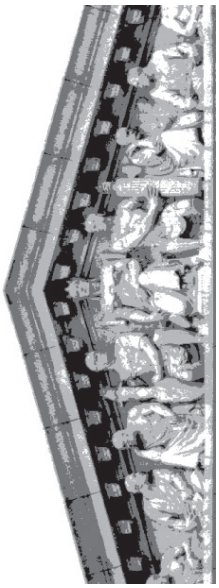

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

New Pathology "Pod" Labs Raise Concerns

A new type of business arrangement in which specialty physicians send pathology referrals to laboratories they operate could potentially drain revenue from local pathology groups, say attorneys and lab groups, who note that these structures raise serious legal and compliance issues.

Under these arrangements, referring physicians such as urologists or dermatologists enter into contracts with outside managers who set up "turnkey" laboratories to which these physicians can refer their pathology specimens. The outside manager also supplies the pathologists who provide the services. Often, in an attempt to comply with federal Stark law requirements, the manager sets up numerous separate "pod" laboratories in a single space, with each pod dedicated to referrals from a separate group practice.

According to the American Clinical Laboratory Association, the growth of these new labs has been fueled by two related developments. First, phase II of the Stark II rule implementing the federal ban on physician self-referrals has eased the in-office ancillary services exception so that, in effect, the pathologist no longer has to be an employee or shareholder in the group practice that refers the work. These rules, released March 25, are effective as of July 26 (*GCR, April 2004, p. 1*).

Second, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 eased the prohibition on reassignment of benefits, allowing physicians to bill for services performed elsewhere so long as the billing physician has a contractual arrangement with the entity furnishing the services (*GCR, April 2004, p. 1*).

This change has also made it easier for referring physicians to bill for these services, notes ACLA, which is concerned that the change ➥ *p. 2*

Government Targets Physician Recruitment Practices

Ongoing Case Has Chilling Effect On Relocation Deals

Physician recruitment practices are coming under increased scrutiny as federal investigators review whether some of the practices, such as offering relocation packages, amount to illegal inducements for referrals.

While criminal charges filed against Alvarado Hospital Medical Center in San Diego is the most prominent case filed thus far, the U.S. attorney in Los Angeles reportedly is conducting a criminal investigation into the practices of some southern California hospitals, and federal investigators in El Paso, Texas, are looking into ties between doctors in that city and Tenet Hospitals.

"This is an area that is under definite scrutiny by the U.S. attorneys community as well as the Office of Inspector General," says Kathleen McDermott, an attorney ➥ *p. 9*

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Pathology "Pod" Labs, *from p. 1*
could have even broader implications if it is interpreted to permit laboratories to bill referring physicians for anatomic pathology services.

Jane Pine Wood

Significant Risk

These new pathology pod arrangements involve significant risk, notes Jane Pine Wood, an attorney with McDonald Hopkins Co. LPA (Dennis, MA). Medical groups who engage in these practices face increased fraud and abuse compliance concerns, increased malpractice risk, continuing administrative and oversight responsibilities, financial expenditures, license and certification issues, and payer issues.

Because pathology services are subject to the Stark self-referral prohibition, it is important that the structure and operation of an in-house histology laboratory by a referring physician practice comply with the in-office ancillary service exception. This exception protects referrals made by a physician to his or her own practice for designated health services (including pathology services) that are provided through his or her practice. The requirements for this exception are substantial, encompassing several pages of regulations, says Wood.

"If the gastroenterology, urology, or dermatology practice with an in-house histology laboratory fails to meet any of the requirements of this Stark exception, then the physicians are subject to the significant penalties for violation of the Stark law, including repayment of the Medicare and Medicaid amounts paid for the pathology services, substantial civil fines, and exclusion from the Medicare and Medicaid programs," she explains.

Pod labs also present issues under the Medicare and Medicaid anti-kickback law, according to Wood, who notes that under a 1989 special fraud alert on joint-venture arrangements issued by the Department of Health and Human Services Office of Inspector General (OIG), many in-house histology laboratories would be labeled as suspect. They would also be suspect under criteria listed in an April 2003 OIG special advisory bulletin on contractual joint ventures (*www.oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVenture.pdf*).

In fact, Vicki Robinson, chief of the OIG industry guidance branch, said recently that her office is concerned about this new type of business arrangement and believes many of them would not comply with the Stark law. Robinson urges organizations that are contemplating such arrangements to review the April 2003 bulletin. In addition, Sen. Charles Grassley (R-IA), chairman of the Senate Finance Committee, has requested that the OIG examine the structure of pod labs and report on their legality.

Wood says she would advise any physician group considering a pod lab to move slowly. "If they're a large enough group that they can put it in their own space and hire a pathologist full-time, I'm not concerned, but the off-site labs raise a lot of issues," she notes.

