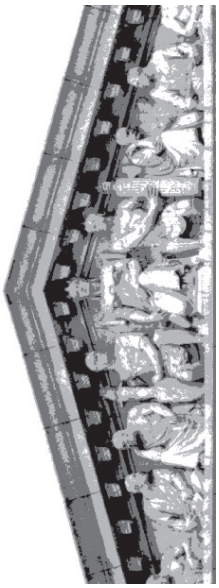

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Corporate Compliance Resource May Aid In Shielding Directors From Liability

New corporate compliance guidance developed by the HHS Office of Inspector General and the American Health Lawyers Association should help corporate boards of directors meet their oversight responsibilities and may even help protect them from liability in the event the organization is found to have broken the law.

The guidance—titled "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors" and crafted in response to widely publicized scandals that have been rocking the corporate board room—poses a series of 18 questions that boards can ask their management team. The questions are designed to help board members educate themselves on how the organization handles compliance issues and to ensure that the organization does, in fact, comply with applicable anti-fraud and abuse regulations.

Among the questions posed:

- What is the process by which your organization evaluates and responds to suspected compliance violations?
- How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?
- What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?
- What guidelines have been established for reporting compliance violations to the board?

The document also includes a discussion of a board member's "duty of care," which is defined as the "obligation of corporate boards of directors to exercise the proper amount of care in their decision-making process." In most states, this duty of care involves determining whether the directors acted (1) in "good faith," (2) with the level of care that ➥ *p. 10*

Inside this issue

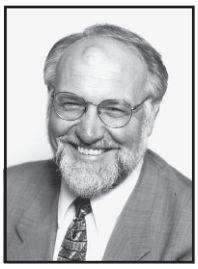
Be Careful With Phlebotomy Services To Docs

Do's & Don'ts To Avoid Anti-Kickback Violations

May clinical laboratories provide physician offices with phlebotomists without fear of violating federal anti-kickback law? Generally yes, as long as the lab and the physician office are careful in how they structure the arrangement, experts tell *G-2 Compliance Report (GCR).*

"As long as the phlebotomist is only doing phlebotomy for the laboratory that is employing him or her, there shouldn't be any problem under federal law," says attorney Hope Foster with Mintz Levin Cohn ➥ *p. 2*

Hope Foster



Larry Small

Phlebotomy Services, *from p. 1*

Ferris Glovsky & Popeo, PC in Washington, DC. But state laws must also be considered, she emphasizes.

While large independent reference labs started the marketing of phlebotomy services to physicians, an increasing number of hospital reference labs are now placing phlebotomists in physician offices as well, points out Larry Small, director of compliance and billing services for PCS Laboratory Services Group (Ann Arbor, MI). "It's becoming more and more common."

The mere placement of a lab employee in the physician's office does not necessarily serve as an inducement prohibited by the anti-kickback statute, as noted in the HHS Office of Inspector General's special fraud alert in December 1994. However, according to the OIG, the statute "is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff," such as taking vital signs or performing clerical services.

"Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory," warns the fraud alert. "In such a case, the physician, the phlebotomist and the laboratory may have exposure under the anti-kickback statute."

Do's & Don'ts

Laboratories and physician offices should keep the following tips in mind when structuring an agreement where the lab provides phlebotomy services to the physician, say Foster and Small:

DO find out what the law is in your state. Several states either prohibit it altogether or strictly limit what is allowed. In California, for example, a lab has to pay for space in the physician's office, and the phlebotomist must be available to any physician in the office building, notes Karen Nickel, chief of laboratory field services for the California Department of Health Services.

DO put the agreement in writing, specifying that the phlebotomist will perform only blood draws for its employer, the laboratory. "The agreement should make clear what the phlebotomist will not do," explains Foster. "It's always best when the ground rules are set forth at the beginning." But the mere existence of a contract prohibiting the phlebotomist from performing services unrelated to specimen collection will not protect the lab or physician office from liability if those contract provisions aren't rigorously enforced, cautions the OIG's special fraud alert.

DON'T ask a phlebotomist provided by a lab to perform work unrelated to the laboratory draws. The exception to this, says Foster, is if a physician agrees to pay fair market value for those services and if that agreement is spelled out in a contract. "The concern is the provision of free services to a physician," she notes.

DO provide separate space for the phlebotomist to perform blood draws. Designating a particular room or workstation for services related to the lab will help keep the phlebotomist from getting drawn into other office activities, says Small.

