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Dear Colleagues:

Before starting to write this last leadership letter as President of HCCA, I took a moment and read my first leadership article after becoming President. The focus of that article was to discuss the hard work that has gone into shaping compliance as a profession and to share with you my excitement about becoming the President of HCCA. Well, today in this article I want to say, "Thanks for the memories," "Goodnight Mrs. Calabash," and borrowing from cowboy wisdom—which flows freely in Texas—"It's better to be a has-been than a never-was!"

I could spend time telling you "how great I art", but I have learned that often times the best skill a leader can have is just learning how to stay out of the way. Most of the work that leads to the impact one might have on an organization takes place in the years prior to becoming the leader of that organization. Then once you find yourself in that leadership role, you want to maintain an environment that allows others to make their contributions. So instead of recounting presidential accomplishments this year, I want to tell you "how great they art." And by “they”, of course, I am referring to the HCCA Board, the CEO, and the HCCA staff. The best evidence of how these individuals work together as a team comes from comments of new board members and guests that we include in our planning processes.

The initial part of our planning process involves celebrating the successes of the past year, and then immediately beginning to look to the future and what needs to be done next. Exhausted at the end of that day-and-a-half planning process, those individuals have shared several observations: "I have never served on a board that is so actively involved in making things happen"; "You fight like cats and dogs and, at the end of the day, you are best friends"; "This is one of the most effective planning processes I have seen, and you actually implemented the plan you developed last year!" There are others, but my point is that the HCCA Board, the CEO, and the HCCA staff are passionate about our organization and the compliance profession as a whole, and it has been great fun staying out of their way.

Roy Snell and I have been accused of sounding like an old married couple. Boy, now there is a scary thought. In fact, we have probably communicated as often as spouses do, and in the same spirit of enthusiasm and unvarnished truth! I can think of no other individual who is more committed to the success of our organization and to getting out the message of compliance than is Roy Snell.

In closing, while many are owed a heartfelt "thank you", it is impossible to do so in this short letter, but I am most grateful for the opportunity to have served as President of HCCA. My family has been most understanding, but, as families do, they keep you grounded when sharing their thoughts, such as "Are you going on another vacation Daddy?" when I was leaving for meetings. And when I was so proud of being elected President of HCCA I got, "Do we get any money out of this?" And then when receiving a negative reply, they just gave me "the look" that conveyed their
heartfelt, “So what’s the big deal?” Well, the “Bid Deal” is that I am rewarded by watching the in-roads our organization has made into all corners of this country’s compliance organizations. And the biggest “reward” of all is just getting to work with such a dedicated and hardworking group of people who have themselves become family to me. To those people, and you know who you are, I say "Thanks" for an unforgettable year.

Letter from the Leadership… Continued

For more information about resources, go to the HCCA Website, http://www.hcca-info.org or call 888/580-8373.

■ The HIPAA Security Rule
■ The Health Care Compliance Professional’s Manual
■ Monitoring & Auditing Practices for Effective Compliance
■ HCCA’s Guide to Resident Compliance Training
■ Compliance 101

■ Compliance, Conscience, and Conduct”, a video-based training program
■ Privacy Matters
■ A video-based HIPAA Training Program
■ Corporate Compliance & Ethics: Guidance for Engaging Your Board Volume 1: The Board’s Perspective
The Centers for Medicare and Medicaid Services (CMS) implemented the Rule establishing a prospective payment system (PPS) for inpatient psychiatric services effective for cost-reporting periods beginning on or after January 1, 2005. The new prospective payment system changes the reimbursement landscape for hospitals either currently providing or planning to develop inpatient psychiatric services by moving reimbursement from a cost-based to a fee-based reimbursement system. The change in the reimbursement system will have an across-the-board impact on existing inpatient psychiatric programs—financially, operationally, and from a compliance standpoint.

The new prospective payment system reimburses psychiatric hospitals and psychiatric inpatient units of acute care hospitals using a Base Rate per diem that is adjusted for a number of factors. The Base Rate per diem is adjusted for location, diagnosis, acuity (co-morbidity), length of stay, the presence of a full-time emergency department, patient age distributions, and being a teaching facility. The PPS system, phased-in for all existing psychiatric hospitals and psychiatric units of acute care hospitals over a four-year period, will be based on a blend of a Federal per diem payment amount and a facility-specific payment rate. New psychiatric units will immediately fall under 100% prospective payment reimbursement.

The unadjusted fixed Base Rate per diem is $575.95. The per diem is adjusted to reflect a labor component and a non-labor portion. The two components are added together to determine the hospital's "wage-adjusted Federal Base Rate".

Facility-level adjustments
Once a hospital determines its fixed Base Rate per diem, Facility-level adjustments are applied to that Base Rate. Facility-level adjustments include a 17% increase for being a hospital located in a rural area; an additional adjustment to the per diem for a patient's first day of care for maintaining a full service emergency department; and a teaching adjustment based on a ratio of residents to occupied beds.

Patient level adjustments
Patient level adjustments are then applied to the facility-adjusted Base Rate. Patient level adjustments are increases or decreases in the facility-adjusted Base Rate and include adjustments for the patient's primary diagnosis (DRG), any co-morbid conditions and the patient's age. The facility-adjusted fixed Base Rate per diem is adjusted for the presence of one of the 15 primary DRG's used for inpatient psychiatric units or hospitals. The rate is further adjusted for one or more of the 17 designated co-morbid DRG conditions. A final patient level adjustment is the application of a graduated adjustment based on the patient's age.

Other adjustments
Resource utilization and length of stay adjustments represent the final component adjustments to a patient's reimbursement. During the first eight days of a patient stay, the adjusted fixed Base Rate per diem is increased to reflect the higher costs and resource utilization associated with the beginning of a patient's inpatient stay. For days nine and 10, the patient is presumed to require minimal additional resource utilization and the reimbursement is the wage adjusted base Facility-level and Patient-level adjusted Base Rate per diem. After day 10 of a patient's stay, there is a gradually increasing negative adjustment to the adjusted Base Rate. There are two further adjustments that apply to determine the level of reimbursement. These adjustments are for outlier cases and a stop-loss provision.

Separate components of the psychiatric PPS include an adjustment for each electroconvulsive therapy (ECT) treatment furnished during the patient's stay in the inpatient psychiatric facility and the "interrupted stay" policy. For patients receiving ECT, the adjusted fixed Base Rate per diem is enhanced with the addition of $247.96 (adjusted for the Area Wage Index) for each ECT treatment provided. The interrupted stay policy applies to patients discharged from any inpatient psychiatric facility (IPF) and returning to the IPF before midnight on the third consecutive day.
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"One major initiative of OIG is the issuance of compliance program guidance to assist recipients of HHS funding in establishing voluntary compliance programs and in developing effective internal controls that promote adherence to applicable Federal statutes, regulations, and program requirements. The adoption and implementation of voluntary compliance programs significantly advances the stewardship responsibilities of the Department's grantee institutions. We are reviewing public comments received in FY 2004 in response to a Solicitation of Information and Recommendations and plan to issue draft guidance in FY 2005 for further comment."

This is the latest in a series of CPG for organizations and health care providers that receive HHS funding. One of the reasons for the issuance of this CPG is "[t]he OIG believes that entities and institutions that receive HHS funds have an ethical and legal duty including an obligation to take measures, such as instituting a compliance program, to detect and prevent fraudulent, abusive, and wasteful activities of the funds." The practice has been that if no specific CPG exists for those receiving HHS funds, an organization can develop an effective compliance program by extrapolating CPG from similar organizations. Therefore, guidance has been available for NIH grantee recipients to structure an effective compliance program for HHS purposes, via extrapolation, for some time. However, organizations with NIH funding have not viewed developing compliance programs for their NIH awards as necessary. With the issuance of specific CPG for NIH awardees, it is apparent that the OIG's has the same expectation for NIH awardees as they do for recipients of other types of HHS funded programs (e.g., Medicare and Medicaid), that compliance plans for HHS funds be developed in accordance with CPG's, regardless of HHS program or source of funds.

In this era of vigorous federal oversight and enforcement of HHS health care dollars and research awards, there are many perceived benefits for recipients of NIH funds in implementing effective compliance programs, including:
1. Developing the organization's ability to detect and self-correct
2. Adding value to the organization because of the possibility of receiving a reduction in sentence in the event that federally proscribed conduct is found
3. Providing a defense against allegations of fraud.

The CPG for Recipients of NIH Research Grants provides a blueprint of the OIG's view on what is required to create an effective program. The issuance of this CPG is a significant development for NIH grant recipients (or for that matter, organizations that receive federal awards, as federal agencies usually follow NIH's lead in research regulation), as it further demonstrates HHS's commitment to ensuring the proper stewardship of its research grants and contracts.

The NIH imposes significant regulatory burdens on those conducting NIH sponsored research. The regulations encompassing NIH grants and contracts are extensive, complex, and in some instances hyper-technical. The regulations can be organization specific (e.g., educational institutions, state and local governments) or applicable for all awards. Such activities include all research involving human or animal subjects, hazardous materials or controlled substances, and other ancillary activities that impact the conduct of research.

For example, there are requirements for proposing, receiving and administering...
NIH grants and contracts. There are regulations for conducting federally sponsored clinical trials. Via the HHS, Office of Human Research Protections (OHRP), organizations must obtain a federal-wide assurance of compliance (FWA) for institutions engaging in human subjects research that is conducted or supported by the HHS. If the human subjects research is also regulated by the Food and Drug Administration (FDA), the research must also comply with FDA human subject protections, and the FDA's Good Clinical Practices. Covered entities must comply with HIPAA [Health Insurance Portability and Accountability Act] research requirements.