ACLA Seeks Limits

Because of its concern over the proliferation of pod labs, ACLA has asked CMS to ensure that steps be taken to limit these new arrangements. Specifically, ACLA wants CMS to:

- Clarify that entities must meet the applicable requirements of the self-referral law even if they qualify for the new contractual arrangement exception to the general ban on reassignment of benefits.
- Define more clearly what is considered a "centralized building" to prevent the space from being subdivided into "pod" labs. ACLA also favors requiring that use of the space be on a full-time basis and be "commercially reasonable." Further, ACLA wants CMS to consider requiring that the centralized building be within a certain radius of the group-practice offices. Certain "pods" are located a great distance from the groups they serve and sometimes are not even in the same city or state.
- Clarify the term "physician in the group" to specify that a pathologist who is hired by the physician practice to supervise technical staff cannot furnish billable services in a centralized building unless the pathologist is a member of the practice.

Resources

- ACLA: 202-637-9466
- Jane Pine Wood: 508-385-5227

For a more detailed discussion of pod labs, be sure to sign up for Washington G-2 Reports' next audio conference—"Pathologists in the Crosshairs: Legal Spotlight on Specialty Labs Run by Non-Pathology Medical Practices." The program will be on August 5 from 2:00-3:30 p.m. For more info, visit our Web site at g2reports.com.

Draft Supplemental Hospital Compliance Guidance Provides Insight, Raises New Issues

Charles Oppenheim

Draft supplemental compliance guidance for hospitals issued in June is a useful update to the original guidance published in 1998 but also raises some interesting issues.

The new guidance, published by the Health and Human Services Office of Inspector General (OIG) in the June 8 *Federal Register*, focuses on areas of current concern and future OIG enforcement activity while continuing to emphasize the principles from the 1998 guidance. According to an analysis of the draft by the law firm of Foley & Lardner LLP, the supplement identifies eight new areas of potential risk:

1 ***Submission of claims and information.*** The OIG believes that the current risks in this area fall into four general categories—outpatient procedure coding, admissions and discharges, supplemental payments (including passthrough items and outlier payments), and information technology. Hospitals should pay particular attention to proper coding and code usage, be vigilant about various types of improper claims, and thoroughly assess all new information technology and software, according to the supplement.

> ***The OIG does not articulate the basis for its conclusion that a hospital could face anti-kickback scrutiny if it requires physicians to perform more procedures than required clinically to maintain their privileges***
>
> ***—Charles Oppenheim***

2 ***Anti-kickback and physician self-referral statutes.*** The OIG encourages hospitals to carefully examine all business relationships to ensure they comport with the Stark law and the anti-kickback statute. The draft also highlights the misuse of medical staff credentialing as an area that could trigger anti-kickback violations. The OIG identifies as risky those situations where a hospital conditions privileges on a particular number of referrals or requires the performance of a particular number of procedures when the number of referrals or procedures exceeds what is necessary to ensure clinical proficiency. However, the OIG indicates that it will not view a credentialing policy that categorically refuses privileges to physicians with significant conflicts of interest with the same skepticism. The OIG has requested comments on this issue to determine whether future guidance in this area is necessary.

3 ***Payments to reduce or limit services (e.g., "gainsharing" arrangements).*** The OIG notes that a number of hospitals have engaged in or considered creating incentive relationships wherein physicians share in any reduction of the hospital's patient care cost attributable, in part, to the physician's efforts. The OIG believes that, even though such relationships can service legitimate business purposes, they may contradict the plain language of the prohibition on paying physicians to reduce or limit items or services provided to Medicare or Medicaid patients. These arrangements might also implicate the anti-kickback statute, if such payments influence referrals. The OIG suggests that whenever possible, hospitals should consider structuring cost-saving arrangements to fit in the personal services safe harbor, although the OIG acknowledges that this protection may not be available to many gainsharing situations, since they typically involve a percentage payment, and the safe harbor requires that aggregate compensation be set in advance.

4 ***The Emergency Medical Treatment and Labor Act (EMTALA).*** The OIG suggests hospitals review their EMTALA obligations, particularly the obligation to provide a medical screening to determine whether a patient suffers from an emergency medical condition.

5 ***Substandard care.*** The OIG suggests that hospitals demonstrate their commitment to providing quality care by continually mea-

suring performance against comprehensive standards established by federal and state governments, accrediting agencies, and the hospital's own internal protocols.

6 Relationships with federal healthcare program beneficiaries. The OIG notes that hospitals generally are prohibited from offering gifts or free services to attract Medicare or Medicaid patients. The OIG counsels hospitals to scrutinize closely any gifts or gratuities to Medicare or Medicaid patients, review their cost-sharing waiver policies for compliance with all applicable laws, and ensure that the provision of any free transportation is not meant to influence the patient's selection of a provider. The draft also notes that until the OIG promulgates a rule on complimentary local transportation, it will not impose administrative sanctions if free patient transportation meets certain prescribed conditions.

