CCH Health Care Compliance LETTER

Volume 9, Issue 6 health.cch.com March 20, 2006

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Effectiveness, accountability of QIOs challenged

by Sheila Lynch-Afryl, JD, Contributing Editor

Sen. Chuck Grassley (R-Iowa), chairman of the Senate Committee on Finance, dubbed the quality improvement organization (QIO) beneficiary complaint process "broken" in a letter to CMS Administrator Mark McClellan and challenged CMS to consider redesigning the program to maximize QIO effectiveness. Preliminary results of Grassley's investigation, which he began last summer, revealed problems with expenditures, board member and executive staff conflicts of interest, the beneficiary complaint process, and the effectiveness of QIOs in improving the quality of health care.

Questionable expenditures. Grassley found the amount of board member compensation, ranging from several thousand to several hundred thousand dollars, "exorbitant" because most QIOs are 501(c)(3) not-for-profit organizations, the majority of which do not compensate their board members. He also questioned the appropriateness of some travel expenses, including travel for leadership and chief executive officer retreats. In addition, audits by the Defense Contract Audit Agency (DCAA) revealed that some QIOs incurred questionable or unallowable costs that should not have been funded with taxpayer dollars. For example, one QIO spent almost $10,000 in fiscal year 2003 to pay for parties at its offices and another paid $13,000 in unallowable advertising and public relations costs.

Potential conflicts of interest. Grassley questioned whether QIOs have necessary controls to prevent inappropriate business relationships. His investigation revealed that some QIOs have financial arrangements or relationships that appear to pose conflicts of interest. For example, the DCAA concluded that arrangements like a QIO board chair's compensation of $3,100 a month for being a "consultant" could cause a loss of objectivity.

QIO effectiveness. Grassley's letter concluded that there is "sparse evidence to suggest that QIOs are effective." There is a lack of measurable objectives to determine the results of QIO efforts. In fact, a recent article concluded that hospitals participating in the QIO program are no more likely to demonstrate improvements in quality than hospitals that do not participate in the program. Furthermore, a number of public and private entities, including the National Committee for Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations, perform activities similar to those of QIOs. In addition, because the current contracting process does not reward QIOs for performance, Grassley suggested that CMS consider subjecting all QIO contract renewals to competition.

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Finally, according to Grassley, the beneficiary complaint process is "broken" because the number of complaint cases is disproportionately low and accessibility to the QIO complaint process is questionable. Grassley urged CMS to make changes that would provide greater transparency and increased responsiveness to beneficiaries during the complaint process. ■

CCH Chicago Bureau, March 8, 2006.

CMS must strengthen analysis of hospital quality data, GAO says

Michelle L. Oxman, J.D., LL.M., Contributing Editor

Because CMS does not assess completeness of the data used in its Hospital Compare web site, its reliability is uncertain, according to a report of the Government Accountability Office (GAO). GAO recommended that CMS implement more rigorous methods used by other reporting agencies so that the information is useful to the public.

Quality measures reported. Hospital reporting of quality data began as a voluntary project jointly operated by CMS and the Health Quality Alliance. Initially, hospitals were asked to report quarterly on the percentage of patients admitted with heart attack, heart failure, or pneumonia, who received each of ten measures recognized as effective at the appropriate time. For example, a hospital would report the percentage of patients admitted for heart attack who received aspirin and/or a beta blocker on arrival and prescriptions for aspirin and/or a beta blocker at discharge. In the past, failure to report the data had no financial impact. The Medicare Modernization Act of 2003 (MMA), however, requires quarterly reports beginning in fiscal year (FY) 2005 and reduces a hospital's annual payment update (APU) for failure to comply beginning with FY 2006.

GAO's analysis. For the public to make informed decisions using the web site, the data must be reliable, accurate, and complete. A hospital may submit incomplete data inadvertently or intentionally by selecting which cases to report and exclude. GAO examined the methods that CMS uses to determine both the accuracy and the completeness of reports submitted from January through June, 2004 and compared them with the methods used by other organizations.

To measure accuracy, CMS compares the data submitted to the clinical warehouse against reabstracted data collected by its clinical data abstraction center (CDAC). CDAC examines five patient records from each hospital for each quarter. If there is 80 percent agreement between the two sets, the hospital qualifies for the full APU.

