G-2 Compliance Report

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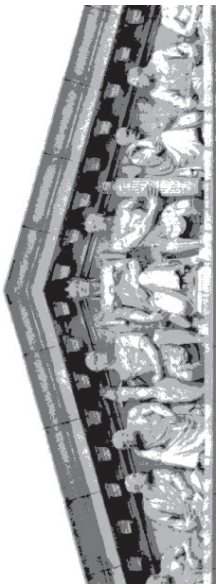

Evaluating Program Effectiveness: Checklists For Compliance

The Supplemental Compliance Program Guidance for Hospitals published by the Department of Health and Human Services Office of Inspector General (OIG) earlier this year provides the OIG's perspective on numerous important issues related to compliance. Last month we provided an overview of the Supplemental Guidance and focused on certain high-risk issues of particular interest to hospitals (*GCR*, March 2005, p. 5). This article will examine material in the Supplemental Guidance that is applicable to those throughout the healthcare industry on how to evaluate a compliance program to make sure it is effective.

Traditionally, one of the benefits of having a compliance program was that the U.S. Sentencing Commission Guidelines (the Sentencing Guidelines) stated that organizations that had violated the law might be eligible for substantially reduced penalties if they had "effective" compliance programs in place. Despite the recent Supreme Court decision in *United States v. Booker*, 543 U.S.___(Jan. 12, 2005), which held that the Sentencing Guidelines are not binding on judges, many government agencies have indicated that they will continue to look to the Sentencing Guidelines when formulating their recommendations on sentencing. ➥ *p. 2*

Inside this issue

Diagnostic Lab, Execs Indicted For Fraud

A California medical diagnostic testing company that operated clinics in Las Vegas and its two top corporate officers have been indicted on federal healthcare fraud, money laundering, and tax evasion charges.

SDI Future Health Inc., a California corporation based in Westlake Village, and executives Todd S. Kaplan and Jack Brunk were indicted by federal grand jury in Las Vegas on March 2. They are charged with one count of violating the Medicare anti-kickback statute, one count of conspiracy to commit healthcare fraud, 124 counts of healthcare fraud, one count of conspiracy to commit money laundering, and 10 counts of attempt to evade or defeat tax. They face up to 20 years in prison and fines of $250,000 on each of the healthcare fraud and money laundering offenses, and up to five years in prison and fines of $250,000 on the anti-kickback and tax evasion counts.

According to the indictment, between January 1999 and January 2002, the SDI defendants defrauded healthcare benefits programs, including Medicare, Blue Cross Blue Shield, and Sierra Health, of money and property estimated at about $22 million. SDI marketed a test for diagnosing sleep apnea, ➥ *p. 9*

Linda A. Baumann, Esq., is a partner with the law firm of Reed Smith (Washington, DC). She can be reached at 202-414-9488. E-mail: lbaumann@reedsmith.com

Checklists For Compliance, *from p. 1*

Moreover, the OIG and other government agencies may well consider the existence of an "effective" compliance program in deciding whether to proceed with an investigation, as well as in deciding what penalties to seek.

However, it is difficult to define "effective," and compliance officers have frequently asked the OIG for additional guidance in this area. A significant portion of the Supplemental Guidance addresses this issue and can be used to create "checklists" for compliance officers, as indicated below. It is important to note that while the Supplemental Guidance is specifically addressed to hospitals, these materials are relevant to all organizations throughout the healthcare industry.

Don't Lose Sight Of The Big Picture

In many compliance documents, the OIG has described the seven basic elements of a successful compliance program. The Supplemental Guidance refers to these seven elements, but strongly recommends going one step further. After implementing a compliance program, a provider should assess the overall program at least annually, rather than simply focusing on the numerical audit results of individual issues. The OIG provides the following criteria, generally linked to the seven compliance elements, to help providers perform this assessment.

Designation of a Compliance Officer and Committee. In performing the annual review of the compliance department, providers should assess the following factors (although it is not clear whether the OIG would find it acceptable for the compliance officer to self-audit or if some other entity must perform this review):

- Does the compliance department have a clear, well-crafted mission, and is it properly organized?
- Does the department have sufficient resources, training, authority, and autonomy?
- Is the relationship between the compliance function and the general counsel function appropriate?
- Does the compliance officer have direct access to the governing body, president or CEO, all senior management, and legal counsel?
- Does the compliance officer have a good working relationship with key operational areas such as the billing, internal audit, coding, and clinical departments?
- Does the compliance officer make regular reports to the board of directors and other hospital management?
- Are *ad hoc* groups or task forces created to carry out special investigations or evaluations?
- Is there an active compliance committee, with trained representatives from relevant departments and senior management?

