G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Specialty Labs Back in CLIA Compliance, But On-Site Monitoring Increased

Compliance troubles at Specialty Laboratories, which led to revocation of its CLIA certification last April, are mostly over for now. Both the state of California and the federal Centers for Medicare & Medicaid Services have deemed the Santa Monica-based national reference lab to be compliant with regulatory requirements under the Clinical Laboratory Improvement Amendments.

The main charge against the publicly traded lab company was repeated failure over several years to comply with state personnel licensure law governing the performance and supervision of clinical diagnostic laboratory testing.

But the clean bill of health comes with increased oversight. California will step up on-site monitoring to make sure Specialty stays on track, and CMS has warned that other new deficiencies found in a recent survey require prompt correction.

Sanctions Lifted

CMS notified Specialty CEO Douglas Harrington on July 17 that all sanctions against the company—including loss of its CLIA certificate, suspension of Medicare and Medicaid payments, and civil money penalties of $3,000 per day of non-compliance—ended June 19. Harrington, a former top official at Nichols Institute (San Juan Capistrano, CA), was brought in to head the embattled company after the sanctions were made public in April.

To reach the quickest possible solution with CMS, Specialty opted to rescind its administrative appeal of the sanctions, to forfeit some $2.3 million in Medicare/Medicaid reimbursement suspended since Feb. 22, and to forego challenging civil monetary penalties totaling $351,000 for the days that it was deemed to be out of compliance.

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Inside this issue

Will Voluntary Disclosure Make You Safe Or Sorry?

Since the HHS Office of Inspector General began issuing compliance guidance in 1997, it has touted voluntary disclosure of compliance problems as a mitigating factor in determining which sanctions, if any, should be imposed on a healthcare provider. To aid providers in coming forward, the OIG has promoted its "Provider Self-Disclosure Protocol."

But a federal appeals court ruling on disclosure of internal documents to federal investigators could make providers think twice about self-disclosing such information during litigation.

The Sixth U.S. Circuit Court of Appeals (Cincinnati, OH) recently ruled that by disclosing certain coding audits to the Department of Justice (DOJ), Columbia/HCA Healthcare Corp. waived the right to keep them private from others. The ruling affirmed a lower court decision compelling HCA to produce documents requested by private insurers and others that claimed the largest U.S. for-profit hospital chain had overbilled them.

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Voluntary Disclosure, *from page 1*

HCA argued that the documents were protected by attorney-client privilege and the work product doctrine. Further, HCA argued, the disclosure agreement with DOJ explicitly declared that the disclosure did not constitute a waiver of privilege.

The appeals court, however, found that HCA waived whatever privileges it had with respect to the documents—primarily coding audits compiled from the company's internal audits of Medicare patient information—when it voluntarily gave them to DOJ as part of an agreement leading to a settlement of criminal and civil Medicare fraud allegations.

The settlement required HCA and subsidiaries to pay the Federal Government approximately $840 million in penalties, but did not resolve any third-party claims of other insurers and benefits payers that may have been overbilled by HCA. The settlement was announced by DOJ in December 2000.

A Question Of Tactics

The appeals court reviewed case law on assertion and waiver of attorney-client privilege (which generally shields from discovery any information relating to discussions between an attorney and his or her client) and concluded that HCA's voluntary disclosure to DOJ, even though subject to a confidentiality agreement, sufficed to waive the privilege with respect to a third-party payer's discovery request.

While the court recognized that its ruling could thwart efforts by government agencies to obtain inculpatory documents voluntarily, it nonetheless found that the privilege was waived under the circumstances of the case.

"The decision [by HCA] to enter into settlement negotiations and to disclose otherwise confidential information in the process is a tactical one made by the client and his or her attorney," the court wrote. "All litigation-related tactical decisions have an upside and a downside."

Promise Not Binding

Harvey Yampolsky, a healthcare attorney with Arent Fox (Washington, DC), says healthcare organizations will have to be more cautious about deciding whether to voluntarily disclose internal documents to federal investigators.

"Companies under investigation will now have to think twice about volunteering privileged information to the government, because the government's promise not to treat that as a waiver of the privilege, according to this ruling, would not bind third parties.

Harvey Yampolsky

"When one considers the pros-and-cons of sharing with the government, there's now one more con to put on the balance scale. While the decision should not come as a total surprise, now that it's rendered, it will cause people to think about [voluntary disclosure] much more and be more careful."

Resources

- Harvey Yampolsky: 202-857-6149
- Court decision: *In re Columbia/HCA Healthcare Corporation Billing Practices Litigation*, *http://pacer.ca6.uscourts.gov/cgi-bin/getopn.pl?OPINION=02a0201p.06*

CMS Sets Oct. 1 Target For ABN Implementation

Medicare provider and supplier use of new standardized formats for Part B Advance Beneficiary Notices (ABNs), approved by the federal Office of Management & Budget, is tentatively scheduled to become mandatory this Oct. 1, according to the Centers for Medicare & Medicaid Services.

The ABNs alert beneficiaries that they are financially responsible for a Part B item or service in the event that Medicare denies payment.

OMB signed off on the new formats June 18. They are virtually identical to the temporarily approved ABNs in voluntary use since June 25, 2001. A program memorandum with implementing instructions is in the clearance process now and is due out soon, says CMS.