As a condition of NIH funding, organizations must comply with regulations from various federal agencies and departments for animal research. For example, USDA [United States Department of Agriculture] regulations require registration and licensing of institutions who breed, sell, transport, hold, or use such animals and the USDA has standards for the humane treatment of laboratory animals. The FDA has established standards for the proper conduct of non-clinical laboratory studies that include animals. The Office of Laboratory Animal Welfare (OLAW), within NIH, is responsible for the implementation and general administration of the Public Health Service policy on the humane care and use of laboratory animals.

NIH grant recipients must adhere to the NIH Guidelines for research involving recombinant molecules, and must establish and register with the NIH Office of Biotechnology Activities an institutional biosafety committee that reviews and approves certain experiments, including all human gene transfer studies. There are also invention reporting responsibilities for NIH extramural funding recipients.

The research compliance infrastructure required by NIH awardees can be daunting, due to the pervasive and often overlapping regulatory schemes. Once research grants or contracts from other federal agencies are proposed and accepted, other terms, conditions and assurances must be incorporated into the research compliance infrastructure as well (e.g., Department of Defense, Centers for Disease Control, National Science Foundation, and Department of Justice). Compliance with terms and conditions are a condition of receipt of federal research awards.

Many non-profit organizations award research grants that stipulate compliance with their own regulations, federal regulations, and "best practices" research regulations. As one can see, research institutions and academic medical centers are highly regulated with respect to research activities, regardless of the source of funding. Therefore, organizations that develop and implement CPG for Recipients of NIH Research Grants should consider establishing a compliance plan that integrates all regulated research activities, for which rules, guidelines, and best practices have been established.

The OIG has been continuously signaling recipients of NIH research grants of its intent to rigorously enforce regulatory compliance, not only by the publication of specific CPG for Recipients of NIH research grants, but by the increase of research compliance measures in the OIG's yearly Work Plans, an increase of OIG audits of NIH awards, and increasing false claims litigation regarding NIH extramural funds.

The CPG or model plans are essentially more detailed renditions of the U.S. Federal Sentencing Guidelines' seven requirements, adapted for particular segments of the health care industry (see below). They identify the specific conduct that the OIG considers necessary for structuring and maintaining an effective compliance program. The specific elements are similar to the mitigating factors delineated in the U.S. Federal Sentencing Guidelines. Failure to meet a mitigating factor under U.S. Federal Sentencing Guidelines may eliminate all benefits associated with a compliance plan. An organization, undertaking the structuring and implementing of a compliance program, should examine the seven requirements of the U.S. Federal Sentencing Guidelines for additional guidance.

The draft CPG for Recipients of NIH Research Grants provides grantees with seven specific elements that NIH grant recipients should include in the establishment of a comprehensive compliance program. These fundamentals originally derived from the Federal Sentencing Guidelines, include:

1. Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;

Continued on page 8
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines;
7. Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate Federal agency.

The OIG is considering adding an eighth element "[d]efining roles and responsibilities and assigning oversight responsibility" that incorporates a discussion of the importance of effectively delegating oversight authority. The OIG further invited comments on the scope of the proposed CPG, particularly on the types of activities that should be subject to the CPG and the risk areas for recipients of NIH research grants, stating "[b]ased on our fraud investigations at research institutions, we have identified internal control deficiencies that may warrant attention..."[8]

Risk areas identified by the OIG include:
(i) proper allocation of charges to grant projects
(ii) "time and effort" reporting, including an accurate reporting of the commitment of effort by researchers
(iii) use of program income.[2]

Developing effective research compliance programs requires input, development and implementation from personnel with varying backgrounds and expertise including: researchers, administrative personnel, attorneys, and research compliance specialists.

Creating and maintaining a compliant organization is, and will continue to be, increasingly challenging for research institutions. Because of the increased amount of regulations, litigation, and regulatory oversight for recipients of NIH and other federal research grants, "institutions will have to be transformed from very decentralized, compartmentalized, and segmented entities, that function quite independently...into integrated multi-specialty regulatory organization where decision making is centralized so that organizations remain cognizant of the institutions regulated research activities and are able to respond quickly and appropriately to an ever evolving research compliance environment."[23]

1. (68 Fed. Reg. 172, 52783-52784 (Sept. 5, 2003)).
6. Id. at 1.
7. (See, NIH Grants Policy Statement (03/01); OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (11/10/1993) (further amended 09/30/1999), OMB Circular A-122, Cost Principles for Non-Profit Organizations (05/10/2004), and OMB Circular A-21, Cost Principles for Educational Institutions (05/10/2004)).
8. Institutions that are NIH subcontractors and those that participate as sub-sites for NIH Multi-Site Cooperative Clinical Trials must obtain PWAs as well.
11. (See, Guidance for Industry, E6 Good Clinical Practice; Consolidated Guidance, HHS, FDA, Centers for Drug Evaluation and Research and Biologics Evaluation and Research (April 1996)).
12. (See, Clinical Research and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Rule (HHS, NIH Publication Number 04-5495 (February 2004))).
15. (Health Research Extension Act of 1985 (Public Law 99-158, Nov. 20, 1985)).
17. 37 CFR Part 401 § 401.14(620 (1997)).
18. The Association for Assessment of Laboratory Animal Care (AALAC) conducts a peer review, and it has no direct regulatory role because it is an advisory group (is not a federal entity). If an institution has AALAC approval, it means that the institution meets all the rules and regulation of the USDA, Public Health Service (PHS) and other regulatory agencies. See http://www.aalac.org, visited 2/8/05.
19. DHHS OIG Work Plan for Fiscal Year 2004, 1\w will evaluate whether...NIH grantees have followed laws, regulations, and other Federal guidance...". Other sections in the Work Plan that address extramural grantee compliance are: 1) [m]anagement and oversight of research grants, 2) [m]onitoring adverse event in clinical trials, 3) [g]rantee compliance with invention reporting requirements, 4) [c]ompliance with Federal cost principles with regard to [d]ebug centers; 5) [b]othe colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants and cooperative agreements; and 6) [g]rantee compliance with invention reporting requirements. Available at http://oig.hhs.gov/publications/docs/workplan/2004/W ork%20Plan%202004.pdf, visited 12/15/05.
20. For example see, Audit of Health Resources and Services Administration Cooperative Agreement Number U30-03-0005 University of Southern California Los Angeles, California (A-09-02-01040) at http://oig.hhs.gov/oaas/reports/region 9/020104(010.pdf), visited 1/21/05, where the OIG determined that USC did not meet the project objectives, conducted research on human subjects without proper authorization, did not adequately resolve a conflict of interest, and claimed costs that were not allowable. As a result, USC had to refund over $1 million dollars in unallowable costs
22. Id. at 1, (68 Fed. Reg. 172, 52783-52784 (Sept. 5, 2003)).
23. Dr. Michael M. Johns, Dean of the John Hopkins School of Medicine, Address at the 15th Private Sector Conference in Medicine, sponsored by Duke University Medical Center, 1994 (general comments as applied to centralizing the compliance function).
following discharge. In such cases the new portion of the stay is considered to be a continuation of the original stay.

There are a number of inherent operational and compliance changes related to the new Prospective Payment System. These changes include changes to the admission assessment and evaluation process; changes to coding requirements; and changes in the level of compliance oversight required.

The psychiatric PPS requires that the hospital document "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received or the length of stay or both."

In order to apply the adjustments for co-morbid conditions, the hospital will have to enhance its evaluation, assessment and documentation of the patient's medical condition at the time of admission as well as document the continuing need for treatment of the co-morbid condition. This is a significant change from operating under the cost-based reimbursement system.

The Prospective Payment System is a DRG-based system. The DRG system does not translate or take into account the coding from DSM-IV which was historically the coding source for psychiatric patients. The primary result of this change in coding is to require that all inpatient psychiatric patient claims be submitted using the appropriate ICD-9-CM code in order to be consistent with the requirements of the DRG system. Practically, this will require that the ICD-9-CM code appropriate to the patient's diagnosis be on the medical record. If the patient's assessment is accomplished using the DSM-IV-CM diagnostic system, the resulting DSM-IV coding will have to be translated to an ICD-9-CM code in order for the IPF to receive payment.

**Conclusion**

The new regulations will require changes to a hospital's process of intake, evaluation and assessment procedures and documentation at the time of admission; the documentation of the need for continued inpatient treatment during the stay; the documentation of treatment for any co-occurring medical conditions impacting on treatment or length of stay; the certification of the patient's need for an inpatient level of treatment; and the coding of the medical record and the associated patient billing.

All of these changes are accompanied by the need for a hospital to provide an enhanced compliance oversight of the process.

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**FOR YOUR INFO**

Tenet Agrees to Settle Pricing Class Action Lawsuits

On March 10, Tenet Healthcare Corporation (NYSE: THC) announced that it had reached an agreement providing for a nationwide settlement of certain class action lawsuits regarding prices that uninsured and some underinsured patients were charged for prescription drugs and other medical products and services at hospitals owned and operated by Tenet subsidiaries. For more: [http://www.tenethealth.com/TenetHealth/PressCenter/PressReleases/TenetPricingClassActionSettlement.htm](http://www.tenethealth.com/TenetHealth/PressCenter/PressReleases/TenetPricingClassActionSettlement.htm)

Mercer Country Geriatric Center Settlement Announced

On February 22, the US Department of Justice announced that it reached a settlement agreement with Mercer County, New Jersey resolving the Department's investigation of conditions and services at the Mercer County Geriatric Center, a nursing home operated by Mercer County. For more: [http://www.usdoj.gov/opa/pr/2005/February/05_crt_073.htm](http://www.usdoj.gov/opa/pr/2005/February/05_crt_073.htm)

Settlement Announced

On February 17, US Attorney for the Southern District of Ohio Gregory G. Lockhart announced that J. Richard Jones and Connie Jean Jones, both of Westerville, and their company Cardio-Diagnostic Technology and Consultants, Inc. of Westerville, were ordered to repay almost $58,000 to the federal Medicare program and state Medicaid program as part of their sentences for their roles in a scheme to bill the programs for services never performed, and for altering records submitted to the programs. For more: [http://www.usdoj.gov/usao/obs/Press/02-17-05.htm](http://www.usdoj.gov/usao/obs/Press/02-17-05.htm)
The U.S. Department of Justice's Principles of Federal Prosecution of Business Organizations (hereinafter referred to as the "Thompson Memo") and the recent amendments to the United States Sentencing Guidelines for Business Organizations (hereinafter referred to as the Sentencing Guideline Amendments) relating to reduction of the culpability score for an organization's cooperation in a federal government investigation have effectively driven a wedge between business organizations and its employees. The effect of the Thompson Memo and the contemplated level of cooperation under the Sentencing Guideline Amendments incentivize a business organization to become a partner with federal enforcement authorities in detecting and preventing misconduct.