Development of Policies and Procedures. The Supplemental Guidance advises that, in addition to formulating the "Code of Conduct," the compliance department should reassess written policies and procedures to ensure that they comport with applicable statutes and regulations concerning federal healthcare programs as well as with the provider's own objectives. Toward this end, providers should consider the following criteria:

- Are the policies and procedures clearly written, readily available, and relevant to daily responsibilities?
- Does the provider monitor staff compliance with internal policies and procedures?
- Has the provider developed a risk-assessment tool to assess and identify operational risks that it reviews on a regular basis?
- Are federal program requirements reviewed regularly to enable the risk-assessment tool to be current and effective?
- Have all standards of conduct been distributed to all staff and employees, the board of directors, all officers, managers, hospital contractors, and medical staff?

Developing Open Lines of Communication. The guidance explains that open lines of communication stem from an organization's culture and the internal mechanisms for reporting fraud and abuse. The following factors may help assess whether potential compliance issues are communicated effectively:

- Has the provider fostered an organizational culture that encourages open dialogues without fear of reprisal?
- Is there an anonymous hotline or similar mechanism for reporting compliance issues?
- Is the hotline well advertised, with calls logged and addressed in a timely manner, and reviewed for possible patterns?
- Are all instances of potential fraud and abuse investigated?
- Are the governing body and relevant departments regularly receiving the results of internal investigations?

- ❖ Are alternative communication methods used, such as a periodic newsletter or intranet site? (It is not clear whether or why an alternative method is necessary in cases where the hotline appears to be working.)
- ❖ Is the governing body actively pursing appropriate remedies to institutional or recurring problems?

Appropriate Training and Education. Criteria highlighted by the OIG for use in reviewing training and education programs include:

- ❖ Does the organization provide qualified trainers to annually conduct both general and specialized compliance training?
- ❖ Are the contents of educational programs reviewed annually, and do they incorporate the latest changes to federal rules and regulations?
- ❖ Does the training reflect audit and investigation results, hotline trends, and federal agency guidance?
- ❖ Has the format of training sessions been evaluated in terms of frequency, length of sessions, and method of information delivery (*e.g.*, live or via computer)?
- ❖ Is post-training evaluation and testing provided to ensure that the training is understood and retained?
- ❖ Is the governing body trained regularly with regard to fraud and abuse laws?
- ❖ Does the provider document who has completed training?
- ❖ Has the organization considered imposing sanctions for failure to attend training or providing appropriate incentives for training session attendance?

Implementing the measures identified in the checklists described above may require a considerable expenditure of time and money. Some cash-strapped providers may be inclined not to implement these recommendations because the Supplemental Guidance is not legally binding, and the OIG has stated that compliance programs may be tailored to fit the provider's circumstances and resources. Nevertheless, all those who do business in the healthcare industry are well advised to work with the criteria in the Supplemental Guidance to the maximum extent possible to get the full benefit from their compliance programs, to prevent errors, detect fraud, and reduce the risk of liability.

Internal Monitoring and Auditing. The OIG emphasizes that effective monitoring and auditing plans can prevent the submission of incorrect claims to federal healthcare programs. Accordingly, providers should develop detailed annual audit programs with consideration of the following standards:

- ❖ Does the audit plan address identified risk areas, high-volume services, and findings from previous years' audits?
- ❖ Is the audit department available to conduct unscheduled reviews and capable of responding in a timely fashion to compliance department requests for further review?
- ❖ Does the audit plan assess both billing systems and claims accuracy to identify the source of common billing errors?
- ❖ Are coding and audit personnel independent, and are their roles clearly established? Do they have the requisite certifications for their positions?
- ❖ If error rates are not decreasing, has the organization conducted further investigations to determine hidden deficiencies in the compliance program?
- ❖ Does the audit consider all billing documentation, including clinical documentation, in support of claims?

Response to Detected Deficiencies. To develop effective corrective action plans and prevent further losses to federal healthcare programs by consistently responding to detected deficiencies, the OIG recommends consideration of the following:

- ❖ Has the organization identified a team of personnel from the compliance, audit, and other applicable departments to quickly evaluate any detected deficiencies?
- ❖ Are detected deficiencies promptly and thoroughly investigated?
- ❖ Are corrective action plans developed to address the root causes of violations, and are they periodically reviewed to verify elimination of the deficiency?
- ❖ Are detected overpayments promptly repaid and probable violations of law promptly reported to the appropriate law enforcement agencies?

Enforcement of Disciplinary Standards. The OIG places special emphasis on the duty to enforce disciplinary standards. Accordingly, providers should assess the criteria below:

- ❖ Are disciplinary standards well publicized and readily available to all personnel?
- ❖ Does the provider uniformly and consistently enforce these standards?
- ❖ Are employees, contractors, and medical staff checked, at least annually, against government sanctions lists, including the OIG's List of Excluded Individuals/Entities (LEIE) and the General Services Administration's Excluded Parties Listing System?

