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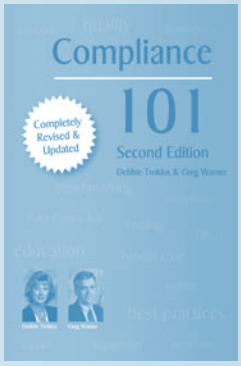

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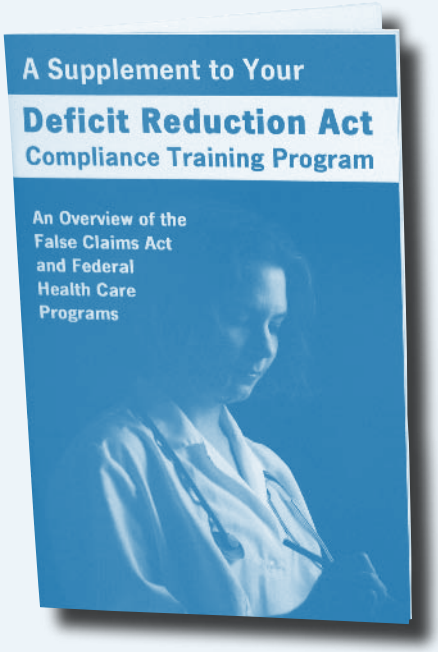

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ASK LEADERSHIP

JOHN FALCETANO

John asks the leadership your questions

Editors note: John Falcetano is Chief Audit/Compliance Officer for University Health Systems of Eastern Carolina and a long-time member of HCCA. This column has been created to give members the opportunity to submit their questions by e-mail to Jfalcetano@cox.net and have John contact members of HCCA leadership for their response.

Question: Healthcare facilities have safety officers in place to ensure compliance with the Occupational Health and Safety Administration (OHSA) regulations. I understand the compliance officer's responsibilities as they relate to billing, but what role does a compliance officer play as it relates to an organization complying with OHSA requirements, since they already have someone responsible for that function?"

The answer was provided by attorney Gabriel Imperato, Esq. a member of the HCCA Board of Directors and an attorney with the law firm of Broad and Cassel.

The compliance officer's responsibilities really are not fundamentally affected just because someone in the organization is more specifically responsible for regulatory compliance in a specific subject area, whether that is OHSA requirements or even billing and coding requirements. The compliance officer is still responsible for ensuring that the organization adheres, to the best of its abilities, to the seven essential elements for an effective compliance program enumerated in the United States Sentencing Guidelines for Organizations. This would require that the compliance officer, for instance, ensure that the governing authority of the organization and high-level management be knowledgeable about the content and operation of the compliance program to detect and prevent misconduct as it may relate to compliance with OHSA requirements (and billing and coding requirements etc.).

The compliance officer would also have to ensure that those responsible for compliance with OHSA requirements in the organization be properly screened, so that an individual who may have a prior history of misconduct is not put into a position of responsibility. In addition, the compliance officer must make sure that proper training programs

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ON THE CALENDAR

2007 Conferences:

Anchorage, AK
- Alaska Local Area Conference July 12–13

Scottsdale, AZ
- Compliance Academy June 4–7
- Audit & Compliance Committee Conference February 26–28

Los Angeles, CA
- West Coast Local Area Conference June 29

San Diego, CA
- Compliance Academy December 10–13

San Francisco, CA
- Compliance Academy February 5–8
- Advanced Compliance Academy June 25–28

Denver, CO
- Mountain Local Area Conference October 26

Orlando, FL
- Compliance Academy November 5–8

Atlanta, GA
- Southeast Local Area Conference February 23

Honolulu, HI
- Hawaii Local Area Conference October 18–19

Chicago, IL
- Compliance Institute April 22–25
- Compliance Academy August 20–23
- North Central Local Area Conference October 5
- Research Compliance Conference October 31–November 2

Louisville, KY
- Mid Central Local Area Conference November 2

Baltimore, MD
- Fraud & Compliance Forum September 24–26
- Advanced Compliance Academy October 22–25
- Medicare Part D Conference December 9–11

Boston, MA
- New England Local Area Conference September 7

Detroit, MI
- Upper North Central Local Area Conference, June 15

Minneapolis, MN
- Upper Midwest Local Area Conference September 14

Kansas City, MO
- Midwest Local Area Conference September 28

New York, NY
- Mid Atlantic Local Area Conference May 18

Philadelphia, PA
- Quality of Care Compliance Conference September 30–October 2
- Physician's Practice Compliance Conference, October 3-5

Pittsburgh, PA
- East Central Local Area Conference October 12

Nashville, TN
- South Central Local Area Conference November 9

Dallas, TX
- Southwest Local Area Conference February 16
- Compliance Academy March 19–22

Seattle, WA
- Pacific Northwest Local Area Conference June 1

- National Corporate Compliance Week May 20–26

INSIDE

Compliance considerations for electronic health record documentation

By Rita A. Scichilone, MSHA, RHIA, CCS, CCS-P, CHC

Editor's note: Rita A. Scichilone is Director, Clinical Data Standards with the American Health Information Management Association. She may be reached by e-mail at Rita.Scichilone@AHIMA.org

The use of electronic health record (EHR) and its documentation tools has great potential to improve the healthcare delivery process by making health services delivery safer and more effective. The features found in many of the EHR systems today allow services to be monitored, measured, and evaluated efficiently, thus saving time and money that can be used to provide care.

Electronic systems also provide documentation tools to facilitate the process, provide more structured data, and enable ease of information retrieval by busy physicians, clinicians, and other allied health professionals. But, a dark side to information technology exists in the hands of those who allow electronic tools to push the envelope of propriety and legality. Like other forms of technology, there are always methods of getting computers to "do the dirty work for you" in cases of fraud or allowing you to "look good on paper" while engaging in noncompliant activity, thereby placing both individuals and organizations at risk for compliance problems.

Say again?

An article entitled "Copy and Paste" in the May 24, 2006 issue of *Journal of the American Medical Association*[1] caught the attention of many concerning activity that only electronic tools could spawn – virulent copy and paste disorders. Author Dr. Robert Hirschtick used this technique to illustrate how inappropriate pasting in physician notes creates unnecessary verbiage in the record, and more seriously, increases the patient safety risk when the information recorded just isn't true. As EHR systems are adopted and the humans who use them adjust their thought flow and work flow accordingly, unintended consequences will occur in the use of information technology. An increased potential for fraudulent activity also exists, as it become easier to manufacture credible looking documentation for undeserved health plan reimbursement.

The Department of Veteran's Affairs (VA) recognized documentation integrity challenges with electronic record systems. This prompted the VA to complete a study to identify plagiarism when text was copied without attribution to the original author in physician-generated notes.[2,3] Six risk categories were developed to evaluate results. The top two levels were associated with potential danger to patients, and the chief of health information management systems identified a need for remedy at these levels. The level-four risk category was deemed to be of concern for inaccurate coding.

Findings yielded a 37% risk category for patient records clinical data and/or code assignment accuracy (6% of patients). Susan Helbig, MA, RHIA from the VA Puget Sound in Seattle, leveraged this study to formulate recommendations for better documentation. Opportunities for remedy included education, the creation of embedded links in an EHR that take users back to the source document they wish to reference, and EHR functionality changes in the display characteristics within the electronic systems. Plagiarism is only one of a number of unintended consequences that result from using technology tools in health records that concern the compliance professional community.

Guidelines to prevent EHR fraud

To evaluate the existing issues that create compliance problems, the American Health Information Management Association (AHIMA) convened an e-HIM® work group of subject

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Inserted in this issue of **Compliance Today** is a quiz related to this article: "Compliance considerations for electronic health record documentation " by Rita A. Scichilone, on this page.

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matter experts to develop suitable guidelines to prevent fraud in electronic health record documentation. The participants included fraud investigators, physicians, attorneys, information technology specialists, health information management professionals, coding and reimbursement specialists, compliance officers, audit managers, and technology vendors. The work group produced a set of guidelines (available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_033097.hcsp?dDocName=bok1_033097), an EHR fraud checklist, and three case studies that are helpful for compliance education and discussion starters.

The identified areas of concern regarding some EHR environments centered around the following functions:

- Authorship integrity
- Auditing integrity
- Documentation integrity, and
- Patient identification and demographic accuracy

Avoiding the path towards dirty data

Health records are generally a composite of observations made by physicians, nurses, pharmacists, therapists, social workers and others who record the interventions made while providing patient care services. All these clinicians have a role in data quality and document completeness. It is important for the record data set to reflect who is responsible for the entries made. Any EHR features or tools that allow unrestricted changes to released documents, or allow authors or others to change or eradicate the work documentation, must be prohibited or carefully controlled.

Determining who is responsible for providing services is a concern in both a paper chart environment and its electronic replacement. One method of healthcare fraud includes using unlicensed or otherwise unqualified individuals to perform services while submitting claims under the provider number of a legitimate practitioner.

Another authorship and documentation integrity issue that is well known to the compliance profession involves academic medical centers and Medicare payments. Teaching institutions must provide evidence pursuant to 42 CFR 415.172 (b) that the documentation must identify, at a minimum, the service furnished, the participation of the teaching physician in providing the service, and whether the teaching physician was physically present. Students may document services, but for evaluation and management (E&M), the documentation is limited to review of systems and/or past family/social history. The teaching physician should not copy and paste student documentation of physical exam findings or medical decision making into their own notes. If a medical student documents E&M, the teaching physician must verify and re-document the history of present illness as well as perform and re-document the physical exam and medical decision making.

Tool time

Documentation tools, such as templates and other forms of automated text production, must be used with care. Appropriate safeguard policies, best practices, or the assistance of software functionality must be applied to prevent degradation of data quality.

Computer-generated "macros" are acceptable for shortening data input for busy clinicians; however, their use should be monitored to make sure the results accurately represent the services provided and will not compromise the integrity of the record in court. To ensure that the record meets legal requirements, appropriate audit trails are required in electronic systems to track changes made in documentation and to preserve the integrity of the content.

Auto-authentication means that a physician or other authorizing person in an electronic health record environment signs multiple documents at one time without opening them. With auto-authentication, judicious review for accuracy falls short of federal and state authentication requirements and this could place the organization at legal risk when accuracy of the record and its ability to serve as a legal document are required.[5,6,7]

Thou shalt not steal

"Borrowing" data from other sources (where copy-and-paste or "pull forward" techniques are used) must be carefully monitored, particularly when this involves E&M service coding for reimbursement. The resulting billing codes are based on work intensity elements and the expectation that the documentation correctly reflects the service rendered at the encounter in question. For example, when a patient comes to a physician office with a new problem, the physician is expected to perform a complete review and update of the family and social history, a history of the present illness, and a current review of systems. This is followed by a physical exam appropriate to the chief complaint, and then medical decisions are made. Finally, a plan of care is developed. If a physician were to "pull forward" the history elements from the initial visit into a subsequent follow-up visit, there is a risk that the E&M may include elements that were not provided during the second encounter. It would be inappropriate to consider the history review in the level of service, despite the fact that the physician note makes it appear that the history elements were repeated at the subsequent visit and should be a factor in the service intensity level. E&M calculation software tools must also be used with care to assure that any documentation generated reflects services actually provided at the level represented.

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The codes that are included in claims for payment are based on data and recorded observations in the patient's health record. There are critical reasons why the record must be kept clean and pure and always reflect what is or what was. Manufactured documentation may support the code assignments for work intensity or medical necessity, but when the documentation is false, dirty data results—even when traditional billing audits fail to uncover problems. All EHR documentation tools should be designed to foil criminals' intent to steal from others, instead of making it easier for them to get away with it.

Building a better approach

The AHIMA-sponsored work group established that preventing fraud caused by the deliberate falsification of information when using EHRs requires three primary conditions: Organizational desire and commitment to

1. Conduct business and provide care in an ethical manner,
2. Purchase EHR systems that include the functions and capabilities to prevent or discourage fraudulent activities, and
3. Implement and use policies, procedures, and system functions and capabilities to prevent fraud.

These are straightforward and common sense observations, but when put into practice, they may be impossible to achieve without the use of behavioral guidance and system knowledge, full assessment of EHR systems capability, and frank discussions with EHR software suppliers, both before and after purchase.

Compliance officers and department staff should be involved in EHR policies and procedures as well as oversight of educational training that includes proper use of electronic tools. The compliance office should also evaluate any EHR features that place the organization at risk for documentation falsification, theft, or misuse of clinical data. Minimum capabilities that must be available to build integrity into the process, avoid legal issues, and reduce compliance risk include:

- Access-control functions to minimize risk of unauthorized access to health information generation and storage systems;
- Capability to attribute the entry, modification, or deletion of information to a specific individual or subsystem;
- Capability to log all activity and produce audit trails that ensure the legal requirements of health records are maintained; and
- Data entry editing to verify the validity of information when possible, checking for duplication and/or conflicts, and controlled and limited automatic creation of information.

Business rules are helpful in creating an environment for documentation compliance with existing standards and regulations, or just to set expectations for users of information within organizations. Rules for authorization of specific users and/or groups of users are used to control performance of specified actions on documents in a particular status of development. Documentation guidelines or medical staff rules and regulations might address or complement guidelines related to the elements of electronic note style and requirements. Dr. Thomas Payne et al[8] offer some tips on writing physician visit notes in an electronic environment by proposing eight different rules to follow. Rule three includes some strong language. It reads:

"Don't copy others' notes: In your written assessment, a clear and intelligent discussion of a patient's problem is a valuable contribution to the patient's care and allows other clinicians to understand your thoughts about a case. You should write this evaluation and plan yourself. Copying others' notes without attribution is plagiarism, a morally and legally indefensible act."[8]

The AHIMA work begins the framework for additional study and investigations that must be carried out at the local level.

Compliance professional community action needed

As we invest in new tools and electronic data capture, storage, and sharing of health information, all members of the healthcare team are required to ensure that they don't discard or ignore the foundational principles that have kept health records a trusted source by patients, providers, and payers who depend on the accuracy and appropriateness of the content. Compliance professionals are a key member of this team in risk assessment, education, regulatory framework confirmation, legal issue resolution, and other initiatives that keep fraudulent activity out of the healthcare delivery system.

As issues are identified, solutions will be developed and applied to preserve the validity of health data. Software tools will be perfected to provide fraud prevention and detection assistance. Now that more systems are in place, there is greater opportunity for standardization and sharing of methods and best practices to make the systems function as they should and keep the dirty data out of the picture. ■

1 Hirschtick, Robert E. "Copy and Paste.". Journal of the American Medical Association, 2006 May 24;295(20):2335-2336
2 Helbig, Susan. "Copying and Pasting in the EHR-S: an HIM Perspective." 2004, IFHRO Congress & AHIMA Convention Proceedings
3 Hammond, Kenric W; Helbig, Susan; Benson, Craig C; et al. "Are Electronic Medical Records Trustworthy: Observations on Copying, Pasting and Duplication" AMIA Annual Symposium Proceedings 2003: 269-273. Full text available at http://www.pubmedcentral.nih.gov/articlerender.fcgIartid=1480345
4 AHIMA Practice Brief: "Guidelines for Electronic Health Records Documentation to Prevent Fraud." Journal of AHIMA, October 2005. Available at www.ahima.org.
5 AHIMA Practice Brief: "Implementing Electronic Signatures." Available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_021585.hcsp
6 AHIMA Practice Brief: "Maintaining a Legally Sound Medical Record." Available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028509.hcsp
7 AHIMA Practice Brief: "The Legal Process and Electronic Health Records." Available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028134.hcsp?dDocName=bok1_028134
8 Payne TH, Hirschmann JV, Helbig S: Elements of electronic note style. Journal of the American Health Information Management Association 2003; 74:68, 70

feature focus

A review of the McNulty Memorandum

Editor's note: The following articles review the U.S. Department of Justice revision of its corporate charging guidelines for federal prosecutors throughout the country. This guidance was outlined during a speech before the Lawyers for Civil Justice in New York on December 12, 2006, by U.S. Deputy Attorney General Paul J. McNulty. It revises the Thompson Memorandum, which was issued in January 2003 by then-Deputy Attorney General Larry D. Thompson and title the "Principles of Federal Prosecution of Business Organizations." The memo provides useful guidance to prosecutors in the field through nine factors to use when deciding whether to charge a corporation with criminal offenses.