7 Health Insurance Portability & Accountability Act (HIPAA). With the implementation in 2003 of new HIPAA rules protecting the confidentiality and transmission of personal health information, hospitals should make sure they comply with all applicable provisions of the privacy rule, the OIG advises.

8 Billing Medicare or Medicaid in excess of usual charges. The OIG reminds hospitals that they may not routinely charge Medicare or Medicaid patients substantially more than they charge other patients. The office is currently considering hospital concerns regarding the effect of discounts to uninsured patients on the hospital's calculations of its usual charges. The OIG states that it will adhere to the interpretation that hospitals do not need to consider free or substantially reduced charges to uninsured or underinsured patients when calculating their usual charges.

Issues Raised

The draft guidance raises some interesting issues, believes Charles Oppenheim, an attorney in the Los Angeles office of Foley & Lardner.

For example, it's not entirely clear why the OIG believes that joint-recruiting arrangements cannot meet the safe harbor, he says. In addition, the OIG does not articulate the basis for its conclusion that a hospital could face anti-kickback scrutiny if it requires physicians to perform more procedures than required clinically to maintain their privileges.

"Does this indicate that the OIG believes that granting privileges is a form of remuneration?" asks Oppenheim. "If so, are hospitals required to determine their value and charge physicians based on that value? Also, at what point does the number of procedures required to maintain privileges exceed what is required clinically and become an anti-kickback statute risk?"

Oppenheim hopes these and other questions will be addressed when the OIG issues the final supplemental compliance guidance.

Resources

- Draft supplemental compliance guidance for hospitals (June 8, 2004): *www.gpoaccess.gov/fr/index.html*
- Charles Oppenheim: 310-975-7790

HHS OIG Nomination Surprises Some

The nomination of General Services Administration Inspector General Daniel Levinson to be the IG at Department of Health and Human Services (HHS) comes as a surprise to some who had anticipated that acting administrator Dara Corrigan would get the nod for the post.

President Bush nominated Levinson on July 19, just a year after Janet Rehnquist resigned as IG amid allegations that she mismanaged staff and other aspects of the agency. From 1995 to 1998, Levinson served as chief of staff and counsel to Rep. Bob Barr (R-Ga.). He was chairman of the Merit Systems Protection Board from 1986 to 1993. Levinson also served as general counsel to the U.S. Consumer Product Safety Commission and as deputy general counsel in the Office of Personnel Management.

"The choice is somewhat surprising since Dara Corrigan was considered a front-runner for the job since taking over from Janet Rehnquist," Robert Rabecs, an attorney with Hogan & Hartson (Washington, DC), tells *GCR*. In addition, Levinson does not have a healthcare background, which makes the selection even more curious, he says.

Corrigan recently recused herself from all hospital-related cases because she is negotiating for employment with a hospital system.

COMPLIANCE PERSPECTIVES

Defining The Role Of A Laboratory Compliance Officer

Ellen Goonan, M.S., M.T. (ASCP), is Technical Director of Regulatory Compliance, POCT, Safety and QI for Brigham and Women's Hospital.

Beth Harubin, M.S., CLS (NCA), is Supervisor of Laboratory QA and POCT for Tufts —New England Medical Center.

Janet Means, M.S., M.T. (ASCP), is Director of Quality & Compliance for the Department of Laboratory Medicine at Boston Medical Center.

The role of a "Laboratory Compliance Officer" traditionally has been expected to include regulatory and billing compliance, but this role has recently been extended to include safety, quality assessment, compliance with the Health Insurance Portability & Accountability Act (HIPAA), and, in some cases, oversight of the point-of-care testing program. The goal of this article is to discuss the expanding roles of the compliance officers at three Boston teaching hospitals.

What Does A Compliance Program Entail?

Laboratory compliance programs are an essential piece of quality and regulatory management of the clinical laboratory. Programs were originally implemented to oversee one or two areas such as regulatory agency compliance, safety, or point-of-care. However, as regulations become more complex and demanding, the programs at the three hospitals have expanded to include other areas. A laboratory compliance program may now include six main areas of focus: regulatory compliance, billing compliance, HIPAA privacy compliance, safety compliance, point-of-care testing, and quality assessment.

Why Have A Laboratory Compliance Program & Who Is Responsible?

The purpose of having a strong laboratory compliance program is to assure that there is a structured approach with all relevant laws, standards, and reimbursement guidelines. The lab compliance program also provides an oversight for areas in the hospital outside of the clinical laboratory that perform their own testing at the point of care.

Each of our institutions has assigned a full-time medical technologist to the role of Laboratory Compliance Officer. The experienced technologists chosen for these positions are familiar with the regulatory standards of the various accrediting organizations as well as government agencies. A sample job description and required expertise for the successful candidate are provided on page 7.