The study showed that the accuracy rate of most hospitals was at least 90 percent. The study also found, however, that examination of five cases per quarter did not produce results that were statistically certain for up to a third of the hospitals reporting. For those hospitals, an examination of more cases was necessary to assure that the sample accurately represented the hospital's care of all patients admitted for the conditions reported.

Inadequate assessment of completeness. GAO was most concerned that CMS had no established method to test the completeness of the reports. Because CMS limited its analysis of noncompliance to hospitals that submitted no clinical data during the reporting period, there was no way to determine whether hospitals submitted incomplete information. Moreover, CMS does not require hospitals to certify that they submitted data for all eligible patients or a representative sample of eligible patients.

GAO noted that most of the seven other organizations whose methods they examined used more rigorous processes to assure accuracy and completeness. All of them checked the submissions electronically for missing data. Most also included site visits in their independent audits, examined at least 50 patient records for each reporting entity and focussed the audits on a subset of facilities or reporting entities.

GAO recommended that CMS take these actions: (1) require facilities to certify that they have submitted complete data on all, or a representative sample of all, eligible patients; (2) assess the level of incomplete data submitted; (3) focus the audits on the group of hospitals for which the accuracy level is statistically uncertain; and (4) increase the number of patient records to be reabstracted and examined. ■

Reliability of Hospital Quality Data, Government Accountability Office Report No. GAO-06-54, Jan. 31, 2006.

CCH Health Care Compliance Letter

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CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

Experts identify Stark law exceptions

Catherine Hubbard, M.A., Contributing Editor

Finding a Stark law exception usually requires some difficult judgment calls, and there is little case law or application guidance. Recently, however, experts have addressed the issue and have offered several pointers to help lawyers guide their clients in the right direction and help providers avoid a Stark violation in the first place.

During a January 25, 2006, audio conference hosted by the American Health Lawyers Association, Patricia Meador, a partner at Kennedy Covington Lobdell & Hickman, Research Triangle Park, North Carolina, outlined "pockets of flexibility" within the Stark definition that are commonly used. "Those are the places we are drawn to avoid the conclusion that a Stark violation has clearly occurred," Meador said.

Indirect compensation definition. Indirect compensation relationships do not reach the requirement for a Stark exception unless they first meet the definitional test of an "Indirect Compensation Arrangement." If you have something that is not a direct compensation arrangement, for instance when you have an oral agreement in which the monthly payment flows through a group of physicians, you may find some relief with this definition, Meador said.

"There must be an unbroken chain of financial relationships between the physician and the DHS [designated health services] entity," said Gadi Weinreich, national chairman of Sonnenschein Nath and Rosenthal's Health Care Group, Washington, D.C., during a February 9, 2006, teleconference sponsored by the American Bar Association (ABA).

Under one test of the definition of indirect compensation arrangement, the aggregate compensation of a physician has to vary with or otherwise reflect the value of the referrals or other business generated, Meador explained. Because the indirect compensation definition requires some payment variability, flat fee payments to groups may not constitute a "financial relationship" under Stark and may not require an exception, she noted.

Agreement in writing. Many Stark exceptions covering compensation arrangements require an agreement that is set out in writing and signed by the parties, Meador noted. Because the statute and rules do not define what constitutes an agreement in writing, she said, it is fair to look for state law contract principles. Most states permit a party to prove the existence of a written contract and signature requirement through a series of written or electronic exchanges, such as correspondence, written policies, board resolutions, purchase orders, E-mails, invoices and endorsed checks. "These scraps of documents taken together may actually constitute and agreement that was set out in writing," she explained.

Isolated transaction exception. Some lawyers have used this exception to settle disputes between DHS providers and referring physicians, Meador said, suggesting that the DHS provider needs to prove the likelihood of the lawsuit, and establish that the dispute is bona fide and that the defense costs and the potential liability would exceed the settlement value regardless of the outcome of the case.

Fair market value determinations. Testing fair market value is one of the most difficult judgments to make in assessing the presence of a Stark violation, Meador said. "It's really easier to set up an arrangement correctly or even to defend it in litigation than it sometimes is to decide for disclosure purposes where one draws the line on fair market value," she said.