DON'T place a relatively new or timid phlebotomist in the physician office, Small advises. The best choice is a seasoned phlebotomist who understands his or her role clearly and isn't afraid to say no if asked to perform a task not authorized by the agreement. "You need someone who has the backbone to stand up to a physician when needed."

DO ensure that the office manager and staff understand the limits placed on the phlebotomist. This may involve some on-site training by the laboratory outreach coordinator, Small says. The coordinator should also make unannounced, documented visits periodically to ensure that the phlebotomist and the physician office are abiding by the agreement.

Resources

- Hope Foster: 202-661-8758
- Larry Small: 727-866-1311
- Karen Nickel: 510-873-6360
- OIG special fraud alert on provision of phlebotomy services to physicians: *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html*

Do Your Privacy Policies Conflict With State Laws?

HIPAA Requires Compliance With Strictest Provisions

Healthcare providers and other entities covered by the HIPAA medical privacy rule should take care that they follow state laws governing privacy if those laws are more stringent than requirements mandated under the Health Insurance Portability & Accountability Act of 1996.

HIPAA's medical privacy requirements set the "floor" for compliance but do not preempt state laws that are tougher than the federal requirements. The HIPAA privacy rule took effect this Apr. 14 for most covered entities that conduct healthcare transactions electronically (small health plans have an extra year to comply).

In general, a state law is more stringent if it provides greater privacy protection than the federal rule when it comes to safeguarding individually identifiable health information. If a more stringent state law is contrary to a provision of the federal privacy rule—in other words, it would be impossible to comply with both—the state law prevails. If the more stringent state law and the federal privacy rule are not contrary, covered entities must comply with both.

To determine which law is more stringent and thus takes precedence, providers should consult a preemption analysis for their state, advises attorney Elspeth Delaney with Hooper, Lundy & Bookman Inc. in Los Angeles, CA. Many state agencies and law firms have already conducted this type of analysis; in some cases, they make it public on the Internet (*www.hipaadvisory/com/regs/StateLaws/htm*).

> ***HHS may, upon specific request from a state or other entity, issue a determination that a contrary state law that meets certain criteria will not be preempted by the federal requirements. This typically would be done only if necessary to prevent fraud and abuse, to ensure appropriate state regulation of insurance and health plans, for state reporting on healthcare delivery or costs or to serve a compelling need related to public health or safety. HHS explained the process for requesting a preemption exception determination in the March 11, 2003* Federal Register**

"Providers don't necessarily have to do a full-blown preemption analysis themselves, but they should consult with someone in the state where they operate to make sure that by complying with HIPAA, they're not actually violating state laws," she explains.

For example, HIPAA allows providers 30 days to respond to a patient's request to access his/her medical records, but California gives providers only five days if the patient wants to inspect the records and 15 days if the patient wants copies of the record. Therefore, providers in California must follow the state's more stringent requirements.

State Laws Vary

Not all states have privacy laws that are stricter than the HIPAA privacy requirements, although several—including California, New York, Florida and Texas—are known for their tough stance on privacy, Delaney notes. In many states, the HIPAA provisions will be more stringent. Some states, however—such as Colorado and Oregon—are considering modifying their laws to align them more with the HIPAA requirements, she adds. "State laws vary tremendously, which can make it difficult to figure out which is more stringent. It really depends on where the provider operates."

Typically, where HIPAA and state laws differ, it relates to the number of days a provider has to respond to requests for access to medical records, provisions governing the reporting of communicable diseases and issues involving minors. In determining which law is more stringent, a covered entity should con-

sider which provides patients with greater access or requires fewer disclosures.

For example, if a state law provides greater privacy protection to a patient's HIV information than the HIPAA privacy rule, the provider should comply with the state law. Similarly, if a state law provides for the reporting of child abuse that is contrary to the federal privacy rule, the provider should comply with the state law.

If a provider has already written privacy policies that are in conflict with more stringent state laws, the provider should not despair, says Delaney. "There is still a lot of confusion out there, especially among smaller providers. You can still go back and revise your policies if you need to."

Resources

- Elspeth Delaney: 310-551-8138
- HIPAA final privacy rule (published Aug. 14, 2002; effective Apr. 14, 2003) and frequently asked questions: *www.hhs.gov/ocr/hipaa*

Interim HIPAA Enforcement Rule Released

The U.S. Department of Health & Human Services plans to adhere to the Office of Inspector General's civil money penalty (CMP) procedures in enforcing the electronic data exchange provisions of the Health Insurance Portability & Accountability Act (HIPAA), the agency said Apr. 15.

