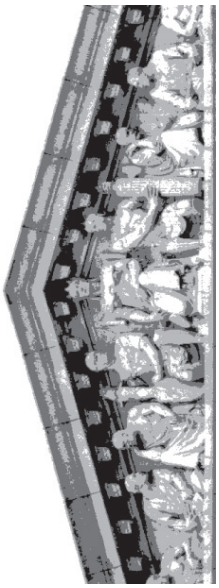

G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Top Concerns For Healthcare Compliance Officers

The role of a healthcare compliance officer requires constantly juggling, from developing and maintaining compliance plans to keeping up with evolving laws, regulations, and guidance issued by federal agencies.

Two assistant U.S. attorneys on April 19 discussed what they consider to be some of the top issues for healthcare compliance officers. Glenn Martin, assistant U.S. attorney for the Western District of Michigan, and Linda Wawzenski, deputy chief, civil division, for the Office of the U.S. Attorney for the Northern District of Illinois, spoke in an unofficial capacity as they gave their own views on compliance and enforcement issues during the Health Care Compliance Association's 2005 Compliance Institute in New Orleans.

One issue compliance officers should be aware of is Section 921 of the Medicare Modernization Act of 2003: "Provider Education and Technical Assistance," advised Martin and Wawzenski. This section, which took effect January 5, requires that Medicare contractors answer written provider inquiries regarding billing issues (including those sent electronically). ➥ *p. 2*

Legal Issues In Lab Outreach: Part II

Because laboratory outreach services are inherently commercial, such ventures automatically raise kickback concerns and thus require an extra degree of caution in structuring, advises Hope Foster, an attorney with Mintz Levin (Washington, DC). Providers must also be careful to address legal and compliance issues in a number of other areas, including sales and marketing, development of requisition forms, pricing, and joint ventures.

"I always urge anyone who is thinking about starting or expanding an outreach program to pay attention to the OIG [Health and Human Services Office of Inspector General] guidances in this area, and there are now three of them," says Foster, who discussed legal issues in outreach testing during Washington G-2 Report's annual lab outreach conference, held March 31 to April 1 in Atlanta. "One relates to clinical labs, and two relate to hospitals. The OIG also issued a new hospital guidance in January. Take a look at it if you haven't already."

Sales & Marketing

Sales and marketing of outreach services is ripe with risk, cautions Foster, who says the enforcement actions she has defended over the last 15 years have almost always involved sales and marketing issues.

"My strong advice is that your employees be sales staff and not independent contractors, particularly if you're paying them ➥ *p. 9*

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This provision offers providers some protection, explained Martin. "If you adequately present facts and follow the written response, no penalties or interest will be due if you are nevertheless overpaid," he said.

Section 921 calls for contractors to respond to providers within 45 business days of the date of receipt of the inquiry. However, if a provider does receive overpayment, it still has to return those monies to the government.

Other top compliance issues highlighted by the assistant U.S. attorneys:

- **Supplemental Hospital Compliance Guidance.** Unlike the first hospital compliance guidance published in 1998, which focused on designing compliance programs, the supplemental guidance, issued January 27, focuses on measuring and improving the effectiveness of existing compliance efforts. The new guidance, issued by the Health and Human Services Office of Inspector General (OIG), "holds compliance plans to a higher standard and looks to see if they are continuously improving," said Martin. He advised re-evaluating your plan at least once a year.

> ***"DOJ expects serious disciplinary action…"***
>
> ***—Glenn Martin, Esq.***

- **Voluntary Disclosure.** Wawzenski recommends that compliance officers make disclosure of problems mandatory, saying "it's worse if we find out about" a problem in an institution. She noted that on the civil side, if a provider makes a voluntary disclosure, the maximum amount the government can ask for is double damages, as opposed to the more severe potential penalties under the False Claims Act (three times the dollar amount the government is defrauded and civil penalties of $5,500 to $11,000 for each false claim).

- **Internal Compliance Audits.** Wawzenski noted that there is much more information about quality of care at providers available than there used to be. Compliance officers should be aware of what their peers are doing to improve quality, she said. You should also listen to complaints from nurses about practitioners and not just rely on written records when a question of quality arises. Wawzenski noted that records may show good care was given, but said she has seen records falsified so that medical charts look fine. "Go behind the records and look at X-rays, films, and other objective evidence" of the care given, she said.