It is the compliance officer's mission to write and maintain policies and procedures surrounding the standards and guidelines for each area under their responsibility. It is a challenge that the compliance professional must address constantly as the regulations are ever changing. Educating and communicating these changes to both the laboratory staff as well as other laboratory leaders are critical components of the job duties. The compliance officer also provides the vital link between the hospital compliance program and the laboratory compliance program. Communication can be accomplished through a variety of ways, including weekly newsletters, monthly medical staff updates, daily e-mail broadcasts, guidebooks, intranet sites, and presentations.

To determine compliance in all areas, the officer must also design effective audits and collect data. Other responsibilities may include customer service, maintaining inventory, troubleshooting, and quality-control monitoring.

Regulatory Compliance

The Clinical Laboratory Improvement Amendments (CLIA) require that any facility that tests human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease must meet federal laws. The main objective of the CLIA program is to ensure the quality of laboratory testing, and laboratories must be properly certified that they meet federal laws to receive Medicare and Medicaid payments.

What does this mean for a compliance officer from a regulatory point of view? It means that they must ensure compliance with regulations as stated not only by CLIA but also by the State Department of Public Health, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists, American Association of Blood Banks, Food and Drug Administration, American Society for Histocompatibility and Immunogenetics, Foundation for the Accreditation for Cellular Therapy, and Occupational Safety and Health Administration.

Audits are necessary to ensure compliance with regulatory guidelines in all areas where patient testing is being performed. One institution has established PREPAIRE (Program Review Evaluate Prepare Audit Improve Respond Exemplify) Audits to allow the hospital to remain continually compliant. A multidisciplinary team that includes the laboratory compliance officer audits both inpatient and outpatient clinical areas using a multi-standard audit tool. The results are reported to managers, appropriate committees, and hospital leadership for follow-up.

An audit conducted in the clinical laboratories includes the review of policies, pre- and post-analytical procedures, proficiency testing records, quality-control records, personnel files, corrective-action logs, and safety. The audit will also include interviews with staff members and compliance with the JCAHO National Patient Safety Goals. Under CLIA, the audit process has been modified to "trace" a sample from collection to reporting.

Point-of-Care Testing

In 1998, approximately 25% of laboratory testing was performed outside of the main laboratory, and it's estimated that point-of-care testing will continue to increase. The clinical laboratories at Tufts-NEMC, BMC, and at BWH have oversight of point-of-care testing sites. Testing includes those that are waived (glucometry, urine dipsticks, fecal occult blood), nonwaived (blood gases, ACT, co-oximetry), and provider-performed microscopy procedures (urine sediments, wet preps, KOH preps). The laboratory compliance officer's responsibilities include training, inventory, troubleshooting, quality-control monitoring, and auditing.

Billing Compliance

The goal of billing and reimbursement compliance is to "Get paid for what we do!" The laboratory billing process begins when a healthcare provider orders a lab test. The lab receives the order, performs the test, and reports the results. In most cases, the bill is generated by the laboratory information system and hospital billing system. The challenge for the laboratory compliance officer is to monitor the entire process to ensure that each test performed is billed and compliant with billing regulations for the payer, whether it is Medicare, Medicaid, or a private payer. Chargemaster annual updates must be done to ensure CPT codes are accurate. This is often the responsibility of the compliance officer and is best achieved by forming an interdisciplinary team composed of the compliance officer and lab managers along with representatives from the laboratory information systems (LIS) and hospital billing systems.

The Health and Human Services Office of the Inspector General (OIG) recommends that every clinical laboratory have a written compliance plan. According to the OIG, there are seven elements that a laboratory compliance plan should include: establishing standards and procedures, designation of a compliance officer and committee, providing effective training and education, developing effective communication and hotline service, enforcement of standards through well publicized disciplinary guidelines, conducting internal audits and monitors, and responding to problems with corrective actions. This requires the work of an interdisciplinary team that includes the compliance officer, lab manager, LIS representative, as well as representatives from charge systems and patient financial services.

Heath Insurance Portability & Accountability Act

A typical scenario encountered in a hospital is the following: The laboratory customer service representative has a desk in the reception area of the laboratory, which is also the waiting area for adult outpatient phlebotomy. The customer service representative not only answers the laboratory phone and faxes results, but also checks-in patients waiting to have their blood drawn. On the rep's desk is a phone, computer with LIS and HIS

access, and a fax machine. When the representative leaves his or her desk, patients in the waiting area can easily see test results on the computer screen and faxes as they come through. Is this area set up to protect patient's privacy? According to HIPAA, the answer is no.