This series focuses on:
1) The McNulty Memorandum's discussion of corporate compliance programs at Section VIII. It is reviewed by Cheryl Wagonhurst and Richard K. Rifenbark. Ms. Wagonhurst is a partner with Foley & Lardner LLP. She is a Certified Compliance and Ethics Professional (CCEP) and a member of the Health Care Compliance Association's Board of Directors. She may be reached by telephone at 310/975-7839. Mr. Rifenbark is a senior associate with Foley & Lardner LLP and may be reached by telephone at 310/97-7793.

2) The discussion of attorney-client and work product privileges, which is reviewed by Gabriel L. Imperato. Mr. Imperato is the Managing Partner of the Fort Lauderdale office of Broad and Cassel and chairman of the firm's White Collar Criminal and Civil Defense Fraud Group. He is Certified in Healthcare Compliance (CHC) and he is a member of the board of the Health Care Compliance Association. He can be reached by telephone at 954/745-5223.

3) The discussion about paying for counsel for individual subjects, which is reviewed by R. Christopher Cook. Mr. Cook is a partner in the Washington, D.C. office of Jones Day. He may be reached by telephone at 202/879-3734.

DOJ's McNulty Memorandum emphasizes that "paper" compliance programs may not be worth the paper on which they're written

By Cheryl Wagonhurst, CCEP and Rick Rifenbark

In the Department of Justice's recently issued memorandum entitled "Principles of Federal Prosecution of Business Organizations," Deputy Attorney General Paul McNulty describes, among other things, the importance of an effective compliance program in a prosecutor's evaluation of whether to criminally charge a corporation. Although it should come as no surprise to those in the compliance community that compliance programs must be "living" programs that have the support of management and the board of directors and continuously evolve to meet identified risks, the "McNulty Memorandum" serves as an important reminder that compliance programs are of little value if they are simply "paper programs." This also gives an organization an opportunity to assess and/or reevaluate the effectiveness of its compliance program.

The McNulty Memorandum

Like the "Thompson Memorandum" before it, the McNulty Memorandum provides guidance to prosecutors who are investigating whether to bring criminal charges against corporations. Prosecutors are required to consider nine factors, one of which is "the existence and adequacy of the corporation's pre-existing compliance program."[1] However, in order for a compliance program to positively influence a prosecutor's decision whether to criminally prosecute a corporation, the McNulty Memorandum emphasizes that compliance programs must be active programs with dedicated resources that detect and deter violations of law. The McNulty Memorandum cites several cases that emphasize that corporations may not avoid criminal liability for the actions of their employees simply because a compliance program is in place that prohibits violations of law. Moreover, a key consideration

is whether management and the board of directors support a corporation's compliance program.

Although the McNulty Memorandum acknowledges that the Department of Justice has no formal guidelines for corporate compliance programs,[2] it does provide certain questions that prosecutors should ask when assessing a corporation's compliance program. These questions include "[i]s the corporation's compliance program well designed" and "[d]oes the corporation's compliance program work?"[3] To help answer these questions, the McNulty Memorandum states that prosecutors should consider:

- The comprehensiveness of the compliance program;
- The extent and pervasiveness of the criminal conduct at issue;
- The number and level of corporate employees involved in the criminal conduct;
- The seriousness, duration, and frequency of the misconduct;
- Any remedial actions taken by the corporation, including restitution, disciplinary action, and revisions to corporate compliance programs;
- The promptness of any disclosure of wrongdoing to the government and the corporation's cooperation in the government's investigation;
- Whether the corporation has established governance mechanisms that can effectively deter and prevent misconduct;
- Whether the corporation has provided for a staff sufficient to audit, document, analyze, and utilize the results of the corporation's compliance efforts; and
- Whether the corporation's employees are adequately informed about the compliance program and of the corporation's commitment to it.[4]

All of these questions are intended to determine whether the corporation's compliance program is simply a "paper program" and whether management may actually be encouraging illegal behavior notwithstanding the existence of a compliance program. Obviously, compliance programs that are determined to be paper programs will not be given positive consideration in prosecutors' determination of whether to criminally charge the corporation.

Practical implications for compliance officers and compliance programs

Corporations and compliance officers should use the McNulty Memorandum as a reminder that compliance programs are only effective if they are actually used and become fully integrated into the corporation's culture. To that end, a corporation should carefully review its compliance program and procedures to assess how they match up with the various items discussed in the McNulty Memorandum.

The McNulty Memorandum prompts prosecutors to consider whether (i) boards of directors exercise independent judgment over corporate management's actions, (ii) internal audit functions are conducted at a sufficiently high level as to ensure independence and accuracy, and (iii) boards of directors receive sufficient information to exercise independent judgment and stay informed regarding compliance activities.[5] Simply stated, a corporation's board of directors should be involved in assessing the corporation's compliance with the law and not simply rubber stamp management's actions. Compliance officers are well advised to evaluate the role of the corporation's board of directors in their compliance programs with an eye towards the points raised in the McNulty Memorandum.

A corporation should evaluate the existing structure and authority for its compliance program and consider whether the program only exists on paper in the form of a compliance manual or handbook or whether it is a program that is appropriately staffed, funded, and fully supported from the top of the organization. This involves looking at the current job description of the compliance officer and making a decision as to whether the position should be a full time employee rather than one combined with another role or job duties in the organization. In addition, the corporation should consider how the various departments and individuals within the corporation could serve to support the overall compliance program. Once the corporation has determined the type of structure that it requires to implement its program, then it should be prepared to devote the necessary funding to support that

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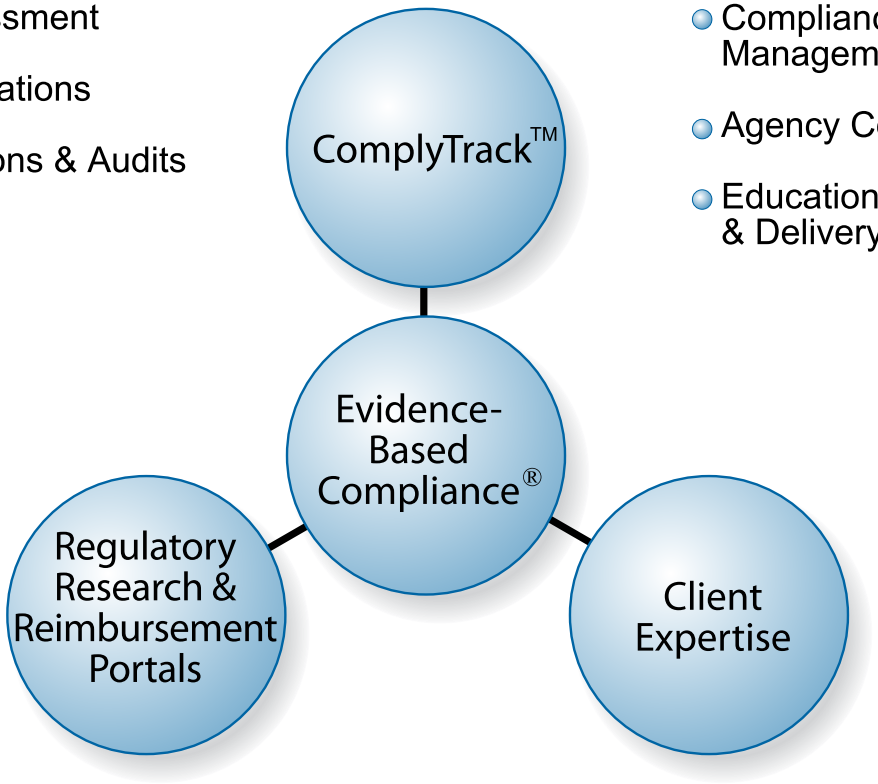

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structure. A corporation should also consider developing a charter for the compliance program which is approved by the board of directors and senior management of the corporation to ensure that the program has full support and authority. The corporation should develop an annual compliance work plan which serves to identify the top risk areas for the corporation and articulates how each risk will be appropriately addressed through policy and procedure development and enforcement, training, monitoring, and auditing. Finally, the corporation should do an annual assessment of its compliance program to ensure that it is a living, breathing, functional program worthy of the paper it's written on.

One way to ensure that a compliance program is not a "paper program" is to consider what measures are in place to test a compliance program's effectiveness. Examples of such measures include questionnaires to employees regarding their knowledge of the compliance program's features, periodic audits of billing and collections or other identified high-risk areas, and use of outside consultants to assess the strengths and weaknesses of the compliance program. Compliance officers should also carefully document other items that demonstrate that their compliance program is publicized and effective, such as documenting attendance of training presentations, hotline complaints and appropriate follow-up, any governmental disclosures, instances where employees are disciplined for compliance violations, and, where appropriate, the results of any internal investigations.

Conclusion

Although the discussion of the corporate compliance programs in the McNulty Memorandum essentially reiterates the guidance set forth in the Thompson Memorandum, it is still worthwhile for compliance officers to reevaluate their compliance programs with the McNulty Memorandum in mind. If such an evaluation reveals only a "paper program," it is time to dust it off and make it a priority.

Department of Justice revises policies regarding waiver of privilege

By Gabriel L. Imperato, Esq., CHC

As noted above, the Department of Justice recently modified its Principles for Federal Prosecution of Business Organizations, published in January, 2003, (i.e. Thompson Memo) related to requests for waiver of the attorney/client and work product privileges and payment of attorney fees for organization employees. These modifications to the DOJ prosecution policies may have the effect of strengthening compliance effectiveness for business organizations.

The revised Principles for Federal Prosecution of Business Organizations (i.e. now referred to as the "McNulty Memo") emphasize that requests for waiver of privilege should be rare and prosecutors should not negatively consider a refusal by an organization to consent to a request for waiver or the advancement of legal fees to organization employees when making charging decisions in criminal and civil enforcement matters. There were a number of reasons for these revisions, but one important reason cited by Deputy Attorney General McNulty in announcing this change in the Thompson Memo prosecution policy was to strengthen organizational efforts to detect and prevent wrongdoing and misconduct and to encourage self policing and cooperation with law enforcement by business organizations.

This article will primarily focus on the issue of cooperation and waiver of the attorney-client privilege and work product protections and how this issue has evolved over the past several years resulting in the McNulty Memorandum.

The Thompson Memo

The original Principles of Federal Prosecution of Business Organizations (previously referred to as the Thompson Memo), reinforced general prosecutorial objectives involving the charging of a corporation, but pointedly focused its emphasis on the thoroughness of and authenticity of a business organization's cooperation in investigating its own wrongdoing during a government investigation. The Thompson Memo, and the aggressive prosecution policies it reflected, was a natural by product of the abuses identified in earlier corporate scandals, such as Enron, World Com, Arthur Andersen, and Health South. The Thompson Memo noted that the DOJ must evaluate the weight of the evidence, the likelihood of success at trial, the deterrent

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effect, the consequences of filing charges and the adequacy of alternative approaches when considering whether or not to bring charges against an individual or an organization. The Thompson Memo, however, acknowledge that a federal prosecutor must examine additional factors before reaching a decision on the treatment of a business organization target of an investigation. The additional factors cited in the Thompson Memo included the:

- nature and seriousness of the offense
- risk of harm to the public
- pervasiveness of wrongdoing within the organization
- history of the organization's similar conduct
- disclosure of wrongdoing
- organization's willingness to cooperate
- existence of a compliance program or remedial action, and
- adequacy of charges against any individuals responsible for the misconduct

The Thompson Memo is perhaps most known for emphasizing its consideration of an organization's cooperation during an investigation and its remedial actions when contemplating a decision on whether or not to charge the organization. The Thompson Memo also cited factors which would play-in to this determination and the measure of an organization's willingness to cooperate including: the organization's ability to make witnesses available; the disclosure of the complete results of the organization's own internal investigation; and, if necessary, a waiver of the attorney-client privilege and work product protection. The comment section to the Thompson Memo further stated that waiver of a corporation's attorney-client privilege is not an absolute requirement, but sometimes it might be necessary. The Thompson Memo quite clearly advised federal prosecutors that in measuring "cooperation" they may consider whether a business organization turned over the results of its internal investigation and whether it waived applicable attorney-client privileges and work product protections.

An address by the then Deputy Attorney General of the United States, James Comey, to attendees of the American Bar Association Health Fraud Institute 2004 in New Orleans, further elaborated on the federal government's view of "cooperation." The Deputy Attorney General noted that the DOJ understands the term "cooperation," as reflected in the Thompson Memo, Sentencing Guideline Amendments of 2004 and in court decisions, to mean assistance that discloses all pertinent information sufficient for the government to identify the individuals responsible for criminal conduct and to understand the full scope of that conduct. According to the Deputy Attorney General, at that time, cooperating organizations should enable government investigators to

gather facts before they become stale and assist in recovering losses incurred by the victims of wrongdoing. However, the Deputy Attorney General did note that what constitutes cooperation can vary from case-to-case and that, at a minimum, it must be recognized that if a corporation has learned precisely what happened and who is responsible, then it must turn the information over to the appropriate authority to receive credit for cooperation or a reduced culpability score under the United States Sentencing Guidelines for Organizations. The Deputy Attorney General emphasized during his remarks that if a business organization expected to receive credit for cooperation, then "it must help the government catch the crooks."

The critics of the Thompson Memo and its application regarding "cooperation" and waiver of the attorney-client privilege and work product protections believe that the Justice Department was mandating waiver as a factor in assessing cooperation. These critics argued, as a practical matter, that the government was routinely demanding waivers, making it the norm, rather than the exception, which was a proposition that Deputy Attorney General Comey expressly rejected during his remarks at the ABA Health Fraud Institute in 2004.

The DOJ position of "give us the necessary information one way or another or face prosecution" is exactly the situation that the critics of the Thompson Memo feared would develop regarding the issue of cooperation and waiver of the attorney-client privilege and work product protections. These critics argued that a waiver of privileged information would cause: (1) less thorough organizational internal investigations in their efforts to detect and prevent wrongdoing (because of the fear that the organization would ultimately have to turn over this factual information as a consequence of "cooperating" with federal law enforcement authorities); (2) a chilling effect on the ability of counsel to give advice to clients in compliance matters (also for fear of it being disclosed to federal law enforcement authorities); (3) an erosion of the fundamental relationship between business organizations and its employees (because of the likelihood of organization "cooperation" with federal law enforcement authorities resulting in the disclosure of information forming the basis for individual employee culpability); (4) a relaxation of government investigation methods by piggybacking the efforts of the organization's review; and (5) an increased exposure to civil litigation by third parties (because of waiver of the attorney-client privileges and work product protections).

The combined effect of the Thompson Memo, the Sentencing Guideline Amendments of 2004, and aggressive incentives for a business organization to cooperate created a climate of dynamics which left business organizations little choice, but to cooperate fully and promptly with federal law enforcement investigators. These circumstances literally coerced business organizations into cooperation and according to critics created a "culture of waiver" of the attorney-client privilege and work product protections for business organizations. The chief executives and the counselors to business organizations have speculated whether "cooperation" under these circumstances really meant anything more than "unconditional surrender."

The criticism mounts and the McNulty Memorandum is published

The application of the principles and guidelines enunciated in the original Thompson Memo by various DOJ attorneys across the country, since its publication in 2003, precipitated a mounting crescendo of criticism and actions by the Courts, the United States Sentencing Commission, and, ultimately, the United States Congress. The Coalition to Preserve the Attorney-Client Privilege (Coalition) lobbied the US Sentencing Commission and the US Congress about its concerns with the application of the Thompson Memo and erosion of the attorney-client privilege. The Coalition consisted of a broad base of business organizations, including the Association of Corporate Counsel, the Business Roundtable, the United States Chamber of Commerce, the Retail Industry Leaders Association, the National Association of Criminal Defense Lawyers, the National Association of Manufacturers and, ultimately, several former Attorney General's of the United States. The United States Sentencing Commission also weighed in on this issue and modified its commentary language, which was associated with the amendments to Chapter 8 of the Sentencing Guidelines for Organizations in 2004. The original commentary language stated the following with respect to cooperation and waiver of the attorney-client privilege:

Waiver of attorney-client privilege and of work product protections is not a perquisite to a reduction in culpability score [for cooperation with the government]…unless such waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization.