- **Medicaid Intergovernmental Transfers.** House Energy and Commerce Committee Chairman Rep. Joe Barton (R-Texas) in January sent letters and congressional subpoenas to 20 facilities, seeking information and documents that would provide insight into controversial accounting mechanisms used by states to generate additional federal Medicaid funding. Martin discussed congressional interest in this issue, which is estimated to cost about $6 billion per year in inappropriate payments, and told compliance officers: "Be aware of this. If you get a subpoena, don't ignore it."

- **HIPAA Criminal Referrals.** Martin said that by late 2004, various U.S. attorney offices had received more than 200 referrals for alleged criminal cases involving Health Insurance Portability and Accountability Act (HIPAA) violations. Thirty of those were opened for investigation, he said, noting that the majority of the cases involved family disputes over medical records for use in court proceedings involving divorce and custody issues. The key for compliance officers is to ask how their institution responds when employees violate HIPAA.

"DOJ expects serious disciplinary action, and DOJ will look twice at institutions and individuals if the proper discipline is not done," Martin said. Wawzenski cautioned that compliance officers "must do something immediately if you find out" about a HIPAA violation, the most common being identity theft by lower-level employees with access to patients' information.

Resources

- Glenn Martin: 616-456-2404
- Linda Wawzenski: 312-353-5300

Compliance Officers Well Compensated, Survey Finds

The mean salary for the chief compliance officer in a healthcare organization is $152,852, according to a survey released recently by the Health Care Compliance Association (HCCA).

The mean salary ranged from $128,485 in the Midwest to $159,318 in the Northeast, found HCCA's seventh annual survey: "2005 Profile of Health Care Compliance Officers." The survey was conducted during December 2004 and January 2005; 20% of HCCA members (624) completed the survey. The median base salary for a compliance officer is $95,174, with salaries ranging from $81,000 to $108,679.

Budgets & Training

Of those responding to the survey, 70% reported not having a budgeted line item for compliance training, while 28% reported a training budget of $50 to $5,000, and 14% reported their training budget as $5,000 to $15,000.

In addition, 25% of respondents reported that their estimated annual budget for the compliance department was less than $100,000, with 62% of the compliance budget spent on salaries, and 7.2% spent on training.

According to the survey, 87% of respondents conducted compliance training beyond the initial training, 64% report that they conduct annual training, and 46% report that employees spent between one to three hours in compliance training annually.

The vast majority, 91%, of compliance officers conduct compliance training as a component of new employee orientation, and 90% say they conduct compliance awareness training for all employees. Meanwhile, 76% report conducting topic-specific, in-depth training that is separate from and in addition to compliance awareness training, and 67% report conducting compliance training for managers and leaders.

For compliance awareness training, 71% of respondents use instructor-led classroom training with the compliance officer as the instructor, while 58% report using computer-based or Web-based training methods.

Program Maturity

The fact that corporate compliance programs, unknown to most healthcare organizations in 1997, have entered into a maturing phase is clearly indicated by the top goals respondents selected: monitoring and auditing (84%), staff training (75%), and conducting effectiveness evaluations (71%).

This year's survey finds that 88% of respondents include privacy and information security in their compliance programs, 84% include conflict-of-interest, and 46% include the Sarbanes-Oxley Act. In addition, 40% include clinical research, and 28% include standards set by the Joint Commission on Accreditation of Healthcare Organizations.

The majority of respondents (61%) reported that their compliance department is a standalone department with budgetary responsibilities and staff. Almost all (93%) said they report compliance activities to a governing board or owner, with 50% reporting compliance activities quarterly and 65% reporting compliance activities through written reports.

Resource

HCCA's "2005 Profile of Health Care Compliance Officers": *www.hcca-info.org.*

Profile By Region

Region	Median Revenue	Median Size (by Number of Employees)	Mean # of Full-Time Compliance Employees	Mean Compliance Budget	Mean Chief Compliance Officer Compensation	Median Compliance Officer Base Salary
Total	$174.5 M	1,750	3.92	$350 K	$149,832	$95,029
Northeast	$174.5 M	1,750	3.21	$315 K	$159,318	$108,679
South	$249.5 M	1,750	4.02	$393 K	$158,305	$90,383
Midwest	$125.4 M	1,250	3.25	$245 K	$128,485	$91,581
West	$249.5 M	1,750	5.18	$436 K	$156,406	$94,457
Other	$124.5 M	813	2.92	$232 K	—	$81,000

CMS Sets Policy On CBC Reflex Billing

Can clinical laboratories bill a reflex manual differential separately when a complete blood count with automated differential is performed and the results are inconclusive, requiring a manual differential?