In the meantime, both forms—one lab-specific (CMS-R-131-L), the other for general use (CMS-R-131-G), including lab testing—may be used, says CMS. The forms and draft instructions issued last spring are online at *http://cms.hhs.gov/medicare/bni/*.

HCA Criminal Probe Over

The U.S. attorney's office in Tampa, FL, has ended its criminal investigation of Columbia HCA Corp. (now renamed HCA—The HealthCare Company, based in Nashville, TN). This clears the way to depose HCA officials in eight whistleblower civil lawsuits, according to the Department of Justice.

The probe of Columbia HCA began in 1993 and resulted in indictments of four HCA executives and a settlement of $840 million with the Federal Government in December 2000. The investigation stemmed from allegations that the for-profit national hospital chain had upcoded diagnoses to obtain higher Medicare reimbursement, falsified Medicare cost reports, paid kickbacks for physician referrals and unbundled clinical laboratory claims. Two of the four officials were convicted, but an appeals court earlier this year overturned their convictions. A third official was acquitted, and a jury deadlocked on a verdict for the fourth official.

Felony Charges Filed Against Lab Operators In Medi-Cal Case

In what is believed to be the most far-reaching prosecution ever by the California Bureau of Medi-Cal Fraud and Elder Abuse, State Attorney General Bill Lockyer on June 26 filed felony criminal charges against 29 laboratory operators accused of bilking the state's Medicaid program of more than $11 million.

Felony complaints were filed against 16 individuals and 13 medical laboratories and businesses operating in Los Angeles, Riverside and Orange Counties. Officials have arrested 12 of the individuals charged: six were arrested in southern California, six in New Jersey, New York, Maryland and Virginia. Fugitive arrest warrants have been issued for the other four individuals.

The government alleges that between 1997 and 2000, the defendants took control of 13 clinical laboratories entrusted with the testing of blood and urine at the request of doctors who treat Medi-Cal and Medicare patients.

"Within months of these acquisitions, the defendants dramatically increased Medi-Cal and Medicare billings through fraudulent claims that involved unauthorized use of physician names and stolen Medi-Cal provider numbers," said Lockyer in a statement.

In all, more than two dozen doctors were the victims of identity theft and never authorized the specimen testing that was the basis for the fraudulent billings.

Alleged Fraud Scheme

The alleged fraud involved a combination of billing for services that were never performed and the testing of blood obtained through the black market from drug addicts and homeless people in order to create the semblance of a legitimate laboratory operation. Investigators found that the labs often billed and shut down quickly, leaving blood and urine samples behind, according to Lockyer.

The 29 defendants were charged with 104 felonies, including conspiracy to cheat and to commit acts endangering the public health, grand theft, submitting false claims to Medi-Cal and Medicare, identify theft, money laundering, tax evasion, creating a false financial statement and illegal transfer of money overseas without a license.

Defendants are accused of acquiring medical labs, quickly turning them into "billing mills" using stolen physician identities and provider numbers and black market blood, then quickly closing the labs

The charges and arrests capped an investigation of more than two years by the Bureau of Medi-Cal Fraud and Elder Abuse and the New Jersey Attorney General's Money Laundering Unit, which got involved when it uncovered a Jersey City market that was cashing several million dollars worth of Medi-Cal warrants. Also participating were numerous federal enforcement agencies as well as California state and local enforcement units.

Resource

- California Attorney General's Office: 916-324-5500

Latest CLIA-Waived Test Kits

Four more test kits have been cleared as waived tests under CLIA (the Clinical Laboratory Improvement Amendments). And CPT codes for several previously waived tests have been changed. The test additions and code changes are noted in a program memo (Transmittal AB-02-091) from the Centers for Medicare & Medicaid Services. The memo's effective date is June 17, 2002; its implementation date is Oct. 1, 2002.

Tests Added To Waived Roster

- CPT 82274QW: Enterix Insure‰ Fecal Occult Blood Test, effective Jan. 1, 2002.
- CPT 80101QW: Alatex Scientific Peace of Mind Multiple Drugs of Abuse, effective Feb. 21, 2002.
- CPT 83036QW: Metrika A1c Now for Prescription Home Use (K020234), effective March 8, 2002.
- CPT 83036QW: Metrika A1c Now for Professional Use (K020235), effective March 8, 2002.

Code Changes

- Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick) has changed from 82044QW to 83518QW, effective June 3, 2002.
- Boehringer Mannheim Chemstrip Micral and Roche Diagnostics' Chemstrip Micral (Urine Dipstick) have changed from 82044QW to 83518QW, effective June 17, 2002, since both tests use methodologies similar to the Diagnostic Chemicals urine dipstick test.

QW Modifier

When billing Medicare for the above tests, the QW modifier must be used to indicate that the tests were performed with a CLIA-waived device. Transmittal AB-02-091 is online at www.*hcfa.gov/pubforms/transmit/memos/comm._date_dsc.htm*.

Specialty Labs, *from page 1*

Inspections To Intensify

A CMS official tells *G-2 Compliance Report* that the agency itself will not conduct on-site monitoring, but that Specialty will be monitored by the state of California and the College of American Pathologists (CAP), which accredits the lab for CLIA purposes.

"Were CMS to receive a complaint, we would [conduct an on-site inspection] under the auspices of the complaint," the official explains. "That hasn't happened, but that's one scenario."