The US Sentencing Commission reconsidered this commentary and in March 2006 deleted the phrase "unless such waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization," thereby staking out "neutral" ground on the issue. The federal courts also addressed the application of the principles in the Thompson Memo related to waiver of the attorney-client privilege in the case of *U.S. v. Stein*, in the Southern District of New York (otherwise known as the KPMG case). This

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feature article

Meet Mildred L. Johnson, JD, CPC, Institutional Compliance Officer at Texas Tech University Health Sciences Center

Editor's note: The following interview was conducted in late November 2006 by Jennifer O'Brien, Allina Hospitals & Clinics Compliance Officer - VP Compliance and Regulatory Affairs, and Secretary of the HCCA. Mildred Johnson may be reached by e-mail at millie.johnson@ttuhsc.edu.

JO: Tell us about your background and the journey that brought you to your current role.

MJ: I am a graduate of Gonzaga Law School and have practiced in various areas of the country, with a primary focus on healthcare law. I became an active member of HCCA in 1997 and in 2000, I received my CPC (Certified Professional Coder) through the AAPC (American Association of Professional Coders). In 1997, I joined Creighton University as Compliance Director. Initially, my primary responsibilities were to implement the billing compliance program for the Health Sciences Schools composed of the School of Medicine, Dental School, School of Nursing and Pharmacy, and Allied Health. I assisted with HIPAA (Health Insurance Portability and Accountability Act) implementation and was given primary oversight of the Radiation Safety Program. As compliance activities evolved, I was heavily involved in the development and implementation of the Research Compliance Program, which included animal research, human subjects research, recombinant DNA and select agents, grants administration, and related areas. For the past three years I have developed and taught a business course on compliance issues through Clarkson College in Omaha.

Based on my role at Creighton University, I was ready to take compliance to the next level in the academic environment, centralizing compliance activities to encompass all regulatory areas impacting the academic environment. The new position of Institutional Compliance Officer at Texas Tech University Health Sciences Center (TTUHSC) gives me the opportunity to centralize compliance activities within an academic environment focused on the health sciences, allowing me to utilize my expertise of regulatory compliance in academic environment devoted to health sciences programs.

JO: What are some of your responsibilities as Compliance Officer at Texas Tech?

MJ: Since this is a new position for TTUHSC (as well as for academia in general), my responsibilities are somewhat in flux. At this time, I am primarily responsible for the billing compliance program and HIPAA privacy. However, my role is much broader, as I will serve as a primary resource for all regulatory areas, including, but not limited to, research compliance, environmental health and safety, FERPA (student records privacy), GLB (Gramm-Leach-Bliley) and other regulatory areas. My initial goal is to develop the lines of communication between and among all of these areas as they, at one point or another, interact with each other and sometimes their activities may impact other areas. Another focus will be to develop mechanisms to minimize the training burdens by centralizing some of these activities through existing mechanisms.

JO: What is your reporting structure?

MJ: I report to the University President. I also have the ability to go to the Board of Regents as necessary to ensure the integrity of the compliance program.

JO: Tell us about Texas Tech University System and the scope of your compliance duties? Has that scope changed recently?

MJ: The Texas Tech University System is

unique in that it has two separate schools, the Texas Tech University (undergraduate and some graduate programs) and the Texas Tech University Health Sciences Center. While each School has its own President, they operate under a single Chancellor and state Board of Regents. The Texas Tech University Health Sciences Center is a five-school university located on four campuses and one academic center, with a second academic center opening in 2007. The four campuses are located in Lubbock (the primary campus), Amarillo, El Paso, and the Permian Basin. We currently have an academic center in Dallas/Fort Worth with one opening in Abilene, both connected with our School of Pharmacy.

Since this is a new position for TTUHSC, I can't really address any change of scope at this time.

JO: What are the unique compliance challenges you face working in an academic setting?

MJ: As you can see, with five schools, four campuses, and two academic centers, one of my challenges in the TTUHSC academic setting will be dealing with the unique cultures of each area. The goal is utilize the strengths of each to develop common policies, procedures, and practices to maximize our resources while focusing of the risk areas that are unique to each campus/academic center and School.

One challenge in the academic setting in general is the need to convince faculty (especially those in the non-sciences) that implementation of compliance oversight will not interfere with academic freedom. Another challenge is to avoid the "them" vs. "us" mentality when implementing corrective action plans, so that all members of the academic community are treated in a uniform manner when there is non-compliance.

JO: What are the biggest compliance risk areas for your institution?

MJ: The compliance risk areas for TTUHSC are similar to those of other academic medical centers, primarily billing activities, especially when residents are involved, and federal research grants as pointed out by the Office of Inspector General in its compliance guidance for PHS (public health service) research facilities. The other risk, which I think is relatively universal for all institutions, is the break down of communication among and between departments.

JO: Where are you in the development of your compliance program?

MJ: TTUHSC is now poised to integrate and consolidate its various regulatory compliance activities under the "umbrella" of the Institutional Compliance Office. This is a work in progress, so you may have to check in with me in a year to see where we have grown. At this time, my focus in on the billing compliance functions, to restructure the current system to achieve efficiency and centralization. One thing that I am working on right now is to emphasize the role of the compliance officer as a resource.

JO: How do you go about getting employee and staff support for your compliance efforts?

MJ: I think that employees and staff want to do the right thing and they will support the compliance efforts IF they know that they will receive support. By "support" I'm not necessarily talking about financial support, but leadership support. The compliance office must not only inform leadership on what is necessary to ensure compliance, but must inform employee and staff of the risks and assist them in developing the controls and tools necessary to minimize those risks. In addition, when necessary, the compliance office needs to stand ready to justify the need for increased financial support when it is necessary to implement the compliance program.

JO: How do you respond to the challenge of keeping education and training interesting and effective?

MJ: Education becomes interesting and effective when it becomes interactive rather than a "lecture." One way to do this is to make the training department-and-job specific; avoid a generic "one size fits all" mentality. This is especially critical when you are dealing with billing compliance risk areas. A training module for anesthesiologists should not have a heavy focus on E&M (evaluation and management) documentation. Conversely, training for cardiologists should not focus on Medicare's Primary Care Exception, because it does not apply to them.

New information also creates interaction. Bringing in new information should never be a challenge as there are always new things to address, whether they be OIG audits of an area relevant to your institution, information from the OIG's Annual Work Plans, CERT (Comprehensive Error Rate Testing) results. I am anticipating that within the next year (and maybe I'm being optimistic) there will be reported results from the Medicaid Integrity Program audits.

In addition to outside resources, your internal monitoring and auditing activity

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can also provide additional information. Not only should you focus on "weak" areas, but you should also identify where staff have improved their practices to minimize risk.

Finally, I think it is critical, where appropriate, to discuss "problem areas" with staff and incorporate that information into your training materials.

JO: Do you have any tips for measuring compliance effectiveness?

MJ: You know that your actions are effective when people within the organization seek out your advice and assistance before implementing changes to ensure that their proposal is compliant. The free flow of information means that people are not only listening, but understand the importance of their role in meeting compliance standards and regulatory requirements.

JO: What do you see as the greatest compliance challenges for your industry in the next five years?

MJ: I think academic institutions are going to receive more focus, not only with respect to their varied research funding and activities, but also with respect to complying with their accrediting standards. Failure to comply with a regulatory requirement could jeopardize their accreditation.

Academic institutions are likely to see more of a focus in the area of hazardous materials through OSHA, especially with respect to clinical and non-clinical laboratories. Many academic institutions have to deal with two separate standards, one for clinical laboratories and another for non-clinical laboratories, such as photo labs, chemical labs, etc.

Healthcare providers, including those in the academic setting, are probably going to see more focus on patient quality-of-care beyond the current trend to monitor quality at the institutional level.

Finally, I think all healthcare providers are going to encounter challenges with implementation of EHRs (electronic health records), especially due to the lack of specific guidance on what is and is not acceptable for documentation of services, teaching physician macros, and usage of "defaults" within the system.

JO: You've attended the HCCA Compliance Institute. What do you feel are the benefits of attending the Institute?

MJ: The HCCA Compliance Institute offerings have been essential to my growth as a compliance officer. It allows for an opportunity to extensively network with peers facing similar issues, to identify best practices, and to share information. The knowledge and expertise of the speakers are invaluable, and many not only bring real life experiences, but also resources that others can use and adapt to their compliance programs. The topics deal with current trends and avoid "glossary" reviews of the information.

JO: HCCA offers a number of educational opportunities. Which most match your needs?

MJ: I think the regional compliance programs are very helpful as they focus on regional risk areas and allow an opportunity to network with your peers in that area.

JO: What advice would you give to someone just starting out in compliance and setting up a program?

MJ: The three most important things to remember are "communication," "communication," and "communication." Without that interaction, the compliance program will not flourish and grow. Beyond that, I think it is critical that the compliance officer learns the organizational structure of the institution. The TTUHSC has a Fact Book, which I found to be an invaluable resource as it "mapped out" in detail the focus of the institution and the organizational structure of each major department/division of the school. Second, it is important to go into the position without any preconceived assumptions—each organization has its own unique culture and process. Finally, develop networks within the organization and within the communities in which it operates—it's amazing what you will learn from your staff and your colleagues. ■

Ask Leadership *...continued from page 3*

are undertaken to address specific risk areas associated with OHSA compliance and that the appropriate auditing and monitoring are adequately designed and undertaken to detect misconduct and/or unethical behavior.

Also, the compliance officer would be responsible for ensuring that appropriate measures are taken if misconduct or unethical behavior is detected, including "internal investigative" activity, appropriate corrective action and perhaps "disclosure" to third parties where this is either mandatory or called for as a voluntary action. Finally, the compliance officer would be the last word in responsibility for ensuring that ongoing risk assessment is taking place with respect to OHSA activity for the business organization.

The bottom line for a compliance officer is that he or she is ultimately responsible for the organization's adherence to the essential elements for compliance program effectiveness, regardless of delegation to other employees within the organization for specific regulatory compliance in discreet subject areas (i.e., OHSA or billing and coding). ■

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case involved the prosecution of individual partners and employees of the accounting and consulting firm, KPMG. The organization had not only waived attorney-client privilege and disclosed information to the federal government in this case, but had withdrawn financial support for the defense of its employees during its cooperation with the federal government and prior to reaching a settlement of potential charges against the organization. The US District Court in reviewing the prosecutorial tactics against KPMG and the business organization's response to those tactics, found that the overwhelming coercion against the organization to waive attorney-client privilege and to withdraw support to its employees, violated the individuals Fifth Amendment right to due process and the Sixth Amendment right to counsel. These findings by the Court had a profound effect on the momentum and criticism of prosecutorial tactics involving waiver and support of the defense of employees by organizations. Finally, the US Senate introduced legislation in November of 2006 entitled the "Attorney-Client Privilege Protection Act of 2006. This proposed legislation prohibits waiver of the attorney-client privilege by an organization and allows for limited and selective waiver of privilege upon disclosure of information to the government. These actions clearly set the stage for a revision of the Principles of Federal Prosecution of Business Organizations reflected in the Thompson Memo, ultimately resulting in publication of the McNulty Memo.

The McNulty Memo is an attempt by the DOJ to amend the content of the Thompson Memo regarding requests for waiver of privileges by organizations and indemnification of the costs for employee legal defense. The McNulty Memo affirmed the nine basic factors reflected in the Thompson Memo, but adds some unprecedented restrictions on prosecutors seeking privileged "factual" and "legal" information from organizations. It creates new procedural approval requirements, within the DOJ, before requests for a waiver of attorney-client privilege and work product protections can be made by line prosecutors in law enforcement investigations. The McNulty Memo states that federal prosecutors must establish a legitimate need for privileged information and must seek approval before requesting such information from the Deputy Attorney General of the United States. The procedures require that when a federal prosecutor seeks privileged "factual" information from an organization, then approval must be obtained from the local US Attorney, who must consult with the Deputy Attorney General. (i.e. facts developed as a result of an organization's internal investigation).

The McNulty Memo cautions that requests for waiver should be sought only in rare circumstances and if a company refuses, after the government makes such a request, then such refusal should not be considered against the business organization when the government determines whether or not to bring charges. The McNulty Memo advises prosecutors to request factual information first and make sure they can establish a legitimate need before requesting waiver of privilege to obtain attorney-client communications or legal advice.

The tone of the McNulty Memo was also reflected in the Deputy Attorney General's remarks to "Lawyers for Civil Justice" in New York on December 12, 2006. The Deputy Attorney General's speech coincided with the announcement and dissemination of the revised Principles of Federal Prosecution of Business Organizations. Deputy Attorney General McNulty emphasized that the "memorandum amplifies the limited circumstances under which prosecutors may ask for waivers of privilege." The Deputy Attorney General further emphasized that prosecutors must show a "legitimate need" for such privileged information and he advised that in order to meet this test, prosecutors must show:

1. The likelihood and degree to which the information will benefit the government's investigation;
2. Whether information can be obtained in a timely and complete manner by using alternative means that do not require a waiver;
3. The completeness of the voluntary disclosure already provided; and
4. The collateral consequences to requesting a waiver.

The Deputy Attorney General went on to say that "the privilege is protected to such an extent, that even if prosecutors have established a legitimate need and I approve a request for a waiver, the DOJ will not hold it against the corporation if it declines to give the information. That is, prosecutors will not view it negatively in making a charging decision" according to the Deputy Attorney General.

The content of the McNulty Memo and the Deputy Attorney General's remarks before the civil lawyers reflect that the revisions to the Federal Principles of Prosecution of Business Organizations are designed to encourage organizations to prevent wrongdoing through self-policing and cooperation with law enforcement. The Deputy Attorney General, in fact, stated that "the best corporate prosecution is the one that never occurs. Through successful corporate compliance efforts, (see review by Cheryl Wagonhurst and Richard K. Rifenbark above) investor harm can be avoided. Corporate officials must be encouraged to seek legal advice if they are in doubt about requirements of the law." The Deputy Attorney General further emphasized that "if that relationship (i.e. attorney-client) is interfered with, if those communications are unfairly breached, it makes it harder for companies

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to detect and remedy wrongdoing."

Finally, it should be pointed out that the McNulty Memo does make a distinction between the disclosure of attorney-client privilege "factual" information and attorney-client privileged "legal" information. The factual information is the kind of information gathered by an organization through its own internal investigation and essentially involves the who, what, where, why, and when of misconduct. This information can be requested with the permission of the local US Attorney who must consult with the Deputy Attorney General. If a corporation declines to provide this information to the government, then the government prosecutors may negatively take that into consideration in measuring the degree of the organization's cooperation. The request for waiver of the attorney-client privilege to obtain the advice of counsel or the mental impressions of counsel must be requested directly from the Deputy Attorney General. If this request is approved and a request for waiver for this type of information is made to a corporation, then a refusal by the corporation to turn over this type of information, would not be negatively held against the organization during consideration of the government's charging decision.

Conclusion

The McNulty Memo clearly seeks to reverse a practice and/or perception involving "routine requests" for waiver of the attorney-client and work product protections by business organizations. The McNulty Memo attempts to emphasize the importance of the attorney-client privilege and work product protections. The procedures for approval of such requests within the DOJ are unprecedented and clearly designed to ensure that such requests are rarely made, and when they are made, it will be uniformly reviewed at the highest levels of the DOJ. It remains to be seen how the McNulty Memo and its principles and procedures are applied in practice and its impact on future organization compliance efforts and effectiveness.

Will the government punish you for standing by your employees? Advancement of legal fees under the McNulty Memorandum

By R. Christopher Cook

Every time a corporation becomes the target of scrutiny by law enforcement, individuals within that organization inevitably come under pressure. Inasmuch as a corporation can act only through its employees and agents, any challenge to the corporation's acts also constitutes a challenge to those individuals' acts. Leaving aside the personal stress and trauma that can come from being the target of a government investigation, these individuals can accrue legal bills that are beyond the ability of any but the richest to pay personally. Accordingly, the corporation's general counsel and compliance officer quickly find themselves asking whether the corporation can pay those legal fees and otherwise support the company's employees consistent with the organization's desire to remain cooperative in the eyes of government investigators.

The recently revised "Principles of Federal Prosecution of Business Organizations" issued by Deputy Attorney Paul J. McNulty on December 12, 2006 (known as the "McNulty Memorandum") assures corporations and other business organizations that they will not be penalized for advancing attorneys' fees to employees and agents who are under investigation or indictment. By contrast, other types of support provided to employees, such as continued employment or information sharing under a joint defense agreement, may still be viewed as inconsistent with corporate cooperation under the McNulty Memorandum. Corporations must assume that they may be penalized if they enter into a joint defense agreement with an employee whom the Department of Justice (DOJ) views as "culpable." The same is true if the corporation fails to terminate or otherwise sanction such an employee.

