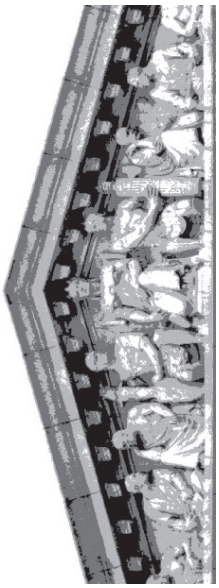

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

California Lab Pays $10 M To Settle Fraud Charges
Health Line Latest Casualty In Crackdown

Health Line Clinical Laboratories (Los Angeles), one of the fastest-growing privately held labs in California, has agreed to pay $10 million to the federal and state governments to settle allegations that it defrauded Medicare and Medicaid by improperly charging the programs for medically unnecessary blood tests.

The case is just the latest in a series of settlements by labs targeted under a federal crackdown on perceived fraud and abuse involving blood tests. Quest Diagnostics, for example, in March agreed to pay $11.35 million to settle charges that two of its predecessor companies, MetPath and Damon Laboratories, as well as the recently acquired Unilab, had improperly billed Medicare and Medicaid for unnecessary lab tests. Over the past 12 years, clinical labs have paid more than $1 billion to settle similar allegations.

Whistleblower Charges

The allegations against Health Line Clinical Laboratories arose from a lawsuit filed by two former HLCL sales representatives, Kim Jenkins and Timothy Mills, under the *qui tam* provisions of the False Claims Act. Jenkins and Mills alleged that the lab and its owners, Aramais Paronyan, M.D., and Natella Lalabekyan, improperly added unnecessary blood tests to comprehensive panels and profiles. The charges involved five specific tests:

- Apolipoproteins (A&B)

➥ *p. 2*

Medicare Drug Card Sponsors Face Hefty CMPs

Medicare prescription drug discount card sponsors could face civil monetary penalties as high as $10,000 for false or misleading marketing practices or other acts considered fraudulent, according to an interim final rule issued May 19.

The Medicare Prescription Drug, Improvement & Modernization Act of 2003 (DIMA) authorizes the imposition of civil monetary penalties (CMPs) against drug card sponsors for certain violations, the Department of Health and Human Services Office of Inspector General (OIG) says in the rule. Drug card sponsors can be fined up to $10,000 each for violations in which they knowingly:

- Misrepresent or falsify information in outreach or enrollment material;
- Charge a program enrollee in violation of the terms of the endorsement contract; or
- Use transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

➥ *p. 8*

Inside this issue

The civil investigation and settlement were handled by the U.S. attorney for the northern district, the U.S. Department of Justice, and the California attorney general's office, with assistance from the HHS Office of Inspector General and the FBI.

California Lab, *from page 1*

- 5-nucleotidase
- Extractable nuclear antigen (ENA) antibodies
- Zinc protoporphyrin
- *Treponema pallidum* IgG antibodies

According to a statement from the U.S. attorney for the northern district of California, HLCL and its owners "caused doctors to order or appear to order these medically unnecessary tests by unilaterally adding the tests to the commonly ordered profiles regardless of medical necessity and not disclosing to physicians that HLCL was charging the Medicare and Medicaid program" for the extra tests.

As part of the agreement, HLCL will implement a corporate integrity agreement that will provide evidence and documentation of the compliance program in place at the lab.

Health Line Denies Charges

Gary Burkhartsmeier, HLCL's chief executive officer, says the lab admits no liability but agreed to settle the case because fighting the charges was proving too costly. The investigation has "clearly taken a toll on our managerial resources and had begun to negatively impact our clients' productivity," he said in a statement.

"Nearly every major clinical laboratory has settled civil suits on similar issues over the past 10 years," he continued. "We had hoped to be the first laboratory to weather the storm and resolve this issue in court. Unfortunately, that desire must give way to the business necessity" of providing lab services to physicians.

According to Burkhartsmeier, HLCL never ordered additional tests without physicians' knowledge. The orders came from referring physicians, and the tests were rarely ordered in "comprehensive panels," he tells *G-2 Compliance Report*. "Instead, they were typically ordered either reflexively or in special-use organ-function panels that had specific applications. We carefully documented physician orders and had proper panel acknowledgements when physicians wanted them included in their custom profiles."