The review of fair market value must begin with the definition in the statute and regulations, which includes the value of arms-length transactions, Meador said. It is also helpful to show evidence of arms-length negotiations with give and take between the parties, she noted. Any comparables that might have existed in the market at the time of this arrangement also could support the payment structure, Meador added. But she cautioned that decisions regarding these steps need to be made carefully. "There needs to be a fair amount of decision and intentionally given to the process," she concluded.

"The safest course of action is to have an appraisal [of fair market value] by a qualified evaluation company," Thomas Bartrum, a partner at Waller Lansden, Dortch & Davis, Nashville, Tennessee, recommended during the ABA teleconference. CMS places the burden on the parties to establish fair market value and will accept any method that is commercially reasonable and provides evidence of comparable compensation for like services, Bartrum added. While there are other methods for determining fair market value beside an independent evaluation, if there are other risk factors in the

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OIG focuses on compliance, administrative issues in draft guidance for PHS research award

by Patricia Brent, J.D., M.P.H., Contributing Editor

Recently, the federal government expanded its efforts to bring biomedical research programs into compliance with its regulations. On November 28, 2005, the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) published its long-expected Draft Compliance Program Guidance (CPG) for Recipients of Public Health Service (PHS) Research Awards.[1] The Guidance sets forth the OIG's general views and fundamental principles of compliance programs for college and university researchers and recipients of extramural research awards from the National Institutes of Health (NIH) and other agencies of the Public Health Service. The purpose of this voluntary Guidance is to assist the biomedical and behavioral research community in preventing and reducing fraud and abuse in federally-sponsored programs. It is part of a larger initiative designed to assist institutions in avoiding criminal and civil fraud investigations.

Like its older "cousins," the Draft Compliance Program Guidance (CPG) stresses the importance of internal controls to effectively monitor adherence to applicable statues, regulations and program requirements and closely follows them in both its format and basic elements.[2] Nonetheless, it departs from earlier guidances in certain areas to accommodate the various differences among the many types of institutions that receive PHS extramural research awards. Specifically, this Draft Guidance focuses on grant compliance and administration issues, i.e., whether the recipients of research awards have misused program funds.

Overall Scope and Structure

The scope of the CPG falls under the rubric of grant compliance and administration, including issues associated with application of statutes, regulations and other program requirements that affect the "allowability" of costs and whether awardees should be subjected to a disallowance action or an investigation for criminal or civil fraud. Although the CPG focuses on PHS awards from the HHS, compliance actions also may touch on areas such as human and animal subject research, conflicts of interest, research misconduct and intellectual property issues. The principles of the Guidance may be more broadly applied by an institution to include other funding sources, such as National Science Foundation awards or awards from other charitable health foundations.

The Guidance addresses the seven basic elements that are widely recognized as fundamental to any effective compliance program. These elements include: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication; (5) developing an internal monitoring and auditing program; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action. The CPG also introduces an eighth element, defining roles and responsibilities and assigning oversight responsibility, which is more specific to research institutions.

These basic elements are shared across a broad range of regulated activities and represent the OIG's suggestions on how institutions can best establish the necessary internal controls to ensure adherence to applicable regulations and program requirements.

While the OIG acknowledges that developing and maintaining a compliance program may require a significant commitment of institutional time and resources, especially for institutions whose program is not yet operational, the OIG stresses the benefits that may accrue from having an effective compliance program. An effective compliance program:

- addresses the government's and the research community's mutual goals of good stewardship of federal research funds by eliminating erroneous or improper expenditures;
- improves operational systems for administering grant awards;
- demonstrates an institution's commitment to honest and responsible scientific conduct; and
- acts as a "mitigating factor" that must be considered as part of any formal debarment action taken by HHS, at least in certain circumstances.

Major Risk Areas

OIG identified three major potential risk areas for recipients of PHS research awards: (1) reporting of time and effort; (2) properly allocating charges to award projects; and (3) reporting of financial support for other sources.

Time and effort reporting

One major cost item for any research project is compensation for the personal services of the researchers, i.e., direct salary and fringe benefits. Thus, it is critical that the percentage of time devoted to a research project be reported accurately, especially because many researchers have multiple responsibilities, such as teaching and clinical work, as well as research. Proper reporting of this information requires effective time-keeping systems so that each activity is properly charged. Moreover, failure to accurately report time and effort may result in an overcharge to a funding source, resulting in an institution being subject to a criminal or civil investigation.[3]

As an example of improper reporting, the OIG cites a situation in which a researcher might report separately to three award agencies that he or she intends to spend 50 percent of his or her time on each of three different projects. Another example cited is improper "commitment of effort" by researchers, such as when an institution fails to account for a researcher's clinical responsibilities in addition to his research and teaching responsibilities.