The McNulty Memorandum represents a policy shift, in some respects, from policies articulated in 1999 and 2003 by the DOJ. How we have come to this point and how these changing policies affect corporate behavior present a fascinating story.

The federal government's war on corporate fraud

Historically, the advancement of legal fees and the provision of other support to accused employees was not an issue. Indeed, the legal and

business community largely assumed that employees charged with misconduct in the course of their employment would have their legal costs paid by and would receive other reasonable support from their employer. Often, these employees would continue to receive a paycheck while they fought the charges against them. Only after a guilty plea or conviction would the employee be terminated.

In recent years, the DOJ has become increasingly aggressive in pursuing perceived corporate fraud. The DOJ's fight against corporate fraud was precipitated by the spectacular collapse of business organizations such as Enron, WorldCom, and Global Crossing. The government established a Corporate Fraud Task Force pursuant to an executive order on July 9, 2002. This task force spearheaded an unprecedented effort to root out and punish corporate fraud. As a direct result of this initiative, many corporations changed their approach to supporting employees who had been accused, but not convicted, of wrongdoing.

The government's campaign against corporate fraud resulted in three phenomena pertinent to this discussion. First, prosecutors pressured corporations to waive the attorney-client privilege and provide to DOJ the work product of the company's lawyers. This gave the government access to the results of internal investigations, as well as the legal advice that corporate counsel gave to management regarding actions now being characterized as criminal. Second, prosecutors and regulators fostered the assumption that corporations would self-report alleged noncompliance with laws discovered within the corporation. Business organizations were expected to self-disclose and "cooperate" or face the fate of Arthur Andersen LLP.[6] Third, the government began to pressure corporations to refuse support to employees viewed by the government as "culpable." It is this last development that we are considering here.

The government's policy regarding corporate cooperation was codified in a January 2003 memorandum from then-Deputy Attorney General Larry Thompson. This memorandum was the predecessor to the McNulty Memorandum and, as might be expected, was generally known as the Thompson Memorandum. The memorandum set forth nine factors that federal prosecutors were required to take into account in deciding whether to bring charges against a business organization. Previously, such decisions were made pursuant to a nonbinding policy set forth by a prior Deputy Attorney General, Eric Holder, in 1999. Unlike the Thompson Memorandum, however, the Holder Memorandum was not binding on prosecutors, but merely recommended the factors to be considered when charging a business organization.

The portion of the Thompson Memorandum relevant to this discussion is quite short, comprising only two sentences. Specifically, the Thompson Memorandum stated:

> *Another factor to be weighed by the prosecutor is whether the corporation appears to be protecting its culpable employees and agents. Thus, while cases will differ depending on the circumstances, a corporation's promise of support to culpable employees and agents, either through the advancing of attorney's fees, through retaining the employees without sanction for their misconduct, or through providing information to the employees about the government's investigation pursuant to a joint defense agreement, may be considered by the prosecutor in weighing the extent and value of a corporation's cooperation.*

In a footnote, the Thompson Memorandum softened this policy slightly by noting that the government would not consider it a "failure to cooperate" if a corporation complied with state law requiring the corporation to pay legal fees prior to a formal determination of guilt. These provisions also appeared in the nonbinding Holder Memorandum.

In the years following the issuance of the Thompson Memorandum, many prosecutors embraced with gusto the policy of demanding corporate cooperation. These prosecutors openly insisted that corporate targets cut off support for employees whom the government viewed as "culpable."

The effect on the behavior of business organizations was immediate. Even in the absence of a demand by prosecutors, many corporations were not willing to take the risk that the government would view them as uncooperative. Companies often fired employees who became the subject of government scrutiny. Likewise, a shrinking number of corporations advanced legal fees to accused employees or shared information pursuant to joint defense agreements.

This new dynamic clearly benefited prosecutors, giving them the power to demand that employees submit to interviews, accept guilty pleas or otherwise do the government's bidding upon pain of being left to defend a criminal investigation without the financial or logistical support of their (often former) employers. Whether this new power-shift in favor of prosecutors resulted in more just outcomes became a question for vigorous debate within the criminal law community. Prosecutors could point to convictions and lengthy prison terms for executives as evidence that justice was being done. Defense lawyers, by contrast, could enumerate constitutional rights given up by individuals on pain of personal financial ruin as

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Letter from the CEO

Roy Snell

Compliance professionals don't care

It dawned on me the other day that compliance professionals don't care, and they should not care. The compliance profession exists because we needed somebody who didn't care. Our profession exists because those who came before us cared too much.

We don't care if the law is fair or unfair; we simply interpret it the best we can and make sure it's followed. We don't care if we need more or less industry regulation; we simply make sure that people understand and follow the laws that exist today to the best of our ability. We don't spend our time running to Washington, DC to encourage the implementation of another law or to get a law changed. We just don't care. Rather than lose focus, we try to make sure that our time is spent ensuring the regulations that exist today are followed.

We don't care who, or how powerful someone is when deciding what to do about an alleged infraction. Although compliance often reduces overall organization costs, we don't care when compliance may affect revenue. We just want to get it right. We don't care how hard it is to comply. We try to minimize the operational impact and effort, but we make sure, in the end, the regulations are followed.

We don't care how many people need to be trained. We don't care if the education is difficult, or if it requires a couple of hours away from work; we just get the education done. We don't care what the outcome of an investigation will be, so long as the investigation is performed correctly. We don't care what auditing will find; we just look. We don't care who has sent in the complaint or what their motives are; we just check to see if the complaint has merit.

We don't care if a regulation is vague; we try to make it as clear as possible. We don't care if a regulation is confusing; we take the time to understand it. We don't care that there are "too many" regulations; we make sure they are followed.

Those who came before us could not resist the temptation to care. That is why our profession exists. People have many reasons and opportunities to fail because there are a lot of reasons to care. We must stay focused and resist the temptations to care.

This article may not be much help to you. The way it's worded, you probably should not show it to anyone. But frankly, I think more people need to realize why compliance is different. More people need to understand what is different now from what was done in the past. I wouldn't tell anybody that compliance doesn't care, because it would be misunderstood. However, I would approach everyday thinking in the back of my mind. The only thing I care about is to ensure that regulations are followed. And I would be very comfortable with the fact that I didn't care about anything else. I would understand that not caring is what will lead to the successful implementation of a compliance program. ■

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evidence that these individuals were being improperly pressured by the government. That is where the matter stood until late 2006.

Indemnification and advancement of fees

Before considering further how the government's campaign to stamp out corporate fraud has changed in very recent months, it is worth pausing to consider the law relating to the payment of employees' legal fees. Notwithstanding the government's antagonism to such support for accused employees, such support was well-established in the law long before the Holder and Thompson Memoranda were published. Payment of legal costs constitutes a legitimate means by which a corporation can assist employees who must defend against accusations of wrongdoing in how they performed their jobs.

Payment of legal fees for employees and other agents involves two interrelated issues. The first question is whether the individual is entitled to be indemnified for expenses incurred in defending against accusations of wrongdoing. Only if the individual is entitled to indemnification must a business organization decide whether it may or must advance those legal fees before the individual's guilt or innocence is determined.

If an employee, officer or director successfully defends against an investigation, lawsuit, or criminal charge, he is almost always entitled to be indemnified for attorneys' fees and expenses. Section 145(c) of the Delaware Corporation Code is a good example, mandating the indemnification of attorneys' fees and expenses when "a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding." [8 Del. C. § 145(c)]. This is consistent with the common law, which has long provided for the indemnification of agents for expenses incurred in connection with the agency relationship. The policy behind this rule is self-apparent; agents who incur costs while acting legally and in good faith should expect to have the principal cover their expenses.

Indemnification is available only after the fact — that is, after the employee or other agent has incurred the expenses and has prevailed in the underlying action. Because the cost of defending a typical criminal investigation can be enormous, most individuals cannot wait to seek repayment, but are compelled by practical circumstances to request the advancement of expenses from the organization. Accordingly, the critical issue often is whether a corporation must or may advance fees and expenses.

If the law requires a corporation to advance fees and expenses, the corporation obviously must comply; even the Thompson and Holder Memoranda recognized as much. Such a legal obligation can arise from a number of sources. Some state statutes grant employees or other agents the right to seek or demand advancement. In New York, for example, employees can petition a court to order advancement not prohibited by the company's bylaws [See New York Business Corporation Law § 725(b)(2)]. In many states, such as Delaware, a corporation can bind itself through its bylaws to advance fees and expenses. Additionally, a corporation can bind itself via contract to advance fees and expenses.

Courts in most states have been quite firm in ordering the advancement of fees and expenses where it is required. This is particularly true when a corporation voluntarily takes on the obligation to advance fees and expenses in its bylaws. Courts generally order such advancement even when the requestor has acted unlawfully or criminally, provided the bylaws contain no exception for such circumstances. Delaware courts are among the most unyielding in this regard, even ordering "fees for fees" when corporations balk at honoring their bylaws' promises to advance fees and expenses. That is, if a Delaware corporation refuses to advance fees to its employee, officer, or director in contravention of its own bylaws and forces the requestor to bring a lawsuit to enforce the bylaws, Delaware courts will order the corporation to pay for the requestor's legal expenses in bringing that lawsuit.

Where a corporation is not obligated by law to advance fees and expenses, the corporation nevertheless may elect to do so. Here again the corporation's bylaws typically govern the terms on which the decision to advance fees must be made. Similarly, if the indemnification and advancement rights arise from a contract rather than the company's bylaws, the terms of that contract will control.

Whether advancement is mandatory or voluntary, it typically is accompanied by an undertaking by the requestor to repay the money if he ultimately does not prevail on the underlying legal dispute. Most corporation codes and bylaws explicitly require such an undertaking, and further require that the requestor certify that he acted lawfully and in the best interests of the corporation. See [Del. C. § 145(e)].

The most difficult decision that a corporation must make in this regard is whether to grant a request for voluntary advancement of fees and expenses when the law or the corporation's bylaws do not require it. The corporation can benefit from ensuring that its employees, officer and directors are represented by capable and ethical counsel. After all, the corporation's interests can be severely compromised if an employee unwisely hurts his own case. Under the doctrine of respondeat superior, the corporation is responsible for the actions of its agents; a conviction of an employee can be the end of the line for the company.

At the same time, however, a corporation may be wary of paying the expenses of an employee who has broken the law. Conferring such a benefit on an employee who has risked the company's well-being may be galling to management. More to the point, outside constituents, including shareholders and the government, may frown on a corporation that seeks to protect an employee who clearly has acted illegally. As we have seen, the Thompson Memorandum codified precisely such a bias against assisting a potentially "culpable" employee.

Joint defense agreements and information sharing

Another common means by which business organizations historically have provided support to accused employees is to enter into a "joint defense agreement" (also known as a "common interest agreement") under which the corporation can share information regarding the government investigation with counsel for individuals. This can be a critical means of leveling the playing field for individual targets of a corporate criminal investigation, whose counsel otherwise are at a disadvantage when dealing with prosecutors. Unlike defense counsel, the prosecutors typically have comprehensive, reliable information regarding the status of the investigation and the facts known to the business organization. Notwithstanding the government's antagonism to such arrangements, the law clearly permits such information sharing among counsel for the corporation and its accused employees.

The purpose behind a joint defense agreement is to avoid waiver of the attorney-client privilege and the work product doctrine. When conducted by legal counsel, an organization's response to alleged wrongdoing presumptively is protected by the attorney-client privilege and the work product doctrine. This is true even in the absence of an active government investigation, but it is especially true when the government is actively scrutinizing the company's actions. Thus, an organization reasonably can expect that internal legal strategy decisions will remain confidential and the communication between its attorneys and its employees will not be subject to subpoena, provided the company does not waive the privilege. This protection is not, however, absolute. Serious negative consequences can flow from blithely assuming that these privileges protect—and will continue to protect—all aspects of an organization's investigation or legal defense.

Just as privileged communications must be kept confidential, an organization facing investigation also must consider how to communicate with other similarly-situated subjects of the investigation, including individual employees. The "joint defense" or "common interest" privilege is a doctrine developed by courts to permit co-defendants and others facing similar legal exposure to cooperate and share otherwise privileged information without waiving those privileges. Virtually all courts recognize some sort of common interest privilege, though some courts have stated that the agreement between the parties should be in writing [See, e.g., *United States v. Almeida*, 341 F.3d 1318, 1326 n.21 (11th Cir. 2003)].

Joint defense agreements can play an important role in an organization's response to a government investigation. At the same time, and for the same reasons, the government typically views such an agreement as an impediment to its investigation. First, a joint defense agreement can limit the ability of the organization to cooperate with the government. For example, if a corporation enters into a joint defense agreement with its employees, interviews conducted pursuant to the joint defense agreement may be subject to privileges held by both the company and the employee. This would restrict the company's ability to waive the privilege, if that is requested in a cooperation agreement with the government. In addition, some prosecutors oppose joint defense agreements on the belief that any advantage given to the target—in this case, accurate information—hinders the government's ability to obtain a conviction. To the extent that these prosecutors equate obtaining a conviction with doing justice, they likewise view joint defense agreements as obstructing that goal.

Judicial and legislative challenges to the Thompson Memorandum

The government's policy of pressuring corporations to refuse to support allegedly "culpable" employees came to a head on June 26, 2006 when federal judge Lewis Kaplan in New York held that the government's actions violated the guarantees of Due Process and the right to counsel embodied in the Fifth and Sixth Amendments to the US Constitution. Judge Kaplan's lengthy opinion is worth reading, as it lays out in detail the government policies and practices that led the court to conclude that the Thompson Memorandum and the manner of its application in that case were not consistent with the Constitution [See *United States v. Stein*, 435 F. Supp. 2d 330 (S.D.N.Y. 2006)]. In short, Judge Kaplan concluded that the government's "zeal" to prosecute crimes clouded its judgment and caused it to "violate… the Constitution it is sworn to defend." Id. at 336.

The Stein decision arose out of the prosecution of nineteen individuals for marketing allegedly unlawful tax shelters through the accounting firm KPMG. Historically, KPMG had paid for the legal defense of any personnel accused of wrongdoing. In this case, however, KPMG refused. Judge Kaplan, after hearing evidence from KPMG's General Counsel and others, concluded that the accounting firm refused to pay "because the government held the proverbial gun to its head." Specifically, Judge

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Kaplan concluded that KPMG cut off financial support and refused to advance defense costs to the individual defendants because prosecutors threatened to retaliate against KPMG for doing so. Judge Kaplan concluded that this conduct by the government, including the policy as set forth in the Thompson Memorandum, was unconstitutional.

Some months later, the Senate Judiciary Committee likewise took aim at the Thompson Memorandum. The Committee held hearings in the Fall of 2006 at which it heard testimony regarding the application of the policies set forth in the Thompson Memorandum. Much of the attention given to this testimony related to the DOJ policy of demanding waiver of the attorney-client privilege. The Committee also heard about the DOJ conduct described in the Stein decision—pressuring target companies to cut off their employees. After hearing this testimony, the chair of the Committee, Pennsylvania Senator Arlen Specter, introduced the "Attorney-Client Privilege Protection Act of 2006" to prohibit the DOJ from demanding waivers of the attorney-client privilege as a condition of avoiding charges. That same legislation prohibited the DOJ from conditioning any civil or criminal charging decision on a corporation's decision to provide counsel to employees, pay for legal expenses, enter into a joint defense agreement, or fail to terminate an employee for exercising his constitutional rights. Five days after the legislation was introduced, on December 12, 2006, the DOJ backed away from many of the Thompson Memorandum's policies by issuing the McNulty Memorandum.[7]

The December 2006 McNulty Memorandum

The McNulty Memorandum, like the Thompson Memorandum, constitutes a binding policy on United States Attorneys and DOJ department heads responsible for criminal prosecutions. It changes dramatically in some respects the government approach to corporate "cooperation" in deciding whether to bring criminal charges. In other respects, however, it does not change government policy at all.