Labs Take Heed

Is there any way that labs can completely avoid the same kind of scrutiny? Probably not, believes Patric Hooper, an attorney with Hooper, Lundy & Bookman (Los Angeles), the firm that represented HLCL. Simply by informing physicians about different tests that might be available, labs could subject themselves to charges that they have unduly influenced physicians, he says.

"I think there's a little bit of a disconnect between the industry and the Office of Inspector General, and I think until they see eye to eye on what a laboratory can do, there's always going to be a problem," explains Hooper. The OIG "is convinced that laboratories determine medical necessity and what is needed, rather than the doctor."

The best thing a lab can do, suggests Hooper, is to be sure to get written acknowledgment from physicians of the tests they are requesting in advance of the services being performed.

Burkhartsmeier has a slightly different view: "I think the only safe thing to do is to stop performing panels entirely," he says.

Resources

- U.S. attorney for the northern district of California: 415-436-7200
- Gary Burkhartsmeier: 800-954-4888
- Patric Hooper: 310-551-8111

Fraud & Abuse Settlements ($MM)

Company (on behalf of)	*Year*	*Amount*
LabCorp (National Health Labs)	1992	$111
Quest Diagnostics (MetPath)	1993	36
LabCorp (Allied)	1994	5
Quest Diagnostics (Damon)	1996	119
Quest Diagnostics (MetPath)	1996	7
Unilab	1996	4
LabCorp (Roche Biomedical/Allied)	1996	187
Spectra Laboratories	1996	10
Franklin Laboratories	1997	5
Unilab (Meris)	1997	5
SmithKline Beecham Clinical Laboratories	1997	325
Unilab (Physicians Clinical Laboratory)	1997	2
Quest Diagnostics	1998	7
Quest Diagnostics (Damon)	1998	15
Fresenius Medical Care (LifeChem)	2000	486
Quest Diagnostics (Nichols)	2001	13
Dianon	2002	5
Quest Diagnostics (MetPath, Damon, Unilab)	2004	11
Health Line	2004	10
Total		$1,363

Source: *GCR*

CMS Plans Pilot To Examine Hospital Compliance Programs

Study Will Identify Best Practices

The Centers for Medicare & Medicaid Services (CMS) said May 18 that it will launch an 18-month pilot program in 13 states and Washington, DC, to determine the effectiveness of the voluntary compliance programs used by many hospitals.

The evaluation will identify best practices to prevent improper activities, such as incorrect billing, and how these approaches can be applied successfully by other providers, according to the agency. Hospitals have until June 25 to apply for the pilot program.

CMS will also look at developing incentives, such as expedited appeals or enhanced claims data, to encourage providers with an effective compliance program to continue it and to encourage additional hospitals to implement best practices.

The Department of Health and Human Services Office of Inspector General is currently developing an update to its 1998 voluntary compliance guidance for hospitals. The draft update will be released within the next several weeks.

"We intend to get the maximum compliance possible by hospitals in preventing waste, fraud, and abuse," said CMS Administrator Mark McClellan in announcing the program. "Most hospitals want to comply, and our goal is to help as broad a range as possible of hospitals implement successful compliance practices. We encourage applications from rural hospitals, as well as large medical centers in urban centers, and from hospitals with either basic or advanced compliance programs."

Compliance programs help providers in implementing internal controls and monitoring to correct and prevent improper activities. These programs also encourage adherence to all federal and state laws that govern hospitals, CMS said.

Focus of Pilot

The pilot program will focus on acute-care hospitals and academic medical centers with a minimum of 100 beds. This is based on the prevalence of compliance programs in hospital settings and the types of hospitals typically having operational compliance programs. In addition, the hospital's inpatient revenues should account for at least 30% of total revenue, and the Medicare billings must account for at least 25% of total revenue.

CMS plans to focus this project on hospitals in three CMS regions, including the six New England states, the District of Columbia, and the eastern states of Delaware, Maryland, New Jersey, New York, Pennsylvania, Virginia, and West Virginia. These 13 states and Washington, DC, have about 1,000 inpatient hospitals.

The project will include outcome measures based on information from contractors, including a provider's Medicare claims rejection and overall error rate. This information is already being collected, so no additional level of scrutiny or review will be required by providers participating in the project, according to CMS.