What's the chief compliance lesson to be gleaned from Specialty's travails? CLIA is more than just federal rules—state laws can also come into play. Make sure you follow your state's applicable laws for clinical diagnostic lab testing as part of your normal business operations. State and federal authorities moved against Specialty for allegedly failing repeatedly to heed California law on lab personnel licensing standards

Karen Nickel, PhD, chief of laboratory field services for the California Department of Health Services, says Specialty will face three years of on-site monitoring and must pay an unspecified fine. "We won't say how often the on-site visits may occur, but they will occur with more frequency initially as we assure things stay on track."

Specialty has worked hard to achieve compliance, Nickel points out. "They've hired about 50 new licensed med techs and reassigned unlicensed people who had been doing testing to other assignments or furloughed them."

Some of the lab's senior employees have taken director-level licensing exams, which include oral and written components, she adds.

CAP plans to keep tabs on Specialty's performance though officials would not elaborate, citing confidentiality issues with the thousands of labs that the College accredits. In previous comments on the case, CAP said it relied on information from Specialty that raised no red flag.

New Deficiencies Noted

Though Specialty has been deemed compliant with state personnel licensure requirements, CMS says a follow-up survey has revealed that the lab is not in compliance with a number of CLIA standard-level requirements. CMS has recommended that Specialty respond with a plan of correction. Though not required to do so, Specialty says it is in the process of submitting one.

Continued problems with standard-level requirements could have serious consequences, warned CMS' acting associate regional administrator, Stanley Marcisz, in a letter to Harrington. "Repeat non-compliance with standard-level deficiencies may result in a finding of condition-level non-compliance, which would result in your laboratory once again loosing its deemed status through accreditation by CAP and possible CLIA sanctions."

CMS and Specialty officials declined to go into detail on the standard-level deficiencies, though Harrington says they are related to quality assurance efforts. "CMS had some suggestions for strengthening our QA program, and we're acting on those, which is all a part of making compliance a part of the culture here." Harrington, who was appointed CEO in May, emphasizes that the deficiencies have nothing to do with lab personnel licensure problems.

Resources

- Douglas Harrington: 310-828-6543
- Karen Nickel: 510-873-6360

Rely On Official Sources For Info, Says OIG

Providers should rely on official sources to understand changes promulgated or proposed by the HHS Office of Inspector General, advises IG Janet Rehnquist in a recent letter to Richard Davidson, president of the American Hospital Association.

The letter was sent in response to an AHA advisory on OIG modifications to the civil settlement process and use of corporate integrity agreements. The modifications were discussed in an open letter to providers issued Nov. 20, 2001.

"While I appreciate AHA's responsibility to inform its membership of new and emerging OIG initiatives, I want to help ensure that your members have an accurate understanding of the open letter," Rehnquist wrote. "To that end, I recommend that providers rely on our official sources to understand the extent to which changes have been proposed in the corporate integrity agreement process."

Specifically, Rehnquist refers providers to the open letter itself and a series of 12 frequently asked questions (both posted on the OIG Website at *http://oig.hhs.gov* in the "Fraud Prevention and Detection" section). The OIG also is contacting providers operating under a corporate integrity agreement and explaining how the modifications in the open letter might apply to them.

The AHA legal advisory, "Protocol for Renegotiating Corporate Integrity Agreements," outlined steps hospitals should pursue to take advantage of changes to corporate integrity agreements. Rehnquist's open letter opened the door for providers to renegotiate many burdensome terms, AHA told its members.

COMPLIANCE PERSPECTIVES

Compliance Training: How One Health System Keeps It Fresh & Innovative

From left: Hyde Frederickson is the compliance officer and Paul Keoppel is the compliance administrator for Intermountain Health Care Laboratory Services, Salt Lake City, Utah

Training is one of the essential elements of an effective laboratory compliance program, but one of the most difficult to maintain.

Most laboratory staff members rarely see the importance of a compliance program and don't want to take the time to find out why it's important. This attitude is almost inconceivable to those of us who "eat and breathe" compliance every day. Why wouldn't someone want to know everything possible about CPT coding or Advance Beneficiary Notices or negotiated rulemaking or the requirements of HIPAA (the Health Insurance Portability & Accountability Act)?

Recognizing the need to conduct training and the inherent difficulties in doing so, we are going to relate the training experiences of Intermountain Health Care (IHC) over the last four years. The IHC laboratory system includes 20 hospital laboratories, four major physician clinic laboratories and 70 smaller physician office laboratories. There are more than 1,000 lab staff members. This presents a number of logistical challenges in addition to the challenge of developing training content appropriate for each person and generating interest in the compliance program. We discuss these challenges below.

Getting Started

The IHC laboratory compliance program began in August 1997 with the appointment of Hyde Frederickson as compliance officer. In November of that year, a full-time compliance administrator, Paul Keoppel, was hired to develop policies, training and an auditing program.

The first project for Paul was to bring the laboratory services' compliance manual together. This included formalizing many of the things the program already did as part of its normal operation. All policies essentially were written from scratch, following the seven compliance program elements recommended by the HHS Office of Inspector General (OIG).