Most of the media attention relating to the McNulty Memorandum has focused on its pronouncements regarding waiver of the attorney-client privilege. Although not discussed in this article (See review by Gabriel L. Imperato, above), those provisions of the McNulty Memorandum impose written approval requirements on prosecutors seeking a privilege waiver and prohibit prosecutors from penalizing corporations for refusing to accede to such requests in some circumstances. Many commentators have questioned whether these procedural changes will lead to substantive shifts in government practice.

The McNulty Memorandum goes further in changing government policy regarding the advancement of legal fees. The new policy flatly prohibits prosecutors from considering a corporation's advancement of legal fees in evaluating the quality of a corporation's cooperation. The only exception is "extremely rare circumstances" where the payment of legal fees is part of an effort by the corporation to impede the government's investigation. In this regard, therefore, the McNulty Memorandum appears to have taken to heart Judge Kaplan's criticisms and extricated the DOJ from a corporation's decision to advance legal fees to its employees.

The most notable aspect of the McNulty Memorandum's new policy regarding the advancement of legal fees is the lack of any distinction between corporations that are obligated to advance such fees and those that have the discretion to do so. The Memorandum itself notes that "[m]any state indemnification statutes grant corporations the *power* to advance the legal fees of officers under investigation prior to a formal determination of guilt." McNulty Memorandum at 3 (emphasis added). The Memorandum further notes that, consistent with this power, "many corporations enter into contractual obligations to advance attorneys' fees through provisions contained in their corporate charters, by-laws or employment agreements." Notwithstanding the fact that this contractual obligation to advance legal fees is a duty voluntarily accepted by the corporation, the McNulty Memorandum unequivocally states that "[a] corporation's compliance with governing state law and its contractual obligations cannot be considered a failure to cooperate." Thus, the McNulty Memorandum applies the same standard to companies that *choose* to advance legal fees as it does to those that *must* do so.[8]

Notwithstanding the DOJ's dramatic change of position regarding the advancement of legal fees, the government did not in any way change its policy regarding other support that a business organization could provide to employees. Accordingly, the DOJ still will consider "whether the corporation appears to be protecting its culpable employees and agents" in deciding whether to bring criminal charges. The McNulty Memorandum specifically sets forth as examples of "a corporation's promise of support to culpable employees and agents," the retention of employees "without sanctions for their misconduct," and the provision of "information to the employees about the government's investigation pursuant to a joint defense agreement." Accordingly, it seems that a corporation still may be penalized for refusing to fire an employee the government considers to be "culpable." The DOJ also may still punish a business organization for entering a joint defense agreement, regardless whether that information sharing actually obstructs the government's investigation.

Finally, the McNulty Memorandum continues to assume that the DOJ

legitimately can decide which employees are "culpable" prior to a determination of guilt. Although this pre-judgment of an employee's culpability has been removed from the process of advancing legal expenses, the DOJ continues to demand that purportedly "culpable" employees be fired and denied access to information regarding the government's investigation long before actual guilt or innocence has been decided at trial.

Conclusion

Under the McNulty Memorandum, a corporation can safely enact by-laws provisions and enter into contractual obligations to advance legal fees to its employees and agents should they in the future become subject to criminal investigation. The government has stated without reservation that such corporate action will not be considered to be "uncooperative" in the event that the corporation later is obligated to pay the legal fees of individuals whom the government considers to be "culpable." Corporations and other business organizations still must be careful, however, when entering into joint defense agreements or other information-sharing arrangements with employees who are the subjects of a government investigation. Moreover, corporations must consider carefully whether to continue the employment of such "culpable" employees, even before their guilt has been determined at trial. The government has made clear that these aspects of the Thompson Memorandum remain valid, effectively demanding that corporations continue to pre-judge their employees' guilt in these regards. Whether the courts or Congress will challenge these policies remains to be seen. If, however, Senator Specter's legislation is re-introduced and passed, we can expect to see these tactics revisited also. ■

1 Memorandum to Heads of Department Components, United States Attorneys, from Paul J. McNulty, Deputy Attorney General, regarding Principles of Federal Prosecution of Business Organizations, p. 4.
2 However, the Department of Health and Human Services has published guidance for a variety of healthcare entities regarding compliance programs.
3 Memorandum to Heads of Department Components, United States Attorneys, from Paul J. McNulty, Deputy Attorney General, regarding Principles of Federal Prosecution of Business Organizations, p. 14.
4 Id.
5 Id.
6 It did not escape notice to corporate America that Andersen was convicted and put out of business even though that conviction was later reversed on appeal. The message was clear: Cooperate or risk corporate extinction regardless of actual guilt.
7 Although Senator Specter's proposed legislation was not enacted in the 109th Congress, both Senator Specter and his successor, Senator Patrick Leahy of Vermont, have promised to reintroduce the legislation in the 110th Congress, if they deem it necessary in light of changes in government policy and practice.
8 The McNulty Memorandum remains silent regarding the timing of a corporation's decision to contractually obligate itself to pay legal fees. Many companies, of course, agree to advance legal fees only after discovering the pendency of the government investigation; that is, the company does not obligate itself to make such payments in it bylaws or an employment agreement. That was the situation with KPMG in the Stein case. The language of the McNulty Memorandum at least suggests that these contractual obligations would not be interpreted as a failure to cooperate. An aggressive prosecutor might, nevertheless, argue that the contractual obligations permitted under the McNulty Memorandum are limited to those that pre-date the initiation of a criminal investigation and do not include after-the-fact decisions to support an employee by paying for his legal expenses. Such an interpretation would be inconsistent with Judge Kaplan's opinion in Stein.

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OIG Compliance Program Guidance for Hospitals

By Lori J. Strauss, RN, MSA, CPC, CPC-H, CHC

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The Office of Inspector General (OIG) is the enforcement arm of the U.S. Department of Health and Human Services (DHS). The mission of the OIG is to protect the integrity of DHS programs, as well as the health and welfare of the beneficiaries of those programs. The first OIG compliance guidance[1] addressed clinical laboratories and was published in the Federal Register in March 1997. The second compliance program guidance,[2] published in February 1998, addressed hospitals and was built upon the basic elements in the clinical laboratory compliance program. It encompassed principles that are applicable to hospitals and to a wider variety of organizations that provide health care services to beneficiaries of Medicare, Medicaid, and other health care programs.

The hospital compliance program guidance was developed with cooperation and input from several provider groups and industry representatives. Many providers and organizations had expressed an interest in protecting their operations from fraud and abuse through the adoption of voluntary compliance programs. The OIG developed this second program guidance to continue as a positive step toward promoting a high level of ethical and lawful conduct throughout the health care industry.

The clinical laboratory and hospital compliance program guidances are voluntary. The OIG has issued other compliance guidance documents for home health agencies; third party billing companies; physicians; durable medical equipment prosthetics, orthotics and supply industries (DMEPOS); the ambulance industry; hospices; and pharmaceutical manufacturers.

The adoption and implementation of voluntary compliance programs significantly advances the prevention of fraud, abuse, and waste in health care plans and furthers hospitals' efforts to provide quality care to patients. The goals are to assist hospitals in developing effective internal controls that promote adherence to applicable federal and state laws, and in meeting the program requirements of federal, state, and private health plans. Compliance programs provide critical internal controls in the reimbursement and payment areas. Claims and billing operations are often the source of fraud and abuse, and therefore, historically have been the focus of government regulation, scrutiny, and sanctions.

Another goal of the compliance program guidance for hospitals is designed to establish an internal culture that promotes prevention, detection, and resolution of instances of conduct that do not conform to federal and state law; federal, state, and private payer healthcare program requirements; or the hospital's ethical and business policies.

Lastly, the OIG guidance for hospitals strives to guide a hospital's governing body, CEO, managers, physicians and other health care professionals, and other employees in the efficient management and operation of a hospital.

The elements of the OIG guidance can be used by all hospitals, regardless of size, location, or corporate structure, to establish an effective compliance program. The elements proposed by these guidelines, based on the seven steps of the Federal Sentencing Guidelines, are similar to those of the clinical laboratory model compliance program and corporate integrity agreements. The OIG believes that every effective compliance program must begin with a formal commitment by the hospital's governing body to include all seven elements.

The seven elements of a compliance program

First, a written standard of conduct and policies and procedures should be developed and distributed to promote the hospital's commitment to compliance. This includes adherence to compliance as an element in evaluating managers and employees, as well as policies and procedures that address areas of potential fraud, such as claims development and submission processes.

Second, a compliance officer who reports to the CEO and governing body and a compliance committee should be designated and charged with the responsibility of operating and monitoring the compliance program. Third, regular, effective education and training programs must be developed and implemented for all affected employees.

Fourth, a compliance program should maintain a process (e.g., a hotline) to receive complaints and adopt procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation. Fifth, a system should be developed to respond to allegations of improper or illegal activity, and enforce appropriate disciplinary action against employees who have violated internal compliance policies, statutes, or federal health care program requirements.

Sixth, audits and evaluation techniques should be used to monitor compliance and to assist in reducing identified problem areas. The seventh, and last, element of a compliance program is to investigate and remediate identified system problems and to develop policies that address the non-employment or retention of sanctioned individuals.

The OIG believes that hospital policies and procedures should consider regulatory exposure for each function or department of the hospital. The OIG recommends that policies and procedures be coordinated with the proper training and education that emphasizes the areas of concern identified by the OIG through its investigative and audit functions.

Since the original hospital guidance was published in 1998, significant changes have occurred in the way hospitals deliver and are reimbursed for health care services. In response to these developments, the OIG published a "solicitation of information and recommendations for revising the compliance program guidance of the hospital industry" in the Federal Register in June 2002. Eleven comments were received from interested parties. The OIG decided to supplement, rather than revise, the 1998 guidance.

The OIG's draft supplemental compliance program guidance for hospitals[3] was published in June 2004. Many public commenters sought guidance on specific Medicare and Medicaid rules and regulations related to payment and coverage, although this area was beyond the scope of the OIG guidance. The OIG sought comments from interested parties on the draft compliance program guidance for hospitals. The draft contained new compliance recommendations and an expanded discussion of risk areas. The draft addressed changes to hospital payment systems and regulations, evolving industry practices, current enforcement priorities, and lessons learned in the corporate compliance arena. The final supplemental compliance program guidance for hospitals,[4] published in the January 2005, provided voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and refining compliance efforts.

The supplemental guidance document lists areas of concern to the enforcement community for hospitals, but it is not inclusive and is not intended to address all potential risk areas for hospitals. The supplement identitifed several fraud and abuse risk areas that are especially relevant to the hospital industry, including:

- submission of accurate claims and information
- the referral statutes (Stark and anti-kickback laws)
- payments to reduce or limit services (gain-sharing)
- the Emergency Medical Treatment Active Labor Act (EMTALA)
- substandard care
- relationships with federal health care beneficiaries
- HIPAA privacy and security rules
- billing Medicare or Medicaid substantially in excess of usual charges

Each hospital should carefully review these risk areas and identify those that may particularly impact the hospital.

The single biggest risk area for hospitals is likely the preparation and submission of claims or other requests for payment from federal health care programs. All claims and requests for reimbursement and all documentation supporting such claims must be complete and accurate. Additionally, they must reflect reasonable and necessary services ordered by an appropriately licensed medical professional who is a participating provider in the health-care program from which the individual or entity is seeking reimbursement. Hospitals must disclose and return any overpayments for erroneous claims. Knowing submission of a false, fraudulent, or misleading statement or claim is actionable, and a hospital may be liable under the False Claims Act.

Common long-standing risks associated with claim preparation and submission include inaccurate or incorrect coding, upcoding, unbundling of services, billing for medically unnecessary services or other services not covered by the relevant health care program, billing for services not provided, duplicate billing, insufficient documentation, and false or fraudulent cost reports. These risk areas are well understood and hospitals are vigilant in addressing these areas. The supplemental guidance addresses new groups of risk areas that the OIG felt were under-appreciated by the hospital industry, including outpatient procedure coding, admission and discharges, supplemental payment considerations, and use of information technology.

Hospitals should review their outpatient documentation practices to ensure that claims are based on completed medical records and that the medical record supports the level of service claimed. Other specific risk areas associated with incorrect outpatient procedures coding were listed in the document. The OIG recommends reviewing how this information is used in a hospital setting to help develop the audit plan.

Some of the topics addressed under outpatient procedure coding include billing on an outpatient basis for "inpatient-only" procedures, submitting claims for medically unnecessary services by failing to follow the

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fiscal intermediaries local coverage policies, submitting duplicate claims or otherwise not following the National Correct Coding Initiative guidelines, submitting incorrect claims for ancillary services because of outdated charge description masters, circumventing the multiple procedure discounting rules, failing to follow CMS instructions regarding the selection of proper evaluation and management codes, and improperly billing for observation services.

Regarding billing on an outpatient basis for inpatient only procedures, CMS has identified several procedures for which reimbursement is typically allowed only if the service is provided or performed in an inpatient setting. Regarding improperly billing for observations services, in certain cases Medicare provides a separate average projected cost (APC) payment for observation services for patients with the diagnosis of chest pain, asthma, or congestive heart failure. Claims for these observation services must correctly reflect the diagnosis and meet certain other requirements. Billing for observation services in situations that do not satisfy these requirements is inappropriate and may result in hospital liability.

The last part of the 2004 draft compliance guidance for hospitals addressed compliance program effectiveness. The shift has been from implementing compliance programs (which is more or less an expectation that hospitals will have compliance programs) to determining if one's compliance program is doing any good.

The recommendation is that hospitals evaluate the effectiveness of their compliance programs annually by reviewing all seven elements. The supplemental guidance goes through the elements of a compliance program and provides several examples of how effectiveness is assessed. Another shift is to intertwine compliance and ethics, for how can one exist without the other? "Do the right thing because it is the right thing to do."

The supplemental guidance identifies some things hospitals can ask themselves about the quality and effectiveness of the audits being done. For example, are audit plans designed to minimize the risks associated with improper claims and billing practices? Does the plan include an assessment of billing systems and claim accuracy with an effort to determine the root cause of the billing errors? Does the audit include a review of billing documentation to support the claim?

The last part of the supplemental compliance guidance for hospitals discusses self-reporting. When a compliance officer, compliance committee, or member of senior management discovers credible evidence of misconduct from any source and, after reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the hospital should promptly report the existence of possible misconduct to the necessary federal and state authorities within a reasonable timeframe, but not more than 60 days after determining that there is credible evidence of a violation. Prompt voluntary reporting will demonstrate the hospital's good faith effort and willingness to work with the government to remedy the situation. Cooperation will be used as a mitigating factor by the OIG in determining sanctions if the hospital becomes subject to an OIG investigation.

Also, on April 30, 2004 the United States Sentencing Commission (USSC) ushered in a new era of corporate compliance when it sent to Congress significant changes to the Federal Sentencing Guidelines for organizations. The amendment to the guidelines[5] enhanced the criteria that an organization needs to follow to create an effective compliance and ethics program. The amendment took effect November 1, 2004. A fundamental component of the amendment is that organizations must promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. The amendment requires boards of directors and executives to assume responsibility for the oversight and management of compliance and ethics programs and that compliance and ethics officers have sufficient authority and resources to carry out their responsibilities. As these publications demonstrate, health care and hospital compliance issues are ever evolving. ■

1. Office of the Inspector General (OIG), "Model Compliance Plan for Clinical Laboratories," Federal Register 62, no. 41, (March 1997): 9435-41

2. OIG "Compliance Program Guidance for Hospitals," Federal Register 63, no. 35 (February 1998): 8987-98

3. OIG "Draft Supplemental Compliance Program Guidance for Hospitals", Federal Register 69, no. 110 (June 2004): 32012-31

4. OIG "Supplemental Compliance Program Guidance for Hospitals," Federal Register 70, no. 19 (January 2005): 4858-76

5. United States Sentencing Commission (USSC), Guidelines Manual, Chapter 8 - Effective Compliance and Ethics Programs

Ten steps to penalty-proofing your organization

By Nick Ciancio

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Like never before, the healthcare industry today is facing an environment rife with risk, exposure, and potential damage. Fraud scandals in the industry, and the corporate world in general, have helped drive a demand for increased visibility and accountability. At the same time, legislation is requiring healthcare organizations to maintain greater operational safeguards.