An additional issue in reporting the commitment of effort to research projects is the accurate and consistent treatment of "institutional base salary" (IBS). IBS effectively serves as the denominator in calculating the proportion of an employee's activity that is allocated to a particular federal grant. While IBS usually includes only nonclinical work based on a more expansive definition of the "institution" for cost reporting purposes, it is critical that the clinical, as well as the nonclinical work activities are reported so that salary is correctly allocated among federal and nonfederal funding sources.[4]

Proper allocation of charges

Because it is common for institutions to receive multiple awards for a single research area, it is essential that accounting systems properly separate the amount of funding from each funding source. An improper practice might include principle investigators on different projects banking or trading award funds among themselves.

The OIG considers the improper allocation of charges to be more than an "accounting problem." Its view is that a failure to account accurately for charges—whether because of poor record-keeping or the intent to deceive the funding source—subverts the government's ability to distribute appropriate research funds to the most worthy projects.[5] Thus, the improper allocation of charges may result in significant disallowances to a research institution or, under certain circumstances, subject it to an investigation for criminal or civil fraud.[6]

Reporting financial support

Without complete and accurate information on other funding sources for a particular research project, PHS may be unable to determine the appropriate level of federal funds to allocate to a particular project. Moreover, the failure to identify other funding sources may cause duplicate funding for a project, resulting in limited federal research funds being misappropriated.

Related to the failure to accurately report support from other financial sources is the practice of charging of grant funds and Medicare or other health insurances for performing the same service. This is a well-documented risk for biomedical research programs, such as clinical trials, and has subjected research institutions to fraud investigations.

For PHS awards, reporting other financial support for a particular research project is a requirement of the award application process and failure to provide this information may result, under some circumstances, in a criminal or civil fraud investigation.[7] Certification by both the Principle Investigator/Program Director and the applicant organization (as done by signing the grant application face sheet) attests to the "true, complete and accurate (information provided) to the best of (their) knowledge" and any false information provided may result in charges of criminal or civil false statements or false claims or the imposition of administrative penalties.

Compliance Program Structure

The Guidance details the minimum elements that should be included in a comprehensive compliance program for PHS grant recipients. They include the seven common program elements of compliance programs, mentioned above, plus an eighth element that the OIG believes is especially important to research environments—establishing roles and responsibilities and assigning oversight responsibility for the program.

Essential elements

Four of the eight elements, discussed in the CPG, which are critical to the operation of any research compliance, including developing effective lines of communication, providing effective training of research personnel, responding to detected problems and developing correction action plans and defining roles and responsibilities and assigning oversight responsibility are highlighted in this section.

Training. Effective training programs are considered to be an important element in any research compliance program and must include personnel at all levels of research activities, including administrators, faculty, department chairs, principle investigators and other research staff. The training should cover such topics as ethical standards and the institution's commitment to compliance issues, as well as the institution's research-related policies and procedures.

The level of training should be designed to meet the level of responsibility for the personnel to be trained. For instance, a general training program may include all research employees, while a more specific training program may be designed for specialized audiences, such as those personnel responsible for human or animal subjects, the Institutional Review Board or administrative matters, including managing and accounting for grant funding.

Communication. For a compliance program to work well, employees must be able to ask questions and report problems. University officials, department chairpersons and other supervisors play a key role in responding to employee concerns and, thus, are an important link in the communication process. When an institution designates a compliance officer to oversee and coordinate its compliance program, the compliance officer can serve as a contact point for reporting problems and initiating corrective actions. The compliance officer is often viewed as someone to whom personnel can go for clarification of institutional policies and procedures, as well as to report concerns about possible violations.

Employee hotlines, suggestion boxes, E-mail alerts and newsletters also serve to provide avenues for the exchange of information and maintain open lines of communication. Exit interviews are another means by which the institution can solicit information regarding policies and procedures, potential misconduct or suspected violations.

Responding to alleged violations. The failure of an institution to comply with applicable federal or state laws or other types of misconduct (e.g., scientific misconduct) threatens an institution's reputation in the scientific and research community.