Once the policies were written, we began work on the education program for all staff members. Initial training consisted of the two of us visiting every hospital with a two-hour PowerPoint presentation for selected staff members. This was a "train the trainer" program that gave a very basic introduction to compliance and explained why it is important. We described the structures of Medicare and HCFA (now the Centers for Medicare & Medicaid Services), and told staff about the OIG. It was a pretty dry program, but we felt it was a necessary foundation on which to build future sessions.

After the initial training, we moved to tailored, job-specific modules designed to bring home to bench technologists the regulations and requirements they must follow. This helped them see, for instance, how running quality control at appropriate intervals relates to the claim for payment that we submit to Medicare. These modules were developed centrally and given to compliance coordinators at each laboratory. The coordinators scheduled classes to give the PowerPoint presentations. This often required many sessions to accommodate staff work schedules.

Current Training Requirements

All staff members of Intermountain Health Care are required to participate in a corporate-wide training program on compliance each year. This provides a general overview of how the compliance effort fits into IHC's mission, vision and values. We hear from senior executives about a particular aspect of the compliance program and how each individual contributes to its accomplishment.

The laboratory presents semi-annual department-specific training. This is where we make compliance real for the technical staff. We chose to hold two courses per year so we could keep them short and focus on specific areas of concern. We have received few complaints about this

frequency. Each program is short enough and easily accessible, so two sessions per year seem reasonable. Our target is to keep the program, including the quiz, to about 45 minutes—certainly less than an hour.

Each laboratory program concludes with an online quiz. Since the goal of compliance training is education, we make it impossible to fail the quiz. Incorrect answers automatically refer the student back to the training material. The question is presented again. When a correct answer is given, the program moves to the next question.

Laboratory compliance training is mandatory for all staff members. Those who don't complete a session will fall into the "not met" category on their next annual evaluation. This means they will not be eligible for a pay raise. They are still required to complete the compliance training. Failure to make up the class will lead to the employee not being scheduled for work and can result in termination. We also require all employed and contracted pathologists to participate in the training program.

Running The Program

Since IHC has more than 1,000 laboratory employees, it becomes very costly and time-consuming to have formal classroom-style compliance training on an annual basis. We did this for the first two years. Employees had to be scheduled for the meetings and coverage arranged for production employees. The program was taught many times to small groups.

Feedback from employees was that the message was being diluted too much from the source material. The training was designed to be taught in a one-hour block, but was sometimes cut to 20 minutes when taught at the facility. We wanted to make sure that every employee was receiving the same message.

Widespread use of Web technology has made it much easier to reach large numbers of people. IHC maintains an Intranet, which hosts many internal Websites. The laboratory site is where we post all our training programs. A simple click of the mouse loads and executes the program.

We started offering the compliance training in an online, Web-based format in 2000. It was a bit crude at the start, consisting of PowerPoint slides converted to an HTML format. The students had to read the information on computer screens and manually advance the slides. The local compliance coordinator administered a paper quiz after the student finished viewing the presentation. The quizzes were sent to the central compliance office where information on who had completed the training was hand-entered into a database. This database was then checked against a current employee file supplied by Human Resources. This created a significant amount of manual work.

Last year, we improved the process by getting away from the PowerPoint look of the online slides. Employees still had to read the material from the slides, but an online quiz was added. There was a link at the end of the presentation to the quiz. The quiz actually resides on the IHC corporate learning management system, which is linked to the Human Resources' employee database. The results of the quiz are electronically scored and entered into the learning management system database for each employee. This information can be queried to find out who took the training and who did not. This has saved us considerable administrative time.

This year, we are using Web-streaming technology for our training. We first created a standard PowerPoint file. We then used the narration feature of PowerPoint to embed audio to each slide. This was converted to a streaming multimedia file and placed on the laboratory Intranet site. We have posted a sample training session on the Utah CLMA Website at *www.utahclma.org*. Feel free to review it and use any ideas it might trigger for you. We appreciate feedback or suggestions.

A great benefit of this electronic training is that we don't need to schedule classes. Each staff member can take the course during a regular shift and at his/her convenience. It doesn't need to be completed in one sitting. Thirty minutes of slow time can get a person through the slides. The quiz can be completed in another 15 minutes. A potential problem with this distribution method is lack of access to computers capable of running the program. You must have the infrastructure in hardware and connectivity to support this activity. This involves commitment to technology by both the organization and the staff members. Fortunately at IHC, we have the commitment and the financial resources necessary to make this technology available.

Keeping It Fresh

The biggest problem we encounter in our ongoing training program is keeping it fresh and interesting for staff members. This involves not just content, but also presentation. There is never a problem finding new rules and regulations to teach. Government entities and other regulators overseeing healthcare delivery are constantly publishing new information.

We struggle with limiting the items to teach, so we can keep the sessions to an acceptable length. We are, after all, here to serve the healthcare needs of our patients and insurance plan members. While we all need to be familiar with the regulations, we cannot let that requirement overtake our primary mission. Some items on which we have trained include daily quality control and its effect on false claims, the need for a legitimate test order with results and billing to complete the claims cycle and the process changes

necessary to properly collect Advance Beneficiary Notices.

IHC has always developed its own programs, but there are commercially prepared ones available for purchase. In some cases, that may be a simpler, more cost-effective method for your organization. Additionally, there are many compliance consultants willing to help with development and distribution of training materials.