The practical impact on business organizations under investigation requires "cooperation" which typically means identification of employees engaged in misconduct to the government to ensure corporate survival. The chief executives and the counselors to business organizations have speculated whether "cooperation" under these circumstances really means anything more than "unconditional surrender".

The fourth and sixth factors in the Thompson Memo reflects that a prosecutor, in assessing the extent of cooperation of a business organization, should consider a corporation's "willingness" to identify the culprits within the corporation, including senior executives; to make witnesses available; to disclose the complete results of the organization's own internal investigation; and to waive attorney-client privilege and work product protection. The comment section to the Thompson Memo states that waiver of a corporation's attorney-client privilege is not an absolute requirement, but sometimes might be necessary. The directive promises leniency to business organizations and practices have dramatic consequences for business organizations.

By Gabriel L. Imperato, Esq.

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This article is Part II of a two-part article on the recent amendments to the U.S. Sentencing Guidelines. Part I was published in the February 2005 issue of Compliance Today, page 4.

1. The nature and seriousness of the offense, including the risk of harm to the public and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime;
2. The pervasiveness of wrongdoing within the corporation;
3. The corporation's history of similar conduct;
4. The corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents, including, if necessary, the waiver of corporate attorney-client and work product protection;
5. The existence and adequacy of the corporation's compliance program;
6. The corporation's remedial actions, including any efforts to ... cooperate with the relevant government agencies;
7. The collateral consequences, including disproportionate harm to [parties] not proven personally culpable and impact on the public arising from the prosecution;
8. The adequacy of the prosecution of individuals responsible for the corporation's malfeasance;
9. The adequacy of remedies such as civil or regulatory enforcement actions.

The Thompson Memo was disseminated during January of 2003 and focuses on the quality of a business organization's "cooperation" with a government investigation and sets forth nine factors that prosecutors should consider in deciding whether to charge a business organization. These factors are as follows:

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organizations which quickly and voluntary comply with disclosure and cooperation. The dynamics of these considerations necessarily compromises the organization's ability to rely on the attorney-client privilege.

The Sarbanes-Oxley Act of 2002 also directed the United States Sentencing Commission to review and amend the organizational Sentencing Guidelines for compliance related policy statements to ensure that they are sufficient to determine and punish organizational misconduct. The Ad Hoc Advisory Group of the United States Sentencing Commission, following this directive, issued a report on October 7, 2003. The report recommended numerous amendments to the Sentencing Guidelines (see article published in the February 2005 Compliance Today), but also focused on cooperation by a business organization in a Federal investigation.

The Sentencing Guideline Amendments emphasized that an organization’s culpability score under the Sentencing Guidelines would be reduced if it "fully cooperated in the investigation" of its own wrong-doing. The commentary on the Sentencing Guidelines state that cooperation does not per se necessitate waiver of the attorney-client privilege and work product protections and is not a prerequisite to a reduction of the culpability score, but notes that in some circumstances it "may be required in order to satisfy the requirements of cooperation". The Sentencing Guideline Amendments became law on November 1, 2004 when Congress failed to amend the proposals of the United States Sentencing Commission.

The sentinel effect of the Sarbanes-Oxley Act and the increased regulation of public companies, combined with implications of the Thompson Memo and the Sentencing Guideline Amendments, has also raised the specter of cooperation and full disclosure before many administrative agencies, but in particular, the Securities and Exchange Commission (SEC). The SEC's "Seaboard § 21(a) Report" exemplifies the practical effect of these governmental guidelines and initiatives for corporate cooperation. The Seaboard case involved a wrongdoer's action, which allegedly led to misstatements in a subsidiary's financial statements. The parent company's management acted within a week to rectify the mistakes and it was noted in the case that the company "did not invoke the attorney-client privilege, work product protection or other privileges or protections with respect to any facts uncovered in the investigation". As a result, the SEC took no action against the corporation and noted in footnote 3 of the report that the attorney-client privilege ensures a very important purpose, but, in certain circumstances, a business organization might feel compelled to waive it. The footnote goes on to state that waiver is not the end goal, but only "a means (where necessary) to provide relevant and critical information".

The report in the Seaboard case lauded the company for the following:

- promptly investigating and publicly disclosing its accounting errors
- dismissing the responsible employee and two of its supervisors
- providing "complete" cooperation with the SEC's investigation of the matter (by, among other things, not asserting its attorney-client and other privileges) and
- strengthening its financial reporting process to prevent similar problems in the future.

The Seaboard report then itemized a non-exhaustive list of thirteen criteria it considers in determining whether, and how much, to credit self-policing, self-reporting, remediation, and cooperation. The essential criteria include the following: the egregiousness and duration of the misconduct; the extent to which a lax corporate culture led to the misconduct; the extent of front office responsibility; the extent of investor harm; the extent to which corporate internal controls failed to detect the misconduct; the promptness and effectiveness of the company's response on discovering the misconduct; the thoroughness and independence of the company's internal inquiry into the misconduct; the company's remedial actions to prevent recurrence of the misconduct; and the extent to which the company cooperated in the SEC's investigation.

The last criteria, again noting cooperation, included the comment that the extent to which the investigated company shares the results of its own internal inquiry with the SEC's staff, voluntary discloses relevant information not specifically requested by the staff, encourages its employees to cooperate, and refrains from asserting attorney-client privilege, work product protection, and other privileges during the investigation will measure the degree of cooperation attributed to the business organization. The SEC has made it clear that not only will it fail to attribute credit for a non-cooperating organization,

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but will move to punish a business organization which does not cooperate in its investigations, even if it does not charge the business organization with violations of the law based on the underlying conduct in question.

The combined effect of these principles of prosecution, application of the Sentencing Guidelines and aggressive incentives for a business organization to cooperate in certain agency investigations has created a climate in which business organizations have no practical choice but to cooperate fully and promptly with federal investigations. The circumstances literally coerce business organizations into cooperation and, therefore, it is difficult to describe cooperation under these circumstances as completely voluntary. Furthermore, if the cooperation involves waiver of the attorney-client and work product privilege, these waivers are permanent and while they do work to provide the government with information which prosecutors can use to criminally charge responsible individuals, they also create information which plaintiff's lawyers can use in support of class action and derivative lawsuits.

A recent address by the 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 presentation by the Deputy Attorney General noted that the issue of waiver of the attorney-client privilege and work product protections frequently comes up in all federal law enforcement efforts, especially where investigations focus on schemes to defraud that are increasingly sophisticated and complex and may often span an entire industry. The Deputy Attorney General also noted that the Department of Justice understands the term "cooperation" as reflected in the Thompson Memo, the Sentencing Guideline Amendments and in court decisions, to mean cooperation 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.

The Deputy Attorney General stated that the Department of Justice does not require or mandate a business organization to cooperate in a Federal investigation or to waive applicable privileges. The Deputy Attorney General went on to say, however, that cooperation does reflect that a corporation is looking to clean house and change its culture; enables government investigators to gather facts before they become stale; assist the government in fully investigating the wrongdoing; 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 in order to get credit for cooperation, they must turn this over to the government to effect a charging decision or a reduced culpability score under the Sentencing Guidelines.

The Deputy Attorney General did acknowledge that business organizations can cooperate without waiving privileges and that prosecutors are generally just interested in the facts and not necessarily the legal advice or opinion work product or information that is at the heart of the attorney-client privilege (i.e. counsel's advice to the corporation or counsel's mental impressions). The fact is that the Federal government has identified key components of cooperation and voluntary disclosure which effect their charging decisions, the culpability score under the Sentencing Guidelines, and relationships with administrative agencies.

These key components are as follows:
1. Timely and complete disclosure. A failure to quickly cooperate can be held against a corporation.
2. The corporation's willingness to implicate those responsible even if they are top management.
3. The corporation's cooperation in making witnesses available to the government and to encourage witness honesty and full disclosure.
4. The disclosure of the results of the corporation's own internal investigation so that the facts and scope of the misconduct can be fully known to the government, even if this requires waiver of the attorney-client and/or work product privileges.

The concept of cooperation is not new, but it has changed in recent years, as reflected by the Thompson Memo and the Sentencing Guideline Amendments, in the following important ways:
1. The completeness of cooperation demanded by Federal authorities.
2. A careful assessment of whether the business organization while purporting to "cooperate" actually engaged in conduct that impeded the government's investigation by doing any of
the following:
(i) making overly broad assertions of legal representations of employees.
(ii) issuing directives to employees and agents not to meet and/or cooperate with the government.
(iii) misleading presentations or submissions of information to the government, including failure to adequately respond to subpoenas and provide documents pursuant to government requests or incomplete or delayed document production.
(iv) failing to promptly disclose illegal conduct known to the corporation.
(v) continuing financial or other support of culpable employees.
(vi) entering into joint defense agreements with culpable employees.
(vii) failing to waive the attorney-client and work product protections when it appears essential (and there is no other alternative means to convey the information to disclose the facts and scope of misconduct to the government).