In an interim final rule in the Apr. 17 *Federal Register*, HHS sets forth the procedures it will follow in imposing civil money penalties for violations of the HIPAA medical privacy rule, as well as the HIPAA electronic transaction/code set standards and the security rule. Compliance with the federal privacy rule became mandatory for most covered entities this Apr. 14.

While HHS intends to promote "voluntary compliance" with HIPAA regulations, it is explaining its general enforcement approach and procedures because "the duty to comply with certain of the HIPAA rules is now a reality for many, if not most, covered entities," says the agency.

By law, HHS is charged with civil enforcement of HIPAA and the U.S. Department of Justice is charged with criminal enforcement. Providers that violate the HIPAA provisions face civil penalties of up to $100 for each violation (up to $25,000 per person, per year). Criminal penalties range from up to $50,000 and one year in prison to $250,000 and 10 years in prison.

The Apr. 17 interim final rule focuses solely on procedural components of CMP assessments, such as definitions of parties and penalties; subpoena and settlement authorities; and explanation of hearing, discovery and decision appeal rights and procedures. The rules does not specify which activities will constitute violations of HIPAA or how specific penalty amounts will be calculated, leaving those substantive issues for future rulemaking.

The interim final enforcement rule becomes effective May 19, 2003. For details, see *Federal Register*, Apr. 17, 2003 at *www.access.gpo.gov/su_docs*.

Lawsuit Challenges Privacy Rule

A coalition of patient advocacy groups, physician organizations and other medical professionals filed a lawsuit on Apr. 10 charging that the HIPAA medical privacy rule actually eliminates patients' rights (*Citizens for Health v. Thompson*).

The suit, brought by Citizens for Health, the American Association of Practicing Psychiatrists and others, asked the U.S. District Court for the Eastern District of Pennsylvania to enjoin further implementation of the August 2002 privacy rule amendments and declare them invalid on a number of grounds. The suit alleges that in the revised rule, the U.S. Department of Health & Human Services and Secretary Tommy Thompson illegally reverse course and eliminate the right of consent in the original HHS rule governing disclosure to third parties of personal medical records and communications between doctors and patients.

The amended rule "eliminates the right of privacy of individuals for their personal medical records and jeopardizes the privacy of past and future communications between patients and their physicians and practitioners within the context of the patient-physician relationship," the complaint said.

COMPLIANCE PERSPECTIVES

Compliance Hot Spots For Hospitals: Keeping Up With OIG Enforcement Targets

Robert Rabecs, Esq., is an attorney in the health law practice of Hogan & Hartson, LLP, Washington, DC

The Fiscal Year 2003 Work Plan of the Office of Inspector General (OIG) at the U.S. Department of Health & Human Services identifies a number of enforcement initiatives relevant to hospitals. Many initiatives reflect new areas of OIG focus, while others are continuations of previously announced projects. The areas identified by the OIG in the work plan, as well as recent OIG enforcement actions, suggest that hospitals should focus on numerous issues involving the submission of Medicare and Medicaid claims in order to reduce exposure under false claims laws.

Inappropriate coding or billing can be very costly for hospitals because enforcement actions will not necessarily be considered overpayment matters, but instead may be handled as false claims. The submission of false claims to federal healthcare programs, such as Medicare and Medicaid, can result in significant criminal and civil penalties, including fines and exclusion from participation in federal healthcare programs.

Below are some of the current key enforcement initiatives.

Medicare Outlier Payments

The work plan includes a review project for "Medicare Hospital Outlier Payments, " noting that the OIG will examine whether such payments made to hospitals were appropriate and will assess the adequacy of controls over these payments.

Beginning in October 1983, Medicare reimbursement to hospitals for inpatient services was moved to a prospective payment system (PPS). Under PPS, hospitals are reimbursed at a predetermined rate for services based on each patient's diagnosis. For each diagnosis there is a corresponding diagnosis-related group, or DRG, used by the hospital to bill Medicare. Pursuant to this payment methodology, hospitals have an incentive to control costs because, with limited exceptions, the reimbursement they receive from Medicare for any given inpatient stay will generally be the same regardless of the costs incurred by the hospitals.

Congress recognized that hospitals occasionally would encounter an unusually costly case. In those instances, the standard payment for a DRG would be insufficient reimbursement. To avoid placing the burden of these higher costs on hospitals, Congress authorized payment for the costs of these exceptional cases in addition to the standard PPS payment. Unlike other payment adjustments made under PPS, outlier payments are not claimed and adjudicated through the Medicare cost report, but are paid on a claim-by-claim basis. The amount of outlier payment received by a particular hospital depends on a number of factors, including the hospital's charge structure and patient acuity.