No, says the Centers for Medicare & Medicaid Services (CMS), which has finally provided an answer to a question long posed by labs. According to agency official Anita Greenberg, CMS has now changed its *National Correct Coding Policy Manual for Part B Medicare Carriers* to address this issue. The manual now states, "It would be inappropriate to report a confirmatory test separate from the ordered CBC test," she said in response to a question asked during the April 25 lab open-door forum hosted by CMS.

Laboratory consultants have differed on how —or whether—to bill for the manual differential after the American Medical Association discontinued CPT 85023 (*GCR*, March 2003, p. 2). Many labs had used this code to bill for automated CBC with a manual differential. In 2002, the code ranked 45 among the top 100 lab and pathology procedures in terms of volume, according to Medicare data analyzed by Washington G-2 Reports.

One interpretation was that when the automated results cannot be reported, this is not a true "reflex" situation, so a manual differential must be run to issue a report; in this case, a lab could bill 85027 and 85007, codes that reflect the old 85023. A conservative interpretation was that 85027 and 85007 should not be billed when a physician orders a CBC with differential (85025) to obtain payment for a manual differential. The reason: CMS considers the manual differential to be part of the procedure required to fulfill the physician's order. This approach, proponents said, was buttressed by CMS instructions citing 85007 among the component codes for CBCs with differential WBC testing and 85025 as the bundled code for a CBC with differential.

Coding consultant William Dettwyler, president of Codus Medicus (Salem, OR), analyzed recently released CMS bill data compiled by Washington G-2 Reports to find out which approach labs followed in 2003, the latest year for which data are available. He found that labs generally took the conservative approach, as the data showed neither a large increase in volume for 85007 nor reduced volume for 85025.

CMS Policy On Reflex Manual Differential

"If, after a test is ordered and performed, additional related procedures are necessary to provide or confirm the result, those would be considered part of the ordered test. For example, if a patient with leukemia has a thrombocytopenia and a manual platelet count (CPT 85032) is performed in addition to the performance of an automated hemogram with automated platelet count (85027), it would be inappropriate to report codes 85032 and 85027 because the former provides a confirmatory test for the automated hemogram and platelet count (85027). As another example, if a patient has an abnormal test result and a repeat performance of the test is done to verify the result, the test is reported as one unit of service rather than two."

—Chapter 10, Pathology/Laboratory Services, *National Correct Coding Policy Manual for Part B Medicare Carriers*. Online at *www.cms.hhs.gov/physicians/cciedits/ncmanual.asp*.

RACs Won't Duplicate Efforts, CMS Says

A new demonstration project aimed at recovering improper Medicare payments will not duplicate efforts already under way by other contractors, officials from the Centers for Medicare & Medicaid Services (CMS) told providers recently.

During an April 28 Open Door forum, a number of providers expressed concern that recovery audit contractors (RACs) would be reviewing claims already scrutinized by quality improvement organizations, program integrity contractors, or other contractors. However, CMS staff said that RACs will be looking only at claims that were not reviewed already. In other words, a provider would not be contacted twice about the same claim.

The three-year RAC demonstration, mandated by Congress in the Medicare Modernization Act of 2003, will use proprietary, private software to identify previously undetected overpayments and underpayments. CMS staff said that RAC contractors already have been sent claims data from fiscal intermediaries and carriers, but would not discuss the volume or scope of reviews RACs would undertake.

COMPLIANCE PERSPECTIVES

Insight Into Joint Commission Laboratory Accreditation

Margaret Peck is director of the Laboratory Accreditation Program at the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, Illinois.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) evaluates and accredits nearly 2,000 organizations with laboratory services. Accreditation is designed to help laboratories improve quality and safety, reduce costs, demonstrate accountability, and increase participation options in managed care and other contractual arrangements—all critical elements for long-term success in a rapidly changing healthcare marketplace.

The Joint Commission began evaluating laboratory services in 1979. Since 1995, clinical laboratories surveyed using Joint Commission standards have received deeming authority from the Centers for Medicare & Medicaid Services (CMS) as meeting or exceeding the Clinical Laboratory Improvement Amendments (CLIA '88) requirements.

Joint Commission laboratory standards are intended for a wide range of laboratories, including:

- hospitals
- clinics
- long-term-care facilities
- home-care organizations
- behavioral health organizations
- assisted reproductive clinics
- ambulatory sites
- reference laboratories
- blood transfusions and donor centers
- federally owned laboratories
- physician office laboratories

Survey Process

The Joint Commission accreditation survey provides an assessment of a laboratory's compliance with state-of-the-art standards. The survey is performance focused and emphasizes the results a laboratory should achieve, instead of the specific method used. Accredited laboratories are surveyed every two years. Surveys are conducted by experienced medical technologists who have passed a rigorous certification examination.