We have found that delivery and presentation methods can provide great variety and improve our ability to reach all staff more effectively. The backbone of each session is still PowerPoint, but new technologies have made it possible to enliven the content and more easily distribute the programs. We have removed the necessity to personally teach each class. This is not quite as interesting for the student as a live presentation, but it's better than simply reading slides. Those who do the narrations have encountered an unexpected challenge—narration is difficult when you aren't speaking to an audience. It is advisable to have verbal content well prepared before adding it to the video portion of presentations.

Future Advancements

Ultimately, we would like to create an employee training program online that is modular, enabling it to be job-specific. This will allow us to custom-fit the training to an employee's job. A laboratory assistant would not need to take all of the modules that a laboratory director would. The training would always be available and could be updated centrally when needed. This would ensure that every new employee is getting the same message.

IHC is in the process of purchasing an enterprise-wide learning management system. It will have many features not available with our current system, such as automatic assignment of training and auto-tracking. A manager, supervisor or other authorized person can assign training modules to employees based on their job categories. This is for all types of training, such as competency testing for CLIA (Clinical Laboratory Improvement Amendments).

Employees log onto the system and are directed to a check-off list of training that has been assigned to them. The system tracks annual training and will automatically re-assign the employee for next year. It also has the capability of notifying employees by e-mail when new training is available.

We also hope eventually to employ the use of more video as our company bandwidth is increased. Right now, video is resource-intensive and may not be practical for large numbers of users.

Because training is an essential element of an effective compliance program, it deserves significant attention. This means a commitment to meet the government's expectations. Even though that commitment can be expensive, preventive measures are always less expensive than corrective actions.

Effective training goes a long way toward creating a compliant attitude throughout the organization. With that attitude, every staff member can see and correct, or better yet, prevent problems that put the organization at risk.

Mr. Frederickson and Mr. Keoppel can be reached at Intermountain Health Care Laboratory Services, 36 South State St., Salt Lake City UT 84111. Tel: 801-442-2860. E-mail: Frederickson, cohfrede@ihc.com*; Keoppel,* copkeopp@ihc.com

Tips On Keeping Compliance Training Fresh

Keeping compliance training interesting is an ongoing challenge. We at IHC try to keep people interested using the following techniques, which are useful tips for anyone developing a compliance training program:

- Don't teach the same things year after year. Offer variety.
- Consider the audience when preparing the material. Teaching new phlebotomists just out of high school requires a different approach from that used when teaching laboratory managers.
- Target content to the employee's job whenever possible. Bench technologists usually will not be interested in topics that do not apply directly to them, such as Stark physician self-referral regulations and collection of Advance Beneficiary Notices.
- Take advantage of technology. Employees like being able to participate in the training on their own time schedule. Online training is available 24/7, even when the instructors are home sleeping.
- Keep training visually stimulating by using good color schemes and plenty of graphics. Almost every feature of PowerPoint can be converted to a streaming file.
- Don't limit yourself to PowerPoint formats. Anything you see on the Internet can be used. Trainers who are proficient in Web programming can create very interesting content pages.
- Use streaming video when possible. Any material on videotape can be converted to a Web video file.
- Combine streaming video and PowerPoint files. This enables the audience to view the presenter and the slides at the same time. This technology is the closest thing to being there in person. You can see an online demonstration of this technology at the DigiScript Website: *http://digiscript.com*.
- Don't be afraid to use humor. Jokes and cartoons are a good way to get people interested. Lighten up.
- Use case studies. These can be actual cases you know of, or you can make up scenarios. Case studies can drive home your points more effectively, especially if they come from your own organization's experience. The cases can be presented as text, audio narration or, for the adventurous, a video scenario.

Stark II Ruling Opens Door To More Legal Challenges
Court Finds Lithotripsy Not Covered By Self-Referral Ban

A recent legal decision on the applicability of federal prohibitions against physician self-referrals (commonly known as Stark II) to lithotripsy services could inspire healthcare providers and their professional or trade associations to become more aggressive about contesting Medicare regulations in court.

The U.S. District Court for the District of Columbia on July 16 ruled that the Centers for Medicare & Medicaid Services erred in classifying lithotripsy, a non-invasive procedure performed by urologists to remove kidney stones, as an "inpatient or outpatient hospital service" subject to Stark II strictures. The court agreed with the plaintiffs—the American Lithotripsy Society and the Urology Society of America—in rejecting CMS's classification.

Stark II prohibits physicians from referring Medicare/Medicaid patients for certain "designated health services," including inpatient and outpatient hospital services, to any entity with which the physicians have a financial relationship by ownership/investment interest or a compensation arrangement, unless an exception applies.

Broader Impact

Charles Oppenheim, an attorney in the Los Angeles office of Foley & Lardner, notes that while the court decision's immediate impact is that Stark II no longer applies to lithotripsy services, the broader impact is that parties mounting a preemptory challenge to Medicare regulations may be more likely to obtain judicial review without first exhausting their administrative remedies.

In reaching its decision, the district court relied on *Shalala v. Illinois Council on Long-Term Care*. In that ruling, handed down in 2000, the U. S. Supreme Court declined to hear a case involving a challenge to CMS's nursing home regulations because the plaintiff, a trade association, and its member nursing homes had not exhausted administrative remedies.

