists, notably Thompson (1992) and Khushf (1997), in reflecting on their experience

with hospital ethics committees, testify to the importance of integrating all ethics and compliance efforts within the full institutional context. If, for example, honesty and consistency are stressed in areas of Medicare regulation but ignored in other areas of organizational activity, then problems are likely. This is precisely why the Office of the Inspector General of the Department of Health and Human Services has issued compliance directives that increasingly require tangible evidence of managerial attention to the full organizational ethics pie, not just to the compliance piece.

In the end the current compliance craze will, I believe, be seen as a milestone in advancing the professionalism and overall performance of healthcare organizations. Compliance and ethics programs are fundamentally more about management than about morality. In challenging the healthcare field to be more rigorous in translating what it says into what it does, today's compliance efforts will decisively improve healthcare delivery in the United States.

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PETER N. GRANT AND CHARLES P. MURDTER

Doing Things Right

It has become a fact of life in the healthcare industry that "voluntary" compliance programs are anything but voluntary, as the existence of a compliance program has become a virtual condition of participation in the Medicare program. In their article on compliance, Yuspeh et al. neatly capture the myriad issues that must be considered in crafting an effective compliance program. Although the article is written from the perspective of a large, multihospital system that has devoted substantial resources to a corporate ethics and compliance program, providers in nonhospital settings with more limited capabilities should not be daunted by the processes described. As the authors aptly note, an effective compliance program must be designed taking into account the particular risks, capacities, and resources of each provider. The *principles* of healthcare compliance apply to all, regardless of size.

The real heart of a compliance program—its true purpose—is risk management, particularly the avoidance of severe financial and criminal sanctions imposed by the government. The original paradigm for corporate compliance programs is contained in the *Federal Sentencing Guidelines Manual* promulgated by the U. S. Sentencing Commission. The investigation and prosecution of healthcare fraud and abuse have been the major federal white-collar criminal priority for several years. Congress has allocated

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millions of dollars to the Departments of Justice (DOJ) and Health and Human Services (DHHS) to increase resources for both criminal and civil investigations. Add the media hype over the "fleecing" of Medicare, and many healthcare providers find themselves searching to find what they can do to protect themselves.

The detection, prosecution, and punishment of healthcare fraud now represent a major emphasis for federal and state law enforcement agencies. The Health Insurance Portability and Accountability Act of 1996 provided federal funds to hire 100 new healthcare prosecutors and 400 new agents. Over the past two years, these new posts have been filled and investigative activity is clearly on the rise. In addition, an increasing number of "whistleblowers" are taking advantage of the *qui tam* provisions of the False Claims Act and bringing civil suits against healthcare providers on behalf of the United States for allegedly submitting false Medicare claims. A successful private plaintiff is entitled to a share of any recovery obtained from the suit. Because the False Claims Act provides for treble damages and a $10,000 penalty for every false billing, these recoveries can be enormous. In this environment, what once was considered a simple mistake or error now can be viewed by a zealous prosecutor as an attempt to cheat the government.

A prudent provider will take the time to assess the risks it faces in its dealings with the government. The most obvious areas of concern are the documentation, coding, and billing areas—errors here have the most direct effect on the

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receipt of public funds, and it is the perceived loss of the taxpayor dollar to healthcare fraud and abuse that is driving the train of most investigations. While most commentators talk about compliance in terms of "doing the right thing," what a provider billing Medicare really has to worry about is *doing things right*, for example, making sure procedure codes are correct and documentation is adequate. Educating yourself and your staff are the first essential steps.

As the authors note, monitoring current performance and auditing past practices are critical to gauging the effectiveness of a compliance program. Mistakes will be made. Ideally, the compliance program will find them early, correct them swiftly, and thus control the damage. But many providers will find themselves in a situation where they have received a substantial overpayment. Like it or not, the provider must then confront the question of whether the overpayment should be disclosed to the government.