The data will be compared with the results of an onsite review of the compliance program to see if any correlation can be identified. For example, the project will examine the nature of the connection between a hospital's compliance program and its overall denial and error rate.

Incentives

To provide an incentive for hospitals and medical centers participating in the pilot, participating hospitals may receive enhanced claims data. This would be a report-card type option, allowing these institutions to get detailed information from the contractor to find out how that provider is doing in various areas tracked by the contractor.

Typically, this information, which is not compiled in one place, would serve as a road map

for a hospital's compliance program to see where possible problem areas are occurring. CMS expects to provide this information to all hospitals that have implemented compliance programs.

Two site visits will be made to each of the pilot's participants to assess the extent of its compliance program. The initial visit will begin soon after providers are notified they have been selected to participate in the project. A second visit will be made at the end of the project to compare results with the initial visit.

CMS will develop a list of indictors to be used during the site visits to come up with a quantifiable measure of the provider's effectiveness. The final list of indicators will be developed with input from the hospital community and compliance professionals. These indicators, says the agency, will primarily focus on certain areas, including auditing and monitoring, education and training, and corrective-action aspects of a hospital's compliance program.

Resource

- The Centers for Medicare & Medicaid Services: *www.cms.hhs.gov* (for more info, write to *compliance@cms.hhs.gov*).

HIPAA Violators May Face Tougher Enforcement

While enforcement of the Health Insurance Portability & Accountability Act privacy regulations remains focused on voluntary compliance, informal resolution, and education, it might not be long before healthcare providers begin seeing criminal and civil penalties for violations.

Almost half of the more than 5,000 complaints filed in the first year of the privacy rule have been resolved, Richard Campanelli, director of the Department of Health and Human Service's Office for Civil Rights (OCR), told a District of Columbia Bar meeting May 5. The rest of the cases are pending, and 50 have been referred to the Department of Justice for investigation and possible criminal prosecution, he said. Cases that are being pursued criminally by DOJ are not subject to civil money penalties imposed by OCR, he noted. HHS issued the privacy rule under authority of HIPAA's administrative simplification provisions.

The most common complaints involve: impermissible use or disclosure of protected health information (PHI); lack of adequate safeguard to prevent such use or disclosure; failure to provide access to PHI; disclosure of PHI that exceed the "minimum necessary" standard; and failure to provide notice of privacy practices. The entities named most in the complaints are private healthcare providers, general hospitals, pharmacies, outpatient facilities, and group health plans.

Diane Faup, an advisor to the Office of HIPAA Standards at the Centers for Medicare & Medicaid Services (CMS), said the agency so far has received 120 complaints with respect to alleged violations of the transactions and code set rules that CMS oversees. She said her office, too, is focused primarily on achieving voluntary compliance.

COMPLIANCE PERSPECTIVES

Laboratory Compliance Hot Button Issues

Kathleen McDermott is a partner in Blank Rome's Health Law and White Collar Practice Groups, where she represents healthcare providers and government contractors in the areas of compliance counseling, internal investigations, government investigations, and healthcare business litigation.

Government enforcement efforts in the 1990s focused criminal and civil investigations on national clinical laboratories for billing and marketing practices that caused the submission of false claims or violations of the federal anti-kickback statute. Some of the allegations involved tests not performed, tests not actually ordered, unbundled test billings, routine standing orders, and add-on tests that were medically unnecessary. Many of the large national laboratories companies settled laboratory false claims billing allegations under the civil False Claims Act and entered into Office of Inspector General (OIG) corporate integrity agreements (CIAs).

In 1998, the OIG issued compliance guidance for clinical laboratories that identified billing and marketing practices that may result in administrative, civil, or criminal sanctions. Some of the practices that were identified included free products or services to physicians or hospitals, misleading marketing that failed to inform the physician, hospital, or patient of all the tests included in panels or profiles, overreliance on standing orders that were not necessary for the condition of the patient, and failing to properly process specimens.

Many of the abuses in the laboratory industry as they relate to billing and coding issues have diminished as a result of government investigations and the industry's response in compliance safeguards.

More recently, however, there has been a renewed focus on laboratory billings and laboratory quality assurance standards at independent laboratories as well as hospital laboratories. There is also an increasing recognition by the government and other enforcement agencies that the compliance efforts of the 1990s do not ensure that the industry is cured of all compliance issues, and there is a greater emphasis on evaluating "effective" compliance programs and strategies.