Joint Commission surveyors are not volunteers, but professionals who have experienced laboratory services in many types of settings. Using Joint Commission certified surveyors, instead of volunteers, offers greater consistency in the survey process. Since Joint Commission surveyors visit a variety of laboratories, they provide an educational experience for staff and often provide information on best practices that saves time and money for laboratory managers. Additionally, the Joint Commission offers the option of enhanced pathology expertise to laboratories that want additional guidance for histology and cytology services. The Joint Commission accepts any CMS-approved proficiency test vendor. The Joint Commission also requires proficiency testing on all CLIA regulated analytes, and requires use of a system for verifying the accuracy and reliability of results obtained for tests not requiring proficiency testing by law.

The On-Site Survey

The purpose of a Joint Commission accreditation survey is to assess the extent of a laboratory's compliance with applicable Joint Commission standards. JCAHO's new accreditation process, Shared Visions-New Pathways, applies to laboratories in the following ways:

- ✔ Ongoing operational improvement is the norm. The focus shifts from survey preparation to actual performance and how the standards relate to individual patients receiving lab services. This continuous systems quality improvement process incorporates a collaborative approach, as well as an intra-disciplinary approach, to ensure that all activities related to lab services are integrated to improve care and safety.

- ✔ Standards chapters in the manual have been reformatted significantly. Many standards are "core" standards that are also used in evaluations of hospitals, long-term-care organizations, and ambulatory care clinics, so that they are easily understood by other professionals in a large healthcare organization. This approach lends itself to systems compliance.
- ✔ The surveyor will be well acquainted with the laboratory even before walking in the door. The new priority focus process takes information from the accreditation application, previous survey recommendations, proficiency testing data, and sentinel event and complaint data, and uses it to recommend priority focus areas for the surveyor to review during the survey. Expect specific, detailed questions about laboratory operations and processes.
- ✔ The survey includes the tracer methodology to track patients and specimens through the continuum of care. For example, a patient comes to the emergency room and has stat electrolytes drawn by the nursing staff. The surveyor would trace the order and receipt processes, specimen identification, collection and transportation processes, equipment calibration, proficiency testing, quality control, test analysis, and distribution of result reports. Laboratory staff, other staff, and the patient, if applicable, would be interviewed.
- ✔ In support of the Joint Commission's focus on continuous standards compliance and operational improvement, a periodic performance review is being developed for laboratories. This incorporates discussion with the Joint Commission staff on how to improve performance.
- ✔ If an organization is not in compliance with one or more standards at the time of survey, or if an organization is given requirements for improvement, laboratories are required to submit an evidence of standards compliance (ESC) report within 90 days of the survey (45 days as of July 1, 2005). The ESC report should detail the action that the organization took to bring itself into compliance with the standards or clarify why the organization believes it was in compliance with the standards for which it received a recommendation. For some standards, the organization will measure its success in making improvements and sustaining improvement over time (this is known as a measure of success, MOS).

An important characteristic of the Joint Commission survey process is on-site education conducted by the surveyors. This support occurs throughout the survey as the surveyor offers suggestions for approaches and strategies that may help laboratories better meet the standards and improve patient safety and quality of care.

All Joint Commission laboratory surveys take at least one day. Typical surveys take two days, and some surveys may take five days or more, depending on the size of the laboratory and the scope of services provided. Often, many CLIA certificates are included in one organization's survey.

Experience With The New Survey Process

The Joint Commission continues to receive good feedback about the new survey process from laboratories.

Nina Piwtorak, M.T. (ASCP), laboratory manager, Stark Memorial Hospital (Knox, IN), a 53-bed hospital in northern Indiana that performs 80,000 to 100,000 tests per year, reports that the new survey process is geared toward patient care and safety. "Because of the tracer methodology, the surveyor was able to look at the complete picture of patient care —from the time the patient walked into the facility until the time they walked out."

"I'd be dishonest if I told you I was looking forward to the Joint Commission survey, but after going through it, we found that it's a much better process than before," says Michael O'Leary, M.D., corporate medical director, Laboratory Alliance of Central New York (Liverpool, NY). Laboratory Alliance is an independent, for-profit laboratory that performs more than 2.4 million tests annually.