Over the last 10 years, the OIG has audited hospitals and fiscal intermediaries periodically with respect to outlier payments. Most of the OIG reviews in past years have been narrow in focus, checking the documentation and medical necessity of the services that produced the outlier charges. However, it appears that a more recent concern of the OIG has been changes to hospital charge structures designed to increase outlier payments. Under current law, the outlier payment is calculated as a percentage of the difference between the hospital's estimated cost of a case and the outlier threshold for the case. The cost of a case usually is estimated at the time the claim is submitted by multiplying the hospital's

For Fiscal 2003, the outlier threshold is set at $33,560 per case, up from $21,025 for FY 2002

current charges by its cost-to-charge ratio (CCR). The CCR is computed on the basis of the hospital's historical cost and charge data from its most recently settled cost reporting period. Thus, where charges increase significantly faster than costs, the CCR may be affected in such a way that a hospital can claim increased outlier payments.

In November 2002, the OIG announced it was commencing an investigation into outlier payments made to hospitals operated by Tenet Healthcare. In recent years, Tenet has aggressively raised its gross charges for services. As a result, according to published reports, Tenet's outlier payments increased from $351 million in 2000 to $763 million in 2002. The OIG began auditing outlier claims at 100 Tenet hospitals in December 2002. In response to the scrutiny, Tenet announced it was voluntarily changing its billing policies in order to reduce Medicare outlier payments by as much as $57 million each month.

The HHS Centers for Medicare & Medicaid Services (CMS) has also announced its own review of the Medicare outlier program. In December 2002, the agency indicated that it would be increasing reviews of hospitals with unusually high numbers of Medicare outlier payments and would direct fiscal intermediaries to undertake immediately a close review of hospital practices. In March 2003, CMS unveiled a proposed rule intended to fix at least one vulnerability in the current system––the time lag associated with use of historical data to estimate a hospital's current cost of a case (*GCR, Apr 03, p. 3*).

In light of the OIG focus in this area, hospitals may wish to consider a number of precautionary steps. They should examine their policies for determining gross charges and whether those charges have been increasing rapidly in recent years. Also, hospitals may wish to consider:

- ❖ temporary freezes on increases in gross charges pending further clarification from CMS
- ❖ bringing gross charges into closer alignment with actual prices charged to patients and insurers, and
- ❖ pursuing managed care and preferred provider contracts based on negotiated per diem rates rather than discounts off of gross charges.

Pneumonia Upcoding

The OIG work plan also indicates that the OIG will examine DRGs that have a history of aberrant coding. A particular focus appears to be upcoding for bacterial pneumonia. Upcoding is the practice of assigning DRGs to Medicare that are not supported by the physician's documentation in the medical record in order to receive higher reimbursement. DRG 79 results when a physician diagnoses that the patient's pneumonia was caused by a specific bacterium and there is no other ICD-9-CM diagnosis code for that particular pathogen (ICD-9-CM 482.89 - bacterial pneumonia - other specified bacteria). DRG 89 results when the physician has not diagnosed a specific bacterium as the cause of the pneumonia (ICD-9-CM 482.9 - bacterial pneumonia - unspecified).

The OIG is concerned that many hospitals have been improperly using diagnosis codes that result in DRG 79 for admissions when the physician has not documented a specific bacterium as the cause of the pneumonia. In such cases, the hospitals should have assigned a different diagnosis code, which would result in DRG 89. Medicare reimbursement per discharge for DRG 79 is significantly higher than for DRG 89. The higher rate reflects the increased level of difficulty involved in treating the patient.

The OIG's pneumonia upcoding initiative has resulted in a number of recent federal government settlements with hospitals. In February 2003, five Florida hospitals paid $4.3 million to settle charges that they upcoded pneumonia cases. The alleged violations occurred from 1993 through 1997. Also earlier this year, Integris Baptist Regional Health Center in Oklahoma agreed to pay nearly $520,000 to resolve federal allegations of upcoding between October 1993 and October 1998. As part of the settlement, Integris also agreed to develop a corporate compliance program. A recent OIG report indicated that the OIG was investigating more than 100 hospitals for pneumonia upcoding.

While pneumonia coding has attracted much government attention, hospitals should assess their coding for other diagnoses as well. Maintaining appropriate documentation to support the diagnosis and resulting DRG code is key to avoiding enforcement actions.