HIPAA calls for security standards to protect the confidentiality and integrity of individually identifiable health information. The role of a laboratory HIPAA officer should include acting as a liaison between the hospital's HIPAA privacy committee and the laboratory, educating the laboratory on aspects of HIPAA privacy, ensuring the laboratory maintains

— SAMPLE JOB DESCRIPTION —

GENERAL SUMMARY AND OVERVIEW

Under the general direction of the (insert who position reports to) and within hospital, departmental, and regulatory policies and procedures, is responsible for assuring that the Department and all CLIA-licensed sites are operating within CLIA guidelines as described in the Federal Register. In addition, all Massachusetts State regulations and the regulatory standards of all applicable laboratory agencies are included in the responsibilities of this position.

PRINCIPLE DUTIES AND RESPONSIBILITIES

REGULATORY COMPLIANCE

1. Establishes goals for regulatory compliance for the Department and all CLIA licenses sites within the hospital.
2. Provides management with information and ongoing updates regarding changes in CLIA, DPH, JCAHO, AABB, ASHI, FAHCT, FDA, NCCLS, HIPAA, CMS and CAP standards as applicable.
3. Verifies that standard operating procedures (SOP's) exist for all laboratories, including decentralized testing areas.
4. Accompanies and assists with the regulatory surveyor(s) during surveys and prepares survey schedules. Prepares all laboratories and decentralized testing areas for successful surveys. Ensures that all required corrective actions are appropriately completed and documented. Prepares response documentation to the regulatory agencies.
5. Develops and implements training programs in all laboratory departments related to billing and regulatory compliance, safety, infection control and hazardous materials management to insure compliance with regulatory standards.
6. Serves as Department liaison to position related hospital committees and any other relevant hospital committees and projects as deemed necessary.
7. Serves as Chair to the Department Compliance Committee.

BILLING COMPLIANCE

1. Responsible for the development, implementation and ongoing updates to the Laboratory Billing Compliance Plan.
2. Keeps current with all billing compliance regulations and CPT code changes.
3. Interacts with practice managers to ensure that their practices provide adequate billing information for laboratory tests.
4. Performs annual chargemaster review.

POINT-OF-CARE TESTING

1. Direct oversight of compliance with all applicable regulations regarding point-of-care testing throughout the hospital.
2. Implements an organizational structure for point-of-care Testing including training of operators, supervision of performance, monitoring of compliance, documentation of records and actions and maintenance of quality control.
3. Perform periodic audits to monitor compliance and reports any issues or problems identified.
4. Serves as chair to the Department Point-of-Care Testing Committee.

QUALITY ASSURANCE

1. Responsible for the development of a comprehensive Quality Improvement Program for all laboratories and decentralized testing areas. Assures that the QI Plan is appropriate, up to date, and in compliance.
2. Designs systems for internal and external incidents and follow-ups. Manages the response and follow-up to all laboratory related incident reports. Recommends and assures the implementation of any necessary corrective action(s).
3. Contributes to the department's goals of efficiency, cost effectiveness, optimization of resources, and revenue enhancement.
4. Plans continual customer service improvements in conjunction with supervisors and outreach operations.
5. Serves as a chair to the Department Quality Assurance Committee.

LABORATORY SAFETY COMPLIANCE

1. Provides continual guidance to all Department laboratories regarding safety, infection control, and hazardous material disposal.
2. Acquires in-depth, up to date expertise in safety compliance including OSHA's safety regulations.
3. Ensures that all requirements for safety are met.
4. Develops and implements the safety program to include annual training, TB testing, competency testing, and self-inspections. Maintains all records.
5. Serves as Chair to the Department Safety Committee.

HIPAA privacy, and answering questions regarding HIPAA privacy.

For us, the implementation of the HIPAA privacy requirements has meant a few policy changes within the laboratories: Anything containing protected health information (PHI) has to be destroyed; only authorized people are able to view a computer screen with patient information; and policies have been developed for oral, mail, fax, and computer communication. In the above scenario, the computer should have had a screen filter placed on it and the automatic logoff time should have been shortened in case the representative did not log off before leaving the area. The fax machine should be placed in a secure location, and faxes should be received upside down.

Lab Safety

It is also the compliance officer's responsibility to make sure the laboratory adheres to regulations that ensure the safety of laboratory staff as set by OSHA. OSHA's standard on "Occupational Exposure to Bloodborne Pathogens" and "Occupational Exposure to Hazardous Chemicals in Laboratories" are excellent to use as a base for your laboratory safety program. They should be kept readily available for all laboratory staff.

Periodic laboratory safety audits are useful tools to ensure that the laboratories are in compliance. Unannounced audits seem to work better as you will get a true sense of whether or not you are in compliance with safety items. Challenges in maintaining compliance include annual safety training and making sure that everyone is up to date with their tuberculosis testing.