"We really appreciated the fact that the majority of the survey was conducted in the laboratory, instead of in a conference room," O'Leary says. "For example, the surveyor selected a particular analyte. She then checked to see if the technologist was credentialed to perform the test on that analyte. Then she asked the tech questions about the test, such as, 'What would you do if you had a critical

value? How would you report it?' You could clearly track how the lab interacted with the different departments in the hospital."

Both O'Leary and Piwtorak noted that the tracer methodology is time-intensive for departments outside the laboratory. "You've got to warn your IT department that you will be calling on them to pull a lot of information for the survey," O'Leary says.

National Patient Safety Goals

The purpose of the Joint Commission's National Patient Safety Goals is to promote specific improvements in patient safety. The goals highlight problematic areas in healthcare and describe evidence and expert-based solutions to these problems. Recognizing that sound system design is intrinsic to the delivery of safe, high-quality healthcare, the goals focus on systemwide solutions wherever possible.

As with Joint Commission standards, accredited organizations are evaluated for continuous compliance with the specific requirements associated with the National Patient Safety Goals. Although these requirements are generally more prescriptive than Joint Commission standards, organizations are permitted to design alternative approaches to meeting goal requirements and to request Joint Commission consideration and approval of such alternatives.

Unannounced Surveys

Unannounced laboratory surveys are targeted for 2006. The Joint Commission has implemented this process to enhance the credibility of quality laboratory oversight by encouraging continual focus on quality of services and patient safety. A small number of laboratories have been involved in the pilot of this process. However, feedback from all programs in general has been very positive as the process eliminates anxiety and ramp-up activity and costs associated with scheduled on-site surveys.

Due to current CLIA requirements, it is anticipated that unannounced laboratory surveys will more than likely occur within the normal 45-day window of the survey due date. Leadership availability for the unannounced survey is not critical; pilot organizations reported the process went smoothly even in the absence of leadership.

The Joint Commission is considering a variance to performing unannounced surveys for 100% of laboratories since there are some labs with operational or security issues that may preclude total unannounced surveys. These laboratories may require limited notice. Additionally, all initial or first-time Joint Commission laboratory surveys will continue to be announced. Details about unannounced surveys will be communicated with all accredited laboratories in coming months.

The National Patient Safety Goals are derived primarily from informal recommendations made in the Joint Commission's safety newsletter, *Sentinel Event Alert*. The Sentinel Event database, which contains de-identified aggregate information on sentinel events reported to the Joint Commission, is the primary, but not the sole, source of information from which the *Alerts*, as well as the National Patient Safety Goals, are derived. A broadly representative Sentinel Event Advisory Group works with the Joint Commission staff on a continuing basis to determine priorities for goals and associated requirements. As part of this development process, candidate goals and requirements are sent to the field for review and comment. Selected existing and new goals and requirements are annually recommended by the advisory group to the Joint Commission's Board of Commissioners for final review and approval. The advisory group also assists the Joint Commission in evaluating potential alternatives to goal requirements that have been suggested by individual organizations.

The 2005 laboratory goals focus on accuracy of patient identification, effective communication among caregivers, and reducing the risk of healthcare-associated infections. These expectations were also included in the 2004 goals. The 2005 National Patient Safety Goals emphasize important precautions necessary to the provision of safe, high-quality care. Focusing on these specific areas of performance will reduce the frequency of unanticipated serious events in laboratories and the organizations they support.

Goal: Improve the accuracy of patient identification.

- ❑ Use at least two patient identifiers (neither to be the patient's location) whenever collecting laboratory samples or administering medications or blood products, and use two identifiers to label sample collection containers in the presence of the patient. Processes are established to maintain samples' identity throughout the pre-analytical, analytical, and post-analytical processes.
- ❑ Immediately prior to the start of any invasive procedure, conduct a final verification process to confirm the correct patient, procedure, site, and availability of appropriate documents. This verification process uses active—not passive—communication techniques. The patient's identity is re-es-

tablished if the practitioner leaves the patient's location prior to initiating the procedure. Marking the site is required unless the practitioner is in continuous attendance from the time of the decision to do the procedure and patient consent to the initiation of the procedure (for example, bone marrow collection or fine needle aspiration).

Goal: Improve the effectiveness of communication among caregivers.

- ❑ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result "read-back" the complete order or test result.
- ❑ Standardize a list of abbreviations, acronyms, and symbols that are to be used throughout the organization.
- ❑ Measure, assess, and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.
- ❑ All values defined as critical by the laboratory are reported directly to a responsible licensed caregiver within time frames established by the laboratory (defined in cooperation with nursing and medical staff). When the patient's responsible licensed caregiver is not available within the time frames, there is a mechanism to report the critical information to an alternative responsible caregiver.