For the reporting mechanism to maintain credibility, it is vitally important that the institution's review of allegations be meaningful and that prompt and appropriate follow-up be conducted. Consequently, reported matters that suggest substantial violations of federal or state regulations or program requirements should be documented and investigated promptly. While the exact nature and level of investigative thoroughness will vary according to the circumstances, any review should be detailed enough to identify the cause of the problem and allow for development of a reasonable corrective action plan.

Moreover, prompt reporting of the existence of any misconduct to the appropriate authorities (i.e., within 60 days after determining there is credible evidence of a violation) will demonstrate the institution's good faith and willingness to work with governmental authorities to correct and remedy the problem. Prompt reporting also may be considered as a mitigating factor by law enforcement or regulatory authorities, such as the OIG.

Defining roles and responsibilities. Defining roles and responsibilities is essential to the overall internal control structure of a research organization, in part because of the complexity and decentralization of organizational structures within a typical research institution. For example, institutions should clearly delineate the responsibilities of all persons involved with the conduct of federally funded research, including both administrative and personnel with oversight responsibility as well as principle investigators and other personnel involved in research.

Usually, under PHS regulations, the institution itself qualifies as the "responsible legal entity" for grant compliance purposes.[8] By defining roles and responsibilities, an institution can better fulfill its legal responsibility to comply with the various requirements outlined in PHS regulations, thus decreasing the risk of a compliance violation. A well-designed compliance program with clear delineation of roles and responsibilities also can aid the institution in defending against allegations that their actions (or lack of action) were taken in reckless disregard for the regulations.

Conclusion

The continued growth in federal funding for biomedical and behavioral research has heightened the government's concern that research projects are at risk for regulatory compliance violations and the Draft Compliance Program Guidance for PHS Grant Recipients provides yet another "notice" of its concern.

The Draft CPG can serve as a checklist of "to-do" items that the OIG believes are essential for any research institution when developing or refining its research compliance program. While the CPG guidelines are voluntary, they can provide several benefits to institutions that implement an effective compliance program. The OIG has designed the guidance to account for differences in research institutional size and organizational structure. Like prior CPGs for other segments of the healthcare community, this CPG is likely to become a textbook for "best practices" within the research community. Comments regarding the Draft CPG were due on December 28, 2005, with the final Guidance expected later this spring.

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1 *Notice,* 70 FR 71312, Nov. 28, 2005.

2 *See, for example,* specific CPGs developed by HHS' OIG for healthcare providers and suppliers. Copies of all OIG Compliance Guidances can be found in the *Health Care Compliance Reporter* under OIG Compliance Guidance or at the OIG Web site http://oig.hhs.gov/fraud/complianceguidance.html.

3 For colleges and universities, the rules governing compensation for personal services, including payroll distributions, are contained in OMB Circular A-21, Cost Principles for Educational Institutions, section J.10. Under this section, institutions must establish as system of payroll distribution and maintain "after-the-fact Activity Reports" or another method to report accurately the distribution of activities for its employees. See also instructions to PHS Form 398 Application for a Public Health Service Grant available at www.grants.nih.gov/grants/funding/phs398/phs398.html.

4 For recent changes in NIH guidelines regarding IBS, refer to" Guidelines for Inclusion of Clinical Practice Compensation in Institutional Base Salary charged to NIH Grants and Contracts," available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-050061.html.

5 *Notice, 70 FR 71312, 71316, Nov. 28, 2005.*

6 The general principles governing the allocation of costs are found in the appropriate sets of cost principles, such as OMB Circular A-21 for colleges and universities. Additional guidance may be found in the NIH Grants Policy Statement, Part II, Cost Considerations, available at http://grants1.nih.gov/grants/policy/nihgps.

7 Other funding support is required to be reported on PHS Form 398, the instructions for which state that the applicant organization must disclose all compensation and salary support. See "Other Support," available at http:// www.grants.nih.gov/grants/funding/phs398/PolAssurDef.doc. See also guidance provided in the NIH Grants Statement Policy, Just-in-Time Procedures, available at http://grants1.nih.gov/grants/policy/nihgps.

8 42 C.F.R. §52.2 (definition of "grantee").

Stark (cont.)

arrangement, an independent evaluation will provide "comfort in the dollar amount that you're paying," he said.