An apparent casualty of stepped-up enforcement in the health care industry, corporate scandals at the turn of the century, the Sarbanes-Oxley Act and the Sentencing Guideline Amendments may be the attorney-client and work product privileges and the ability of an organization to protect itself whether they engaged in wrongdoing or not. A business organization may be willing to fully cooperate and disclose privileged information to law enforcement authorities. However, this may well mean that private plaintiffs with their own agendas will have access to this information for purposes of civil litigation against the business organizations. A corporation may be put in a position of furthering its objectives with law enforcement authorities, but at the expense of liability to aggressive plaintiff’s seeking recoveries.

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

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

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

For more information on how you can become CHC Certified, please call 888/580-8373, email hccb@hcca-info.org, or visit the HCCA Website: http://www.hcca-info.org/Template.cfm?section=HCCB_Certification
Editor's note: This interview, conducted in March with Odell Guyton, Director of Compliance for Microsoft Corporation and the Health Care Compliance Association’s President for 2005 was conducted by HCCA’s 2004 President Al Josephs, Director of Corporate Compliance for Hillcrest Health System.

**AJ:** Odell, tell me about your current position.

**OG:** For the past three years I have been employed as the Director of Compliance for Microsoft Corporation. The position is responsible for the supervision of Microsoft’s global compliance and ethics responsibilities. The compliance function reports administratively to the Office of General Counsel but is supervised by the Board of Directors Audit Committee. The compliance responsibility at Microsoft is built on cross-collaboration and inter-collaboration throughout the company. I am also the Board-appointed Antitrust Compliance Officer, responsible for certifying Microsoft’s compliance under the Federal District Court’s Final Judgment Order.

**AJ:** Please tell me about your involvement with HCCA.

**OG:** I first became involved with the HCCA when I served as the Corporate Compliance Officer for the University of Pennsylvania and the University of Pennsylvania Health System. I have been involved with the HCCA as a Board member since a few months after it was founded. I am presently serving in my second term on the HCCA Board of Directors.

**AJ:** What is the primary goal you have set for yourself as President of HCCA?

**OG:** Compliance professionals today, especially those in the health care arena, face many challenges that were not present just a few years ago. The legislative changes impacting the "for profit" world is likely to have collateral impact on the "not-for profit" world. These factors coupled with the views of federal enforcement agencies are setting a high bar for establishing what are considered to be "effective" compliance programs and the individual success of those who are charged with running them. My primary goal for the HCCA, as the largest organization for compliance professionals in the United States, is to ensure that the HCCA continues to be fully resourced and committed to service the growing and emerging needs of our membership.

The HCCA as an organization, our staff, and our Board of Directors are well regarded inside and outside of health care. We must leverage this reality to achieve continued success. The HCCA is uniquely qualified and is in a position to anticipate our members' needs, provide educational opportunities to advance our mission, and to be a leader in the broader compliance industry so that the compliance profession is elevated and respected in the eyes of corporate professionals. This is the primary goal I have set for myself as President of HCCA.

**AJ:** What do you see as the most important challenge to Compliance as a profession?

**OG:** I believe that the most important challenge today for Compliance as a profession, and for the health care compliance professional in particular, is
for the profession and the individual practitioner not to be seen as a key player in the larger role of corporate governance.

As more widely recognized and established professional organizations (i.e., lawyers, accountants, auditors, finance) carve out larger chunks of the compliance function for themselves, the compliance officer must be perceived as providing real value and having a real voice in the organization’s business planning activities, risk assessment activities, and executive levels of accountability at the entity.

**AJ:** How can members become involved helping meet those goals?

**OG:** We must be advocates in the organization for our programs; we must be advocates for the compliance profession, and we must provide support for one another in these roles. We should make it a point to be mindful of what is occurring in our regulatory and social environment and be agents for change in our organizations where change needs to occur. We must also be full supporters for our professional organizations, such as the HCCA, so that we grow credibility as a professional group.

**AJ:** Where would you like to see the compliance profession in five years?

**OG:** The evidence already exists to indicate that the compliance profession in five years will have importance in the areas of risk management and, for most global corporations, will be a foundation element for global citizenship. The profession is moving up in the rankings for most important job and I see the compliance profession and the compliance professional being critical in the success of a company’s business objectives—on par with the roles of the general counsel, internal auditor, or finance professionals.

**AJ:** Tell us about the growth of compliance in the non-health care industry.

**OG:** The growth of compliance in the non-health care industry is nothing short of phenomenal. This growth is on a global scale and is across industries. The hard lessons learned as compliance professionals in the health care world are transferable and provide a solid foundation in non-health care arenas. A working knowledge of the federal sentencing guidelines and the knowledge gained by implementing compliance processes and working with regulators in the health care industry provide instant credibility points for those members of our profession who wish to branch out to other compliance and/or corporate governance areas.

The potential for international growth opportunities is at an all time high in this regard.

**AJ:** What do you see as the greatest challenge facing compliance professionals?

**OG:** The greatest challenge facing compliance professionals is maintaining the systems and processes in your organization that provide credibility for your program and credibility for you as compliance professional. We must be prepared for our compliance programs to undergo internal and external scrutiny and to pass with superior scores and sound processes that are well known and highly regarded by employees of your organization as well as the leadership of your organization. This level of recognition and credibility must not only be held by your CEO, CFO, and Board of Directors, but by other professionals who play a role in the corporate governance structure. These groups include the company’s lawyers, internal auditors, external auditors, controllers, and business group managers, as well as your program’s reputation amongst external regulators. We are all in this together!

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Editor's note: Greg Endicott CPA/ABV, ASA (greg.endicott@sinaikohc.com) is the managing director of valuation services and Jeff Sinaiko (jeff@sinaikohc.com) is the president of Sinaiko Healthcare Consulting. For more information, please contact Mr. Endicott at 310/826-4935 or go to www.sinaikohc.com.

The need for valuations of physician services arrangements has increased dramatically in recent years as these types of deals have become more complex and more ubiquitous throughout the health care industry. Valuation in this context is becoming increasingly important for a variety of reasons. First and foremost, we are generally in an era of heightened compliance awareness and regulatory enforcement. Second, an increase in more complex business arrangements between hospitals and physicians create both a plethora of compliance requirements and more complex business decisions in which valuation indications are determinant. Many more physicians can no longer afford and are no longer willing to provide certain services to hospitals without compensation as they have done historically. Third, there is increasing concern about the perception of non-arm's-length transactions between health care organizations and physicians.

In this article, we will discuss various considerations related to the valuation of physician services agreements.

Overview

The role of valuation in health care is more complex than just simply to facilitate solely business decisions or compliance issues. One of the unique aspects of valuation in health care specifically is that the compliance and business issues are often interrelated—yet they also remain distinct. With respect to the compliance aspects related to physician services agreements, Medicare fraud and abuse, Anti-kickback, Stark, Private Benefit and Inurement all present regulatory issues which need to be addressed. Sarbanes-Oxley concepts, which are being increasingly applied to non-public companies, along with state laws, also present additional compliance hurdles. Add into this mix, a multitude of regulatory authorities including the Office of the Inspector General, the Centers for Medicare and Medicaid Services, the Internal Revenue Service and State Attorneys General and it becomes clear that even the compliance aspect alone is not straight forward.

It would be helpful if there were significant amounts of case law specifically addressing some of these valuation issues to assist in providing direction. Unfortunately, although there have been a few recent well known cases which address valuation issues such as Stahome Health, there is not much case precedent to provide additional guidance regarding these physician compensation valuation issues in a regulatory context. Guidance such as the Stark II Phase II Interim Final Rule is a step in the right direction with respect to clarification; however there still remains a significant amount of ambiguity. Even this clarifying guidance has recently come under attack by physician organizations. One aspect, which is consistent across the regulatory spectrum, is the concept of arms-length relationships and fair market value. It is this concept that must be supported and documented. In addition to the regulatory compliance issues, one almost always has underlying business issues with respect to the subject of valuation. For example, how much should you pay for physician services? These business issues need to be addressed in their own right, yet they also need to be addressed within the framework and boundaries of regulatory compliance. For example, a prospective physician services arrangement may make business sense, yet it may not meet the compliance tests. Alternatively, just because a prospective arrangement meets the compliance tests, doesn't mean it is a good business decision. It is in this context that health care executives and legal counsel need to evaluate these issues. There are a variety of agreements negotiated with physicians that necessitate "arms-length" transactions. Call coverage arrangements, management services agreements, medical director compensation, employment agreements and other types of services arrangements all reflect compensation paid for services provided by physicians.

Valuation methodologies

With respect to valuation methodologies, there are three general conceptual approaches considered when valuing
physician services agreements. These approaches are the Income approach, the Market approach, and the Cost approach. Although the application of each of these approaches and the specific methods used vary depending upon the nature and purpose of the valuation, the concepts remain the same.

The income approach is based upon the concept of economic returns from the provision of services. Theoretically, the income approach is the most sound of the three because, by definition, it is based upon the present value of the expected future cash flows. It is also frequently the most time consuming and difficult methodology to apply due to inadequate information and numerous assumptions often required to properly utilize the data provided by physician practices or hospitals, for example. Unfortunately, many compensation arrangements cannot be appropriately or completely valued on this basis.

One of the more common valuation approaches is the market approach, which looks at comparable compensation benchmarks to provide an indication of fair value. This approach is frequently used with respect to services provided by individual physicians. With respect to compensation for services, the application of the market approach is through benchmarking data which is primarily categorized by specialty and productivity.

The last conceptual approach is the cost approach. The cost approach is based upon the principle of substitution. In other words, how much would it cost to provide the services in-house or contract for the services from an independent third party? This approach is the most relevant for situations where limited market data exists and/or the income approach is not easily applied.