Tenet Agrees To Settle Pricing Class-Action Lawsuits

Tenet Healthcare Corp. has reached an agreement providing for a nationwide settlement of certain class-action lawsuits regarding prices that uninsured and some under-insured patients were charged for prescription drugs and other medical products and services at hospitals owned and operated by Tenet subsidiaries.

The settlement is subject to certain conditions, including court approval. Tenet has established a reserve that it believes will be sufficient to cover the claims and expenses associated with the settlement, the company said in a statement.

Class-action lawsuits are currently pending against the company and some of its hospitals in Alabama, California, Florida, Louisiana, Missouri, Pennsylvania, South Carolina, Tennessee, and Texas. If a nationwide settlement is approved, those class-action lawsuits will be subject to dismissal, according to Tenet, which expects the approval process to take several months.

As part of the settlement agreement, Tenet and its subsidiaries make no admission of liability and continue to dispute the allegations made in the lawsuits.

The cases have been brought primarily on behalf of uninsured patients, who were billed at the hospitals' undiscounted gross charge rates, according to Tenet's recent 10-K filing with the Securities and Exchange Commission. While the specific allegations and relief sought vary from case to case, the plaintiffs generally allege violations of state consumer protection statutes, breach of contract, and other state law claims. In California, over a dozen state cases have been coordinated into one proceeding in the California Superior Court, Los Angeles County, called *Tenet Healthcare Cases II*.

Settlement Provisions

Under the proposed settlement, for a period of four years, Tenet would:

1 Provide financial counseling to all uninsured patients, "including help in understanding and applying for governmental financial assistance and charity care programs," and would post information on the availability of such financial assistance on hospital Web sites and at certain locations in its hospitals.

2 Care for uninsured patients "fairly and with respect during and after treatment, and regardless of their ability to pay for the treatment they receive."

3 Offer uninsured patients "reasonable" payments and payment schedules and do not attempt to collect fees from patients who have applied for financial assistance while eligibility determinations on their completed applications are pending.

4 Follow "a uniform credit and collection policy, including, among other things, a commitment not to pursue legal action for nonpayment of bills against any patient who is unemployed or without other significant assets or to place a lien on a patient's home."

5 Disclose to uninsured patients the estimated charges for anticipated treatment, subject to applicable legal requirements.

6 Offer uninsured patients discounted pricing "at rates comparable to the hospital's current managed care rates."

According to Tenet, the company has agreed to provide a reimbursement mechanism for uninsured patients who received medically necessary services at any of its hospitals between June 15, 1999, and Dec. 31, 2004—the period covered by the lawsuits—and who paid more than a certain percentage of the hospital's gross charges.

"The specific percentage varies depending on the year the patient was treated," the company says. "Tenet also has agreed to offer to discount outstanding unpaid bills for uninsured patients who were treated at its hospitals during the settlement class period, and to make a $4 million charitable contribution to a healthcare-related charity specified by the plaintiffs' counsel."

Resource

Tenet Healthcare: 469-893-2200

COMPLIANCE PERSPECTIVES

Compliance Spotlight: Conflicts Of Interest In Clinical Research

H. Guy Collier is a partner and Jennifer S. Geetter is an associate in the Washington, DC, health law department of McDermott Will & Emery, LLP

In recent months, concern over conflicts of interest in research-related activities has topped the headlines of major newspapers, featured prominently in a number of high-profile lawsuits, and been the focus of major policy changes at the National Institutes of Health (NIH). As a result, the identification and management of potential and actual conflicts of interest in the conduct of clinical research has moved to the fore of research compliance initiatives.

Even without this emphasis on conflicts of interest, efforts to engage in meaningful research compliance or to develop an effective research compliance plan have been elusive for many healthcare institutions with a clinical research program. The presence of an institutional review board (IRB) – with its mission of approving and monitoring clinical research activities – has too often been seen as the start and finish of a research compliance program. However, with the greater attention to research conflicts of interest, healthcare institutions need to implement comprehensive compliance plans for their research programs that include, but are not limited to, rigorous management of conflicts of interest.

Concern over conflicts of interest in research is not a new phenomenon. Several years ago, there was a significant push within academic circles to prohibit (or severely limit) the role of the private sector in research, and some commentators criticized any type of financial interest between vendors, device manufacturers, and pharmaceutical companies (loosely described as "industry" throughout this article), and the research entities. However, it is fundamental that industry plays a crucial role in promoting bona fide research studies and that the ethical and regulatory focus cannot be on eliminating financial relationships between industry and researchers, but in managing these relationships to ensure the integrity of the scientific process and the safety of human subjects participating in clinical research.