Goal: Reduce the risk of healthcare-associated infections.

- ❑ Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
- ❑ Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a healthcare-associated infection.

Surveyors

Experienced medical technologists (or pathologists) who have a minimum of a bachelor's degree, three years of clinical experience, and three to five years of management experience, preferably in a laboratory, conduct Joint Commission laboratory surveys. Most of the laboratory surveyors also have graduate degrees. Surveyors are required to pass a certification examination every five years (with "mini-exams" administered in the interim years as standards are revised). The certification examinations test surveyors' knowledge and enhance the credibility of the surveyor cadre.

Deemed Status

The Centers for Medicare & Medicaid Services officially recognizes Joint Commission Laboratory accreditation as meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA regulations require that all laboratories be surveyed on a two-year cycle.

Lab Advantage

Laboratories may choose the Lab Advantage option that combines Joint Commission accreditation, American Proficiency Institute (API) proficiency testing, and American Society for Clinical Pathology (ASCP) continuing education into one seamless process. The Lab Advantage option brings the strength of each organization together to address important issues of quality and efficiency in laboratory performance. For organizations participating in this option, Lab Advantage offers:

- ❖ competitive pricing;
- ❖ enhanced surveyor expertise;
- ❖ centralized purchasing;
- ❖ new educational opportunities; and
- ❖ personal customer service.

Joint Commission Fee Schedule

The Joint Commission reviews survey fees annually as needed to maintain the cost of its operations. Currently, accredited laboratories are billed biennially. The Joint Commission bases an organization's survey fees on several factors, including:

- ❖ type of services provided, and
- ❖ sites and/or locations of service

An organization may request a longer survey for an additional fee. Organizations experiencing an initial survey may benefit from an additional day. Multiple laboratories that are part of the same organization may be included in one survey and one accreditation decision.

Effective January 2006, the Joint Commission will begin annual subscription billing. Subscription billing will involve annual billing plus, during the year of survey, an assessment of an on-site survey fee to cover the direct costs that the Joint Commission experiences in conjunction with this activity.

For more information about JCAHO's laboratory accreditation, please visit www.jcaho.org, or contact Margaret Peck, Laboratory Accreditation Program, at 630-792-5287 or mpeck@jcaho.org.

Hope Foster, Esq.

Legal Issues In Lab Outreach, *from p. 1*

on a commission basis," she says. "Commissions paid to independent contractors create kickback issues. The federal anti-kickback statute makes it a crime to pay anyone, other than an employee, an amount to arrange for or recommend the referral of a service paid for by a federal healthcare program, and I can't imagine what the function of a salesperson is other than seeking referrals of testing services."

Sales representatives must be carefully trained, so they understand the kickback laws and understand what sales techniques are and are not permissible. Foster advises ensuring that sales representatives are not on the exclusions list published by the OIG *(www.oig.hhs.gov/fraud/exclusions.html)*. She also recommends keeping a list of every whistleblower who has brought a *qui tam* or whistleblower suit against any healthcare provider, so you can be sure not to hire them. "I'm not kidding because I have defended cases that have involved the same sales representative whistleblower time after time after time," says Foster. "Sales representatives understand how to make money, and filing whistleblower suits is one way to do it."

Requisitions

One key area where outreach testing differs from outpatient testing is the importance of requisition form design and review, Foster stresses. "This is something independent laboratories have been subjected to and have understood for 10 to 12 years, ever since the NHL [National Health Laboratories] case came down, but for hospitals, this is an area where there has been less attention," she says. "When you enter the commercial marketplace, it's very important that you are following the same types of compliance guidelines that commercial labs have been following."

- Make sure your ordering forms promote conscious ordering of tests, with adequate choice and disclosure.
- Remind physicians that Medicare, and in many cases, Medicaid, will only pay for services that are medically necessary for the patients for whom the tests are being ordered.
- Avoid use of custom profiles, which raise concerns about unbundling of services. "If you really must have custom profiles, go through a series of steps to make sure it's being done for medical reasons that are not economically motivated, that the physicians want them, and they're willing to sign a document that says they want them," advises Foster. Tests that comprise the custom profile must also be offered individually so physicians have the option of choosing just one test.

Pricing

Pricing of outreach services can also be a touchy area since the types of creative pricing permitted in other industries can be construed to be criminal in healthcare, notes Foster.

"The first thing you need to be sure of is that you don't do anything that would impede physicians from doing what they feel is medically necessary," she advises. "You also need to make sure that you don't artificially inflate utilization. Pricing discounts and waivers are always an issue that you must think about because volume is important and it can sometimes be increased through effective pricing practices."