Compensation for services
Over the past several years, there has been a tremendous increase in awareness of the compliance implications of physician compensation/employment compensation, compensation for medical director services, coverage arrangements, and other such professional services. While there are certainly business implications for the fair market value analyses done in these situations, such analyses are the most purely compliance-driven uses of valuation in our industry. Even valuation professionals and lawyers will agree there are times when it can be a bit frustrating that such analyses are required at all. That said, heightened awareness of the issues can make the process more palatable and an integral part of the overall negotiation process, rather than an impediment at the final stages of the process once agreement has already been reached.

In general, analyses of direct physician compensation are primarily done by utilizing a market approach. They are based on the prevailing rates for similar services in the market. Therefore, benchmark data of one type or another is the key underlying documentation used to support fair market value conclusions. In some cases, call coverage, and management service agreements, for example, a cost approach is also employed in order to make sure the market approach conclusion is reasonable with respect to the cost of providing the services.

Physician services compensation. The issue providers face, both those paying and those receiving compensation for services, is that such compensation arrangements must be at fair market value and must not take into account the volume or value of any referrals that may exist among the parties. Typically, these analyses start with the collection and analysis of data related to similar arrangements in the market. Defining the services and the market, therefore, is mandatory. The extent to which such definitions can be agreed upon as early in the process as possible by the parties only enhances the process. Routine employment of primary care physicians or readily available specialties typically results in routine fair market value analyses. Any number of sources of such data exists for most specialties, published as well as proprietary, and if the compensation appears to be in the range of the compensation for such specialties, relative to the market and productivity, the analysis is usually fairly straightforward. When the compensation desired moves higher toward the 75th percentile or greater, or if little data exists because the specialty in question is rare, the analysis is more complicated and typically, methodologies including the “cost” or “income” approaches to valuation are employed. While there are no strict rules, it is generally accepted in the industry that employment compensation at the 75th percentile or above must be supported by an equivalent level of productivity, thereby justifying the compensation on the basis of the business economics as they would exist were the physician to be in private practice. If the physician is being hired to replace a previous physician in the position, that physician’s productivity

Continued on page 18
can be used in the analysis. If it is a new position or program and the desired compensation is high, business plans and proformas are essential. Typically three to five year projections are developed. The compensation is then evaluated in the context of the reasonable business economics of the overall arrangement and fair market value is determined based on the combination of approaches.

Based on experience, clients are best served by being aware of these issues and processes and incorporating them in their own recruitment/retention processes. If such advice is sought early in the process—before the parties reach agreement and establish expectations of a given compensation level—the information can be quite valuable. First, it helps avoid the unenviable possibility of appearing to go back on previous agreements should the agreed upon compensation prove to be outside the range of fair market value. Second, whether strictly market driven or driven by the economics of the position, such analyses can provide the employer the information required to make reasonable, rational compensation offers, thus preventing a problem that has plagued the physician employment industry—overpaying. One additional factor relates to the increased prevalence of productivity-based compensation arrangements. When structuring these types of arrangements, it is recommended that financial models of that potential compensation be built to ensure that physician incomes ultimately derived from the formula will continue to produce income in line with productivity standards and the market.

**Medical director compensation.** Until the Stark II Phase II Interim Final Rule came out earlier this year, there had been a debate as to whether there was a separate market and methodology for medical director services as compared to hourly compensation derived from physician clinical compensation rates. The recent rule eliminates some of the ambiguity by providing reasonably specific guidance with respect to safe harbors for hourly compensation arrangements with physicians. First, if the hourly rate is less than or equal to the average hourly rate for emergency room physician services, provided some additional conditions are present, then the arrangement shall be deemed at fair market value. Second, the fair market value of the hourly rate can be established by averaging the 50th percentile national compensation level within the same specialty. These compensation levels can be established by utilizing four out of six approved benchmarking surveys. Although this is a step forward in terms of establishing approved methodologies for determining fair market value, its reach is limited because it only applies to hourly physician compensation arrangements and only defines the safe harbor methodology.

**Call coverage compensation.** Call coverage compensation is somewhat more involved than straight physician compensation because the providers typically generate professional fees while providing the coverage services. Accordingly, the reasonable amount of compensation can vary in every different situation depending upon the overall volume of professional services provided while providing coverage, varying reimbursement and the "opportunity cost" involved in providing the services. As a result, you generally cannot rely exclusively on the benchmarks. You must also look at the potential revenues and costs involved in the physicians providing the services.

**Management services agreements.** When assessing a fair market rate for management services agreements both the market approach and cost approach can typically be utilized. The key issue when assessing management services agreements are the scope of services—items that can vary greatly and certainly impact the value of the services provided. Such compensation arrangements drive a significant need for valuation work because they exist in virtually every institution across the country and represent significant compliance risks. Recent IRS announcements that compensation of insiders and other highly paid individuals within not-for-profit organizations are under scrutiny only further emphasizes the need for prudence in these relationships. However, these analyses can provide additional value from a business perspective over and above the compliance aspect when properly utilized. As we have discussed in this article, valuation is becoming increasingly important in the health care industry for a variety of reasons.

Valuations are crucial protection for health care organizations to ensure compliance with regulatory requirements. Additionally, the valuation should be timely, supportable, understandable and consistent with the actual services and compensation agreement.
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April 2005
Accomplishment and Change

We are five weeks away from the Compliance Institute and are excited to have 1200 people already registered for our annual meeting. For those of you who can’t make the annual business meeting at the Compliance Institute, I would like to share some recent changes and significant accomplishments. We look forward to reviewing and discussing more of the following information at our annual business meeting at 12:00 p.m. on Monday, April 18th, in New Orleans.

In the past three years, HCCA has experienced significant change and explosive growth. We now manage our own office. The web site, newsletter, and certification are amongst the most respected in the industry. Membership has grown 25% and attendance at the Compliance Institute increased 40% in 2004. Along with these changes, the HCCA Board has made administrative changes to ensure proper oversight and governance of the association. HCCA changed the start date of the Board members’ terms from January 1, to coincide with the Compliance Institute, approved an increase in the size of the HCCA Board from 15 to 18, and now appoints two of the six new Board positions each year.

By starting the Board terms at the annual meeting, we are now able to properly recognize the efforts of departing Board members and conduct the strategic planning meeting in January, as opposed to midsummer. We now invite incoming Board members to the strategic planning session for orientation, which helps facilitate their ability to hit the ground running when their term starts in April.

When HCCA began, the Board size was 20. Later the Board size was cut to 15. As we downsized, it became clear that this change put a significant burden on the remaining Board members. The HCCA Board is actively involved in each of our 38 meetings, newsletter, web site, certification and many other leadership projects. This, combined with the recent growth of the association, led the Board to increase its size from 15 to 18. Each year, six Board terms end and six begin.

Along with the increase in Board size, the election process was changed to elect four and appoint two members. Each year members select four Board members from a slate of nominees (typically eight). The Nomination Committee selects two who are reviewed and approved by the Board. This change has allowed the nominating committee to facilitate a voice for underrepresented groups, find those with unique or independent perspectives, and ensure compliance with current thought leadership on proper governance.

I have watched this organization grow from three to 3,700 members in nine short years. Peers and partners of this organization often comment with admiration on the governance and growth of this organization. We have not only dealt with the change but we are setting an example that others follow.

One could cite many reasons why HCCA has done well; however, it is clear that the membership, leadership, and strong governance play a key role. Generally speaking, entrepreneurial behavior, decisiveness, and a willingness to take chances helps explain the growth. More specifically, the success is a credit to the governing Board and members who have taken on leadership positions, speak at conferences, plan conferences, write articles, contribute to the web site, and coordinate projects such as certification and effectiveness. It is due to the involvement of great advisors and outside supporters who have contributed intellectually and financially to the success of HCCA. We have also been blessed with a very committed staff. With all of these changes and continued participation by the aforementioned individuals, we will continue to do well. We look forward to continued discussion about HCCA’s accomplishments and change at our business meeting and other venues.
Share Compliance Documents With Other HCCA Members…

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Each time you add a compliance document to the HCCA Website you will have an additional chance to win a Polaroid Portable DVD Player *, **, courtesy of Brown McCarroll L.L.P. Add 30 documents and you will have 30 chances to win each month for a period of 12 months– November 2003 to October 2004. One Portable DVD Player will be given away each month for 12 months. Any non-copyrighted compliance document will count, such as policies, procedures, forms, memos, presentations, educational tools, government documents, articles, white papers, or miscellaneous documents. Just visit eCommunities on the HCCA Website:

www.hcca-info.org

*No repeat winners.
**HCCA staff members are not eligible.
Implementing a core set of compliance policies and procedures

By Randall Brown

Editor's note: This is the sixth article in a series offered by The HCCA/AHIA Auditing & Monitoring Focus Group regarding seven components to expand on the roles of compliance and internal audit functions, provide detailed "how to steps", and discuss the essential coordination links between compliance, internal audit, legal, and management that are necessary for each component. The final article will address compliance education/awareness tools and techniques. The author's contact information may be found at the end of this article.

A focus group of Health Care Compliance Association (HCCA) and Association of Healthcare Internal Auditors (AHIA) members has been meeting the past nine months to explore opportunities to better define and explain auditing and monitoring, clarify the roles of compliance, and internal audit functions as they address issues within their health care organizations, and develop guidance and reference materials on key aspects of health care auditing and monitoring processes.

The Seven Component Framework developed by the HCCA/AHIA focus group for compliance auditing and monitoring is comprised of the following activities:

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

This article provides guidance on implementing a core set of compliance policies and procedures.

The requirement to establish written policies and procedures is listed as the first element of the seven elements of an effective compliance program identified by the U.S. Department of Health and Human Services Office of Inspector General (OIG). This fact demonstrates the importance of health care organizations having written compliance policies and procedures to serve as a guide for establishing and maintaining an effective compliance program.