On October 22, 1998, the Office of Inspector General (OIG) for the DHHS released a 13-page Provider Self-Disclosure Protocol. The Protocol is supposed to provide "detailed guidance to health care providers that decide voluntarily to disclose irregularities in their dealings with the Federal health care programs." The Protocol tells a provider *how* to disclose, but not what will happen as a result. The Protocol merely states that "while not protected from civil or criminal action under the False Claims Act, providers disclosing fraud are advised . . . that the self-reporting of wrongdoing could be a mitigating factor in the OIG's recommendations to prosecuting agencies."

The OIG states that it is not bound by the findings of the provider's investigation or obligated to resolve a matter in any particular manner. After review, the OIG may conclude that the disclosed matter warrants a referral to the DOJ for consideration for civil or criminal action. The only thing the OIG apparently promises to do in return for voluntary disclosure is "report on the provider's involvement and level of cooperation throughout the disclosure process to any other government agencies affected by the disclosed matter."

Disclosure must be considered because the risks of nondisclosure are high. Although the law is not settled, several prosecutors have asserted that Federal law makes it a felony, punishable by up to five years in prison and fines to $25,000, for a healthcare provider to fail to disclose an overpayment. That statute upon which the prosecutors rely reads, in pertinent part, as follows:

> [Anyone who possesses] knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for is receiving such benefit or payment . . . *[to] . . . conceal . . . or . . . fail to disclose such event* with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized. *42 U.S.C. § 1320a-7b(a)(3).*

Representatives of the OIG have stated publicly that they interpret this statute to impose a burden upon a provider to disclose *and return* overpayments.

Although Yuspeh et al. do not elaborate on this issue, it is helpful to involve counsel in the disclosure process. Not only can involvement of counsel assist in interface with DOJ and OIG investigators and counsel, but counsel with specific knowledge of Medicare rules and regulations can provide guidance in the development of policies, practices, procedures, and the overall compliance program.

Finally, the article is silent on one important issue—the unexpected. Healthcare providers, as other organizations, need a strategy when served with a subpoena or search warrant or when federal agents arrive to interview employees. Organizations should identify in advance a "go-to" counsel that has experience in governmental investigations to provide support and guidance to the employees and management staff.

JOHN E. STEINER, JR.

The Compliance Program: An Application

This commentary discusses how the principles addressed in Yuspeh et al.'s article are being implemented across the Cleveland Clinic Health System (CCHS). This commentary also provides additional information on compliance techniques applicable to providers engaged in structuring and implementing voluntary compliance programs.

Given the relatively recent issuance of formal guidance by the Office of Inspector General (OIG) of the Department of Health and Human Services for structuring corporate compliance programs across healthcare sectors, many providers are adopting compliance programs that blend reactive and proactive elements. For example, most Medicare participating hospitals have some semblance of a compliance program in place as a condition of entering a settlement agreement for one or more national healthcare "fraud" recovery projects pursued jointly by the Department of Justice (DOJ) and OIG. These reactive compliance programs tend to generate more institutional awareness of the need for proactive compliance programs that address a broad range of risk areas and require a formal, ongoing committment to be effective. Given that healthcare fraud was moved to the number two priority of the DOJ in 1994, and given the increased emphasis at all levels on this issue, it is not surprising that government agencies would prefer providers to take a voluntary approach toward compliance programs. Government preferences and pressures notwithstanding, sustained voluntary compliance efforts do help providers identify risks across an organization, allow for coordinated responses to those risks, and help improve internal controls.

In many respects, as acknowledged in the OIG's Voluntary Compliance Program Guidance for Hospitals (February 1998), voluntary compliance programs are evolutionary and must be tailored to each provider's unique circumstances. This evolutionary aspect of voluntary compliance programs is addressed in the lead article. In addition, the attached matrix compiles risk areas by OIG Voluntary Compliance Guidance Models published to date and evidences the overlap and expanding scope of risk areas identified by government agencies. The similarity of identified risk areas across industry sectors is instructive for many audiences, including those in operations who may have limited involvement or control over the sequence of events that ultimately may lead to noncompliant corporate activity.

The attached grid is intended as an inventory that compliance officers may wish to use to monitor multiple risk areas, delegate focused audits by risk area, and design compliance monitoring techniques. The grid also should help the compliance committee, audit committee of the board and other standing committees appreciate the breadth of risk areas identified to date by the OIG.