If you are considering discounting your services, Foster suggests reviewing state law since a number of states make it illegal and being careful not to discount at a level that makes the price paid for the test below cost. One of the issues here, she says, is whether the cost of the outreach test is different than the cost of tests you perform for patients. You also must be careful that you are not billing "substantially in excess" of "usual charges," which is prohibited by federal law. The OIG in 2003 issued a proposal rule to define these terms, *oig.hhs.gov/authorities/docs/FRSIENPRM.pdf*. While the rule has not been finalized, Foster urges caution in pricing.

Other potential hot spots for outreach labs include:

1 **Professional courtesy.** Foster advises against offering special treatment to referring physicians or their families since they can be viewed as kickbacks.

2 **Provision of services, supplies, and other benefits to referrers.** The Medicare kickback statute makes it a crime to pay

or receive money or anything of value in return for referring or arranging referrals of patients or services that are paid for by the federal government. Many states have similar laws. Also, inducements to beneficiaries (such as coupons) also raise issues under the anti-kickback statute and many state laws. "If you're thinking about doing this, get your lawyer involved," says Foster. "They can be offered, but it must be done very carefully. I wouldn't use coupons with Medicare patients."

3 **Billing.** There are federal and state laws that determine who can bill for these services. Foster advises ensuring that your coders are well trained. "You've got to be sure that your CPT codes are correct and that your ICD-9 codes are correct," she says. "You need to get those codes from your doctors – don't guess. A lot of education and training is required here. You want to be sure that if you get narrative diagnoses, you have qualified people who are converting those diagnoses to proper ICD-9 codes." If the outreach program is using the hospital's billing system, there's a good chance the billing staff are unfamiliar with coding for outreach services because they are unlike services offered under Part A and even under outpatient Part B. Make sure you are bundling and unbundling correctly, and review your chargemaster on a regular basis, she says.

4 **Income tax**. Nonprofit hospitals that conduct outreach testing have an obligation to pay unrelated business income tax, so you need to track your outreach patient revenue to take care of your tax obligations.

Share Ownership

Foster also advises seeking legal counsel if you are considering joint ventures or other forms of shared ownership with physicians. Such arrangements can raise questions about improper referrals and potentially lead to sanctions and corporate integrity agreements (CIAs), which can be burdensome.

Foster cites a CIA recently reached with Pharmerica, which the OIG alleged paid kickbacks to obtain business. The CIA requires the company to create a database that contains a list of all covered transactions, which is defined as "the acquisition or sale of any interest in a business unit or entity that furnishes [healthcare items or services] that are reimbursed by Medicare, Medicaid, or other federal health programs." This includes the names of the acquiring and selling party, the type of transaction, the purchase price, the name of the individual who provided the management representation, the name of the lawyer who conducted the legal review, the date of closing of the transaction, and the file number, says Foster.

The CIA also contains a host of other requirements, such as: the agreement must be set forth in writing, a written description must be obtained from the most senior member of the company's management involved in the transaction, and a statement that the entire arrangement between the parties must be reflected in the written agreement and documents.

"Perhaps the most interesting aspect of this, besides the fact that it is extraordinarily broad and puts the OIG smack dab in the middle of this company's business, is that the day this was issued I received two e-mails: one from Jim Sheehan, a federal prosecutor in Philadelphia, and one from a lawyer with the OIG's office," says Foster. "They both suggested that I read this, noting that this is a different approach to kickbacks. They're right, it is. It suggests a much more aggressive approach to enforcement of the kickback authorities."

Resource

Hope Foster: 202-661-8758

Texas AG Sues 12 Drug Companies

Texas Attorney General Greg Abbott (R) filed a lawsuit on May 5 against 12 drug manufacturers, charging them with ignoring a three-year-old state law that requires them to report the average manufacturer price (AMP) of Medicaid-covered drugs to the Texas Health and Human Services Commission (HHSC).

The lawsuit seeks a permanent injunction to compel the companies to file accurate prices with the government as required by Texas law. AMPs are the average price wholesalers pay to manufacturers for drugs they then distribute to retail pharmacies, less any customary volume purchase discounts and incentives for prompt payment.

Prior to filing the suit, the attorney general sent letters to 160 companies, notifying them of the requirement to file AMPs with the state. In response to those letters, the vast majority of the companies began filing the prices. The 12 defendants named in the May 5 lawsuit are the only companies that failed to respond to the demand letter, according to the Abbott.