Recent Laboratory Prosecutions

The government has continued to predominantly use the False Claims Act and its multiplier damages to address laboratory compliance issues related to nursing home services, hospitals, and other healthcare providers.

Since 2003 there have been several False Claims Act settlements involving laboratory practices. In March 2004, Quest Diagnostics settled False Claims Act allegations, paying over $11 million to resolve allegations that it defrauded the United States by billing Medicare for medically unnecessary tests. The medically unnecessary tests included apolipoproteins, which are part of profiles in panels relating to coronary testing, urine microscopy exams, and calcium tests. The government alleged that Quest automatically calculated "free" thyroid test panel indexes that should have been included as part of disease test panels.

In April 2004, Health Line Clinical Laboratories paid $10 million to settle allegations that its billing practices defrauded Medicare and Medicaid from 1996 to 2003 (*see related article, pg. 1*). The allegations were made by two former sales representatives who brought whistleblower suits under the civil False Claims Act. The allegations involved unnecessary blood tests added to blood-test panels and profiles ordered by physicians.

Genesis Clinical Laboratory, owned by MacNeal Health Services, was a subject of a whistleblower suit under the False Claims Act relating to allegations that its laboratory requi-

sition forms improperly bundled tests, encouraging physicians to order tests that were not medically necessary.

Abington Memorial Hospital, near Philadelphia, settled a False Claims Act suit that alleged it submitted over 70,000 false claims related to outpatient clinical laboratory tests. The hospital allegedly submitted claims that unbundled or duplicated charges for blood chemistry tests and more than 10,000 claims for blood tests for auditing iron binding capacity that were not medically necessary as add-on tests. The government alleged there was double billing of platelet counts and hematology profiles and unbundling of two hematology procedure codes. The Abington settlement is significant because the government alleged the hospital failed to respond to internal compliance questions about hospital laboratory operations by self-auditing its outpatient laboratory billings to Medicare and failed to undertake any sample review of individual laboratory complaints.

The concern regarding laboratory test quality is not limited to the OIG or federal prosecutors in the U.S. attorneys' offices.

OIG 2004 Work Plan

Laboratory compliance issues have frequently been viewed as billing issues, but, increasingly, quality of care issues have received notice. There have been False Claims Act whistleblower suits alleging substandard or poor quality laboratory testing, which is actionable under the False Claims Act as a "worthless service." Medicare pays over $4 billion annually for clinical laboratory services, all of which must meet condition-of-participation requirements.

The OIG 2004 work plan indicates that it will undertake a study to determine whether Medicare pays for any testing outside the scope of a laboratory's Clinical Laboratory Improvement Act (CLIA) certification. Laboratories are required to certify for each specialty in which testing is conducted. Some laboratories have been certifying additional specialties, which raise the cost of certification. Currently, Medicare does not reconcile billed testing with CLIA specialty certification before paying claims and, therefore, may be overpaying certain laboratory claims. The OIG will compare claims of certification records to quantify whether there is any improper payment or any loss CLIA certification fees.

The OIG will also evaluate laboratory compliance with the CLIA 1988 requirements to participate in proficiency testing. Proficiency testing is required as a condition of participation in which laboratories are graded for their accuracy in analyzing clinical specimens. The OIG is not simply concerned with independent clinical laboratories. The 2004 OIG work plan will evaluate whether hospitals separately bill Medicare for laboratory services that are already included in their end-stage renal disease composite rate (ESRD). Under Medicare's composite-rate reimbursement system, the ESRD facilities are reimbursed for 100% of their cost. Hospitals that separately bill laboratory services relating to ESRD services are in effect double billing the Medicare program.

The OIG will also undertake a review to determine the extent and nature of any medically unnecessary or excessive imaging and laboratory services provided to nursing home residents. Medicare pays more than $200 million a year for imaging and laboratory services in nursing homes, and it will undertake a sample of services and utilization patterns for nursing facilities. This is an area where routine standing orders have been in place and may be subject to scrutiny.

Increased Scrutiny

The concern regarding laboratory test quality is not limited to the OIG or federal prosecutors in the U.S. attorneys' offices. CMS has indicated that it will conduct on-site inspections of laboratories, particularly laboratories with waivers that allow them to perform routine testing without regular federal review. As a part of reviews undertaken in Ohio and Colorado in 2002, CMS identified a pilot program that would expand CLIA in-

spections to eight states because of concerns regarding significant quality and certification problems.