The *Illinois Council* ruling focused on two factors, notes Oppenheim: the severity of the penalty incurred by a violation and the ability of the nursing homes to access administrative review. The Supreme Court concluded that the administrative penalties were minor and determined that the trade association, or its members, could incur a small penalty and receive an administrative hearing before proceeding to federal court.

In the Stark II case, however, the district court held that judicial review was warranted because the statutory penalties for violating the Stark law are so severe that the plaintiffs or their members could not risk incurring them in order to challenge the regulations, Oppenheim explains. Requiring the plaintiffs to exhaust their administrative remedies would have been tantamount to denying them the ability to obtain judicial review.

Charles Oppenheim

"This holding potentially expands the ability of providers and their trade associations to engage in anticipatory challenges to Medicare regulations that they believe to be invalid, especially if they seek to challenge Stark," he concludes. "Assuming the decision is not overturned on appeal, it is very helpful to providers, who appeared to have little hope after the *Illinois Council* decision."

Resource

- Charles Oppenheim: 310-975-7790

OSHA To Target Hazards In Nursing Homes

The Labor Department's Occupational Safety & Health Administration has developed a new program to focus on specific hazards in nursing homes, including injuries related to the handling of residents and risks of exposure to tuberculosis.

OSHA announced the program, which will be formalized in a compliance directive, on July 15. The agency also intends to focus outreach efforts and inspections on exposure to blood and other potentially infectious materials, as well as slips, trips and falls.

The program will target nursing and personal care facilities that have 14 or more injuries or illnesses resulting in lost days or restricted activity for every 100 full-time workers. Approximately 1,000 of these facilities will be inspected under the new program, according to the agency.

Last February, OSHA notified about 13,000 employers, including 2,500 nursing home and personal care facilities, that their injury and illness rates were higher than average and suggested ways to lower them.

More information on OSHA's national emphasis program should be available soon on the agency's Website at *www.osha.gov*.

CMS Revamps Procedures For Local Limited-Coverage Policies

Contractors Must Have Reconsideration Process in Place

The Centers for Medicare & Medicaid Services has revised procedures that local Medicare contractors must follow when developing, reviewing and reconsidering local medical review policies (LMRPs). These policies typically restrict Medicare coverage and payment to specific ICD-9-CM diagnosis codes and specify frequency limits for a covered item or service.

Transmittal 27, issued July 2, modifies current policies on LMRP development and review. Transmittal 28, issued July 10, standardizes an informal process carriers have used in reconsidering LMRPs. Both transmittals are effective Oct. 1, 2002.

What Contractors Must & May Do

According to the instructions, contractors *must* develop a new or revised LMRP when they have identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of a national coverage decision (NCD) or coverage provision.

Contractors *may* develop LMRPs when any of the following occur:

- A validated *widespread problem* demonstrates a significant risk to Medicare trust funds (potentially high-dollar and/or high-volume services). Multi-state contractors may develop uniform LMRPs across all their jurisdictions, even if data analysis indicates that the problem exists only in one state.
- An LMRP is needed to assure beneficiary access to care.
- A contractor has assumed the LMRP development workload of another contractor and is undertaking an initiative to create uniform LMRPs across its multiple jurisdictions, or the contractor is a multi-state contractor aiming to create uniform LMRPs across its jurisdictions.
- Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

Timetables

According to CMS, contractors must review and appropriately revise LMRPs within 90 days of the publication of program instructions containing a new or revised NCD, a new or revised coverage provision in an interpretive manual or a change to national payment policy. Additionally, contractors must review and revise policies within 120 days of the publication of an update to the ICD-9 or HCPCS coding systems.

At least once a year, contractors must review and revise LMRPs based on new coverage provisions and payment policies. CMS specifically advises that contractors must strengthen vague or incomplete sections of their local policies and ensure that policies adequately address all the elements required by the LMRP format.

If an LMRP has been rendered useless by a superceding national policy, it must be retired. This process must include a review of the policies at *www.LMRP.net* and on the contractor's Website.

Requests To Reconsider

Contractors that develop LMRPs must have a system in place to allow interested parties to request reconsideration of the policies, CMS says in Transmittal 28. They must consider all LMRP reconsideration requests from beneficiaries residing or receiving care in their jurisdiction and from providers doing business in their jurisdiction. Contractors may accept reconsideration requests for final LMRPs but not for other documents, such as national coverage decisions, draft LMRPs or individual claim determinations. If modification of the LMRP would conflict with an NCD, the request would not be valid, and the requestor should be referred to the NCD reconsideration process.

Requests must be submitted in writing, identify the language the requestor wants changed and include justification supported by new evidence.

Contractors have 30 days to determine whether the request is valid or invalid and 90 days to make a final LMRP reconsideration decision on a valid request and notify the requestor of its decision. If the decision is to revise the LMRP, the contractor is to follow the normal process for LMRP development. Contractors also are instructed to keep an internal list of LMRP reconsideration requests they receive and the relevant dates, subject and disposition of each.

Resource

- Transmittals 27, 28: *www.hcfa.gov/pubforms/transmit/transmittals/comm_date_dsc.htm*

Call For Nominations Extended

2002 Lab Public Service National Leadership Award

The deadline to submit your nominations for this award has been extended to Aug. 12. The award is presented annually by Washington G-2 Reports in conjunction with our national Lab Institute program, scheduled this year for Oct. 23-26.