The HHSC reimburses pharmacies for prescription drugs for eligible beneficiaries in the state's Medicaid, Children with Special Healthcare Needs, Kidney Healthcare, and Children's Health Insurance Programs. The amount the program pays pharmacies equals either the usual and customary price the pharmacy charges the general public or its best estimate of the pharmacy's actual acquisition cost plus a dispensing fee, whichever is less, according to the attorney general's complaints. The agency estimates the pharmacy's acquisition cost for a drug, based on pricing information reported to it by the drug's manufacturer. The AMPs help the agency ensure the reimbursement amount it pays to pharmacies is accurate, says Abbott.

The defendants named in the lawsuit: Healthpoint, Ltd. (Fort Worth, TX); Clay-Park Labs (Bronx, NY); E. Fougera and Co., a division of Altana Inc. (Melville, NY); ESP Pharma (Edison, NJ); Hercon Laboratories (Emigsville, PA); LifeCycle Ventures (Upper Saddle River, NJ); Person & Covey (Glendale, CA); Pharmaceutical Associates (Tampa, FL); Pharmascience Laboratories (Tonawanda, NY); Savage Laboratories (Melville, NY); Somerset Pharmaceuticals (Tampa, FL); and American Pharmaceutical Partners (Schaumburg, IL).

Get Your National Provider ID

Healthcare providers can apply for a national provider identifier (NPI) starting May 23, using the Centers for Medicare & Medicaid Services' Web-based application process. Paper applications will be available beginning July 1.

The NPI will replace healthcare provider identifiers that are in use today in standard transactions. Implementation of the NPI will eliminate the need for healthcare providers to use different identification numbers to identify themselves when conducting standard transactions with multiple health plans. Many health plans, including Medicare, Medicaid, private health insurance issuers, and all healthcare clearinghouses, must accept and use NPIs in standard transactions by May 23, 2007. Small health plans have an extra year to comply.

According to a letter sent to providers May 6, they can apply for NPIs in one of three ways:

1. As of May 23, you may apply online at *https://nppes.cms.hhs.gov.*
2. As of July 1, you may submit a paper application. The application and mailing address will be available online at the address listed above.
3. Beginning in the fall, an organization (such as an association or a healthcare provider who is your employer) may submit your application on your behalf.

The May 6 letter to providers is available at *www.cms.hhs.gov/hipaa/hipaa2/npi-provider.pdf.*

Specialty Hospital Referral Ban: Senate Finance Committee Chairman Charles Grassley (R-IA) and Ranking Minority Member Max Baucus (D-MT) May 11 introduced legislation that would prohibit physicians from referring Medicare and Medicaid patients to new specialty hospitals in which they have an ownership interest. The Hospital Fair Competition Act of 2005 would essentially exclude specialty hospitals from the "whole hospital" exemption in the Stark physician self-referral law. Opponents of specialty hospitals have argued that these types of limited service facilities are more akin to a whole hospital subdivision than a whole hospital and therefore should fall outside the protection of the whole hospital exemption. The Medicare Modernization Act of 2003 established an 18-month moratorium on physician referrals to specialty hospitals in which they have an interest. The moratorium is set to expire June 8.

Conflict of Interest: The Permanente Medical Group (TPMG), the largest medical group in the country, has tightened its conflict of interest rules to counter the growing influence of companies selling pharmaceuticals, medical devices, and equipment to its 5,992 doctors in northern California. The new policy covers a wide range of activities and relationships, from accepting gifts to participating in speakers' bureaus and vendor-sponsored research.

"Born Alive" Enforcement: The Centers for Medicare & Medicaid Services told state survey agencies April 22 that breaches of the Born-Alive Infants Protection Act of 2002 should be investigated as potential violations of the Emergency Medical Treatment and Labor Act (EMTALA). The guidance came at the same time that Health and Human Services Secretary Michael Leavitt issued a statement that existing HHS-enforced regulations covered enforcement of the Born Alive Act. The act prohibits healthcare institutions from denying care to infants born alive at any stage of development, even if the birth is the result of a failed abortion attempt.

FTC Focus: The Federal Trade Commission (FTC) will continue its focus on competition in the healthcare sector and is looking at a series of mechanisms for achieving better compliance by providers, physicians, and insurers, commission member Jon Leibowitz told lawyers May 12 at the Antitrust in Healthcare Conference in Washington, DC. Leibowitz cited ongoing problems in the pharmaceutical industry, joint negotiation of prices by physicians, and healthcare mergers—involving both payers and providers—as areas of FTC concern.

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