Quality Assessment

The objective of quality assessment (QA) is to design laboratory quality programs in accordance with the requirements of the regulatory agencies and the organization's Quality Improvement Department. The quality assessment program contributes to the departmental goals of efficiency, cost effectiveness, optimization of resources, revenue enhancement, and customer satisfaction. Quality assessment works by clearly identifying a problem, collecting data, developing a hypothesis, creating an intervention, measuring the improvement, adopting the new process, and then starting over. Among some of the current popular quality assurance programs – FOCUS-PDCA, DMAIC, Six Sigma, FMEA, and RCA.

Performance improvement projects include both intra- and interdepartmental indicators that are monitored and reported on a monthly basis. One example of a hospital-wide laboratory performance improvement project is the reduction of preanalytical laboratory variables. By using an online incident reporting system, all three of our institutions are able to close the loop on preanalytical errors, such as mislabeled or clotted specimens. One institution has actually reduced the number of redraws due to preanalytical error in the neonatal intensive care unit with the help of its online incident reporting system. Interdepartmental projects might include reducing the emergency department turn-around time or number of contaminated blood cultures.

Summary

The laboratory compliance program's objective is to identify, correct, and prevent illegal or noncompliant conduct. It also should promote honest and ethical behavior, which should be demonstrated by everyday behavior of the compliance professional. And most importantly, the compliance program protects the laboratory assets, customers, and the organization's image.

When a laboratory is seeking a compliance officer, it should look for someone who exhibits integrity, confidence, and honesty. Compliance officers should be ethical and reliable, consistent and determined, and good communicators. They should also be fair and tough enough to enforce adherence to regulations. Lab compliance officers should enjoy teaching, problem solving, learning, and facilitating. They should also possess good researching, documenting, and decision-making skills.

To assist each other with compliance issues, two of the authors established the Greater Boston Laboratory Compliance Group, a group of compliance professionals from Boston-area hospitals who meet quarterly to discuss all aspects of laboratory compliance. The group is currently working on a benchmarking project on specimen labeling.

The authors can be contacted by e-mail: *egoonan@partners.org, bharubin@tufts-nemc.org* or *janet.means@bmc.org.*

Kathleen McDermott

Physician Recruitment Practices, *from p. 1*

with Blank Rome (Washington, DC) and a former federal prosecutor. "This has been identified as a significant healthcare fraud issue. Whether it is or not remains to be seen, but I think we'll see more of these kinds of cases."

Alvarado Case

In a criminal case filed against Alvarado Hospital Medical Center last year, U.S. attorney Carol Lam charged the hospital and its former chief executive, Barry Weinbaum, of bribing doctors with "relocation agreements" in exchange for the doctors' referrals of patients to the hospital.

According to the indictment, Alvarado Hospital and Tenet Health Systems paid about $10 million to fund more than 100 physician relocation agreements, purportedly to recruit needed medical services to the Alvarado service area. However, money as part of the agreements went not only to doctors being recruited, but also to the "host" medical practices with whom the recruited doctors were placed, in exchange for patient referrals, Lam alleged.

Among the arrangements described in the indictment were relocation agreements with four physicians who joined the practice of Dr. Paul Ver Hoeve, located in the Alvarado service area. According to the charges, the defendants arranged for Ver Hoeve personally to receive at least $600,000 of the relocation agreement money. The indictment also charges that defendants arranged for physicians practicing in the Mid-City Medical Group to receive $230,000 in relocation agreement money after the physicians solicited funds from the hospital while promising to increase admissions to Alvarado Hospital.

> ***"We're counseling our hospitals to do a benchmark review of their physician arrangements, particularly with private group practices."***
>
> ***—Kathleen McDermott***

"Kickbacks to doctors can wear many disguises, including sham relocation agreements," said Lam in announcing the indictment. "They are still kickbacks, they are still illegal, and they threaten the integrity of our medical system."

The 17-count indictment charges defendants with one count of conspiring to violate the anti-kickback statute and with 16 counts of offering and paying illegal remunerations. Each count carries a maximum penalty of five-years imprisonment and a $25,000 fine.

Alvarado, Tenet, and Weinbaum deny any wrongdoing in the case, which is scheduled to go to trial in October. However, Tenet is seeking to negotiate a settlement with the government over this issue and other fraud allegations. The settlement could amount to more than $1 billion.

Be Careful What You Offer

Hospitals that wish to offer physicians recruitment or relocation packages should ensure that the deals are structured in a way that they comply with federal and state laws.

"We're counseling our hospitals to do a benchmark review of their physician arrangements, particularly with private group practices," she says. "Many arrangements include joint projects, and some may include recruitment-style benefits, which are governed by the final Stark regulations and need to be compliant. It's a significant area of concern."

Hospitals in urban areas may find it especially difficult to defend recruitment and relocation practices since it's less likely that they have fewer problems recruiting physicians than hospitals in rural areas, believes McDermott. While legitimate physician recruitment efforts are allowed by law, practices that are a camouflage for purchasing a referral stream clearly are illegal, she notes.