The award honors an individual's contributions to basic or applied research; business creativity/innovations; education and training; professional or scientific achievement; or special service in the public interest to promote patient care and laboratory professions.

To request a nomination form, contact us at 202-789-1034 or download the form from our Website, *www.g2reports.com*.

No Change In Nov. 25 Effective Date For Uniform Lab Policies
Delay Till Jan. 1 Applies Only To Software Implementation

While enforcement of new uniform national Medicare policies affecting coverage and reimbursement of 23 frequently ordered laboratory tests has been postponed until Jan 1, 2003, the effective date of the new policies remains Nov. 25, 2002, a CMS official confirms.

The delay, announced in a June 26 program memorandum (Transmittal AB-02-087), applies only to enforcement of the policies through a national electronic edit module, the official tells *G-2 Compliance Report*. Some providers have mistakenly believed they would not have to comply with the new coverage decisions for these tests until local Medicare contractors had installed the new software in January.

Labs and contractors will still be held accountable for compliance with the new policies as of Nov. 25, says the official. If a lab is submitting a claim that it knows is not covered, it should use the GZ modifier to ensure that the claim is not paid in error during the period when the new software edits are not in place.

Waiting For Software

CMS announced the new lab coverage policies in a final rule issued Nov. 23, 2001. They will replace current varying local medical review policies developed by Medicare contractors for the 23 tests and will apply to clinical laboratories regardless of setting, whether in physician offices, hospitals or independent facilities. *(For a list of the tests, see GCR, Jan. '02, p. 4)*.

One of the major purposes of developing the new policies was to promote national uniformity in processing claims for these commonly performed clinical diagnostic laboratory services, CMS notes in the June 26 memo. The policies limit test coverage and payment to specific frequencies and specific disease conditions identified by ICD-9-CM diagnosis codes.

To avoid having all Medicare fiscal intermediaries and carriers individually establish separate programs with thousands of edits necessary for enforcement of the new lab policies, CMS contracted for development of a downloadable system module. However, the new module will not be implemented by the Nov. 25 effective date of the policies, but should be in place by the first of next year, CMS says.

Even with the delay, contractors are still required to change any local medical review policies that conflict with the uniform lab policies by Nov. 25. "Any claims incorrectly processed during this period of absence of an electronic edit module may be corrected upon post-payment review, once the software is implemented," says the CMS official.

A CMS program memorandum officially implementing the new lab policies is expected to be issued in the near future, as progress on the system changes evolves. Note: though the argot for these policies in the lab community refers to them as the uniform lab policies developed via a congressionally mandated negotiated rulemaking process, CMS calls them national coverage decisions.

Resources

- Transmittal AB-02-087, online at *www.hcfa.gov/pubforms/transmit/AB02087.pdf*
- Final Medicare rule on uniform lab coverage, online at *www.cms.hhs.gov/coverage*

Appeal Of Revocation Of Lab's Certification Dismissed

A federal appeals court recently rejected a challenge to revocation of a Michigan medical group's lab certification under CLIA, saying the group did not exhaust its administrative remedies before filing the lawsuit (*Oakland Medical Group v. Secretary of Health & Human Services*).

In December 2000, the U.S. Department of Health & Human Services revoked the group's testing certificate and withdrew its approval to receive Medicare payments after an administrative law judge found that the group failed to meet condition-level requirements for proficiency testing in 1998, failed to meet the condition-level requirement for laboratory director and violated the standard for technical supervisor. Oakland Medical Group, based in Warren, MI, provides a range of medical services, including clinical laboratory services at multiple locations.

Oakland appealed to the U.S. Court of Appeals for the Sixth Circuit. But in a June 21 opinion, that court affirmed a lower court's determination that it did not have jurisdiction to decide whether HHS was correct in revoking Oakland's certification.

Oakland had argued that HHS violated the due process clause of the Fifth Amendment by failing to continue Medicare payments while it sought review of the revocation decision.

The appeals court also noted that while the economic impact of withdrawing a provider's Medicare eligibility is significant, Oakland's financial need to be subsidized for the care of its patients was only incidental to the purpose and design of the Medicare program.

Court Finds California Lab Entitled To Attorneys' Fees

The U.S. Court of Appeals for the Ninth Circuit (San Francisco, CA) ruled July 19 that a clinical laboratory that was reinstated in California's Medicaid program is entitled to attorneys' fees (*Labotest Inc. v. Bonta*).

In 2000, following an investigation, the California Department of Health Services suspended Labotest Inc. (Lynwood, CA) from Medi-Cal and disenrolled the lab from PACT, the state's family planning, access, care and treatment waiver program. Labotest and Frank O. Brown, an Oakland physician, filed a federal class-action complaint against the Department and other state officials, alleging deprivation of due process and civil rights violations.

Before trial, the district court approved a joint settlement under which the Department agreed to reinstate Labotest in Medi-Cal and lift all remaining Medi-Cal sanctions, but agreed with the Department that disenrollment from PACT was appropriate. The court denied Labotest's request for attorneys' fees and costs, except for the amounts associated with the PACT issue, and Labotest appealed.