Yuspeh et al. make a critical observation about fundamental elements for effective corporate

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compliance. Without these elements, attempts to build and support the foundation of an effective compliance program likely will fail. Moreover, without those key elements it would be difficult for a provider to have confidence in its ongoing compliance program efforts, let alone present a good-faith institutional effort toward meaningful compliance to an independent party. To restate those fundamentals, the voluntary compliance program must:

1. Have visible, continued support of senior management;
2. Instill in all employees and independent contractors the idea that the organization is committed to doing the right thing;
3. Be understood and accepted as a decentralized responsibility, with guidance and oversight provided by an office of corporate compliance; and
4. Be part of the regular duties of line managers and others in operations.

When these elements are present and tangible, compliance accomplishments are achieved; the results usually become evident to those who assisted in identifying and, in many cases, resolving the issues.

The compliance officer must develop methods for monitoring these incremental accomplishments and reporting them to reinforce to senior management the significance of a committment to the compliance program. For example, CCHS recently provided intensive compliance education on clinical research issues, ranging from Medicare coverage principles to the subtle distinctions between the "practice of medicine" and "standard of care" for human subjects. This effort was well-received by the personnel who help support a major institutional committment to clinical research. This initial, broad-based education provided the attendees with the opportunity to suggest specific compliance education follow-up topics to a central office. Senior management's committment to the compliance program can be affirmed at each educational session. This educational effort allowed me as a compliance officer and my staff to learn more about our large, decentralized

organization and work with individuals whose line responsibilities relate to clinical research. I highlight this experience as as example of the value of a centralized, coordinating office to guide the compliance program and gain the critical support of others who understand the fundamental elements of effective compliance programs, as emphasized in the lead article.

Another key aspect of comprehensive compliance programs is a committed group of subject matter experts to contribute to specific compliance topics as needed.

Currently, our organization is reemphasizing the importance of department "ownership" of various compliance program elements. For example, a Medicare coverage and payment principle might be posted on our compliance intranet site, with supplemental explanation or direction from the office of corporate compliance. A line manager in each department is instructed to read the policy, determine whether it applies to the department and, if so, develop a procedure to implement the policy. Over time, each department should appreciate the difference between the function of a policy statement distributed by a central, supporting office—such as the office of corporate compliance or office of general counsel— and the need for a tailored procedure to implement the policy in that department. Periodically, follow-up confirmation of these steps can be undertaken by the office of corporate compliance as part of the monitoring component of the compliance program. This step-by-step approach needs to be understood by key administrators so that they can assist the office of corporate compliance in identifying appropriate subject matter experts to implement compliance steps. Ideally, in each organization the compliance officer can identify and work closely with administrators and the physician leaders responsible for the many functional areas in which risks may be highest. Those contacts will prove invaluable to the compliance officer when difficult and complex issues arise with program implementation and maintenance. Many of those issues are described in greater detail in Yuspeh et al.'s article and merit careful consideration by healthcare providers.