Industry and research institutions are often very good partners, and these partnerships have led to critically important medical breakthroughs. However, when a human subject is injured or the scientific integrity of a study is questioned, commentators, public advocates, law enforcement, and other researchers are quick to identify any potential but unresolved or undisclosed conflicts of interest.[1] These conflicts are viewed through the lens of a "but for" analysis: but for the conflict of interest, the injury or misconduct would not have occurred. Oftentimes, the conflict—even if real—has little or nothing to do with the harm. However, the presence of an unmanaged or undisclosed conflict necessarily impugns the motives of the participants and is an easy and available scapegoat. Therefore, managing conflicts is also an important factor in instilling public confidence in an institution's research program and in managing legal liability.

Lastly, the renewed focus on managing conflicts of interest and on the important relationship between such management and improved subject safety and the preservation of scientific integrity is an issue for any institution or individual engaged in research. Although the need for industry players to be aware of, and properly manage, conflicts of interest is self-evident, and institutions receiving federal dollars have long been required to comply with the federal standards regarding conflicts described in greater detail below, less conventional research participants need to manage conflicts as well. As recent court decisions illustrate, an emerging view of informed consent on the part of the research subject agreeing to participate in research incorporates the subject's awareness of finan-

[1] *See, e.g., Gelsinger v. Trustees of U. Pennsylvania, No. 001885, Pa. C.P., settled 11/2/00. See also, e.g., Wright v. Trustees of the Fred Hutchinson Cancer Center, Wash. Super Ct., No. 01-2-008376 (2001).*

cial relationships of the researchers and the research site that could have the appearance of influencing their independent judgment.

In other words, consent is not truly "informed" if the subject is not told that the researcher or research site is being paid by the industry sponsor or that the researcher or research site has a commercial interest in the successful development of a medical technology. This information is considered material to the decision to participate in a clinical trial. In addition, even conflicts that do not result in the compromising of scientific integrity or undermining of subject safety, if left undisclosed and unresolved, create the appearance of impropriety. Once uncovered, such conflicts inflict significant harm on a researcher or research site's reputation and discourage individuals from participating in research. Thus, any individual or institution that wishes to engage in clinical research must put into place a comprehensive conflicts-of-interest policy as part of the institution's overall compliance obligations.

Conflicting Signals On Conflicts

There is no clear authority dictating what constitutes a conflict or how an institution should respond to a conflict. Some healthcare entities – most notably, the National Institutes of Health – have taken the powerful step of prohibiting researchers affiliated with or employed by their institutions from accepting any type of financial remuneration from industry.[2] Government and non-government entities adopting this approach have either concluded that any type of financial relationship with industry compromises the integrity of the research program or that the lack of clear rules for permissible and impermissible financial relationships necessitates a bright-line rule.

For most research institutions, however, such a stark approach is neither feasible nor necessary. For healthcare institutions that will continue to partner with industry, the key is a managed set of expectations and rules that prospectively govern all relationships with industry. This prospective approach guards against institutions and individual researchers settling upon answers that are convenient and ensures that the institution's approach is not based on expediency, but a reasoned and rational assessment of the potential interests at stake. Over the last several years, a number of associations have released influential guidances. Although non-binding, these guidances are important sign-posts in the legal evolution of conflict-of-interest management and should inform an institution's development of its conflict-of-interest policy.

The Association of American Medical Colleges (AAMC) issued a two-part guidance on individual and institutional conflicts of interest. AAMC first issued its guidelines for individual conflicts in 2001.[3] A year later, AMMC published its second guidance focusing on institutional conflicts of interest.[4] Instead of focusing on all possible financial interests, the two reports focus on those financial interests that, in AAMC's view, may significantly undercut either the individual's or the institution's ability to act independently and objectively. According to AAMC, a potential conflict exists when there is a financial relationship that affects or appears to affect the investigator's or institution's ability to conduct human subjects research safely.

The Association of American Universities issued a similar guidance in 2001.[5] The report encourages universities to aggressively adopt procedures to address conflicts of interest. In particular, the report recommends that universities adopt higher standards than government regulations require by recommending that all financial interests be disclosed regardless of whether they meet the federal reporting threshold and that the conflicts policy apply to all research regardless of funding source. The report lays out a detailed list of components for a comprehensive conflicts policy to govern both individual and institutional conflicts.

Lastly, the Department of Health and Human Services (HHS) issued guidance on financial conflicts of interest just last year.[6] This guidance replaced the interim guidance issued by the department in January 2001. HHS pointedly noted that unmanaged conflicts of interest "may affect the rights and welfare of human subjects." The guidance does not announce any hard and fast rules, but instead suggests a process for each institution to develop comprehensive procedures. The guidance encourages institutions to consider what types of interests constitute potential or actual conflicts, at what level within an institu-

[2] In February 2005, the Department of Health and Human Services issued the "Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services," 5 CFR Part 5501.