"What needs to be examined is whether there are unnecessary inducements to the physician practice that do not bear any clinical relationship to the arrangement," she says. "For example, if a private physician is coming into a cardiology group and is making half a million dollars a year, it's difficult to understand why the hospital, who is not the employer, is engaging in loan forgiveness or relocation expenses."

Whether Lam will be successful in prosecuting Alvarado is uncertain, but hospital attorneys have their work cut out for them, believes McDermott, who calls Lam a formidable opponent.

Resources

- U.S. Attorney's Office, Southern District of California: 619-557-5927
- Kathleen McDermott: 202-772-5813

Pathology Lab May Donate Its Service, OIG Rules

A proposed laboratory arrangement to provide free services to low-income, uninsured patients would pose no risk of fraud and abuse to federal healthcare programs, according to an opinion issued June 10 by the Department of Health and Human Services Office of Inspector General (OIG).

The requestor, a for-profit pathology lab partly owned by pathologists, sought the OIG's opinion about its participation in a medical assistance project operated by a charitable foundation. The lab told the OIG that it would provide pathology laboratory services at no cost to project participants who were referred by volunteer physicians also associated with the program. Project participants must be county residents with no medical insurance and incomes that do not exceed 150% of the federal poverty level guidelines, and they must not be eligible for Medicare or Medicaid benefits.

The lab certified that no remuneration would be paid to volunteer physicians, the volunteer pathology lab, pathologists performing the lab services, or the project. The lab also said some of the program's volunteer physicians may refer patients, outside the scope of the project, for services that are reimbursable by federal healthcare programs, but that participation in the project is not related in any manner to any nonproject business.

Based on the facts, the OIG concluded that the lab's participation in the project did not put it at risk for administrative sanctions because there would be no resulting economic value to any party that is in a position to refer health program business to the lab.

Resource

❖ Opinion No. 04-5: *http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0405A.pdf.*

Grand Jury Indicts Former UraCor Executives

A federal grand jury had indicted three former executives of UraCor on charges of conspiracy to commit healthcare and securities fraud.

Both William Hagstrom and Mark Dimitroff have been accused of conspiracy to provide kickbacks to physicians. Hagstrom, of Oklahoma City, is the former president, chief executive officer, and chairman of the board of UroCor. Dimitroff, of Gainesville, Virginia, was vice president of sales and marketing. Michael McDonald, the former controller and chief financial officer for UroCor, was indicted on conspiracy to commit securities fraud.

UraCor, a national lab that provides testing and diagnostic services for urological diseases, was acquired by Dianon in 2001. LabCorp subsequently acquired Dianon in early 2003.

Prosecutors allege that Hagstrom and Dimitroff conspired to increase UroCor's market share and revenues by inducing doctors to refer Medicare patient specimens for lab testing work through the use of "special pricing" discounts, insurance reimbursement agreements, and consulting agreements that provided financial benefits to the physicians.

Hagstrom and McDonald are charged with falsely representing the financial condition of UroCor to the investing public, company shareholders, and the Securities and Exchange Commission to increase and/or maintain stock value and financially benefit the defendants.

If convicted, the men face up to five years in prison and a $250,000 fine.

Medicare Proposes New Preventive Services As Part Of Physician Fee Schedule Revisions

The Centers for Medicare & Medicaid Services (CMS) on July 27 proposed regulations to implement the preventive benefits provisions of the Medicare Prescription Drug, Improvement & Modernization Act of 2003.

Beginning in 2005, all new enrolled Medicare beneficiaries will be covered for an initial physical examination, and those at risk will be covered for diabetes screening. The tests to be covered include a fasting plasma-glucose test and post-glucose challenges.

Beneficiaries eligible for this screening will not have to meet a deductible or co-pay for the test. In addition, beneficiaries will be covered for periodic cardiovascular screening blood tests to measure cholesterol, high-density lipoprotein, and triglycerides.

The proposal also includes changes to mammography screening, Pap smears and pelvic exams, colorectal screening, prostate cancer screening, and glaucoma screening.

The full proposal, included as part of the revisions to the 2005 physician fee schedule, will be published in the August 5 *Federal Register.*

E&Y To Pay $1.5M In False Claims Case

The national accounting firm Ernst & Young LLP (New York City) has agreed to pay $1.5 million to resolve allegations that its bad advice resulted in client hospitals submitting false claims to Medicare.

The settlement, announced July 20, puts to rest the False Claims Act complaint filed by the government this January in the U.S. District Court for the Eastern District of Pennsylvania, charging the healthcare consulting division of Ernst & Young with knowingly causing nine hospitals to submit more than 200,000 fraudulent claims for payment under the Medicare program. The government alleged that from 1991 through 1997, the hospitals filed the claims for certain outpatient blood tests that were not medically necessary (*GCR, Feb. 2004*).