Inventory of OIG-Identified Risk Areas for Voluntary Compliance Programs

Risk Areas	Hospitals	Home Health Agencies	Clinical Lab	3rd Party Medical Billing Companies	DME Prosthetics Orthotics	Medicare + Choice	Hospice
Incentives to actual or potential referral sources that may violate the anti-kickback statute	yes	yes	yes	yes			yes
Upcoding	yes		yes	yes	yes		
Billing for items or services not actually rendered	yes	yes			yes		
False Cost Reports	yes	yes	yes		yes		
Joint ventures—between parties, one of whom can refer Medicare or Medicaid business to the other	yes	yes		yes	yes		
Stark physician self-referral law	yes	yes			yes		
Billing for services provided to patients who are not "homebound"		yes			yes		
Improper patient solicitation activities and high pressure marketing of uncovered, unnecessary services or ineligible beneficiaries/improper marketing		yes	yes				yes
Knowing misuse of provider certification numbers, which results in improper billing		yes		yes			yes
Knowing failure to return overpayments made by Federal healthcare programs/ inadequate resolution of overpayments		yes		yes			yes
Unbundling items or supplies	yes			yes	yes		
Providing medically unnecessary services	yes		yes				
Outpatient services rendered in connection with inpatient stays	yes			yes			
Teaching physician and resident requirements for teaching hospitals	yes						
Billing for discharge in lieu of transfer	yes			yes			
Patient's freedom of choice	yes						
Financial arrangements between hospitals and hospital-based physicians	yes						
Patient dumping/patient abandonment in violation of applicable status, regulations, and Federal healthcare program requirements	yes	yes					
Knowing failure to provide covered services or necessary care to members of a HMO	yes						
"DRG creep"	yes			yes			
Billing for medically unnecessary services							
Duplicate billing		yes		yes			
Credit balances—failure to refund	yes	yes					
Billing for visits to patients who do not require a qualifying service		yes					
Over-utilization and under-utilization		yes					yes
Knowingly billing for inadequate or substandard care		yes					yes
Insufficient documentation to evidence that services were performed and to support reimbursement		yes		yes			
Billing for unallowable costs of home health coordination		yes					

Inventory of OIG-Identified Risk Areas for Voluntary Compliance Programs

Risk Areas	Hospitals	Home Health Agencies	Clinical Lab	3rd Party Medical Billing Companies	DME Prosthetics Orthotics	Medicare + Choice	Hospice
Billing for services provided by unqualified or unlicensed clinical personnel		yes					
False dating of amendments to nursing notes		yes					
Falsified plans of care		yes					yes
Untimely and/or forged physician certifications on plans of care		yes					yes
Inadequate management and oversight of subcontracted services		yes			yes		
Discriminatory admission and discharge of patients		yes					
Billing for unallowable costs associated with the acquisition and sale of home health agencies		yes					
Compensation programs that offer incentives for number of visits performed and revenue generated		yes					
Improper influence over referrals by hospitals that own home health agencies		yes			yes		
Duplication of services provided by assisted living facilities, hospitals, clinics, physicians, and other home health agencies		yes					
Knowing or reckless disregard of willing and able caregivers when providing home health services		yes					
Failure to adhere to home health agency licensing requirements and Medicare conditions of participation		yes					
Improper requisition design			yes				
Failure to provide physicians with Medicare Medical necessity policy on an annual basis			yes				
Failure to provide physicians with detailed descriptions regarding Medicare billing for each lab profile			yes				
Failure to obtain physician signature on a Physician Acknowledgement form for customized lab profiles			yes				
Improper monitoring of test utilization and ordering abuses			yes				
Failure to insure CPT or HCPCS code accuracy			yes				
Fraudulent and abusive practices caused by reliance on standing orders			yes				
Inappropriate balance billing				yes			
Failure to maintain confidentiality of information/records				yes			
Lack of integrity in computer systems and software that may lead to improper billing				yes			
Failure to properly use modifiers				yes			
Routine waiver of copayments and billing third-party insurance only				yes			
Discounts and professional courtesy				yes			
Billing for services that the DMEPOS supplier believes may be denied					yes		

Inventory of OIG-Identified Risk Areas for Voluntary Compliance Programs

Risk Areas	Hospitals	Home Health Agencies	Clinical Lab	3rd Party Medical Billing Companies	DME Prosthetics Orthotics	Medicare + Choice	Hospice
Billing patients for denied charges without a signed written notice					yes		
Billing for items or services not ordered					yes		
Using a billing agent whose compensation arrangement violates the reassignment rule					yes		
Billing for new equipment and providing used equipment					yes		
Continuing to bill for rental items after they are no longer medically necessary					yes		
Resubmission of denied claims with different information in an attempt to be improperly reimbursed					yes		
Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee schedule basis					yes		
Inadequate management and oversight of contracted services, which results in improper billing					yes		
Charge limitations					yes		
Providing and/or billing for substantially excessive amounts of DMEPOS items or supplies					yes		
Providing and/or billing for an item or service that does not meet the quality and standard of the DMEPOS item claimed					yes		
Capped rentals					yes		
Failure to monitor medical necessity on an on-going basis					yes		
Delivering or billing for certain items or supplies prior to receiving a physician's order and/or appropriate CMN					yes		
Falsifying information on the claim form, CMN, and/or accompanying documentation					yes		
Completing portions of CMNS reserved for completion only by the treating physician or other authorized person					yes		
Altering medical records					yes		yes
Manipulating the patient's diagnosis in an attempt to receive improper payment					yes		
Failing to maintain medical necessity documentation					yes		
Inappropriate use of place of service codes					yes		
Cover letters that encourage physicians to order medically unnecessary items or services					yes		
Improper use of the ZX modifier					yes		
Routine waiver of deductibles and coinsurance					yes		
Improper telemarketing practices					yes		
Co-location of DMEPOS items and supplies with the referral sources					yes		
Non-compliance with the Federal, state, and private payor supplier standards					yes		