Even the Environmental Protection Agency has focused its enforcement eye on New England facilities after finding numerous environmental violations at hospital laboratories.

Maryland General Hospital: Laboratory Compliance Gone Awry

Laboratory quality problems uncovered recently at Maryland General Hospital (Baltimore) provide a powerful illustration of the kind of mistakes that could provoke criminal and civil investigations, not to mention a public health crisis. Maryland General Hospital is a 245-bed facility affiliated with the University of Maryland Health System. Over a two-year period, numerous laboratory technicians advised supervisors that the laboratory blood analyzer machine was malfunctioning and providing questionable results. They also reported concerns regarding lab-billing practices. The laboratory quality issues were a source of considerable internal controversy at the hospital before being brought to the attention of hospital management and to the Maryland Office of Health Quality, which is responsible for state oversight of hospital operations.

What happened at Maryland General Hospital may have national repercussions for hospital laboratories

The lab technicians reporting the laboratory testing deficiencies were not taken seriously, and no corrective action was undertaken in response to their concerns. It is reported that a climate of intimidation existed in which hospital employees felt that they would lose their jobs if they pursued the allegations. Additionally, during this time, state surveys of the hospital lab were conducted but found no serious deficiencies. The accrediting agency also undertook a review that found no serious deficiencies.

However, in March 2004, Maryland Hospital revealed that over 340 HIV tests were conducted improperly, and said that patients would have to be notified of inaccurate results. Other testing deficiencies became public thereafter. It is reported that state inspectors have subsequently found that test data may have been manipulated or eliminated and that manufacturing standards may not have been followed.

What happened at Maryland General Hospital has become a public health scandal, one that could have been avoided had the hospital listened to its laboratory technicians. The incident may have national repercussions for hospital laboratories. Recriminations aside, an effective compliance program could have resulted in a more timely and appropriate response to the testing deficiencies and avoided a public health crisis in the Baltimore area. It is reported that the hospital is now under criminal investigation by the Maryland Medicaid Fraud Control Unit, as well as other state and federal enforcement agencies. Congressman Elijah Cummings (D-MD) has commenced congressional hearings on the efficacy of the state inspection process and the reliance on outside accrediting bodies to detect and report quality assurance issues. During the two-year period that the hospital employees were reporting laboratory overbilling and quality-assurance concerns, the accrediting agency was rating the hospital laboratory as in good standing.

There is a growing concern among state and federal regulators that laboratory quality assurance issues are a big problem. This concern will capture the attention of government prosecutors and whistleblowers and launch False Claims Act investigations against independent and hospital laboratories. It is a good bet that laboratory billing and quality-assurance issues will be a focus of future government enforcement efforts. Laboratories that have compliance programs should consider a meaningful evaluation of the effectiveness of their compliance activities in light of recent enforcement developments.

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Drug Card Sponsors, *from page 1*

Certain low-income Medicare beneficiaries enrolled in the Medicare drug discount program are eligible to receive transitional assistance of up to $600 per year, which may be applied toward the cost of covered discount-card drugs obtained under the program. Sponsors are required to administer the assistance and to account for the assistance provided. Drug card sponsors also are required to provide beneficiaries adequate information by which to make informed choices in selecting a discount-card program.

The rule also provides for CMPs of as much as $25,000 in cases where drug card sponsors misuse the Medicare name or emblem in a way that knowingly gives a false impression that an item is approved, endorsed, or authorized by HHS.

The interim final rule takes effect June 18, 2004. OIG will consider comments if received by July 19.

Shared Enforcement

The authority to sanction card sponsors who violate the Medicare law is shared between the Centers for Medicare & Medicaid Services (CMS) and the OIG, according to the notice. The OIG is responsible for violations that concern "misleading or defrauding" a beneficiary and for misuse of transitional assistance funds.

CMS, meanwhile, has the authority to impose CMPs in those instances where the endorsed sponsor's conduct constitutes "noncompliance with an operational requirement not directly related to beneficiary protection."