Physicians At Teaching Hospitals

In 1996, the OIG announced a nationwide initiative, known as PATH (Physicians at Teaching Hospitals), to review compliance with rules governing the Medicare Part B payment for doctors at teaching hospitals. The initiative was designed to ensure that all claims for teaching physicians' services accurately reflected the level of care provided to the patient.

OIG Website Helps You Keep Tabs On Enforcement Actions

The OIG Work Plan for Fiscal Year 2003, as well as recent enforcement actions, pinpoint areas of current interest to the OIG and, therefore, areas which hospitals should closely monitor. In this regard, earlier this year, the OIG launched a new enforcement section on its Website. The "Fraud Prevention and Detection" section (*http://oig.hhs.gov/fraud enforcementactions.html*) includes summaries of recent cases that have been resolved as well as background information on the general categories of enforcement actions undertaken by the OIG.

Under Medicare billing rules, in order to receive reimbursement from Part B for professional services, the teaching physician must have either provided the services personally or been personally and identifiably involved in the performance of services that were rendered by an intern or resident.

Although the number of PATH investigations and settlements has decreased in recent years, teaching hospitals should not think they no longer need fear PATH investigations. In fact, the PATH initiative has resulted in numerous investigations and settlements involving teaching hospitals over the last year. Most notably, in February 2003, Johns Hopkins University agreed to pay $800,000 to resolve allegations that it fraudulently billed Medicare for the services of its teaching physicians. The settlement agreement resolves a federal investigation arising from alleged improper billings for the services of the university's teaching physicians to Medicare beneficiaries from January 1994 to December 1994. According to the government, the claims did not contain "sufficient documentary evidence" showing that the physicians were personally involved in providing the services for which payment was claimed. Instead, the government contended, the services actually were delivered by an intern or resident of the teaching hospital. Under terms of the settlement, Johns Hopkins agreed to review its Medicare billing practices to ensure that teaching physicians properly document their involvement in the care they bill to Medicare.

The possibility of a PATH enforcement action requires teaching hospitals to ensure that proper documentation is maintained for professional services billed through teaching physicians affiliated with the institution. The medical record must reflect physicians actually spending time with the patient—not just reviewing and approving the work of a resident or intern. The initiative encourages teaching hospitals to examine their Medicare billing practices by voluntarily participating in a review under a self-audit protocol established by the OIG.

Miscellaneous Projects

The OIG Work Plan for Fiscal Year 2003 identifies other projects involving hospitals, none of which has resulted in any reported enforcement activity this year. However, hospitals should remain mindful of these projects, which include:

- Hospital quality oversight (focusing on accreditation and state agency certification of Medicare-participating hospitals);
- Medicare payment claims by long-term care hospitals operating as satellite units of host hospitals (focusing on whether average length of stay requirements are being met by hospitals);
- Inpatient psychiatric stays in PPS-exempt and specialty psychiatric hospitals (focusing on whether the medical necessity for services furnished in such facilities is supported by the patients' medical records);
- Medicaid hospital patient transfers (focusing on whether hospitals are correctly reporting such transfers);
- Review of critical access hospitals' cost reports (to ensure that reported costs for inpatient and outpatient care are reasonable); and
- Review of hospitals' efforts to collect Medicare beneficiary copayment and deductible amounts.

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Two Drug Companies Pay $344 Million To Settle Overcharge Allegations

In the largest-ever Medicaid fraud settlements, Bayer Corp. (Leverkusen, Germany) and GlaxoSmithKline (London, England) have agreed to pay more than $344 million to settle allegations that they illegally repackaged drugs and sold them at prices below those paid by the Federal Government and state Medicaid programs.

Bayer will pay $257 million, including a $5.6 criminal fine. GlaxoSmithKline will pay $87.6 million in civil damages. About 55% of the settlement will go to the Federal Government, 45% to 49 states and the District of Columbia.

According to Michael Sullivan, U.S. attorney for the District of Massachusetts, the two pharmaceutical firms engaged in a scheme known as "lick and stick," in which they sold re-labeled drugs to the Kaiser Permanente Medical Care Program at deeply discounted prices, then concealed the arrangement from the government, thereby avoiding an obligation to pay millions of dollars in additional rebates to Medicaid.

Federal law requires drug manufacturers participating in the Medicaid program to report their "best prices" to the Federal Government and to pay rebates to Medicaid to ensure the program receives the same favorable drug prices offered to other large purchasers of drugs.

The charges against Bayer and GlaxoSmithKline are the first brought against any drug manufacturer for a "lick and stick" scheme, said Sullivan. He declined to say whether other firms are being investigated for similar activities.