[3] "Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research," AAMC Task Force on Financial Conflicts of Interest in Clinical Research, December 2001.

[4] "Protecting Subjects, Preserving Trust, Promoting Progress II: Policy and Guidelines for the Oversight of an Institution's Financial Interests in Human Subjects Research," AAMC Task Force on Financial Conflicts of Interest in Clinical Research, October 2002.

[5] "Report on Individual and Institutional Financial Conflict of Interest," October 2001.

tion should such conflicts be reviewed, what procedures are necessary to execute a conflict of interest policy, who should be trained within an institution on these issues, and what bodies within the institution should be charged with reviewing conflicts.

In addition, the guidance is significant because it focuses both on individual conflicts of interest (financial interests held by a person) and institutional conflicts of interest (financial considerations of the entity). Lastly, the guidance sets forth general parameters for the different roles of the Institutional Review Board (IRB) and the conflicts committee and highlights that IRB members can have conflicts as well.[7]

Conflict-Of-Interest Policy

Although the guidances reviewed above reach different conclusions on the best way to resolve conflicts of interest and to mediate the assumed tension between promoting high-level research with the assistance of industry with the need to protect human subjects and ensure scientific integrity, they all ask a number of key questions. These questions can form the basis of an institution's conflict-of-interest policy. In particular, the healthcare institution must consider the following:

- How do we define an "individual" conflict of interest?
- How do we define an "institutional" conflict of interest?
- What is the difference between a financial and nonfinancial, or associational, conflict of interest?
- How will we identify our financial interests and those of our employees and affiliates in order to manage potential conflicts of interest?
- How will we manage conflicts of interest once identified?
- Who is in charge of reviewing conflicts of interest?
- How will we educate our employees and affiliates on conflicts of interest?
- How will we enforce our conflicts-of-interest procedures?

As these questions illustrate, even if an institution has an existing generic conflicts of interest policy, the best approach is to address potential conflicts in research through a separate policy because of the unique issues involved. There are a number of foundational features that should be incorporated into any comprehensive conflicts-of-interest policy:

- **Conflicts in Research Committee**. The central feature of any conflicts of interest policy is the creation of a committee that will monitor and manage conflicts of interest in the research setting (the Conflicts in Research Committee, or CRC).
- **Membership**. The members of the CRC should have the appropriate training to assess all types of conflicts as they pertain to research and have familiarity with the Food and Drug Administration, Public Health Service, Office for Human Research Protections, NIH, and any other federal oversight agencies' conflicts of interest and financial disclosure requirements. Institutions should also consider involving a community member unaffiliated with the institution.
- **Mandatory reporting**. Conflicts cannot be adequately managed if financial (or other) interests are not identified. An institution must adopt procedures for routine, mandatory reporting of financial interests held by "covered persons," which would include investigators, IRB members, the institution itself, and high-level institutional officials with oversight or authority over the research program.
- **Specialized Committee**. An institution can constitute a separate committee to address research conflicts of interest as opposed to conflicts in other settings. A CRC need not report to the general conflicts committee. Although institutions have flexibility in developing strategies to manage conflicts of interest, it may be appropriate to have a committee specifically targeted to research conflicts in which the CRC and the general conflicts committee have parallel authority to identify, manage, and resolve any conflicts falling within their individual charters. In addition, some institutions create different committees to deal with individual and financial conflicts.
- **Independence.** CRC members cannot have their own conflicts of interest by virtue of competing financial or associational relationships with industry or sources of financial support. The committee must be independent of the institution's research program and should not report to anyone responsible for promoting research activities at the institution. The committee must have a clear reporting channel to the institution's leadership.

[6] "Final Guidance Document: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," May 5, 2004.

[7] Prominent research institutions are also at the fore of developing cutting edge conflicts-of-interest policies. See, e.g., "Policy on Conflicts of Interest and Commitment," Harvard Faculty of Medicine, Harvard Medical School, amended May 2004.

- **Policies and Procedures**. An institution should adopt written policies and procedures addressing the management of conflicts of interest in research (these policies and procedures can be incorporated into any existing compliance policies). These policies should set forth the parameters for identifying a conflict, measures to manage and monitor conflicts, the mechanism through which the CRC will communicate with the IRB, and the independence of the CRC.
- **Oversight.** The institution should have an audit and compliance plan that includes provisions for monitoring the conflicts-of-interest program. The audit and compliance plan can be incorporated into the institution's general compliance plan, or can be a sub-policy in the IRB/Research Office's standard procedures.
- **Coordination between the CRC and the IRB**. The institution should develop a pathway for the IRB to review the findings and recommendations of the CRC so that it can incorporate and reference this information throughout its original and ongoing assessment of the research proposal. Though some institutions have the IRB itself conduct the conflicts of interest review, in general, this practice is not encouraged. Rather, the CRC should have a systematic approach for sharing its findings with the IRB *prior* to the IRB approving the affected research proposal.