Resource

Drug Discount Card Interim Final Rule (May 19, 2004): *www.gpoaccess.gov/fr/index.html*

OIG Offers Guidance On Reviewer Independence

The Department of Health and Human Services Office of Inspector General has offered healthcare providers additional guidance to help them determine the independence of independent review organizations (IROs) that evaluate compliance with corporate integrity agreements (CIAs).

The FAQs and their answers are available on the OIG's Web site at http://oig.hhs.gov/fraud/cia/docs/ciafaqiro.pdf.

According to the OIG, the office has received a number of inquiries from individuals and entities subject to CIAs concerning circumstances that might affect the independence of an IRO conducting CIA reviews. The questions have been prompted both by the Sarbanes-Oxley Act, which imposed new requirements for corporate and financial managements, and a greater focus on issues relating to auditor independence.

The OIG has determined that it is appropriate to adopt the standards for auditor independence set forth in the General Accounting Office (GAO) Government Auditing Standards (2003 Revision), commonly referred to as the "Yellow Book." Under these standards, CIA reviews would be considered performance audits, and IROs would be subject to the independence standards set forth in the Yellow Book relating to such audits.

These independence standards require, among other things, that the audit organization have an internal quality control system to help determine whether auditors have any personal impairments to independence that could affect their impartiality (such as family relationships or financial interest).

In addition, IROs that perform CIA reviews would be subject to the independence standards that apply when an audit organization agrees to perform nonaudit services for the same client. When assessing independence, the two overarching principles that must be considered are that: 1) audit organizations should not perform management functions or make management decisions; and 2) audit organizations should not audit their own work or provide nonaudit services in situations where the nonaudit services are material to the subject matter of the audits.

The OIG guidance, issued May 6, also includes a list of frequently asked questions that address specific situations, such as whether an IRO may conduct a provider's CIA review if the IRO has performed specific compliance services for the provider or a review identifying strengths and weaknesses.

Texas AG Sues Abbott, Others In Alleged Pricing Scheme

Texas Attorney General Greg Abbott on May 26 filed a lawsuit against Abbott Laboratories, Baxter Healthcare Corp., and B. Braun Medical Inc., alleging that they engaged in a deliberate scheme to falsely report the wholesale prices of specific drugs and devices prescribed for Medicaid patients.

The suit seeks three times actual damages, estimated at $8 million, plus civil penalties and legal fees. This latest case comes on the heels of a $27 million settlement between the state and Schering-Plough Corp. over allegations that the drug manufacturer inflated prices for prescription asthma products to the Texas Medicaid program.

Ven-a-Care of the Florida Keys Inc., a specialized pharmacy that participates in the state Medicaid program, brought the latest scheme to the attention of the state and may be eligible to recover damages. Ven-a-Care blew the whistle on Schering-Plough and recovered $5.4 million under its settlement with the state.

The May 26 lawsuit alleges that Abbott Labs and the other two companies erroneously reported prices for intravenous fluids and other products, leading the state Medicaid program to reimburse clinics, pharmacies, distributors, and wholesalers at vastly inflated rates.

According to the attorney general, the "windfall" dated to 1995 and induced customers to favor business relations with the three companies, creating a long-term, illegal market niche for them.

CMS Clarifies EMTALA Responsibilities

The Centers for Medicare & Medicaid Services (CMS) on May 13 issued interpretive guidelines designed to provide additional guidance on the responsibilities of hospitals in emergency cases.

The revised Emergency Medical Treatment and Active Labor Act (EMTALA) guidelines are effective immediately, CMS said in a memo to regional offices and state survey agencies. EMTALA prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition. The provisions of EMTALA apply to all individuals—not just Medicare beneficiaries—who attempt to gain access to a hospital for emergency care.

The revised guidelines incorporate changes made in the 2003 EMTALA final rule, including defining a "dedicated emergency department" as any department or facility of the hospital that is licensed as an emergency department, or held out to the public as providing treatment for emergency medical conditions, or where one-third of the visits the preceding year provided treatment for emergency medical conditions.

The guidelines also detail the measures hospitals with dedicated emergency departments are required to take, such as posting signs, maintaining a list of physicians on call, maintaining a log of individuals who come to the department seeking treatment, and providing an appropriate transfer of an unstabilized individual to another medical facility.

CMS also discusses investigations of facilities to determine compliance with EMTALA. All investigations are to be unannounced and must be completed within five working days of the regional office authorization. Once the investigation is complete, the regional office should share as much information with the hospital as possible, according to the guidelines.