The Bayer settlement resolves criminal charges and civil liabilities in connection with pricing of Cipro, an antibiotic, and Adalat CC, an extended release anti-hypertensive. GlaxoSmithKline's agreement settles civil False Claims Act liabilities in relation to the re-labeling of Paxil, an anti-depressant, and Flonase, a nasal spray.

"We are experiencing a time of skyrocketing prices for prescription drugs, where state and federal budgets are stretched to the breaking point," Sullivan said in announcing the settlements. "The effect of leading corporations seeking to avoid paying millions of needed dollars to our nation's healthcare programs can be devastating.

"Such conduct by pharmaceutical companies is intolerable and we in law enforcement will remain focused on protecting our nation's Medicaid program."

Resource

❖ Michael Sullivan: 617-748-3139

Lab Owners Convicted In California False Claims Case

In what is believed to be the biggest criminal case of its kind in California, the owners of a Glendale medical laboratory were sentenced on Apr. 7 to 51-month prison terms for submitting about $19 million in false claims to Medi-Cal, the state's Medicaid program. Luisa Gonzalez and Juan Carlos Ciraolo, who operated the Los Angeles Bio-Clinical Laboratory in the mid-1990s, also were ordered to pay $6,413,319 in restitution.

The two were charged with submitting false claims to Medi-Cal for blood tests in 1996 and early 1997, according to federal prosecutors. The claims indicated that the lab tests were ordered by particular physicians for specific patients. In reality, the "referring physicians" listed on the Medi-Cal claim form did not refer blood samples to the lab, nor did the samples belong to the patients identified on the claim forms, according to Debra Yang, U.S. attorney for the Central District of California.

Three other defendants have also been convicted on federal charges related to the billing scheme. Ciraolo's wife, Constanza, is scheduled to be sentenced Apr. 28; Alfredo Morales, an owner of La Guadalupana Medical Clinic, is scheduled to be sentenced May

12; and Dr. Luis Lombardi, the owner/operator of San Gabriel Medical Clinic, was previously sentenced to probation. A sixth defendant in the case, Roberto Calderon, is a fugitive who is being sought by authorities.

According to Yang, La Guadalupana Medical Clinic and San Gabriel Medical Clinic facilitated the fraudulent billing scheme. La Guadalupana was used as a location to purchase blood from individuals. Morales, using La Guadalupana, and Lombardi, using San Gabriel, then created false records to submit the purchased blood samples for testing to Los Angeles Bio-Clinical Laboratory.

Gonzales and Ciraolo paid Morales and Calderon for the blood samples and corresponding false records, authorities charged. The proceeds from the fraudulent billing to Medi-Cal were diverted to various personal bank accounts owned by Gonzales and Ciraolo.

Resource

❖ Debra Yang: 213-894-6947

Court Clears Whistleblower Case Against Illinois Lab

The U.S. District Court for the Northern District of Illinois will allow a *qui tam* (whistleblower) action against Genesis Clinical Laboratory (Berwyn, IL) to go forward, clearing the way for whistleblower Sandra Johnson to proceed with charges that the lab improperly bundled tests.

The court on Mar. 27 denied a motion by Genesis to strike the testimony of Johnson, who began serving as director of operations for the lab in 1994. Johnson alleged that the requisition form that Genesis used bundled tests and encouraged physicians to order tests that were not medically necessary.

In addition, Johnson contended, billing clerks at Genesis improperly entered diagnosis codes on their own so the lab could bill Medicare more quickly. Under Medicare regulations, a valid diagnosis must be given by a physician for every test billed to Medicare. Johnson estimated that Genesis filed about 10,000 false claims between 1994 and 1997. Shortly after informing Genesis about the Medicare violations, Johnson was terminated.

Attorneys for Genesis argue that Johnson's allegations of 10,000 false claims is "mere speculation." Further, Johnson's job responsibilities did not include overseeing Medicare billing, they contend, asserting that she had never actually seen a false claim submitted by Genesis.

Whether Genesis filed 10,000 false claims was not particularly relevant, the court determined, noting that its concern is whether Genesis was liable under the federal False Claims Act. "There is no legal requirement that Johnson must have physically held a bill submitted by Genesis and scrutinized its information for Medicare compliance," wrote Chief District Judge Charles Kocoras. "Whether or not that circumstantial evidence is sufficient to establish Genesis' liability is a determination" for the court.

CMS Chief Sued For Attempted Intimidation

The Gallup Organization has filed a lawsuit against the head of the Centers for Medicare & Medicaid Services, Thomas Scully, charging him with attempting to intimidate a senior official of Gallup.