Ongoing consolidation and growth in the industry continue to create ever larger employee populations spread across an ever growing number of facilities, making the task of oversight more difficult. Meanwhile, the Office of the Inspector General (OIG) stands ready to penalize healthcare providers who violate the industry's regulations. The OIG has been empowered to exclude individuals and entities from participation in Medicare, Medicaid, and other federal healthcare programs as a penalty for misconduct. Furthermore, the OIG can negotiate compliance obligations in the form of Corporate Integrity Agreements (CIAs) as part of the settlement of federal healthcare program investigations that arise under a variety of civil false claims statutes. A provider or entity consents to the obligations of a CIA as part of a civil settlement and in exchange for the OIG's agreement not to exclude the organization from participation in federal healthcare programs.

What proactive steps can healthcare organizations take to avoid being placed under a CIA? And when a CIA is imposed upon an organization, what steps can it take to meet the obligations of the agreement? Whether operating under a CIA or not, every organization should dedicate itself to detecting and preventing malfeasance and promoting ethical and compliant behavior.

First, effective codes of conduct are vital to establishing a framework of good organizational governance. Codes present a series of supporting rules that define good practices, what is allowed or prohibited. A code of conduct should offer clear guidance regarding what is expected of the members of the organization, whether they are officers, employees, contractors, vendors, or any other stakeholders. The code should amplify the organization's overall vision. Moreover, a code of conduct should be a dynamic document. It has little value if it is simply filed away and forgotten after its initial launch. Therefore, annual reviews and regular employee certification on the code of conduct should be implemented to ensure that the code is more than just words on paper. It is a set of values ingrained into the organization's corporate culture.

Second, an effective ethics program begins at the top, with the Board establishing directions to be carried out by senior management and communicated throughout all levels of the organization. Management must stress ethics and compliance in their daily routines. The tone from the top should resonate at every level; the idea that different rules apply to different people should be avoided at all cost.

Third, education and training are paramount in maintaining an elevated and ongoing awareness of an organization's ethics and compliance program. Steps must be taken to communicate standards and train all employees, including those in upper management. This training should include communicating information on new or amended laws and regulations, as well as changes in internal processes and procedures.

Fourth, organizations should utilize a confidential reporting mechanism. The mechanism should allow employees and other stakeholders to report concerns anonymously and without fear of retribution. The mechanism should also enable the organization to follow-up with those who report concerns, while maintaining their anonymity, in order to gather additional information and provide feedback. The mechanism should operate independently of the normal chain of command, which is why more and more organizations are outsourcing their hotlines and Web applications to third-party vendors.

Outsourced vendors also offer the advantage of 24/7 availability, multilingual interpretation, and specialized expertise. Organizations must ensure that any outsourced vendor is able to comply with the privacy laws specific to the industry and locations in which they operate, such as the Health Insurance Portability and Accountability Act (HIPAA), the Family Education Rights and Privacy Act (FERPA), the Gramm Leach Bliley Financial Modernization Act (GLBA), and other regulatory sensitivities that may arise. If an organization is conducting business in Europe, it should also ensure that its vendor is Safe Harbor certified, meaning it complies with the European Commission's Directive on Data Protection. Thus, companies operating in the European Union can do business

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with the vendor without fear of violating the Directive.

While hotlines are the most accepted and proven type of reporting mechanism, Web submission is also becoming increasingly popular. The more vehicles an organization uses to collect reports in addition to its normal chain of command, the more likely it is to receive actionable information.

Fifth, reports of allegations, regardless of how they are submitted, should be stored in a centralized data repository. A repository makes it possible to efficiently manage and assess submitted reports of misconduct, fraud, and other concerns. The most effective data repositories not only store hotline and Web reports, they also allow users to generate their own reports based on information they may collect from other sources, such as internal complaints within their organizations. Keeping all reports in one database ensures the greatest accountability possible, with no worries that the odd complaint will fall between the cracks.

Sixth, in conjunction with the central data repository of Element Five, organizations should use a robust case management system to document the actions taken to investigate and resolve allegations reported through their hotlines or Web submission mechanisms. Any good case management system should allow a case manager to assign investigators and case status as well as append case notes and other documentation.

Seventh, the central database described in Element Five should also allow an organization to conduct real-time queries and analyses of all report and case management data. With this ability, an organization can identify trends and conduct statistical analyses of its compliance program's activity. Of great benefit to many organizations, report writer tools take data searches a step further and empower users to build their own ad hoc management reports based on their collected information.

Eighth, organizations must possess the ability to pursue investigations to resolution. Whether investigations are conducted internally or by a third-party firm, they should be tracked using the case management system described in Element Six to ensure resolution is achieved in a timely and efficient manner.

Ninth, organizations should devote resources to preventing malfeasance before it happens, by using such tools as background checks and sanction screens. This is especially true in the healthcare industry, where one of the main elements of many CIAs is a requirement to "restrict employment of ineligible persons," meaning that employee backgrounds must be checked periodically for sanctions. The Medicare Modernization Act of 2003 (MMA) imposed even stricter OIG monitoring of healthcare organizations for ineligible employees and increased possible CIA requirements. Healthcare organizations should use an employee screening service to identify individuals who have been sanctioned or otherwise excluded from participation in federally-funded healthcare programs.

Tenth, and finally, evaluation and validation, (a method of self-assessment) also helps prevent noncompliant, fraudulent, or otherwise undesirable behavior. Validation consists of running controlled inputs through organizational systems in order to measure associated outputs. One form of validation is mystery shopping, in which disguised healthcare "shoppers" gain patient perspective on fairness and equity of service, attitude, process, and procedure. Another form of evaluation is an employee survey to gain perspective on the perceived organizational culture and willingness to speak up if misconduct is observed. Evaluation and validation can identify weaknesses in staff or employee comprehension, perception, or performance, so that additional training, management tactics, or communications campaigns can be employed to correct the problems and beliefs.

Any healthcare organization that follows these ten guidelines will find itself well on its way to establishing a robust ethics and compliance program and a culture of integrity among its employees and other stakeholders. Not only will the requirements of existing CIAs be fulfilled and potential CIAs be averted, these steps will also lead to a more efficient and effective organization across the board. In the current climate of high exposure, dangerous risk, and damaging penalties, every healthcare organization must ask itself not whether it can afford to take the steps necessary to build a comprehensive ethics and compliance program, but rather, whether it can afford not to. ■

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CMS issues guidance on compliance mandates in the Deficit Reduction Act

By Frank Sheeder, Esq.

Frank Sheeder is a healthcare partner in the Dallas office of the law firm of Jones Day. He may be reached by telephone at 214/ 969-2900 or by e-mail at fesheeder@jonesday.com.

On February 8, 2006, President Bush signed the Deficit Reduction Act of 2005 (DRA). Section 6032 of the DRA sets forth new conditions that will require certain entities participating in Medicaid programs to inform their employees, contractors, and agents about the details of state and federal false claims statutes and whistleblower protections. January 1, 2007 was the deadline for compliance with Section 6032. The penalty for noncompliance may be harsh: Providers can lose all of their Medicaid reimbursement.

Section 6032 of the DRA

DRA Section 6032, entitled "Employee Education About False Claims Recovery," mandates that each state Medicaid plan require entities that receive or make annual Medicaid payments of at least $5 million to establish certain written policies for all of their employees, contractors, and agents. Importantly, doing so is a prerequisite to receiving Medicaid reimbursement.

As of January 1, 2007, the states must require such entities to:

(1) Establish written policies that all employees (including management) and any contractor or agent of the entity must be provided with detailed information about:
   (a) the Federal False Claims Act;
   (b) remedies for false claims and statements;
   (c) any state laws pertaining to civil or criminal penalties for false claims and statements;
   (d) the whistleblower protections under the federal False Claims Act and state laws; and
   (e) the role of such laws in preventing and detecting fraud, waste, and abuse in federal healthcare programs.

(2) Include, as part of their written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse. This is essentially the organization's compliance program.

(3) Include, in any employee handbook for the entity, a specific discussion of:
   (a) the state and federal laws referenced above;
   (b) the rights of employees to be protected as whistleblowers; and
   (c) the entity's policies and procedures for detecting fraud, waste, and abuse.

Section 6032 does not address (1) what or how much information would constitute "detailed information" or (2) how an entity should inform its employees, contractors, and agents of the necessary false claims law information and written policies (other than inclusion in the employee handbook). Also missing are definitions of "entity," "employee," "contractor," and "agent," which are all critical terms in Section 6032.

Guidance on Section 6032

On December 13, 2006, the Centers for Medicare and Medicaid Services (CMS) issued a letter to State Medicaid Directors offering them "guidance" on how to implement the requirements of Section 6032 into their State Medicaid Plans, which will then become binding on providers (http://www.cms.hhs.gov/smdl/downloads/SMD121306.pdf). CMS also provided sample State Plan language (http://www.cms.hhs.gov/smdl/downloads/SMD121306a.pdf). Note that this guidance is not addressed directly to providers. The letter reiterates the elements of Section 6032 and confirms the January 1, 2007 deadline for compliance with them. It also clarifies which "entities" will be subject to the requirements of Section 6032 and provides that "[a]n 'entity' includes a governmental agency, organization, unit, corporation, partnership, or other business arrangement (including any Medicaid managed care organization, irrespective of the form of business structure or arrangement by which it exists), whether for-profit or not for profit, which receives or makes payments, under a

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State plan approved under title XIX or under waiver of such plan, totaling at least $5 million annually." The letter further provides that the $5 million annual threshold is met if the aggregate reimbursement to an entity reaches $5 million.

This definition appears to encompass any type of business arrangement where the aggregate Medicaid payments totaled at least $5 million during the preceding federal fiscal year. According to CMS, the $5 million threshold may be met even if: (i) the items or services are provided at more than a single location; (ii) the items or services are under more than one contractual or other payment arrangement; or (iii) the entity submits claims for payments using one or more provider identification or tax identification numbers. This definition ignores the separateness of legal entities and provider numbers and leaves providers to wonder whether their particular "business arrangements" subject them to the mandates in Section 6032.

CMS has also offered definitions of "contractor" and "agent" (which encompasses "any contractor, subcontractor, agent, or other person which or who, on behalf of the entity, furnishes or otherwise authorizes the furnishing of Medicaid health care items or services, performs billing or coding functions, or is involved in monitoring of health care provided by the entity"). This is good news for providers because it limits these otherwise expansive terms to people and entities that actually have something to do with Medicaid billing, coding, or monitoring.

CMS also confirmed that each entity must establish written compliance policies, but the letter goes further and provides that it is also the responsibility of each entity to disseminate such written policies. While an entity's written policies may be on paper or in electronic format, they must be readily available to all employees, contractors, or agents. Even though Section 6032 refers to inclusion of certain information in an employee handbook, providers who do not have such a handbook need not create one. CMS has also gone a step further than simply clarifying Section 6032 by requiring that the written policies be adopted by an entity's contractors or agents. This, of course, creates another challenge: How will providers ensure that these third parties "adopt" the provider's policies?

CMS has also provided some guidance on what actions an entity should take to comply with Section 6032. However, it is still not clear what or how much information a provider would need to communicate to employees, contractors, and agents to satisfy the mandate for "detailed information." Indeed, CMS has said that it is not qualified to provide sample language discussing the federal False Claims Act. CMS has also indicated that a provider must disseminate its written policies, but it has not clarified the acceptable methods for doing so.

Another wrinkle is that the CMS guidance letter suggests that entities must be in compliance with Section 6032 by January 1, 2007, even if states have not yet amended their Medicaid Plans. If a state determines that it needs legislation to change its Plan, however, it must request through CMS that the Secretary of HHS concur with the determination that legislation is required. Nonetheless, CMS has stood by its position that providers were required to comply with Section 6032 by January 1, 2007.

The conference call

On January 11, 2007, CMS held a conference call with providers to answer their questions about Section 6032. CMS stood by its December 13, 2006 guidance to the State Medicaid Directors. While CMS provided some information, it stated that the call was intended to be informal and informational —it did not constitute official policy or anything that was binding on HHS or CMS.

CMS did clarify one critical point: Providers are not required to conduct educational sessions in order to comply with Section 6032. They must simply disseminate the information mandated by the DRA. This will decrease the burden on providers. CMS also noted several open questions, and committed to providing written questions and answers on its Web site "soon." This is also good news for providers that are still struggling with how to comply with Section 6032.

Conclusion

While CMS has offered indirect guidance to providers in a letter to State Medicaid Directors and informal verbal guidance on a conference call, there has not been any official written guidance to providers from CMS. In summary, it seems that without further guidance, entities that fall within the requirements of Section 6032 will be forced to take an overly broad approach when attempting to comply with its requirements. CMS is has stated that the requirements were effective January 1, 2007, notwithstanding several unanswered questions and practical challenges. ■

Compliance: Getting everyone on board

By Lawrence A. Fogel, MBA

Editor's note: Lawrence Fogel, principal, is a member of BKD Health Care Group, a division of BKD, LLP, in Kansas City, Missouri. Mr. Fogel frequently speaks on compliance matters around the country and consults with clients on a broad spectrum of compliance issues. He may be contacted by e-mail at lfogel@bkd.com

Your organization's compliance leaders are expected to provide clear guidance on how to detect and resolve compliance issues. Clearly, your compliance officer has the primary oversight responsibility for monitoring compliance issues. However, your compliance committee plays an important supporting role as well. Both parties can help in their own way to detect and resolve compliance issues before they turn into compliance violations. The challenge: Only reported issues get examined. It is crucial that your health care organization's compliance program be well defined and clearly communicated, not only to your compliance committee, but to all personnel.

Identifying compliance issues

The first step to resolve a problem is to identify one exists. To accomplish this, everyone needs to be on the same page about what a compliance issue is, their duty to report it, and the reporting process. All compliance issues should be taken seriously, even if on the surface they appear to be minor. The organization should fully document the investigation and resolution of reported compliance issues. Compliance programs that are effectively operated enable organizations to either avoid serious compliance violations or detect them through prompt identification and reporting.

For an organization to stay out of hot water, it must be able to recognize a potential compliance issue, so it can conduct a prompt and thorough investigation. If an organization does not believe it has any compliance issues and a government agency subsequently determines that compliance issues were not detected and investigated, then serious fines, sanctions, and penalties could be assessed because the organization failed to police itself. It is usually better for an organization to identify and resolve issues for itself than to have an enforcement agency find them. Government agencies are typically more lenient when imposing fines, sanctions, and penalties on an organization that is self-policing and self-reporting..

Common misconceptions about compliance issues

Some compliance officers and committees mistakenly believe they don't have compliance issues because they receive few complaints on their hotline. Too often, the reality is that some common warning signs may be overlooked due to a lack of communication and not enough coordination among areas that can work together to identify problems. For example, the human resource department may have processed personnel offenses that required disciplinary actions. In addition, patients may be providing clues about compliance issues. Most healthcare organizations have a formal process for patients to report complaints about their bills, quality-of-care issues, and safety issues. Many complaints can indicate compliance issues. Still another avenue to help identify compliance issues is the risk management department. In fact, risk management and compliance issues frequently go hand-in-hand.

Because compliance programs don't come in one-size-fits-all packages, healthcare organizations use a variety of mechanisms to identify potential compliance issues. It is essential to coordinate and communicate compliance issues received by human resources, the business office, risk management, administration, and other areas of the organization that may receive compliance-type complaints. Effective coordination and communication will result in detecting more compliance issues that must be addressed and resolved. Patterns may be identified, and preventative measures can be taken.

Role of the compliance officer

Most compliance programs require the compliance officer to investigate and process all compliance issues. Without a compliance program that is clearly defined and thoroughly communicated to all employees, chances are the compliance officer may know about only a fraction of the compliance issues that occur in the organization.

The compliance officer should be aware of all compliance issues. Investigations should be conducted promptly and, if possible, the individual raising the compliance issue should be informed of the results of the investigation. Documentation is crucial and should reflect a description of the issue, interviews conducted, audits performed, results of the investigation, and corrective actions taken.

Role of the compliance committee

The compliance committee can be an effective resource to help identify potential compliance issues. The committee members should be alert for potential compliance issues and report to the compliance officer. At compliance committee meetings, members should discuss potential compliance issues that could pose risks to the organization. The compliance committee should provide oversight and provide guidance for your compliance program.