Reviewing Your Compliance Plan

Although a critical component, a research conflicts-of-interest policy, and a committee enforcing it, is only one piece of a comprehensive compliance plan for a clinical research program. To be effective, a conflicts-of-interest policy must work in tandem with policies designed to prevent scientific and research misconduct, up-to-date IRB and research administration policies and procedures, an institutional approach to intellectual property and data ownership and management, HIPAA procedures, and research reimbursement billing procedures. Together, these policies set forth a global strategy for how researchers and the institution work together to identify research priorities, structure clinical trials, and manage the flow of funds.

In addition, for a conflicts-of-interest policy to work, the institution and the researchers must be fully committed to it. Oftentimes, a newly enacted conflicts-of-interest policy will prohibit long-standing practices that were well intentioned but simply cannot persist in today's research and legal environments. Researchers may resist severing old industry ties or reconfiguring long-standing professional relationships to comply with new standards. Institutions should be sure to accompany the roll-out of any new or revised conflicts-of-interest policy with an institutionwide training and the requirement that every investigator attest to their familiarity with the new policy.

Conclusion

Research makes possible remarkable advances in clinical diagnosis and treatment and ultimately saves lives. However, when a research subject is injured or misled, the public and the legal community are quick to identify conflicts and then assume that "but for" the conflict of interest the harm would never have occurred. Entities that do not aggressively seek to manage conflicts of interest are playing legal roulette and jeopardize the very integrity and longevity of their research programs.

Accordingly, any institution that has a clinical research program—even if small—must have a conflicts-of-interest policy that can be appropriately scaled to the type and extent of research at that institution.

Of course, there is likely to be natural tension between prominent researchers who often receive much needed financial and in-kind support from industry and an institution's renewed focus on conflicts, to the extent that this new focus alters the types of support that a clinical researcher can receive. This tension is unavoidable and only underscores the complexity of the question and the competing and legitimate priorities of underwriting and promoting research, while incorporating strict safeguards to ensure the integrity of that same research. Ultimately, however, though an investment up-front, a comprehensive approach to conflicts of interest will protect the institution, its researchers, and most importantly, the people who agree to be research participants.

H. Guy Collier and Jennifer S. Geeter can be reached at McDermott Will & Emery, 600 13th St., NW, Washington, DC, 20005-3096. Collier phone and e-mail: 202-756-8009, gcollier@mwe.com. Geetter phone and e-mail: 202-756-8205, jgeetter@mwe.com.

Execs Indicted For Fraud, *from p. 1*

a common sleep disorder. The test was referred to as a sleep study or polysomnography. SDI also marketed a series of heart monitoring tests, which SDI called a Cardiac Risk Assessment, or CRA, said Daniel Bogden, U.S. Attorney for the District of Nevada, in announcing the indictment.

SDI billed healthcare benefit programs between $1,775 and $3,725 for the first sleep study ordered, and between $4,225 and $5,350 for the second sleep study ordered. SDI billed the programs between $145 and $3,995 for the CRA, depending on the type of heart monitoring test performed.

The indictment alleges that the SDI defendants induced physicians, including doctors in Las Vegas, to accept remuneration, or kickbacks, from SDI in exchange for referring patients to the company's labs. According to the indictment, the kickbacks took the form of assigning SDI employees, referred to as health service coordinators, to work free of charge in the offices of physicians. They also allegedly took the form of direct cash payments under the guise of medical director fees, gifts of expensive sports memorabilia, and assignment of fees.

Prosecutors alleged SDI used its health service coordinators to evaluate patients for sleep studies and to write prescriptions for medically unnecessary tests. The prescriptions often were written by the coordinators without evaluation of the patient's medical condition by a physician, and without the presence of signs and symptoms indicating a medical need for the sleep studies or heart monitoring, Bogden said.

SDI defendants also allegedly pressured patients to make appointments at SDI clinics and informed them that their treating physicians had ordered the sleep studies.

Bogden's said no Las Vegas physician is specifically charged in the indictment. However, it is alleged that SDI entered into agreements with five unnamed physicians who were practicing in Las Vegas, and that the agreements called for payment of kickbacks in return for referrals to SDI.

Resource

U.S. Attorney Daniel Bogden: 702-388-6336

BCBS Plans Sue CA Clinics Over Surgeries

A dozen Blue Cross and Blue Shield (BCBS) plans have filed a lawsuit against nine southern California-based outpatient surgery clinics, seven medical management companies, and 34 individuals alleging a massive fraud scheme in which hundreds of patients from across the country underwent unnecessary and sometimes dangerous surgical procedures that resulted in the submission of tens of millions of dollars in fraudulent medical claims.