According to the lawsuit, filed Apr. 8 in the U.S. District Court for the District of Columbia, Scully tried to intimidate Gallup managing partner for healthcare programs Robert Nielsen after the public opinion survey organization attempted to make the Office of Management & Budget (OMB) aware of "potential collusion" between Scully's agency and another survey firm.

Gallup alleges that Scully tried to dissuade OMB official Brenda Aquilar from meeting with Nielsen about concerns that a survey of hospital performance data was tainted by the involvement of government employees with conflicts of interest. Scully reportedly told Aquilar in an e-mail that "if you meet with this guy, it will be the last time I ever speak to you about CMS issues." In an e-mail to Nielsen, Scully allegedly called him a "weasel" because "you can't come discuss this with me like a normal person."

House Commerce Committee chairman W.J. "Billy" Tauzin has launched an investigation into the allegations and into the processes used to select the vendor to administer the hospital survey.

Corporate Compliance Resource, *from p. 1*

an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interests of the organization.

Demonstrating "Good Faith"

While the guidance does not offer definitive legal protection to boards of directors, it can help shield directors when used as an integral part of an otherwise complete compliance program, says attorney Sandy Teplitzky, a shareholder with Ober/Kaler (Baltimore, MD).

"It demonstrates the good faith of the board of directors in terms of the corporate compliance program," he explains. "There has been some case law over the years, including the *Caremark* case a few years ago, indicating that the board doesn't have to be involved in the day-to-day implementation of the compliance program. However, it has to know about the program, it has to adopt the program, it has to be briefed on the program and it has to ask the right questions along the way. This is a very helpful document in terms of identifying the kinds of questions that boards ought to address."

The new guidance may come too late for HealthSouth Corp. (Birmingham, AL), which has been charged with accounting fraud and now faces bankruptcy. The company's Board of Directors recently announced that it is adopting new corporate governance guidelines to ensure adequate separation between the board and management

In the *Caremark* case, a shareholder sued the Board of Directors of Caremark International for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal healthcare programs. The court found that corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

Asking questions about the compliance program, following-up on the answers and documenting the exchange can be particularly important if the corporation is found to have violated the law, Teplitzky notes. "You would be in a better position to argue, for example, that the problem is a rogue employee or somebody not following the corporation's compliance program."

That said, it's important to keep in mind that the questions posed by the guidance document are a starting point, not an ending point, he adds. "There may be questions that aren't here that may be appropriate for particular organizations. As with everything else, you need to adapt your compliance activities to your business."

Resource

- Sandy Teplitzky: 410-347-7364
- OIG guidance, "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors": *http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf/*

JCAHO Moving Toward Unannounced Surveys

The Joint Commission on Accreditation of Healthcare Organizations plans to begin conducting all regular accreditation surveys on an unannounced basis beginning in January 2006. Unannounced surveys will be pilot-tested in volunteer organizations during 2004 and 2005.

"The new accreditation process—dubbed Shared Visions-New Pathways—creates the expectation that each accredited organization be in compliance with 100% of the commission's standards 100% of the time," says JCAHO president Dennis O'Leary, MD. "Organization leaders we talked to not only agreed with this expectation but further suggested that the next logical step would be the introduction of unannounced surveys."

During 2004, the Joint Commission expects to initiate pilot testing of the unannounced triennial survey process in up to 100 hospitals that have volunteered to be among the first participants. Four multi-hospital systems and alliances—Ascension Health, Tenet Healthcare, the Veterans Health Administration and North Shore-Long Island Jewish Healthcare System—have committed to having a number of their hospitals participate in triennial surveys in 2004 or 2005.

For the Record

New Timeframe For Appealing Medicare Claim Determinations

Effective Apr. 1, physicians, suppliers and beneficiaries have an additional 60 days to file appeals of Medicare Part B claim determinations made on or after Oct. 1, 2002.

The Medicare Benefits Improvement & Protection Act of 2000 (BIPA) implemented a uniform 120-day timeframe for requesting appeals of initial determinations for Part A and Part B claims. Prior to BIPA, requests for Part B reviews had to be filed within 180 days and requests for Part A reconsiderations had to be filed within 60 days of an initial determination.

Thus, under the BIPA provisions, providers and beneficiaries would have an additional 60 days to appeal Part A claims, while physicians and other suppliers (as well as beneficiaries) would have 60 days fewer to file an appeal of a Part B claim.