Inventory of OIG-Identified Risk Areas for Voluntary Compliance Programs

Risk Areas	Hospitals	Home Health Agencies	Clinical Lab	3rd Party Medical Billing Companies	DME Prosthetics Orthotics	Medicare + Choice	Hospice
Providing false information on the Medicare DMEPOS supplier enrollment form					yes		
Misrepresenting a person's status as an agent or representative of Medicare					yes		
Knowing misuse of a supplier number, which results in improper billing					yes		
Failing to meet individual payor requirements					yes		
Failing to refund overpayments to patients					yes		
Employing persons excluded from participation in Federal healthcare programs					yes		
Improper billing resulting from a lack of communication between different departments within the DMEPOS					yes		
Improper billing resulting from a lack of communication between the DMEPOS supplier, physician, and patient					yes		
Performing tests on a beneficiary to establish medical necessity					yes		
The election process					yes		
Benefits and beneficiary protection					yes		
Quality assurance						yes	
Premiums and cost sharing						yes	
Solvency, licensure, and other state regulatory issues						yes	
Claims processing						yes	
Appeals and grievance procedures						yes	
Uninformed consent to elect the Medicare Hospice Benefit							yes
Discriminatory admission							yes
Admitting patients to hospice care who are not terminally ill							yes
Insufficient oversight of patients receiving more than six consecutive months of hospice care							yes
Overlap in services that a nursing home provides resulting in insufficient care							yes
Providing hospice services in a nursing home before a written agreement has been finalized							yes
Failure to adhere to hospice licensing requirements and Medicare conditions of participation							yes
Failure to comply with applicable requirements for verbal orders for hospice services							yes
Sales commissions based upon LOS in hospice							yes
Arrangement with another healthcare provider who a hospice knows is submitting claims for services already covered by Medicare Hospice Benefit							

This matrix was generously supplied by John E. Steiner, Jr.

REPLY

As evidenced by the commentaries by John Steiner, John Worthley, and Peter Grant and Charles Murdter, the development of ethics and compliance programs in healthcare is of great interest to varied audiences. We found their commentaries complementary to our article and are grateful for the value added by their insights and experiences.

Mr. Steiner's experience with the Cleveland Clinic Health System supports our position that healthcare providers of varying size and perspective benefit from the development of an ethics and compliance program. He also affirms our claim that for a compliance program to be successful, it must have the support of all elements of an organization (senior management, line management, and all employees and contractors) and must build in effective monitoring mechanisms. Finally, Mr. Steiner highlights the important role that subject matter experts or, as we call them, responsible executives, play in the effective development

and implementation of an ethics and compliance program. As discussed in our article and reiterated by Mr. Steiner, these elements are critical to the success of any compliance program.

Dr. Worthley's commentary, while also complementary to ours, brings a different focus to the issue—that of how a compliance program raises awareness of and emphasizes organizational ethics, two points with which we certainly agree. We agree specifically with Dr. Worthley's six observations and hope that time will bear out that they are true in our organization and in others that choose to develop a compliance program.

Finally, Dr. Grant and Mr. Murdter's commentary elaborates on two aspects of an effective ethics and compliance program— reporting and refunding overpayments and having a strategy for responding to investigations. Both points should be considered in any comprehensive ethics and compliance program.