The lawsuit, *Blue Cross and Blue Shield of Alabama, et al. v. Unity Outpatient Surgery Center, Inc., et al.*, was filed March 10 in the U.S. District Court for the Central District of California. The plans seek recovery of more than $30 million.

Under the scheme, which BCBS dubbed "Rent-A-Patient," the clinics and their recruiters offered patients either cash for each procedure or credits toward free or discounted cosmetic surgery, the complaint said.

"The case is unique in that the defendant clinics and surgeons allegedly performed the unnecessary procedures on healthy patients," said Paul Brown, BCBS Association vice president and deputy general counsel at a March 11 press conference announcing the lawsuit. He added that before recruiters, called "marketers" or "cappers," persuaded individuals to undergo a particular surgical procedure, they were very careful to verify that the patients had insurance.

According to Brown, the unnecessary procedures included diagnostic procedures, colonoscopies and endoscopies, to diagnose gastrointestinal problems; nasal surgeries; gynecological procedures; and tonsillectomies. One of the riskiest surgeries, Brown said, was surgery to treat "sweaty palms," which involved collapsing the patient's lung to access and sever the nerve that controls perspiration.

Resource

BCBS Association: 312-297-5954

Medicare Urged To Require Test Results With Lab Claims

The Medicare Payment Advisory Commission (MedPAC), which advises Congress, has recommended that Medicare require clinical laboratories to report patients' test results with the claims they submit. The results would be used in assessing the quality of care that physicians furnish, MedPAC said in its annual report to Congress, issued March 1.

Eventually, the panel noted, results would help support the kind of quality incentive payments to doctors that MedPAC has urged Congress to establish.

The test results data would have to adhere to a standard format and vocabulary, such as the LOINC (Logistical Observations: Identifiers, Names, Codes) standards that the federal government has adopted and many clinical laboratories already use, MedPAC said, suggesting a "two- or three-year transition before using [the data] to pay for performance might be prudent. But adoption and implementation of standards must begin now."

The recommendation was MedPAC's most controversial, with two of its 17 members voting against it. All the other recommendations in the panel's 2005 report were unanimous, save for a health system member's "no" votes on recommendations to set inpatient and outpatient prospective payments 0.4% below market basket.

MedPAC acknowledged that requiring test results with lab claims would "result in some increased burden for those who conduct lab tests," but did not suggest paying extra for the data.

To avoid creating a new data stream, MedPAC called for including the test results, which it calls "laboratory values," on new or existing fields on lab claim forms or as attachments to the forms. With attachments, it would be easier to include the in-depth information, including text, required to describe some test results, the panel said.

MedPAC did acknowledge concerns voiced by lab and physician groups that it would be difficult to blend information from clinical and payment systems and to design claim form fields to capture the variety of results reported, including textual and panel test results. Also, it would take time to redesign systems to fully conform to standards such as LOINC.

MedPAC envisions phasing in federally mandated standards that are based on industry consensus standards, as with the HIPAA standards governing electronic transactions and code sets. For example, CMS could require LOINC for coding lab data and HL7 for sending it. MedPAC suggests a "phased approach could allow additional time for smaller labs to comply."

MedPAC advised initially setting aside 1% to 2% of physician payments to be distributed as quality bonuses. "As our ability to measure quality improves, this amount should increase significantly." Perhaps recognizing that Congress may be tempted to divert the set-aside to other uses such as debt reduction, the commission stressed that it "intends for all of the withheld dollars to be distributed."

Renal Care Provider DaVita Inc. Target Of Probe

The Office of U.S. Attorney for the Eastern District of Missouri James Martin issued a subpoena March 4 to renal-care provider DaVita Inc. in an investigation into the company's compensation arrangements with physicians, joint-venture agreements, and pharmaceutical services provided by patients.

The subpoena, which was issued in connection with a joint civil and criminal investigation, sought documents from DaVita facilities around the country and covered the period from Dec. 1, 1996, to the present, according to a company statement. It overlapped substantially with an information request issued to the company in February 2001 by U.S. Attorney for the Eastern District of Pennsylvania Patrick Meehan, said DaVita's chairman and CEO, Kent Thiry.

Thiry discussed both subpoenas March 7 during a conference call with investors. He said prosecutors in Missouri and Pennsylvania have said they will cooperate in the investigations.

Broader Investigation

DaVita also was issued a subpoena as part of a broader investigation of the renal-care industry in October 2004 by U.S. Attorney for the Eastern District of New York Roslynn Mauskopf. That subpoena sought documents concerning parathyroid hormone testing and vitamin D therapies, the company said at the time.