Deadline Extended Until July 12th

Laboratory Public Service National Leadership Award for 2004

This award is presented annually by Washington G-2 Reports, in conjunction with our annual Lab Institute program, to honor an individual's contributions in one or more of the following categories: professional or scientific achievement; basic or applied research; business creativity/innovations; education and training; public policy or special service in the public interest to promote patient care or the laboratory professions.

Nomination forms are available at *www.g2reports.com*, or by calling 202-789-1034.

Compliance Programs Integral To Healthcare Companies
Survey Finds Most Are In Maturing Phase

Corporate compliance programs, unknown to most healthcare organizations in 1997, are now an accepted part of their framework, with almost all organizations reporting that they have either an active compliance program or one under development.

While the compliance function has become an accepted part of most healthcare companies, monitoring and auditing remain key issues, as do education and training, according to the Healthcare Compliance Association's Sixth Annual Survey – 2004 Profiles of Healthcare Compliance Officers. Compliance with the Health Insurance Portability & Accountability Act (HIPAA) also continues to be a top concern.

The online survey, conducted in early 2004, was expanded over previous surveys to include data about compliance training, budget, staff education, compensation, and background checks. The results provide benchmark data to practitioners about the state of the healthcare compliance industry.

According to the survey, 91% of respondents conduct compliance training beyond just the initial training, 70% conduct annual training, and 50% report that employees spend between one and three hours in compliance training each year. Instructor-led training by the compliance officer was the top method used (73%), while 55% reported they use computer-based or Web-based training, and 41% use video training.

Many organizations (30%) have a budgeted line item for training, with 25% reporting a training budget of $50-$5,000, and 22% reporting a training budget of between $5,000 and $15,000.

Annual budgets for most compliance departments ranged from less than $100,000 to $300,000, with a few organizations spending slightly more. Almost a quarter of respondents (23%) had budgets of less than $100,000, while 21% report having budgets of between $150,000 and $299,999. The largest single-line item in compliance budgets was salaries, with the rest divided among such things as training, outside attorneys, and compliance staff education.

Resource

HCCA's Sixth Annual Survey – 2004 Profile of Healthcare Compliance Officers: *www.hcca-info.org/Content/NavigationMenu/Compliance_Resources/Surveys/Annualsurvey6th.pdf*

Teaching Hospital Settles Billing Fraud Case

The University of Washington will pay $35 million in restitution, damages, and penalties to resolve charges of fraudulent healthcare billing practices by university physicians' groups. This is the largest settlement involving billing fraud at any U.S. teaching hospital.

Federal and state investigators uncovered fraudulent billing practices at two university physician groups – University of Washington Physicians and Children's University Medical Group – with regard to Medicaid, Medicare and TRISTAR claims, according to John McKay, the U.S. attorney for the western district of Washington. The case has already resulted in guilty pleas to criminal charges by two university physicians, he said.

As part of the settlement, the university agreed to an institutional compliance agreement with the Department of Health and Human Services Office of Inspector General.

"Innocent Mistakes"

Paul Ramsey, M.D., university vice president for medical affairs and dean of the School of Medicine, admits the university made mistakes, but adds that it has taken steps to remedy the problems.

"There's no question that billing errors were made," he said. "While most of these errors were the result of innocent mistakes, we recognized our responsibility and took immediate steps to improve our compliance efforts."

According to Dr. Ramsey, the billing procedures in question occurred during a period when federal rules involving Medicare and Medicaid billings were changing and widely acknowledged to be confusing.

"When we first became aware of the government's investigation in November 1999, we were shocked," he said. "But as the investigation continued, it became clear that our compliance program was not up to the task in certain respects."

The government would have sought a larger amount in the settlement, but "took into consideration the incredibly important role" of the university medical system for the region, McKay said, adding that prosecutors did not want to "damage the core medical system in this region."

Throughout the investigation, the university has been implementing comprehensive, concrete measures to enhance its billing compliance system, he added. Enhancements included improved oversight at several levels, additional staff and physician training, and efforts to enhance communication between professional fee coordinators and physicians regarding coding and documentation issues. The university now spends almost $4 million a year on compliance, Dr. Ramsey said.