"The physician and supplier communities have argued that it is unfair for the [Centers for Medicare & Medicaid Services] to implement the shorter timeframe for Part B appeal requests absent full BIPA implementation," notes CMS in Transmittal AB-03-039, issued Mar. 28. Making the transition to the shorter filing timeframe may be difficult in situations where appellants need to obtain documentation from other sources in order to file an appeal, the agency acknowledges.

"In order to alleviate any hardship associated with the possible need to gather documentation faster than in the past, we are instructing all contractors to grant extensions of up to 60 days in the 120-day filing deadline for appeals of Part B claims, provided that the appeal request includes a credible explanation from the beneficiary, physician or supplier that the time was needed to gather the necessary supporting records," says CMS in the transmittal.

Extensions will be granted for appeals of initial determinations made on or after Oct. 1, 2002. Once a final regulation to implement all BIPA provisions is released, CMS will issue further instructions.

Transmittal AB-03-039 is available at *http://cms.hhs.gov/manuals/memos*.

OIG Nixes Management Reimbursement Arrangement

The HHS Office of Inspector General has declined to sign off on a company's proposal to develop and manage distinct-part inpatient rehabilitation units in general acute care hospitals in exchange for a management fee.

In an advisory opinion issued Apr. 3 (No. 03-8), the OIG said the arrangement could generate prohibited payments under the anti-kickback statute and could be subject to administrative sanctions.

The type of compensation treated in the opinion—calculated on a per patient per day basis—was generally thought to be safer than a percentage fee arrangement and is common in hospitals, say health lawyers. In fact, Brad Tully, an attorney with Hooper, Lundy & Bookman (Los Angeles, CA) notes that this type of arrangement is fairly common for all kinds of programs, not just rehabilitation programs.

The OIG concluded that the plan would not qualify for the personal services safe harbor under the anti-kickback rule because the aggregate compensation paid by hospitals to the requesting company under the management agreement would not be set in advance, as required by the safe harbor. The principal concern is that "per patient" and similar arrangements promote overuse and unnecessarily lengthy stays, the OIG said, adding that while the arrangement has certain features that appear to reduce the risk, it cannot conclude that the residual risk is sufficiently low to grant protection prospectively.

Advisory Opinion No. 03-8 is available at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0308.pdf*

More Outlier Fallout? Tenet Healthcare Corp. (Santa Barbara, CA) may face up to $5 billion in legal liability to the Federal Government resulting from what a company shareholders' group said was a scheme by the hospital chain to defraud Medicare through inflated outlier payments. In a letter to Thomas Scully, administrator of the Centers for Medicare & Medicaid Services, the Tenet Shareholder Committee said it had conducted a two-month investigation and legal analysis of Tenet's legal liability with regard to Medicare outlier payments and found the hospital chain may have "exorbitantly" increased its charges. Tenet has been under federal investigation for receiving unusually high outlier payments in the past several years.

Contractual Joint Ventures: The HHS Office of Inspector General has cautioned providers serving Medicare and Medicaid beneficiaries against entering into joint venture arrangements that reward providers for improper patient referrals. In an Apr. 23 advisory bulletin, the OIG warned about the use of "shell" entities and subcontracting arrangements with providers of related health services, such as durable medical equipment or home oxygen suppliers, to disguise illegal kickbacks. The bulletin is available at *http://oig.hhs.gov/fraud/docs/alertandbulletins/042303SABJointVentures.pdf*.

Sexual Harassment Settlement: Lutheran Medical Center in Brooklyn, NY, has agreed to pay $5.4 million and institute a program of remedial measures to settle sexual harassment charges involving the conduct of a staff physician who conducted job-related physical examinations of female employees, the Equal Employment Opportunity Commission announced Apr. 9. This is the largest settlement the EEOC has obtained in any case in New York. Lutheran Medical was charged with failing to act on complaints by nurses that they had been subject to sexually invasive touching and intrusive questioning by the physician during pre-employment or post-medical leave examinations.

Don't Misuse "Medicare": The HHS Office of Inspector General issued an alert Apr. 8 reminding individuals and organizations that it is a violation of federal law to misuse words, symbols or emblems of the U.S. Department of Health & Human Services to market their services. The alert was prompted by what the OIG calls "particularly egregious" violations by U.S. Seminar Corporation (La Mesa, CA), which has been fined more than $1 million. According to the OIG, U.S. Seminar has sent hundreds of thousands of solicitations to healthcare providers in which it has used the words and letters of the Medicare program and HHS in a way that could be construed as conveying the impression that its seminars are approved, endorsed or authorized by Medicare.

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