Unrelated designated health services exception. The Stark statute contains fairly large flexibility for financial relationships that are unrelated to DHS, noted Meador. CMS narrowed the exception with Stark II, Phase II, but the exception is available for many arrangements dating prior to Phase II. "Many of us looking at pre-Phase II arrangements that are under review find some comfort in the definition ...that was in place prior to the narrowing by CMS," she said, adding, "whether the narrowing will stand under analysis of its regulatory authority is yet to be determined."

Knowledge and temporary noncompliance provisions. Although narrow in scope, these exceptions sometimes provide some room under Stark, Meador said. Under the provisions, a provider must have had actual knowledge of, or acted in reckless disregard or deliberate ignorance concerning, the identity of the physicians who made the referral. The provisions also state that the provider must have been compliant for at least 180 consecutive days and noncompliance arose for reasons outside of the provider's control and did not last more than 90 days, she concluded. ■

CCH Washington Bureau, Feb. 17, 2006.

Corporate Governance

Ethical leadership leads to improvements in business

by Catherine Hubbard, M.A., Contributing Editor

By weaving sound ethical standards into their health care organizations, leaders can improve performance, raise employee morale and reduce costs, according to Rich Cohan, vice president for Corporate Responsibility at Healthcare, Denver, Colorado. "A focus on business ethics and compliance is just good business," Cohan told listeners during a February 15, 2006, audio conference sponsored by the Healthcare Financial Management Association (HFMA).

Business ethics initiatives have been tied to greater efficiency in daily operations and greater employee commitment that leads to higher retention, lower turnover and lower costs, Cohan explained. It also can result in improved financial performance, higher quality services and products, improved decision making, increased customer loyalty and improved reputation.

Code of conduct and trust. To foster ethical standards leadership should develop a well thought out and implemented code of conduct. "Too often the code of conduct ...is overlooked as a decision making tool," according to Cohan.

Also, keeping the trust of employees is key. "Trust is the glue that holds the organization together," Cohan emphasized. A trusting environment, one where all organizational members share a sense of trust and trust exists between departments within an organization can even have a positive effect on the bottom line profits, he noted.

Cohan recommended that leadership focus on: (1) ensuring that employees and other stakeholders may openly express ethical concerns without fear of reprisal; (2) providing ethical guidance and resources for employees including mechanisms for discussion of ethical issues; (3) aligning work efforts of staff with the company's broader mission, vision and organizational values; and (4) providing staff with the tools necessary for them to have confidence in their ability to make well reasoned, sound decisions.

Noting widely publicized corporate and accounting scandals, such as WorldCom, Tyco and Solomon Smith Barney, Cohan noted that individuals alone did not cause the current crisis. Board members, top management, attorneys, accounting firms and securities analysts as well as other stakeholders were involved in supporting a culture of deception and manipulation.

Sarbanes-Oxley connection. One tool used to increase ethical standards is the Sarbanes-Oxley Act of 2002 (SOX), Cohan said. SOX provides oversight to restore stakeholder confidence, requires business ethics infrastructure, and is designed for the for-profit world, but is embraced by many nonprofits.

"Sarbanes is a modern-day miracle," he said, calling it the ultimate regulation of leadership ethics. Under SOX, corporations must have an independent accounting oversight board, chief executive officers (CEOs) and chief financial officers (CFOs) must certify financial statements, and board audit committees must consist of independent members. In addition, there is a code of ethics for senior financial officers.

Many corporations, both for- and nonprofit have incorporated the principles underlying SOX, such as split roles of CEO and chairman, outside directors meeting alone as often as necessary and independent internal ombudsman encouraging internal reporting of misconduct.

Reporting misconduct. Due to a perception that leadership will not take action when someone reports misconduct, many employees do not report observed misconduct. Surveying employees about their views on ethics can help. Such a survey could be used to gather information on whether employees (1) know how to report misconduct, (2) fear a negative outcome, and (3) trust that top management keeps their promises and commitments and holds employees accountable if they violate the company's code of conduct, Cohan said.

To encourage people to report observed misconduct, employers should not only provide a hotline, but also should enter into a dialogue with employees. "The ethical leader communicates thought processes and involves others in that thought process."

When leaders model ethical behavior in all they do, team members will feel less pressure to compromise ethics standards, will be more satisfied with responses to misconduct, will be more satisfied with their organization and will feel more valued as an employee, Cohan stressed. ■

CCH Washington Bureau, Feb. 27, 2006.