"This settlement should provide a wake-up call not only to healthcare providers, but also to the consultants on whose advice they rely," said U.S. attorney Patrick Meehan. "It is the duty of an independent reviewer to be alert to abuse and not to remain, as the complaint alleges, 'deliberately ignorant.'"

Meehan maintains that Ernst & Young not only failed to discontinue its improper Medicare billing advice, but also knowingly prepared reports to the government that failed to disclose the improper conduct of the hospitals that relied on the firm for analysis and reporting of their improper billing.

Ernst & Young filed a motion to dismiss the complaint on March 1, asserting that it did not cause any false or inaccurate claims to be submitted under the Medicare program, according to the settlement agreement. Further, the firm contended that it did not conceal or fail to disclose any false claims, and that the allegations in the complaint were without factual or legal merit.

"The agreement is neither an admission of liability by [Ernst & Young] nor a concession by the United States that its claims are not well founded," the settlement agreement said. "In order to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of these claims, the parties reached a full and final settlement."

New 2005 Lab Test Codes Unveiled

The Centers for Medicare & Medicaid Services (CMS) has released 11 new lab codes that will go into effect in 2005. The coding additions, developed by the American Medical Association's CPT Editorial Panel, include six in chemistry, four in immunology, and one in microbiology. CMS held a public forum July 26 to get input on how fees should be set for the new codes.

CMS also has published a list of new CPT codes for which it wants recommendations regarding their placement on the lab-fee schedule and recommended payment levels. Of special interest to pathologists, the list includes five new flow cytometry codes and three new morphometric analysis codes.

Chemistry

8204x Albumin; ischemia modified
8265x Elastase, pancreatic (EL-1), fecal, qual. or seminquant.
8300x Helicobacter pylori; blood test analysis for urease activity, non-radioactive isotope (eg, C-13)
8363x Lactoferrin, fecal, qual.
8416x Pregnancy-associated plasma protein-A (PAPP-A)
8416x Protein, electrophoretic fractionation and quantitation; other fluids with concentration (eg, urine, CSF)

Immunology

8606x B cells, total count
8633x Immunofixation electrophoresis; other fluids with concentration (eg, urine, CSF)
8637x Natural Killer (NK) cells, total count
8658x Stem cells (i.e., CD34), total count

Microbiology

8780x Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus

Cytopathology

8818x Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
8818x each additional marker (list separately in addition to code for first marker)
8818x Flow cytometry, interpretation; 2-8 markers
8818x 9-15 markers
8818x 16 or more markers

Surgical Pathology

8836x Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semiquant., each antibody; manual
8836x Morphometric analysis, in situ hybridization (quant. or semiquant.), each probe; using computer-assisted technology
8836x manual

TAP Defendants Acquitted: Jurors found eight employees of TAP Pharmaceutical Products innocent of charges they offered kickbacks to doctors to boost sales of two of the company's drugs. Jurors deliberated for four days following a trial in U.S. District Court in which the TAP workers were accused of offering hefty consulting fees, resort trips, and educational grants to doctors. Prosecutors alleged that the workers offered those favors, along with free drug samples, in exchange for the doctor's agreement to prescribe TAP's prostate cancer drug Lupron and the heartburn drug Prevacid. But defense lawyers argued that the employees offered the drug samples to promote the drugs—a practice that is legal.

Pharmacy Settles Kickback Charges: An institutional pharmacy company faces $21.8 million in civil monetary penalties and a 10-year exclusion from federal health programs for allegedly offering kickbacks to the owner of Medicaid-participating nursing homes and assisted living facilities, according to the Health and Human Services Office of Inspector General (OIG). The government alleges that PharMerica Drug Systems, Inc. purchased an institutional pharmacy, Hollins Manor I (Roanoke, VA.) for $7.2 million, in exchange for the seller's agreement to refer its Medicaid patients' pharmacy business to PharMerica. The IG said the purchase price for the pharmacy was excessive, given its nearly nonexistent operating history.

Specialty Hospital Exempt From Moratorium: A physician-owned orthopedic and neurological surgery hospital will be exempt from the 18-month moratorium imposed on specialty hospitals in the Medicare Modernization Act (MMA), according to a rare advisory opinion issued by the Centers for Medicare & Medicaid Services (CMS). CMS concluded that the specialty hospital in question was under development as of Nov. 18, 2003, and thus would not be subject to the moratorium. The opinion is available at *www.cms.hhs.gov/medlearn/ao-2004-06-01.pdf*.

Accreditation Reform Proposed: Two key lawmakers July 20 introduced legislation to give the government more say in how hospitals are accredited under Medicare, following the release of a federal report highly critical of the job being done by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Senate Finance Committee Chairman Charles Grassley (R-IA) and House Ways and Means Health Subcommittee ranking minority member Fortney "Pete" Stark (D-CA) say their bill will remove the so-called deeming authority given JCAHO when Medicare was founded in 1965.

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