"We have worked hard to create and sustain a culture of compliance at DaVita, as well as the policies and systems to support that culture," said Thiry. "We look forward to answering whatever questions the government has."

Based on comparisons with recent government investigations into other renal-care providers, Thiry said DaVita is prepared to spend several years on the process "if that's what it takes to achieve a complete and fair resolution."

A federal investigation into the renal-care division of the Fresenius Medical Group AG lasted five years before being settled in 2000, Thiry said, while an investigation into Gambro Healthcare lasted three years before being settled in 2004.

Fresenius agreed to pay $385 million to settle four whistleblower lawsuits related to its kidney-dialysis units, while Gambro agreed to pay $350 million to settle a whistleblower lawsuit alleging that it overcharged the Medicare program.

DaVita announced plans to acquire Gambro in December 2004. Thiry said during the conference call that the government investigation will have no effect on the acquisition.

The three areas covered by the subpoena were the same as those covered in the Gambro investigation, Thiry said: compensation of medical directors, joint ventures, and pharmaceutical services.

DaVita has carried out arms-length negotiations with its medical directors since at least 2000, when the current management team came on board, Thiry said. Beginning in 2002, the company began using a compensation model for its medical directors based on objective criteria, such as physician duties and responsibilities, and qualifications and experience, he added. The system currently in place at DaVita is "about the same" as the system put in place at the conclusion of the government's investigation, Thiry noted.

Resource

DaVita: 310-536-2400

'Date Of Service' Defined

Under the negotiated rulemaking that developed the laboratory national coverage decisions, the Centers for Medicare and Medicaid Services (CMS) specified that the date of service for stored specimens is the date of retrieval from the archives. But this led to questions about how long a specimen had to be stored to be considered "archived." In a proposed rule (*Federal Register*, Dec. 23, 2003), the agency suggested a time frame of more than 30 days.

Now, in a final notice issued February 25, CMS has adopted the standard of more than 30 calendar days. The agency also changed its policy on the date of service when the specimen collection spans more than 24 hours. Previously, that date was the date when the collection began. CMS now specifies the collection end-date as the date of service, noting that it is common practice in the lab community to use the end-date.

In the final notice, CMS also finalized proposals for three separate processes to request changes to the lab national coverage decisions (NCDs):

- An abbreviated process for handling requested coding changes that flow from the "covered indications" narrative.
- A streamlined process for clerical coding changes, such as when ICD-9-CM diagnosis codes or CPT procedure codes are updated.
- Reserving the normal evidence-based NCD process for substantive changes.

GSK Investigation: The Department of Justice (DOJ) is investigating whether certain pricing arrangements GlaxoSmithKline PLC (GSK) had with Medicaid violated civil statutes or laws, according to the U.K. company's March 9 filing with the Securities and Exchange Commission. The issue is whether certain pricing arrangements GSK had qualified under the "nominal price" exception to best-price reporting requirements under the Medicaid Drug Rebate Program. Company officials are cooperating with the investigation and have provided documents and information regarding nominal pricing arrangements for a number of the company's products, GSK wrote in its annual report.

FL Lab Bid Stalled: The Florida Agency for Health Care Administration has pulled back its invitation to negotiated a winner-take-all capitated contract to provide independent laboratory services to Medicaid recipients throughout the state. The agency announced the move, without comment, on February 18, following a challenge from the American Clinical Laboratory Association and protests by its two largest members, Quest Diagnostics and LabCorp. If the state awards no contract by April 1, however, a provision in this year's funding measure would automatically cut lab fees under Florida Medicaid by 10%, at least until July 1, when the state's next fiscal year begins.

Grassley Seeks Settlement Details: Legislation introduced March 16 by Senate Finance Committee Chairman Charles Grassley (R-Iowa) would require that the Department of Justice report details about how it reached settlement agreements in False Claims Act (FCA) cases. The bill proposed that the DOJ inspector general submit semiannual reports to Congress that include information about FCA settlements, such as estimated damages suffered by the government, the actual amount recovered through individual settlements, the multiplier used to calculate settlement amounts, criminal fines imposed in connection with alleged illegal activities, and whether defendants had been liable in previous cases.

Blood Billing: The Centers for Medicare & Medicaid Services (CMS) has announced new billing policies for blood and blood products furnished on or after July 1, 2005. Transmittal 496, issued March 4, provides billing instructions for a new HCPCS modifier, BL, to use when purchasing blood or blood products from a community blood bank, or when assessing charges for blood or blood products collected by the provider's own blood bank, if the charges exceed their blood processing and storage costs. Transmittal 496 is available at *www.cms.hhs.gov/manuals/pm_trans/R496CP.pdf*.

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