The policies and procedures developed by an organization should address its principal risks, clarify the purpose of the compliance program, establish internal standards for compliance with laws and regulations, aid in the communication of organizational values and expectations regarding employee behavior, and facilitate employees' understanding of the consequences of non-compliance, for both the organization and the individual.1

This article focuses on the following steps necessary to implement a core set of compliance policies and procedures:

1. Determining those policies and procedures most relevant to your organization
2. Identifying the various types of compliance policies and procedures
3. Establishing the role of the Compliance Officer related to the Implementation of compliance policies and procedures
4. Implementing a process for ongoing communication and updating of compliance policies and procedures

Determining those policies and procedures most relevant to your organization

In preparing to develop your organization's compliance policies and procedures, it is important to establish some ground rules to aid in consistent and effective communication of those policies and procedures.

We suggest:

- First, establish a standard format in which all policies and procedures will be written. Having a standard will provide consistency in how the policies and procedures look and allow employees to readily recognize them as relevant to compliance.
- Second, it is important to establish a controlled revision process for all policies and procedures, including maintaining a history of changes made over time. A crucial part of this revision process is to ensure the policies and procedures are reviewed and approved by all relevant parties before being communicated to the entire organization.
- Third, ensure the policies and procedures are readily available to employees, management, and the Board for quick reference/clarification. Having these policies and procedures in a location and format that

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1. This article focuses on the following steps necessary to implement a core set of compliance policies and procedures:
is easy for employees to find and read increases the likelihood that they will have an adequate understanding of them.

An organization should develop policies and procedures which are designed to address its principal business risks. This is facilitated by the organization periodically assessing its risks to identify and prioritize its greatest risk areas. Tips on how to conduct a compliance risk assessment can be found in the article titled "Performing a Compliance Risk Assessment" published in the November 2004 issue of Compliance Today. The risk assessment should take into consideration issues identified in the OIG Work Plan, recent enforcement actions by the OIG, and other government agencies, as well as any significant internal control weaknesses which have been previously identified within the organization. 2

In developing its core set of compliance policies and procedures, an organization should include policies and procedures that describe the purpose, function, and authority of its compliance program.

Figure 1

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<td>HIPAA Privacy Program</td>
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<td>Compliance Education/Training</td>
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<td>Coding of Medical Records</td>
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<td>CR</td>
<td>Corrective Action &amp; Patient Billing and Human Resources</td>
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<td>Responding to Subpoenas / Search Warrants</td>
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<td>Discounting of Services</td>
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<td>Vendor Relations</td>
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Start by reviewing the objectives, rights, and authorities that have been outlined in your organization's compliance charter and the job description of your Corporate Compliance Officer.

Additionally, review the established Code of Conduct and those processes in place to promptly identify and remedy instances of non-compliance to ensure that the organization's policies and procedures address the seven elements of an effective compliance program as defined by the OIG.

**Identifying various types of compliance policies and procedures**

Establishing an effective compliance program does not require the development of hundreds or even dozens of policies and procedures. Most compliance programs include policies and procedures that fall into the following categories:

- Policies relating to the operation of the compliance program (CP) - These policies are typically focused on "operationalizing" the compliance program. Policies may include information regarding the compliance program itself, the reporting mechanisms that have been established, expectations regarding employee conduct related to various compliance issues, and corrective/disciplinary actions for violations of the code of conduct.

- Policies addressing the organization's significant compliance-related risks (CR) - Health care organizations face compliance risks related to numerous and complex regulations. The policies to address these risks may vary based on the type or specialty of an organization.

**Figure 1** is a representative list of the types of policies and procedures that most health care organizations should consider including as part of its core set of compliance policies and procedures.

**Establishing the role of the compliance officer related to the implementation of compliance policies and procedures**

The Compliance Officer serves as the focal point for compliance activities and is responsible for oversight of the development, implementation, and daily operation of the compliance program and any related policies and procedures. The Compliance Officer is also responsible for identifying those compliance policies and procedures which are required for the organization.

The Compliance Officer works in conjunction with organizational management and its Board to ensure the compliance policies and procedures currently in place or under development:

are in agreement with existing processes

*Continued on page 24*
Implementing compliance policies and procedures ...continued from page 21

- satisfy all legal and regulatory requirements
- reflect the focus of the organization's compliance program
- can be reasonably implemented and followed
- are periodically reviewed to identify those in need of updating

Additionally, the Compliance Officer should monitor corrective actions and disciplinary measures taken to ensure that they are effectively and consistently applied. It is essential that appropriate action is taken and documented when there are instances of non-compliance with policies and procedures.

Implementing a process for ongoing communication and updating of compliance policies and procedures

The specific policies and procedures necessary to establish and maintain an effective compliance program vary widely from one organization to the next. Yet, all programs should include the same basic principles of commitment of organizational management at the highest levels, an established collection of processes designed to provide adequate internal controls, and regularly conducting a self-assessment of the organization's existing program. A byproduct of doing so is that these organizations are often better able to prevent, detect, and correct problems.

Organizations which have a culture that promotes and embraces compliance are more likely to have effective compliance programs.

A vital step in successfully implementing a core set of compliance policies and procedures is to effectively communicate them to all employees and other relevant parties. Effective communication and awareness activities include publishing and distributing the policies and procedures as well as providing adequate education and training to facilitate an effective understanding.

An important aspect of implementing a core set of compliance policies and procedures in an organization is to establish a protocol for periodically reviewing and updating them to ensure they are accurate and relevant in light of any changes in laws, regulations, or internal processes. This may be accomplished by conducting a self-review of the established compliance policies and procedures within an organization at least every three years and comparing them to the OIG’s seven elements of an effective compliance program. Some organizations may gain additional benefits by having an external party assess the entire compliance program, including a review of any established policies and procedures.

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1. HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 11)
2. HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 11)
3. HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 10)
4. HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 12)
5. OIG Supplemental Program Compliance Guidance for Hospitals, January 2005 (Page 67)

The 7th Annual Survey – 2005 Profile of Health Care Compliance Officers

data is still being tabulated, however, the complete survey results will be distributed in New Orleans to those attending the 2005 Compliance Institute, April 17-20, 2005, Sheraton New Orleans and mailed to all members. The preliminary results indicate that the mean salaries for Chief Compliance Officer and the Compliance Officers are on the rise. It appears that the mean salary for Compliance Officers, those responsible for daily operation of the compliance program, is reported to be $95,174; the mean salary for Chief Compliance Officers, those responsible for general oversight of the compliance program, is reported to be $152,852. Last year, the 6th Annual Survey reported the mean salary for the Compliance Officers to be $90,335 and $127,872 for the Chief Compliance Officer.

Compliance Officers’ Goals have shifted from compliance program development and implementation to monitoring and auditing the compliance program. In 1999 Compliance Program Development/Implementation was the top goal; in 2001 it was HIPAA Privacy Regulation; from 2003 to 2005 it has been Monitoring/Auditing.

visit HCCA’s Website –
http://www.hcca-info.org
The topic of auditing elicits many reactions among CIOs and IT Directors for health care organizations faced with meeting the Health Insurance Portability and Accountability Act’s (HIPAA) security compliance mandates. Most often though the issue is not whether auditing should be required, but that the rule does little to provide guidance on what constitutes a reasonable and appropriate approach to implementation of this provision. Add to this the potential costs of auditing and the number of systems and applications that don't provide basic audit functionality and this becomes an even more daunting task for organizations serious about compliance. The ambiguity from this lack of definition has made it difficult for organizations to know how much auditing is enough or where to begin.

The HIPAA security final rule provides that auditing is a required activity for covered entities, but does not specify either the "how to" or "how much" is sufficient. This leaves organization to presume that auditing, like the rule itself, is a risk-based activity. The rule specifies that entities must "implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information." While the final HIPAA security rule may not provide an exact set of definitions for its auditing requirements, it does provide enough guidance to determine its intent. An examination of each auditing standard against the rest of the rule's requirements can provide a useful road map for structuring an audit strategy. It also helps to adopt an industry-accepted definition of auditing. Auditing is generally defined as having the ability to identify who has accessed or performed some function on what data (in this case electronic protected health information) and when they did it. This article proposes a process for getting started using what the rule does provide and the results of your risk analysis, along with some suggested steps to structure an audit approach.

The rule

The rule specifically discusses auditing in four sections. The Security Management Process Standard requires the periodic review of an entity's internal security controls. This is part of its information system activity review implementation specification. The intent of this specification is for organizations to collect and review such items as system logs, access logs, and other information like incident reports for systems containing protected health information. Under the Security Awareness and Training Standard, organizations are required to monitor login attempts to systems with electronic protected health information. The Evaluation Standard requires both technical and non-technical testing to measure effectiveness of its security controls. Lastly, the Technical Safeguards section of the rule has a specific Audit Standard that requires organizations to record and examine system activity on systems containing or using electronic protected health information. It is clear that the intent is to implement processes, either manual or automated, that provide a means of recording and reviewing both system and user activity for systems containing electronic protected health information. The final rule's high-level and technology-neutral approach makes sense when considering the rapidly changing world of technology and the diversity in health care organizations due to size, type, and level of risk.

Incorporating risk analysis

The rule encourages organizations to take a risk-based approach to determining its implementation strategy for security. It recognizes that there are multiple ways of implement auditing. Performing an accurate and thorough risk analysis upfront makes it possible to decide the best strategy. A risk analysis is designed to take a balanced look at the systems environment. It enables the identification of risks, allows for prioritization of information assets, as well as supports the development of an implementation strategy. Done correctly, this process will provide the information necessary to support development of a proper audit scheme. Those performing the risk analysis process will collect and document information concerning current audit capabilities and gaps; audit risks will also be collected and documented. The initial step of the risk analysis process requires that organizations identify all information systems and applications while defining the information.

Continued on page 26
technology environment.

This inventory of information assets is then analyzed to determine key risk factors associated with compliance and security such as:

- Does the system/application contain protected health information?
- Does the system/application allow role-based access?
- Does the system/application audit system and user activity?
- Does the system provide alarms?
- Can the system/application be recovered prior to negative impacts?