Fraud & Abuse

Miami hospital excluded from participation

Susan Smith, J.D., M.A, Contributing Editor

The Office of Inspector General (OIG) has excluded Miami's South Beach Community Hospital (South Beach), formerly known as South Shore Hospital and Medical Center, from participation in Medicare, Medicaid, and all other federal health care programs because of South Beach's material breach of the terms of a corporate integrity agreement (CIA) it had negotiated with OIG in 2002. The CIA was part of the resolution of a False Claims Act case against the hospital.

Breach of obligations. On December 2, 2005, OIG notified South Beach that it intended to exclude the hospital because of its failure to meet the obligations of the CIA including the failure to: (1) meet multiple reporting requirements, (2) retain an Independent Review Organization to perform required audits, and (3) provide notification of the sale of the hospital. South Beach had 30 days to demonstrate that it was in compliance with the obligations of the agreement, had cured the breach, or was timely pursuing cure of the breach with due diligence. In December 2005, South Beach represented to OIG that it would cure the breach by February 28, 2006.

Failure to cure. OIG reviewed written submissions and performed a site visit at the facility to evaluate the extent to which South Beach may have cured the material breach. Based on this review, OIG determined that the hospital had failed to take timely corrective actions necessary to cure the breach and to meet its own timetable to take such actions. Therefore, OIG has exercised its contractual right to exclude South Beach from participation in all federal health care programs for a period of five years. The hospital has the right to request a hearing before an administrative law judge, with a right to further appeal to the Departmental Appeals Board. ■

OIG News Release, March 10, 2006.

In the News

AHRQ Council to hold meeting

The National Advisory Council for Healthcare Research and Quality has announced that it will hold a meeting on Friday, April 7, 2006, to discuss the status of the Agency's current research, programs, and initiatives; ambulatory care safety; and findings on breast cancer from Agency for Healthcare Research and Quality's (AHRQ's) Effective Healthcare initiative. The Council advises the Secretary and the AHRO Director on agency actions related to the financing and delivery of health care services to enhance quality, improve outcomes, reduce costs, improve access through scientific research, and promote improvements in clinical practice and in the organization. The official agenda will be available on AHRQ's Web site at http://www.ahrq.gov no later than March 31, 2006. The meeting, which is open to the public, will be held from 8:30 a.m. to 4:00 p.m. in Room 800 of the HHS, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. ■

Notice, 71 FR 11670, March 8, 2006.

OIG, GAO to review specialty hospitals

Senators Grassley (R-IA) and Baucus (D-MT) have asked the HHS Inspector General and the Government Accounting Office to review patient safety and quality as well as financial arrangements at physician-owned specialty hospitals. Both senators have been involved in an effort to understand the impact of physician-owned specialty hospitals on patients, community hospitals, and the Medicare and Medicaid programs. The senators previously requested information from HHS regarding the enforcement of a moratorium on new specialty hospitals following the death of a resident at a specialty hospital that was established during the moratorium period. They also have asked the Medicare Payment and Advisory Committee (MedPAC) to further examine the impact of specialty hospitals on community hospitals. The two primary areas of concern are patient safety and the use of taxpayer dollars through Medicare and Medicaid. According to Baucus, "[I]f patient health is at risk in these facilities, we need to uncover that now. If Medicare and Medicaid dollars are paying for less than the best care in these facilities, that demands immediate attention."

Senate Finance Committee Press Release, March 6, 2006. ■

JCAHO expands quality information resources, launches performance data initiative

Actions have been taken by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Board of Commissioners to enhance the depth and transparency of the publicly available, quality-related performance information currently provided by the JCAHO and to provide new information resources to support quality improvement efforts in hospitals and other health care organizations. At its March 3 and 4 meeting, the Board also framed a series of rationales and data element justifications as the basis for initiating a dialogue with the hospital field around potential acquisition of case-identified data that would protect patient privacy. In addition, the Board approved the immediate launching of a new public policy initiative to address the development of a national strategy for the gathering, preparation, and dissemination of performance data, including (1) the issues surrounding the creation of a national public utility for performance measurement data; (2) the potential design of a national data system that could meet multiple stakeholder needs; and (3) how best to protect patient confidentiality in such a system, among other issues. ■

JCAHO News Release, March 6, 2006.