If the members of your compliance committee were asked to list 10 compliance issues,

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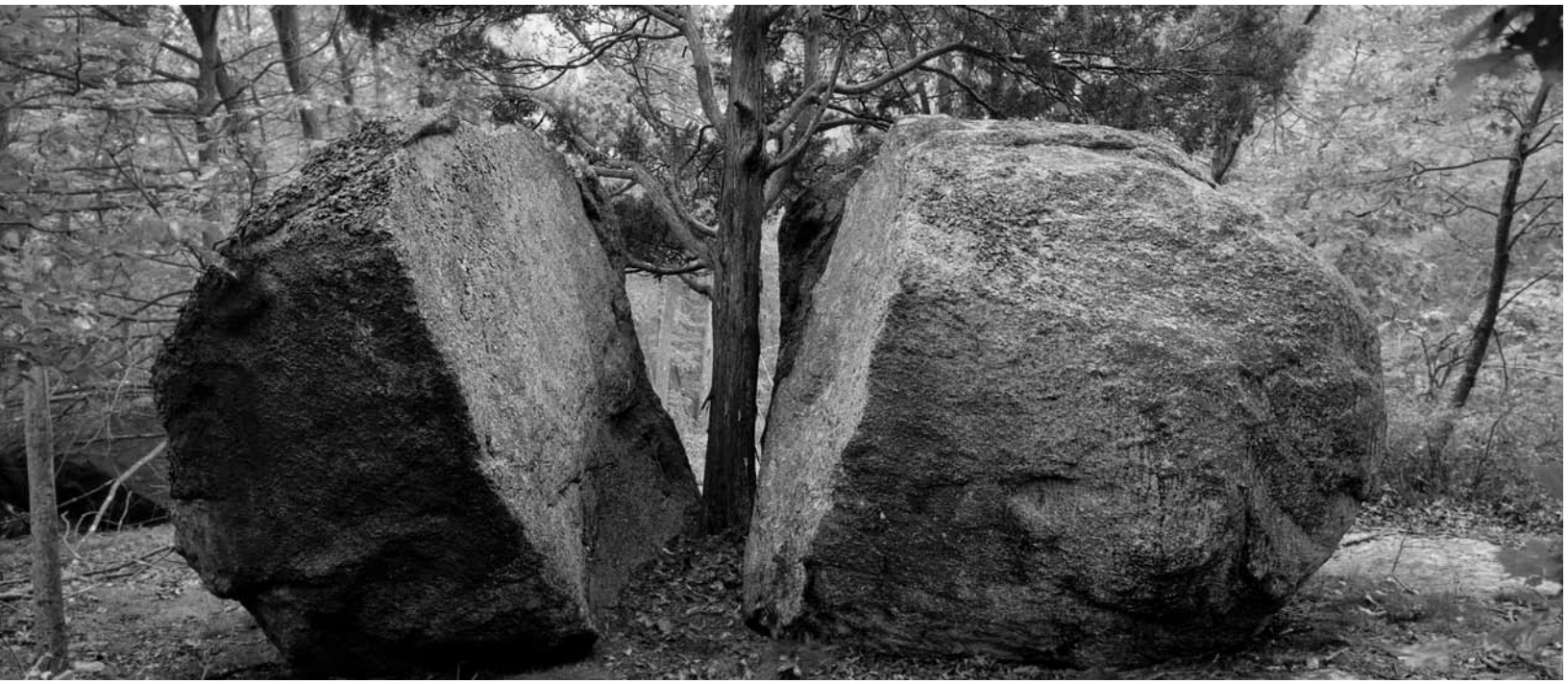

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how similar or dissimilar would the issues be? Dissimilarity or disagreement indicates a potential concern for your organization and a need for action. Consistency is key, because the compliance leadership of your organization is expected to provide clear guidance on how to detect compliance issues.

Role of each employee

Ground-level employees should be treated as the eyes and ears of an organization. All employees should understand (1) the laws that relate to them, (2) what constitutes a compliance violation, (3) the process for reporting a violation and (4) what protections are afforded them if they do report a problem. Educating employees on what constitutes a compliance issue will enable them to connect the dots and know what to report on the hotline or through other reporting mechanisms.

If you asked your employees for an explanation of what compliance means to them, what would they tell you? If most of your employees either don't know or give you an off-the-wall answer, it can spell trouble for your organization. Compliance programs cannot be effective if your employees don't know what a compliance issue is.

Compliance education—Where are you now?

Without education, compliance may mean different things to different people. Has your healthcare organization attempted to define what a compliance issue is and communicated examples and guidance to your employees? It may be time to test how effective your program is. Here is a brief compliance quiz to begin to evaluate what your employees or compliance committee understands about compliance.

Examine the answers and use the assessment to initiate discussion about why each item is a potential compliance issue. Determine whether it is possible that your employees do not believe these are compliance issues because they haven't been effectively educated on what a compliance issue really is. The goal is to help your employees readily pinpoint compliance issues based on definitions common to the organization. Help your employees help your organization.

Do you believe the following issues are compliance offenses?

Yes	No	
____	____	Claiming personal expenses on a time/expense report
____	____	Borrowing the company's pickup truck on weekends without approval
____	____	Timing out for another employee who left work without permission
____	____	Doing business with an immediate relative's company without disclosing the transaction or seeking approval
____	____	Borrowing office supplies to use at home
____	____	Providing physicians with free or discounted rent
____	____	Claiming unallowable expenses in the cost report
____	____	Selecting incorrect codes that result in the submission of improper claims
____	____	Receiving tickets to several NFL football games from a friendly vendor
____	____	Failing to report that a co-worker committed a compliance violation
____	____	Disclosing confidential business information to a friend at a cocktail party
____	____	Working for a competitor and providing confidential business information
____	____	Paying a physician for services that were allegedly rendered but not documented in time records or contracts
____	____	Providing a patient's private medical information to her friend or family member
____	____	Billing for services not provided
____	____	Receiving a free trip to a tropical resort for training
____	____	Making false statements to your financial auditors
____	____	Disclosing confidential salary information of a co-worker

Practical tips

The following are six tips to use for defining compliance for your employees:

1. Review the organization's code of conduct to determine if compliance issues are clearly defined and if the scope matches your organization.
2. Ask compliance committee members to illustrate potential compliance issues with examples or scenarios germane to your organization, share the information at a compliance committee meeting, and summarize common compliance issues.
3. Ask department heads to discuss compliance issues at periodic department meetings, collect examples of compliance issues and provide a list to the compliance officer.
4. Include examples of compliance issues at new employee orientation; for example, employees should understand that taking office supplies home for personal use would constitute a compliance issue.
5. Consider using an employee training video to demonstrate the impact of various compliance issues on specific job functions and the organization as a whole.
6. Educate employees about the major laws pertaining to their specific job functions; awareness of the existing laws and requirements is key to lessening inadvertent violations.

In summary, compliance involves everyone in a healthcare organization. Each person can be a valuable ally in prevention, identification, and resolution of compliance infractions. Cultivate a consistent understanding of compliance issues and their importance, the responsibility to report violations and the compliance process. Set the tone that all compliance issues are taken seriously by providing full documentation of an investigation and resolution of reported compliance issues. Effective compliance programs may enable organizations to either avoid serious compliance violations or detect potential issues through prompt identification and reporting. Compliance programs can be improved by making your organization's personnel and compliance leaders vigilant partners in the compliance process. ■

The OIG's 2007 Work Plan: Actions hospitals should undertake

By Gary W. Herschman and Alexandra Miller Khorover

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The Office of the Inspector General's Work Plan FY 2007 identifies issues and projects which the OIG believes are crucial to its mission and which will become the primary focus of the OIG's efforts during the 2007 fiscal year.

New areas to be covered in 2007

The Work Plan encompasses 23 separate areas of focus for hospitals, as well as many other topics which impact hospitals, such as medical equipment, laboratory services, ambulatory services, Medicare Part D drug benefits, nursing home care, and Medicaid services.

The 2007 Work Plan, while containing many of the same topics which the OIG focused on previously, identifies several new areas of concern which may directly impact hospitals and other healthcare providers. These areas include:

1. **Inpatient dialysis services:** Inpatient dialysis admissions will be reviewed to determine whether the services should be reimbursed by Medicare as "admission to inpatient status" or "admission to observation status." Physicians admitting dialysis patients must clearly state the level of care required in their orders.
2. **Hospital outpatient department payments:** The OIG will review outpatient Medicare payments to determine the appropriateness of payments for multiple and repeat procedures, and global surgeries performed in hospital outpatient departments. The OIG will also consider the extent to which outpatient claims are being improperly "unbundled."
3. **Medical necessity and diagnosis-related group (DRGs):** The OIG plans to analyze inpatient hospital claims to identify providers who exhibit high or unusual DRG patterns. It will examine claims submitted by these providers for medical necessity and appropriate coding levels to ensure that reimbursement is not being increased through upcoding.
4. **Inappropriate payments for diagnostic x-rays in hospital ERs:** The OIG will scrutinize diagnostic x-ray claims to assess the extent of inappropriate payments. Emergency room physicians should not bill Medicare separately for interpretations of diagnostic x-rays.
5. **Inpatient laboratory services:** Medicaid laboratory payments will be scrutinized to identify instances of inadequate documentation and improper bundling. Medicaid will specifically focus on improper duplication of chemistry, hematology, and urinalysis tests.
6. **Emergency health services for undocumented aliens:** The OIG will review Medicaid payments for services to undocumented aliens to ensure that Medicaid is only paying for services necessary to treat an emergency condition.
7. **Disproportionate share hospital payments:** DSH payments will be reviewed to analyze whether state payments to individual hospitals exceed the hospitals' uncompensated care costs, in violation of federal law. The OIG will also examine whether the states are properly determining hospital eligibility for DSH payments.
8. **Billing for Medicaid nursing home patients transferred to hospitals:** The OIG will determine whether Medicaid is making duplicate payments to hospitals and nursing homes for the same patients, and whether hospitals are receiving payments for patients who have been discharged.
9. **Long-term care hospitals (LTCH):** The OIG will scrutinize LTCH admissions to ensure that admissions come from a variety of acute care hospitals. If an LTCH receives most of its admissions from a single acute-care hospital, it may be effectively functioning as a unit of that hospital and therefore receiving improper Medicare reimbursement.
10. **Provider self-disclosure:** The OIG continues to encourage providers to self-disclose potential violations of Medicare and Medicaid law. Overpayments or billing errors which do not indicate a violation of the law should not be reported to the OIG, but instead brought to the attention of the responsible payor.

Other new areas of OIG focus include: hospital capital payments, inpatient hospital payments for new technologies; oversight of quality of care and staffing at specialty hospitals; the improper submission of claims by outside providers servicing assisted living facilities; erroneous Medicaid payments for transportation to and from providers; identification of providers with abusive Medicaid claims volume; and physician assistant reimbursement.

Actions to take to ensure compliance

To demonstrate that your hospital's compliance program is "effective" and being

updated to address new regulatory issues, we recommend taking the following actions in light of the 2007 Work Plan:

1. **Compliance committee.** Convene meetings of your hospital's compliance committee to discuss the OIG's 2007 Work Plan, placing particular emphasis on new OIG focus areas which your hospital has not yet reviewed. Document these efforts by keeping written minutes of all such meetings.
2. **Audits.** Initiate internal and/or external audits of some of the new areas of OIG focus (especially those that the hospital has not recently audited) to evaluate the hospital's compliance in these areas. Document these efforts thoroughly, by preparing a written summary of the methodology and results of such audits, including any corrective actions taken as a result.
3. **Address detected deficiencies.** If any deficiencies are detected as a result of the audits or other compliance initiatives, develop an effective corrective action plan to prevent future noncompliance. Thoroughly investigate the root of the deficiency and identify any overpayments. Incorporate all findings into the corrective action plan.
4. **Risk areas.** If your compliance program sets forth risk or audit areas, amend it to add new risk areas reflected in the 2007 Work Plan.
5. **Dissemination to management.** Send copies of the 2007 Work Plan to members of the hospital's management with a memo explaining its significance. Or follow a more "tailored" approach, by sending each manager the selected sections of the Work Plan that pertain to his/her area of responsibility. Keep copies of all memoranda and material distributed.
6. **Inservice hospital personnel.** Conduct seminars for hospital personnel to familiarize them with areas of the 2007 Work Plan applicable to their work duties and responsibilities. Document all such efforts. Administer post-training testing to ensure understanding of new topics. Document which personnel have completed the training.
7. **Presentation to hospital Board.** Prepare a separate presentation to the hospital's Board to provide them with updates on federal compliance initiatives, including the 2007 Work Plan. Discuss any audit reviews to be performed within the upcoming year. Document these efforts by keeping written minutes of all such meetings.
8. **Copies to physicians.** Physicians cognizant of compliance issues in their private practices will be more aware of compliance issues in a hospital setting. Send a copy of the 2007 Work Plan (or just the sections applicable to physicians, on pages 9-12) to every physician on your medical staff along with a letter explaining its significance. Keep copies of all such letters in your compliance officer's files.
9. **Seminars for physicians.** Offer seminars to physicians on your hospital's medical staff about the specific areas identified by the OIG which are relevant to physicians, and document all such efforts.
10. **Hospital-wide training.** Incorporate features of the 2007 Work Plan into your hospital's compliance training. Refer to the 2007 Work Plan and highlight areas which are of particular relevance to your hospital.

The new areas of focus identified in OIG's 2007 Work Plan should be carefully reviewed by hospitals in connection with their compliance program activities. Physicians, staff, administration, and the hospital board should work closely together on education, training, and prevention initiatives to avoid compliance pitfalls and potential OIG scrutiny. Physician recruitment arrangements present an excellent opportunity for hospitals to work collaboratively with physicians and group practices, and at the same time, to enhance the availability of medical services to the community. By working closely with the physicians and group practices, and by taking the time and care to draft compliant agreements, hospitals can help protect their interests in the event that the terms of the agreements are not being followed, or if the agreements need to be terminated for any reason. ■

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FYI FOR YOUR INFORMATION

University of Miami Settles, Agrees to Pay $2.2 Million

On December 21, 2006 the *Miami Herald* reported that "The University of Miami medical school agreed Thursday to pay $2.2 million to settle allegations that it overcharged Medicare patients from 1995 through 1999.

"The alleged overbilling occurred when Donna Shalala, now UM's president, was head of U.S. Health and Human Services, the federal group that includes Medicare." For more: *http://www.miami.com/mld/miamiherald/16293003.htm*

DOJ Files Appeal

On January 3, 2007 *Associated Press* reported that "Federal authorities have asked the U.S. 9th Circuit Court of Appeals to overturn a ruling that prohibits them from viewing a legal file created on behalf of four heart surgeons suspected of defrauding Medicare and Medicaid.

"Federal agents, joined by the state Department of Justice's Medicaid Fraud Unit, have been investigating the Eugene-based practice of Drs. David Duke, Stanley Baldwin, Warren Glover and Richard Hicks since August 2003. Hicks is now retired, and the doctors sold the practice in 2004.

"Federal authorities want the appeals court to overturn U.S. District Judge Anna Brown's ruling that the doctors each retained individual attorney-client privilege over the file. The documents in question were created by a Boston lawyer the doctors hired before selling the practice. "The U.S. Justice Department filed the appeal Dec. 29 in Portland." For more: *http://www.oregonlive.com/news-flash/regional/index.ssf?/base/news-17/1167814546122940.xml&storylist=orlocal*

Tennessee Cardiologists Settle, Agree to Pay $2.9 Million

According to the January 6, 2007 *Mountain Press*, "A group of 42 cardiologists with East Tennessee Heart Consultants (ETHC) has agreed to pay $2.9 million in restitution and settlement of a civil claim that they have kept overpayments from patients, federally-funded health care programs, and insurance companies since 1995, according to an announcement by the U.S. Attorney's Office.

ETHC has offices in Knox and surrounding counties, including an office at 681 Middle Creek Road in Sevierville. For more: *http://www.zwire.com/site/news.cfm?BRD=1211&dept_id=169689&newsid=17673973&PAG=461&rfi=9*

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New HCCA Members

The Health Care Compliance Association welcomes the following new members and organizations. Please update any contact information using the Member Center on the Web site, or e-mail Karrie Hakenson *(karrie.hakenson@hcca-info.org)* with changes or corrections.