Investigation Ends

The settlement ends an investigation that resulted in guilty pleas to criminal charges against two university physicians.

One pleaded guilty to fraudulent healthcare billing in 2003 and was sentenced to five-years' probation and 1,000 hours of community service. The other pleaded guilty to obstructing a federal and state investigation into fraudulent billing practices and was ordered to pay $500,000 to the federal healthcare programs in addition to serving probation and performing community service.

The University of Washington investigation is the only billing fraud case that has involved criminal charges, according to McKay. Mark Erickson, a former university auditor who filed the complaint in August 1999 that led to the billing fraud investigation, will receive 22.5% of the settlement.

Resources

U.S. attorney for the western district of Washington: *www.usdoj.gov/usao/was/press_room/2004/apr/UW.htm*

Warner-Lambert To Pay $430M In Off-Label Case

Pharmaceutical manufacturer Warner-Lambert has agreed to plead guilty and pay more than $430 million to resolve criminal and civil charges that its Parke-Davis division illegally promoted unapproved uses for one of its products, Neurontin.

Neurontin was approved in 1993 for the treatment of partial seizures with and without secondary generalization in adults with epilepsy. However, according to Michael Sullivan, U.S. attorney for the district of Massachusetts, Warner-Lambert aggressively marketed the drug to treat a wide variety of ailments for which it was not approved. The company promoted Neurontin for the treatment of bipolar mental disorder, various pain disorders, amyotrophic lateral sclerosis, attention deficit disorder, migraines, drug and alcohol withdrawal seizures, restless leg syndrome, and as a first-line monotherapy treatment for epilepsy (rather than in addition to another drug).

Warner-Lambert also paid doctors to attend so-called "consultants meetings." At these meetings, physicians received a fee for attending expensive dinners or conferences during which presentations about off-label uses of Neurontin were made, according to Sullivan. The company also sponsored purportedly "independent medical education" events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants.

Pfizer, Warner-Lambert's parent company, said in a statement that it cooperated fully with the government to resolve the matter. The underlying allegations and related investigations originated in 1996, well before Pfizer's acquisition of Warner-Lambert in 2000.

❖ Physicians should expect the Centers for Medicare & Medicaid Services (CMS) to move forward with advisory opinions on and enforcement of the physician self-referral rules, despite a third phase of the rules expected in the future, say attorneys familiar with the so-called Stark regulation. Leading up to the release of phase II of the regulations, CMS had not issued advisory opinions, saying it would undertake the process when the second part of rule making was finalized, according to Kevin McAnaney, an attorney with his own private practice in Washington, DC. He believes the agency will now begin issuing advisory opinions. Robert Saner, an attorney with Powers, Pyles, Sutter & Verville (Washington, DC.) also expects enforcement of the Stark II provisions to pick up. McAnaney and Saner discussed their predictions during a May 7 audio conference sponsored by the Bureau of National Affairs.

❖ Skilled nursing facilities (SNFs) must have a written agreement in place when they use an outside supplier to furnish certain services to their residents, the Centers for Medicare & Medicaid Services (CMS) reminded facilities in a May 21 transmittal. The services in question are those subject to "consolidated billing," in which the SNF submits to a Medicare intermediary almost all of the services that a resident receives during a stay covered by Part A. The bundled services also include some that are billable under Part B, such as various therapies and services that are furnished "incident to" a physician's service (including laboratory and other diagnostic tests). The actual physician services are excluded from consolidated billing. The transmittal is available at *www.cms.hhs.gov/manuals/pm_trans/R183CP.pdf*.

❖ The tools and resources gained from passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) significantly increased the number of healthcare fraud cases and associated recoveries, Karen Morrisette, chief deputy director of the fraud section in the Department of Justice Criminal Division, said May 13. Speaking at the American Bar Association Healthcare Fraud 2004 conference in New Orleans, Morrisette said the total return to the Medicare trust fund since the institution of HIPAA exceeded $4 billion. In terms of numbers, from 1996 to 2003, "criminal cases filed increased 47 percent a year," she said. In 2003 alone, 531 criminal defendants were charged, 437 were convicted, and there were almost 1,600 criminal investigations pending. These increases reflect the use of a series of prosecution authorities that did not exist before HIPAA and that are distinct from the more widely publicized health information privacy protection provisions of the act, said Morrisette.

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