The appellate court held that Labotest and Brown were the prevailing parties for purposes of attorneys' fees when they obtained the court-approved settlement to lift sanctions against the lab. Thus, Labotest and Brown are entitled to attorneys' fees, the court said. The decision is online at *www.ca9.uscourts.gov*.

Privacy Act Requirements Updated

The Centers for Medicare & Medicaid Services on July 23 updated Privacy Act requirements for routine disclosure of information about individuals in three of its programs, including Medicare managed care.

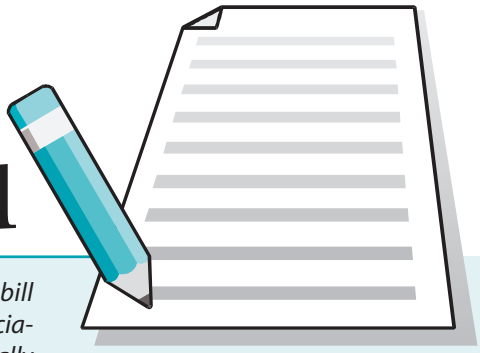
In three separate notices of "Modified or Altered System of Records," CMS is making revisions relating to such matters as disclosures to researchers and quality improvement organizations. The changes should help in fighting fraud and abuse, the agency says.

The Privacy Act of 1974 established restrictions on use of data collected on individuals, but allows exceptions when the data are disclosed for routine and other uses. Information may be disclosed without an individual's consent if it is used for certain purposes.

The July 23 notices modify or alter routine disclosure provisions to third parties in the "Medicare Health Maintenance Organization/Competitive Medical Plans Beneficiary Reconsideration System," the "Intern and Resident Information System" and the "Medicare Supplier Identification File System."

For more information, see the July 23 *Federal Register*, online at *www.access.gpo.gov/su_docs*.

For the Record



How do healthcare providers bill secondary payers and beneficiaries for services deemed not medically necessary by Medicare in cases where the beneficiary is not given an Advance Beneficiary Notice?

Twila Henning, a compliance specialist with CareMedic Systems Inc., based in St. Petersburg, FL, posed this question recently to an official of the Centers for Medicare & Medicaid Services.

Specifically, she asked if, in the scenario cited above, a healthcare provider could accept payment from a secondary payer as payment in full or whether the provider should still attempt to collect any applicable 20% co-payment from the beneficiary.

According to the CMS official, if Medicare does, in fact, deny the claim due to lack of medical necessity and the provider did not give the beneficiary an ABN, the beneficiary is not financially liable and may not be billed at all, even for a co-payment.

Providers that expect an item or service to be denied as not reasonable and necessary and fail to obtain a signed ABN from the beneficiary (for example, in an emergency situation) should use the GZ modifier when submitting the claim to Medicare, CMS says.

"The GZ modifier is provided for physicians and suppliers that wish to submit a claim to Medicare, that know an ABN should have been signed but was not, and that do not want any risk of allegation of fraud or abuse for claiming services that are not medically necessary," says the agency in guidance on the proper use of modifiers.

The guidance, including charts on use of modifiers and a matrix showing the applicability of ABNs to types of claims denials, is online at *http://cms.hhs.gov/medicare/bni/*.

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*.

The Back Page

News-At-A-Glance

Contractor Audit Fraud: Blue Cross of California (BCC) and its parent company, WellPoint Health Network, will pay $9.25 million to settle allegations that BCC defrauded Medicare by knowingly falsifying data on its auditing of cost reports for the federal program. BCC was a Medicare Part A fiscal intermediary processing claims in California until December 2000. Its responsibilities included auditing of cost reports from hospitals and other Medicare providers to ensure they were properly reporting allowable costs and seeking appropriate reimbursement.

The fraud allegations were initially made in a whistleblower lawsuit under the False Claims Act. A former company auditor alleged that BCC falsified audit activity dates entered into an audit tracking database in an effort to deceive the government into thinking that it performed more audit work than it actually did during the pertinent fiscal year. Performance of required audit work was one of the criteria the government used to evaluate BCC's work and renew its contract as an intermediary each year.

The settlement resolves claims submitted between 1990 and Nov. 30, 2000 for the covered work.

Who Fills Privacy Officer Slot? Of 366 organizations responding to a recent survey by the Health Care Compliance Association on the function of privacy officers, 48% reported that their compliance officer (CO) also served as the privacy officer (PO). Of the 52% who said their CO did not serve as PO, 67% said a separate privacy officer had been hired. The majority of respondents (77%) said their PO would not also serve as security officer. In terms of which unit the PO reports to, 40% said Compliance, 17% Operations, 9% Health Information Management, 8% Legal, 1% audit and 25% "none of the above." More on the findings are online at *www.hcca-info.org/html/compliance/html*.

Paying Too Much For Lab Tests: A federal audit of Medicaid clinical laboratory services in Oklahoma between January 1996 and December 1999 found that the Oklahoma Health Care Authority (OHCA) did not have adequate edits in its claim processing system to ensure that all reimbursement for lab tests did not exceed amounts recognized by the Medicare program. The HHS Office of Inspector General determined that during the four-year period, OHCA paid out $54,780 (federal share, $38,690) in excess of what Medicare recognizes for the same tests. In addition to procedural corrections, OHCA has agreed to a financial adjustment for the $38,690. The audit report is online at *http://oig.hhs.gov/oas/reports/region6/60100026.pdf*.

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