Florida

- Hans Alvarez, Brooks Rehabilitation
- Lourdes Arcos, RN, Larkin Community Hospital
- Cheryl S. Armstead, RN, BSN, Palm Beach Garden Medical Ctr
- Robin Barton, CHC, Sheridan Healthcorp, Inc.
- Linda M. Beeman, CPC, Shands Healthcare
- Smaro G. Bloodworth, NCICS, Shands Healthcare
- Ivette M. Castillo, RHIA, Mercy Hospital
- George Chiu, George M. Chiu
- Mitchell A. Cohen, Fowler White Boggs Banker
- Victoria Cooper, DoctorCare, Inc.
- Mayling Cuesta, RN, CHQ, QM, Baptist Health S Florida
- Tina Dunsford, Fowler, White, Boggs & Banker PA
- Kenneth Engel, Martin Gott Lieb & Asso.
- Mary Linda Frierson, RN,CHC, Bay Care Health System
- Barbara L. Gallaher, Gulfside Regional Hospice, Inc
- Raymond Garofalo, Boringuen Health Care Center
- Cheryl Golden, Ernst & Young
- David M. Hall, WellCare Health Plans, Inc.
- Phyllis Heba, Univ of FL Jacksonville Healthcare
- Marcella Henry, Sunrise Community Inc
- Gerald Herrmann
- Joseph Ireland, III, HealthPoint Medical Group
- Nettie McFarland
- Christine McMahon, Sheridan Health Corporation
- Mary Ann E. Moore, Pediatrix Medical Group, Inc
- Shevon Nelson, KOS Pharmaceuticals, Inc
- Nancy Odeh, Iasis Healthcare (Palms of Pasadena Hospital)
- Mark L. Rabinowitz, MD, Miami Beach Comm Heatlh Ctr
- Karuna Rao, JD, CuraScript, Inc.
- Cherie Sample, Liberty Healthcare Group
- Patti Simmons, Tampa General Hosp
- Tonya M. Singer, WellCare Health Plans
- Donna Smallwood, Orthopedic Center of Palm Beach County
- Josian Sprauve, Adventist Health System
- Patricia Thorbin, Citrus Health Care
- Louis C. Velez, America's Hlth Choice Med Plans, Inc
- Terri Wentz, Jupiter Medical Ctr

Georgia

- David Anderson, WellStar Health System
- Cathleen Armato, Regency Healthcare
- Jeanne Babers-Warren, Pershing Yoakley & Associates
- Mary Jane Beeson, AmeriChoice
- Giselle S. Bernard, Child Neurology Associates
- Julie Blan, Blue Ridge Nursing Homes, Inc.
- Ron Bowen, Cobb/Douglas Community Services Board
- Dennis Cowart
- Lisa A. Dagostino, Emory Univ
- Patricia Dear, AlphaQuest
- Susan J. Doty, Wellstar Health System
- Teresa Engel, RN, CCS, KPMG, LLP
- Carol Eyer, Pershing Yoakley & Associates
- Kelley Fletcher, Reinhardt, Whitley, Wilmot, Summerlin & Pittman, P.C.
- Amy E. Fouts, Arnall Golden Gregory LLP
- Richard Gardner, III, Arnall Golden Gregory LLP
- Amy M. Helms, RN,CHC, Upson Regional Medical Center
- Greg Hembree, South Georgia Medical Center
- Glenn P. Hendrix, Arnall Golden Gregory LLP
- Mitchell P. Hilsen, Village Podiatry Group
- Dipinder Keer, Ernst & Young LLP
- Debra L. Keppler, South GA Medical Center
- Blaine W. Lindsey, Arnall Golden Gregory LLP
- Becky D. Livingston, Bethany Home, Inc.
- Diane L. Merritt, AMAC
- Charlene Ragin, Radiotherapy Clinics of GA
- John Reynolds, WellStar Health System
- Melanie Salsgiver, Hughston Orthopedic Hosp
- Diane A. Todd, Athens Regional Med Ctr
- Larry Tyler, Tyler & Company
- Debi Weatherford, CHAN Healthcare Auditors
- Sidney Welch, Powell Goldstein, LLP
- Kim S. Wills, Smith Northview Hosp

Hawaii

- Helen H. Arakaki, The Queen's Medical Center
- Michelle M S Doo, Gene W Doo MD
- Ouida M. Ferguson, AlohaCare
- Debbie Hiraoka, SH Consulting LLC
- Sylvia Shimonishi, Kaiser Permanente
- Kimberly M. Yamahara, CHC, Kalihi Palama Health Ctr

Idaho

- Linda J. Hall, VAMC
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- Marcia S. Flessner, Mendota Community Hospital

- Fran H. Free, Health Care Services Corporation
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- Kathleen Krusie, Mercy Medical Center
- Denise Krutzfeldt, Univ of IA Hospitals and Clinics
- Thane Peterson, Iowa Foundation for Medical Care

Kansas

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- Laraine I. Gengler, Lindsborg Community Hosp
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- Debra A. Vermillion, Shawnee Mission Med Ctr

Kentucky

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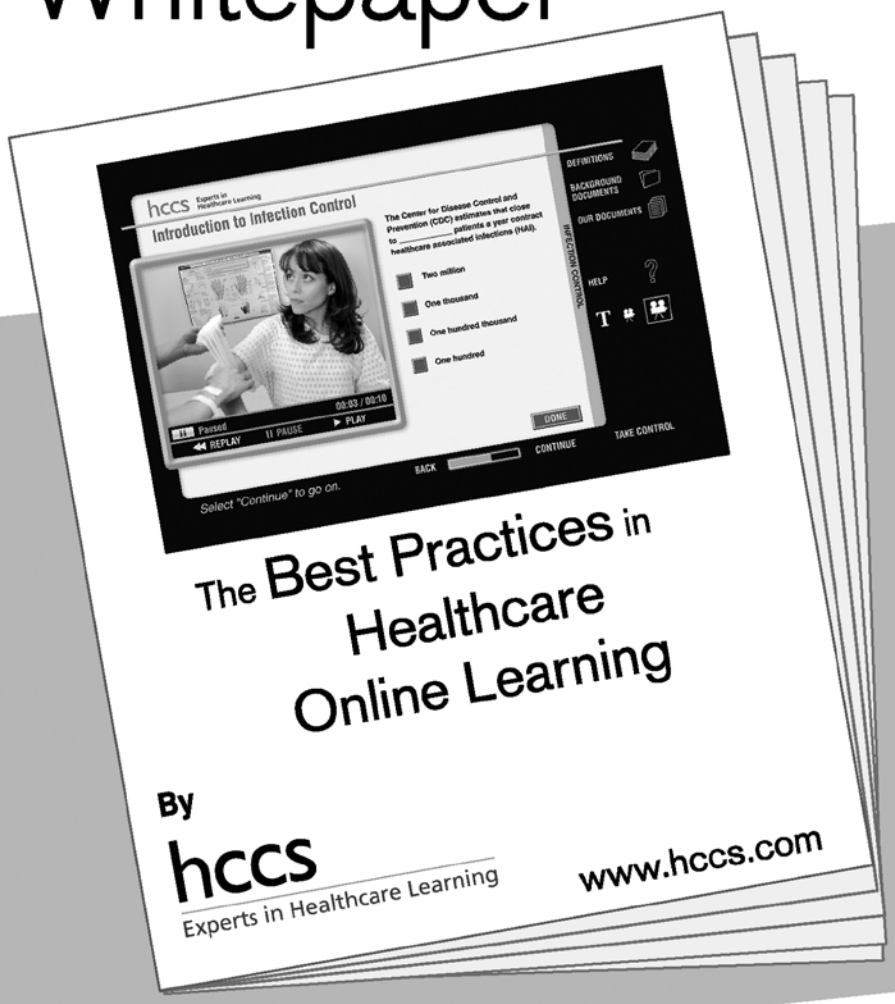

The HCCS whitepaper "**Best Practices in Healthcare Online Learning**" will:

- ✓ Provide a structured way to plan, build, rollout and evaluate online training
- ✓ Identify the differences between departmental and enterprise E-Learning initiatives
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- ✓ Discuss the critical issue of "open standards"
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Read It. Share It.

Go to www.hccs.com/whitepaper

Call for Speakers

2007 HCCA National Conferences

The Health Care Compliance Association is looking for topics and quality speakers for our 2007 National Conferences. If you would like to be considered as a speaker or know of someone who would be a good speaker for any of these conferences, please complete the appropriate form on our Web site at ***www.hcca-info.org/cfs***. You may also mail the information to HCCA, ATTN to the specific conference's name, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

Please contact the HCCA office at 888-580-8373 if you have any questions regarding submissions. All submissions must be received by the deadlines listed below. Submissions received after the appropriate deadline will NOT be considered during speaker selection.

Quality of Care Compliance Conference

September 30—October 2, 2007
Radisson Plaza Warwick Hotel Philadelphia
Philadelphia, PA
All forms and supporting documentation must be submitted by Friday, February 9, 2007.

Physician Practice Compliance Conference

October 3–5, 2007
Radisson Plaza Warwick Hotel Philadelphia
Philadelphia, PA
All forms and supporting documentation must be submitted by Friday, February 16, 2007.

4th Annual Research Compliance Conference

October 31—November 2, 2007
Chicago Marriott Downtown Magnificent Mile Hotel
Chicago, IL
All forms and supporting documentation must be submitted by Friday, February 16, 2007.

Medicare Prescription Drug Part D Compliance Conference

December 9–11, 2007
Renaissance Harborplace Hotel
Baltimore, MD
All forms and supporting documentation must be submitted by Friday, March 30, 2007.

Apply by visiting www.hcca-info.org/cfs

 Continued from page 45

HCCA Members Select Top 12 Hot Topics from 2007 OIG Work Plan

Recently, the Health Care Compliance Association asked its members to select which topics in the 2007 OIG Work Plan they consider to be "hot button issues". HCCA asked its members how often they expect to encounter the topic and if they perceive it as an area of high risk for compliance. HCCA members rated the relevance of each of the topics by using the following scale:

- Not a concern = will not face this issue in the next 12 months or it is not a compliance risk area
- Minor concern = might face this issue, but we do not perceive it as a compliance risk area
- Moderate concern = high probability we will face this issue, this is a compliance risk area
- Definite concern = will definitely face this "hot button" issue, this is a major risk area

The following are the top 12 topics they selected. The first number next to each topic is the percent of survey respondents who ranked this as a definite concern; the second number is the percent of respondents who ranked it a moderate concern. In other words, almost 70% of respondents were concerned or very concerned about coding and DRG services.

- 32/37- Medical appropriate of Coding and Diagnosis-Related Group services
- 30/33 - Unbundling of hospital outpatient services
- 27/39 - Outpatient department payments
- 26/32 - Evaluation of "incident to" services
- 23/33 - "Inpatient only" services performed in an outpatient setting
- 23/30 - Physical and occupational therapy services
- 23/23 - Inpatient rehabilitation facility compliance and Medicare requirements
- 20/37 - Outpatient outlier and other charge-related issues
- 20/28 - Payments for observation services vs. inpatient admissions for dialysis
- 18/28 – Cardiography and echocardiography
- 17/28 Review of evaluation and management services during global surgery periods
- 17/28 Inappropriate payments for interpretation of diagnostic x-rays in hospital emergency departments

For more to: *http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/Surveys/OIG-WorkPlan.htm*

UMDNJ Sets Policy to Encourage Reporting Abuses

On January 18, the Philadelphia Inquirer reported that "Trustees of the embattled University of Medicine and Dentistry of New Jersey have approved a new policy encouraging workers and students to report suspicious activity and to protect whistle-blowers from retaliation.

"The whistle-blower policy, approved Tuesday, reinforces the obligation of workers and students to report suspicions of possible misconduct to an appropriate authority. It sends an important message to our faculty and staff and students that wrongdoing will not be tolerated and we want them to come forward if they have any information," said Anna Farneski, a university spokeswoman." For more: *http://www.philly.com/mld/inquirer/news/local/states/new_jersey/16486295.htm*

Clinic Employee Admits Role in Identity Theft

On January 11, 2007, U.S. Attorney for the Southern District of Florida R. Alexander Acosta announced that defendant Isis Machado pled guilty to Superseding Indictment charging her with conspiracy to commit computer fraud, conspiracy to commit identity theft, and conspiracy to wrongfully disclose individually identifiable health information, in violation of 18 U.S.C. § 371. For more: *http://www.usdoj.gov/usao/fls/PressReleases/070111-03.html*

SCCI Health Services and Subsidiary Settle, Pay U.S. $7.5 Million

Texas-based SCCI Health Services Corporation (SCCI) and its subsidiary, SCCI Hospital Ventures Inc., have paid the United States $7.5 million to settle allegations that the companies violated the Stark self-referral statute and the False Claims Act, the Justice Department announced January 5, 2007. SCCI, which was purchased by Triumph Hospital in 2005, operates long-term acute care facilities across the United States.

The government complaint alleged that from November 1996 through at least 1999, SCCI entered into prohibited financial relationships with three physicians and paid these physicians illegal payments in violation of the Stark statute. The government further alleged that from November 1996 through at least 1999, SCCI either submitted or caused false claims to be submitted to the Medicare program, as a result of these prohibited financial relationships, in violation of the False Claims Act. For more: http://www.usdoj.gov/opa/pr/2007/January/07_civ_003.html

Atlanta Physician Pleads Guilty of Medicaid Fraud

On January 5, 2007, U.S. Attorney for the Northern District of Georgia, David E. Nahmias announced that Aaron M. Hurowitz, a doctor of osteopathic medicine and former owner and operator of "Midtown Medical Center, Atlanta, Georgia, pleaded guilty in federal district court to having perpetrated a scheme to defraud the State of Georgia Medicaid Program. For more: *http://www.usdoj.gov/usao/gan/press/index.html#pdf*

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HCCA's 2007 Conference Calendar

For complete details, visit HCCA's Web Site at www.hcca-info.org

HCCA has a number of national specialty conferences, academies, and local conferences planned for 2007.

Local conferences are offered by HCCA to provide inexpensive compliance education and local networking opportunities for compliance officers and their staff. You will find conference details on the HCCA Web site at www.hcca-info.org, or you may call HCCA at 888/580-8373 with questions.

National Specialty Conferences and Compliance Academies

Audit & Compliance Committee Conference
February 26–28, 2007 | Scottsdale, AZ

Compliance Academy
March 19–22, 2007 | Dallas, TX

Compliance Institute
April 22–25, 2007 | Chicago, IL

Compliance Academy
June 4–7, 2007 | Scottsdale, AZ

Advanced Compliance Academy
June 25–28, 2007 | San Francisco, CA

Compliance Academy
August 20–23, 2007 | Chicago, IL

AHLA/HCCA Fraud & Compliance Forum
September 23–25, 2007 | Baltimore, MD

Quality of Care Compliance Conference
September 30—October 2, 2007 | Philadelphia, PA

Physician's Practice Compliance Conference
October 3–5, 2007 | Philadelphia, PA

Advanced Compliance Academy
October 22–25, 2007 | Baltimore, MD

Research Compliance Conference
October 31—November 2, 2007 | Chicago, IL

Compliance Academy
November 5–8, 2007 | Orlando, FL

Medicare Part D Conference
December 9–11, 2007 | Baltimore, MD

Compliance Academy
December 10–13, 2007 | San Diego, CA

Local Area Conferences

Southwest Local Annual Conference
February 16, 2007 | Dallas, TX

Mid Atlantic Local Annual Conference
May 18, 2007 | New York, NY

Pacific Northwest Local Annual Conference
June 1, 2007 | Seattle, WA

Upper North Central Local Annual Conference
June 15, 2007 | Detroit, MI

West Coast Local Annual Conference
June 29, 2007 | Los Angeles, CA

Alaska Local Annual Conference
July 12–13, 2007 | Anchorage, AK

New England Local Annual Conference
September 7, 2007 | Boston, MA

Upper Midwest Local Annual Conference
September 14, 2007 | Minneapolis, MN

Midwest Local Annual Conference
September 28, 2007 | Kansas City

North Central Local Annual Conference
October 5, 2007 | Chicago, IL

East Central Local Annual Conference
October 12, 2007 | Pittsburgh, PA

Mountain Local Annual Conference
October 26, 2007 | Denver, CO

Hawaii Local Annual Conference
October 18–19, 2007 | Honolulu, HI

Mid Central Local Annual Conference
November 2, 2007 | Louisville, KY

South Central Local Annual Conference
November 9, 2007 | Nashville, TN