Answers to these questions permits an organization to perform the criticality analysis necessary to prioritize its systems and applications. It also provides an understanding of which systems/applications currently have audit capabilities and which don't, as well as what level of audit is possible. This process enables organizations to base audit criteria of systems/applications on those most at risk and provides a starting point for considering audit requirements. A properly accomplished risk analysis, allows organizations to determine by system and risk:

- Audit priorities
- Method of audit required
- Audit frequency
- Who should audit

Once the risk analysis is completed and this information is available an organization can then follow a simple process to develop its implementation strategy for auditing.

**Five step approach**

**Step 1.** Deciding audit priorities begins with determining “what to audit”. Minimally, we know this includes system and user activity, as well as integrity and security controls of all systems containing protected health information. Basically, audit schemes need to address the review of specific events that permit the real-time assessment of how well security controls are providing for the integrity, availability, and confidentiality of electronic protected health information. Generally, auditing is performed at the network, application, database, and user level and focuses on definable events such as changes, deletions, adds, access attempts, missing patches, unsafe practices, or other discernable actions. Utilizing results of the risk analysis, the list of systems, controls, and events to be audited should be prioritized.

**Step 2.** Once you know what you want to audit, organizations should first review current audit capabilities and then determine the most appropriate approach. This can include both automated and manual processes. In many environments, complexity of the enterprise and the sheer volume of information or events to be audited will necessitate consideration of automation. At the network level, there are numerous system analyzers, traffic and content monitors, and vulnerability scanners to audit system integrity, security controls, and user activity that may be employed to facilitate the audit process.

However, just as in security generally, robust auditing is best approached in a layered fashion. While network monitoring and vulnerability assessments are critical components to a successful audit program, these approaches don't address all required areas. Network monitoring traditionally functions at the low to middle levels of abstraction—ports are blocked or sniffed, and packet flows are analyzed for patterns that signify a deviation from safe operation. Vulnerability assessments typically look for deviations from prescribed rules in configuration and policy. Vulnerability assessments are assertions about the state of the system at specific points in time. The real problem for most has existed with auditing at the file level.

Fortunately, there are some new technologies developing specifically for health care as a result of HIPAA to audit protected health information at rest in both structured and unstructured file environments and to address these other areas. Mapping and auditing protected health information in unstructured environments, such as Microsoft Office Documents (Word, Excel and PowerPoint), a problem area frustrating many organizations, is now possible, as is the monitoring of activity between applications and their associated databases, helping solve the inability to monitor viewing information for those systems that currently only track the standard adds, deletions, and changes. Together these technologies respond to the two most commonly voiced concerns by many health care CIOs with respect to auditing. Many have expressed frustration that they can't always audit the actions of users on data in databases, using application capabilities alone.

Another frustration I've heard expressed is that they don't know how much electronic protected health information is resident in user-generated documents, but they know it exists out there in the unstructured file environment.

**How these technologies work.** Within
the enterprise there are typically a number of repositories of unstructured data; public file system shares, departmental shares, public folders within the email servers, intranets, and others. Much of the information that flows into the public repositories originates as a byproduct of the daily activities of the medical facility’s business. As a result, sensitive patient information tends to migrate from secure applications to unstructured forms, such as Microsoft Office Documents (Word, Excel, and PowerPoint), instant messenger logs, and other document formats. These sensitive documents residing in public shares can include benefits claim information, treatment histories, workers’ comp claim data, and other sensitive electronic Protected Health Information.

Using content-based file classification engines these technologies are now capable of methodically scanning common storage systems, and identifying all files that contain electronic Protected Health Information. Their classification engines support hundreds of different file types, and are supported by customizable medical, financial and appropriate use lexicons that identify electronic Protected Health Information, financial and illegal or inappropriate content files based on identity, drug names, medical terms, financial data, inappropriate language and file type. Combining advanced linguistic analysis and scanning of patterns among words and phrases with medical and pharmaceutical lexicons allows for a thorough and exhaustive search for electronic Protected Health Information in millions of files. This unique combination of technologies allows the system to identify electronic Protected Health Information-relevant content the first time it is encountered. The information describing the files and associated content is collected in Metadata Repositories; databases that represent a virtual map of the targeted file system.

Also, within every environment there are usually multiple structured repositories of data or databases, some of which are not capable of auditing all actions of users or database administrators. Just as new technologies have been developed to address the needs for auditing data in unstructured files there are new systems focused on monitoring the flow of information within the system.

The ability to sniff network traffic and reconstruct the conversations that applications have with their database servers permits the tracking and recording of actions previously not possible. Application/database interactions are archived and stored at a selectable granularity for a defined period of time supporting analysis. Data collected is then maintained separately from either the application or database systems, allowing greater security control for the organization. Generally, these systems sit on the network between the application and their databases, requiring no software to be loaded on either the application or the database system, mitigating performance impacts and adding to their transparency.

Transparency is an important success factor in security auditing. Depending on the physical network layout this sniffing is generally undetectable. Health care compliance officers can finally ask and answer questions such as:

- Have any DBA-level operations been performed from systems located in the purchasing or accounting departments?
- Over the past six months, what users have read or may have read database entries containing information about patient X?
- After a fault in the perimeter security system, we’ve determined that the fault has existed for 40-hours and was contained to systems in a particular subnet. What database operations were performed by systems in that subnet over that period?

Step 3. Determining how often to audit comes next. Audit frequency will vary based on what is being audited, the extent of the audit, the purpose of the audit, the risk involved, and the audit method used. Understandably, automated audit processes can and will be accomplished with greater frequency. Manual processes may be prioritized based on risk to compliance and may employ sampling techniques and/or be incident driven. If manual audit procedures are required or selected, consider carefully the events and frequency necessary to provide sufficient information to determine compliance.

Step 4. Determining who should audit. First, it is always a good idea to ensure a proper segregation of duties; meaning that someone other than the person directly involved in an action should audit that action. In smaller organizations, this may not always be possible or practical. Second, individuals assigned the audit duties must understand what they are auditing. This means having an appreciable understanding of what is normal or expected in order to be able to determine variances. Third, ensure

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**By Lance S. Loria**

The U.S. Department of Health and Human Services Office of Inspector General's (OIG) Supplemental Compliance Program Guidance (CPG) for Hospitals was published in the January 31, 2005 Federal Register. The CPG reflects recent changes to hospital payment systems and changing industry practices. The original 1998 CPG focused on compliance program design while the supplemental CPG serves as a benchmark for comparison and as a roadmap for enhancing the effectiveness of existing compliance plans.

The OIG states that an effective compliance program demonstrates a hospital's good faith effort to comply with applicable statutes, regulations and other federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

The supplemental CPG is not intended to be one-size-fits-all guidance. The OIG strongly encourages that compliance risk areas unique to each provider be the focus of compliance efforts. What is appropriate for small hospitals may not be effective in large, multi-facility providers. The CPG presents nine fraud and abuse risk areas considered by the OIG as particularly relevant to hospitals. Therefore, every hospital should evaluate whether each risk area applies and whether it should be included.

### Billing

Submission of accurate claims and payment requests may represent the greatest compliance risk area. Claims and payment requests, as well as supporting documentation, must be complete and accurate to avoid exposure under the False Claims Act. Documentation which reflects a hospital's efforts to comply with Medicare requirements should be maintained.

The supplemental CPG focuses on evolving risks identified by the OIG including:

1. **Outpatient procedure coding.**
   - Under the Outpatient Prospective Payment System (OPPS) hospitals are reimbursed a predetermined amount for each procedure code regardless of the cost. Accordingly, procedure coding and supporting clinical documentation is required to support the level of service and medical necessity. In addition to coding risks, the OIG identified the following risk areas:
     - (a) Billing "inpatient-only" procedures
     - (b) Failing to follow FT's [fiscal intermediaries] local medical review policies
     - (c) Submitting duplicate claims
     - (d) Coding claims without current National Correct Coding Initiative (NCCI) edits
     - (e) Using outdated Charge Description Masters
     - (f) By-passing the multiple procedure discounting rules
     - (g) Ensuring use of proper Evaluation and Management (E/M) codes
     - (h) Requesting separate APC payment for observation services not meeting requirements

2. **Admissions and discharges.** The method and amount of reimbursement for inpatient services may be affected by a patient's status at the time of admission or discharge. Accordingly, admission and discharge policies should be consistent with current CMS [Centers for Medicare and Medicaid Services] rules. The OIG identified the following risk areas in the admission and discharge process:
     - (a) Complying with the "same-day rule" for all services provided
     - (b) Abusing partial hospitalization payments
     - (c) Reviewing clinical decisions and coding of same-day discharges and readmissions
     - (d) Failing to comply with the post-acute care transfer policy
     - (e) Transferring patients between host and co-located long-term care hospitals

3. **Supplemental payment considerations.** Hospitals may be eligible for certain payments in addition to normal reimbursement depending on eligibility. The OIG identified examples of specific risk areas which should be addressed by hospitals:
     - (a) Reporting "pass-through" items for new technology and certain drugs
     - (b) Abusing DRG [diagnosis related group] outlier payments
     - (c) Designating provider-based-providers
     - (d) Claiming services under clinical trials
     - (e) Reporting organ acquisition costs
     - (f) Claiming cardiac rehabilitation services
     - (g) Calculating the number of full-time
equivalent (FTE) residents

4. Use of information technology. The OPPS’ reliance on proper coding has increased the need for expanded computerization of hospital billing. Hospitals should ensure the accuracy of new computer systems and software used for coding, billing or information related to claims.

Physician referrals

The OIG has explained in detail its concerns regarding physician referrals, remuneration, and other transactions. The CPG highlights provisions of the Stark Law and Anti-Kickback Statute which represent risk areas for hospitals.

1. Physician Self-Referral Law.

Commonly referred to as “Stark,” this law should be viewed as a threshold statute and hospitals must diligently review all financial relationships with referring physicians.

The OIG offers the following three-part inquiry for evaluating compliance with Stark:

- Is there a referral from a physician for a designated health service (DHS)? If not, there is no Stark law issue. If yes, go to the next inquiry.
- Does the physician (or an immediate family member) have a financial relationship with the entity furnishing the DHS? Again, if the answer is no, there is no Stark law issue. If the answer is yes, go to the next inquiry.
- Does the financial relationship fit in an exception? If not, the Stark law has been violated.

A Financial relationship can be almost any kind of direct or indirect ownership or investment relationship, or direct or indirect compensation arrangement, whether in cash or in-kind, between a referring physician or immediate family member, and a hospital.

For an exception, an arrangement must comply with all of the conditions set forth in the exception. Unlike the anti-kickback safe harbors which are voluntary, fitting in an exception is required by Stark. Even if a transaction qualifies for a Stark law exception, it must also be evaluated under the anti-kickback statute as discussed below.

2. Federal Anti-Kickback Statute. The statute affects business arrangements related directly or indirectly to items or services reimbursable by any federal health care program. It provides a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made to induce or compensate the referral or generation of Federal health care program business.

Compliance with the anti-kickback statute is a condition of payment under Medicare and other Federal health care programs and accordingly, liability may arise under the False Claims Act where the anti-kickback statute violation results in the submission of a claim for payment.

Importantly, liability under the anti-kickback statute relies on intent of the parties. For purposes of analyzing transactions under the anti-kickback statute, the OIG offers the following two inquiries:

- Does the hospital have any remunerative relationship between itself (or its affiliates or representatives) and persons or entities in a position to generate Federal health care program business for the hospital (or its affiliates) directly or indirectly?
- With respect to any remunerative relationship so identified, could one purpose of the remuneration be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program?

It should be noted that neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose. Likewise, a violation of the statute due to one element of an arrangement will cause the entire remuneration to be a violation.

Some considerations for hospitals to evaluate arrangements include:

- Does the arrangement or practice have a potential to interfere with clinical decisions?
- Does the arrangement or practice have a potential to increase costs to Federal programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of over-utilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

The anti-kickback statute and regulations set forth “safe harbors” for common business arrangements. Those safe harbors most applicable to hospitals include:

- Investment interests (42 CFR 1001.952(a)),
- Space rental (42 CFR 1001.952(b)),
- Equipment rental (42 CFR 1001.952(c)),
- Personal services and management contracts (42 CFR 1001.952(d)),

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(e) Sale of physician practice (42 CFR 1001.952(e)),
(f) Referral services (42 CFR 1001.952(f)),
(g) Discounts (42 CFR 1001.952(h)),
(h) Employee (42 CFR 1001.952(i)),
(i) Group purchasing organizations (42 CFR 1001.952(j)),
(j) Waiver of coinsurance and deductible amounts (42 CFR 1001.952(k)),
(k) Physician recruitment (42 CFR 1001.952(n)),
(l) Obstetrical malpractice insurance subsidies (42 CFR 1001.952(o)),
(m) Cooperative hospital service organizations (42 CFR 1001.952(q)),
(n) Ambulatory surgical centers (42 CFR 1001.952(r)),
(o) Ambulance re-stocking (42 CFR 1001.952(v)),
(p) Managed care and risk-sharing arrangements (42 CFR 1001.952(m), (t), and (u)).

Strict compliance with all elements of the safe harbor is required. Safe harbor compliance is voluntary and failure to comply with a safe harbor does not mean an arrangement is illegal per se. Those arrangements which do not comply with a safe harbor should be assessed based on the individual facts and merits.

The OIG has identified the following seven activities which must be properly structured to minimize risk of non-compliance:

**Joint ventures**—The OIG is concerned that remuneration from a joint venture might be a disguised payment for past or future referrals. Therefore, the economic benefit (e.g., dividends, profit distributions, etc.) received by investors must be evaluated by hospitals.

**Compensation arrangements with physicians**—Numerous business arrangements give rise to compensation to physicians from hospitals, including: medical director agreements, personal or management services, space or equipment rentals, and billing or other administrative support services. The remuneration must be at fair market value for actual and necessary items furnished or services rendered based upon an arm’s-length transaction and the past or future referrals or other business must not be considered.

**Relationships with other entities**—When furnishing inpatient or outpatient services, hospitals may refer patients to or order items or services from: home health, skilled nursing, DME suppliers, laboratories, pharmaceutical companies, and other hospitals.

**Physician recruitment arrangements**—Incentives provided to physicians to establish a practice can implicate the anti-kickback statute. Some safe harbor protection is available for arrangements offered to primary care physicians in health professional shortage areas (HPSAs). The entire area of recruitment arrangements poses significant risk and hospitals should examine the following factors:
- The size and value of the recruitment benefit
- The duration of payout of the recruitment benefit
- The practice of the existing physician
- The need for the recruitment

**Discounts**—Discounts must be a reduction in price at the time of sale, be properly disclosed, and accurately reflected on hospital cost reports.

**Medical staff credentialing**—Basing credentialing on the volume of referrals, beyond volumes necessary to ensure clinical proficiency, may implicate the anti-kickback statute. The OIG is continuing to study this area and has solicited comments and may issue further guidance at a later date.

**Malpractice insurance subsidies**—Although a hospital’s subsidy of malpractice insurance premiums for potential referral sources may be suspect under the anti-kickback statute, the OIG has established a safe harbor for subsidies provided to obstetrical care practitioners in HPSAs.

**Gainsharing arrangements**
The Civil Money Penalty (CMP) section of the Act prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items of services furnished to Medicare or Medicaid beneficiaries. The payment will violate the act if it influences the physician to reduce care even if not tied to reductions in individual patient care or services. Cost-savings payments under Gainsharing arrangements may violate the statute if used to influence referrals. Likewise, if the intent is to foster physician loyalty and attract more referrals, the arrangement may be illegal. Finally, Gainsharing arrangements may also implicate the Stark law.

**Emergency Medical Treatment and Labor (EMTALA)**
Hospitals should review obligations under EMTALA to evaluate and treat individuals that present at emergency departments and, in some cases, other facilities. If a hospital’s ED is on diversion status, the hospital is still required...
to provide emergency medical screening and stabilizing treatment, if needed.

**Substandard care**
If a hospital provides unnecessary or substandard care, the OIG has authority to exclude the hospital from program participation. Neither knowledge nor intent is required under the exclusion provision and can be triggered by care to any patient, even if not a Medicare or Medicaid beneficiary.

**Relationships with beneficiaries**
A hospital that offers or transfers remuneration to a Medicare or Medicaid beneficiary to influence services will be in violation of the Act and subject to CMPs. Offers of gifts to beneficiaries, that the hospital knows or should know is likely to influence the selection of a provider, practitioner, or supplier for Medicare or Medicaid payable services is prohibited. Other risk areas include: cost-sharing waivers and free transportation.

**HIPAA Privacy and Security**
All electronic transactions for which standards have been adopted were required to comply with HIPAA effective April 14, 2003. The security rule is effective April 20, 2005.

**Claims substantially in excess of usual charges**
Any claim based on costs or charges that is "substantially in excess" of its usual charges or cost exposes the hospital to the permissive exclusion provisions. The OIG’s policy regarding the application of this issue is described in the CPG. Section III of the CPG describes the OIG’s views regarding important elements of Compliance Program Effectiveness. The commitment of the hospital’s governance and management at the highest levels; structures and processes that create effective internal controls; and regular self-assessment and enhancement of the existing compliance program are elements of an effective compliance program. The OIG also sets forth the following elements:
- Code of conduct
- Periodic compliance program effectiveness assessment
- Designating a compliance officer and compliance committee
- Implementing policies and procedures
- Open lines of communication
- Training and education
- Internal monitoring and auditing
- Response to detected deficiencies
- Enforcement of disciplinary standards

Section IV sets forth the OIG’s views regarding Self-Reporting of discovered evidence of misconduct and a violation of the criminal, civil, or administrative law. For some violations the OIG believes a provider should immediately report misconduct, whereas other violations should be reported within a reasonable period, but not more than 60 days.

**Conclusion**
The Supplemental Compliance Program Guidance reveals much about the OIG’s view of hospital compliance risk areas and elements of an effective compliance program. All hospitals should become familiar with the CPG and use it as a resource to improve the effectiveness of compliance programs towards the goal of reduced errors, fraud, and abuse and increased compliance with federal health care program requirements.

that they have the right tools and training to accomplish the tasks assigned.

**Step 5.** The fifth and final step is to properly store and protect audit reports and information. Network monitoring might involve establishing a separate syslog server where system logs are automatically saved and protected from unauthorized access. System logs may also be downloaded to some media and encrypted to avoid tampering or disclosure. Most automated tools have functionality for the segregation of log or audit information and its protection. Audit information related to security incidents should be protected and retained according to HIPAA’s documentation retention rules.

**Conclusion**
The purpose of HIPAA is to promote the appropriate protection of critical information assets and electronic protected health information. Auditing is required to properly monitor the sufficiency of security controls and to proactively monitor for reasonably anticipated threats to those systems and data. Auditing, like any other security feature, should demonstrate a balance between risk and business imperatives and take into consideration the unique environmental factors associated with each organization. Both manual and automated processes should be considered. Where possible, native audit functionality should be optimized before employing other measures. The implementation strategy selected should provide the most efficient and cost effective means of accomplishing the audit function. The rule itself provides a roadmap to determining what needs to be audited, but each organization will need to determine how much is appropriate based on criticality and risk.
The Health Care Compliance Association welcomes the following new members and organizations (States Nevada - Tennessee). Member contact information is available on the HCCA website in the Members Only section - http://www.hcca-info.org. Please update any contact information using the HCCA Website or email April Kiel (april.kiel@hcca-info.org) with changes or correction to your membership information.

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