



G-2

Compliance

Report



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For Hospitals, Laboratories and Physician Practices

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California Lab Fraud Case Split Into Separate Complaints *Trial Dates Set for Large National Labs*

Charges by the California attorney general (AG) that seven clinical laboratories overcharged Medi-Cal for services provided have been split into several separate complaints, with an additional lab added to the charges.

Rebecca MacLaren, a spokesperson for AG Edmund Brown Jr., tells *G-2 Compliance Report* that the AG has settled with one of the defendants, WestCliff Medical Laboratories, which had acquired defendant Taurus West Inc. (formerly know as Health Line Clinical Laboratories). Westcliff has since been acquired by LabCorp (Burlington, N.C.), which is also one of the defendants in the case.

“We’re exploring the possibility of a settlement with Seaciff Diagnostics Medical Groups and are still pursuing the other four groups of defendants,” says MacLaren. “The AG is also pursuing a case against Primex Clinical Laboratories Inc., a defendant that was not named in the complaint” announced in March 2009.

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Opposition Grows Against Physician Signature Proposal

Clinical laboratory, hospital, and health care organizations have come out strongly against a proposed new Medicare payment policy that would require the signature of a physician or a nonphysician practitioner (NPP) on all requisitions for tests reimbursed via the Part B lab fee schedule.

This would reverse longstanding Medicare policy agreed to in 2001, the letter noted, following a negotiated rulemaking that involved 18 laboratory and health care organizations, including the American Medical Association, as well as the Centers for Medicare and Medicaid Services (CMS).

The change would lead to confusion, a complicated and unnecessary administrative process, and potential harm to patients forced to wait too long for lab tests, the organizations said in a letter to Donald Berwick, M.D., head of CMS.

Currently, a physician’s signature is one way to document that the treating doctor ordered a service for a Medicare beneficiary, but not the only permissible way, and it is not required as long as documenta-

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For The Last Word In Healthcare Compliance

California Lab Fraud, from page 1

The trial for Quest Diagnostics (Madison, N.J.) is scheduled to begin on May 2, 2011, and the trial for LabCorp is set to begin Sept. 6, 2011, MacLaren tells *GCR*.

AG Alleges Fraud

Brown announced in March 2009 that his office had joined a whistleblower lawsuit filed against the seven labs by Chris Riedel, the CEO of Hunter Laboratories in Campbell, Calif. (*GCR, May 2009, p. 1*). The suit alleged that the labs charged the state Medicaid program up to six times more for tests compared to other clients over the past 15 years. Named in the initial charges were Quest, Health Line, Westcliff, Physicians Immunodiagnostic Laboratory (Burbank, Calif.), Whitefield Medical Laboratory (Pomona, Calif.), Seaciff (Monterey Park, Calif.), and LabCorp. The labs have denied allegations of wrongdoing.

According to the AG, California law states that “no provider shall charge [Medi-Cal] for any service . . . more than would have been charged for the same service . . . to other purchasers of comparable services . . . under comparable circumstances.” Brown alleged that the labs charged Medi-Cal up to six times as much as they charged some of their other customers for the very same tests.

In exchange for these steep discounts, the defendants expected their customers to refer all of their other patients to the labs, Brown alleged. Under California law, this amounted to providing an illegal kickback.

In statements provided after the complaint was announced, several labs—including Quest and Seaciff—declared their innocence and vowed to fight the charges. 🏛️

**FDA Fines American Red Cross \$16 Million
For Prior Failures to Meet Blood Safety Laws**

The Food and Drug Administration (FDA) has fined the American Red Cross \$16 million for prior failures to comply with federal laws and regulations related to the collection and manufacture of blood products.

Despite the compliance failures, FDA found no evidence that the Red Cross violations endangered any patients and that the blood supply is believed to be safe. However, the agency notes that these types of violations decrease the assurance that blood products manufactured by the Red Cross will continue to be safe.

The FDA assessed fines totaling \$16.18 million—\$9.79 million for violations related to mismanagement of certain blood products and \$6.39 million for Good Manufacturing Practice violations.

In a statement, the agency says it is encouraged by recent efforts made by the Red Cross leadership and will work closely with them to achieve full compliance. “The FDA is hopeful these fines will encourage the Red Cross to act more quickly to take the actions necessary to address and correct the issues that have contributed to these violations,” it says.

In October 2009, the agency notified the American Red Cross that FDA inspections conducted during fiscal years 2008 and 2009 revealed violations that in-

cluded failure to identify problems that occur during manufacturing and failure to adequately investigate identified problems.

The fines announced in June were assessed under an amended 2003 consent decree that outlines requirements to the American Red Cross to ensure safety of the nation's blood supply. The agency has previously sent 12 similar letters to the American Red Cross and imposed a total of more than \$21 million in fines under terms of the amended 2003 consent decree.

"Since 2003, the American Red Cross has made progress addressing some of its quality issues, including standardizing procedures, upgrading its national testing laboratories, and increasing oversight of the organization. However, to fully comply with federal regulations and consent decree provisions, the American Red Cross must make swift, additional progress on all of the issues the FDA has identified," says the FDA in its statement. 🏛️

CMS Pressed to End Pathology Self-Referral Arrangements

Pathology and clinical laboratory groups are again urging the Centers for Medicare and Medicaid Services (CMS) to close regulatory loopholes they say an increasing number of medical specialty groups are exploiting to boost Medicare revenue by insourcing anatomic pathology work.

"Physician specialists are increasingly taking advantage of gaps in the anti-markup and self-referral rules and entering into business arrangements that permit them to order, bill, and be paid the full fee schedule rate for anatomic pathology, even though the services are actually furnished by physicians who have little or no relationship with the ordering physician and his or her group."

– ACLA

Specialty practices defend such arrangements, saying they enable them to make rapid diagnoses and initiate treatment during a patient's office visit, improve care coordination, and encourage patients to comply with diagnostic and treatment recommendations.

The Stark law prohibits Medicare and Medicaid referrals of beneficiaries for designated health services to entities with which they have a financial relationship (either by ownership

interest or compensation arrangements or both) unless it fits within an exception. The anti-markup rule does not bar a billing physician from marking up the payment for the professional component and the technical component of a pathology service as long as the performing physician shares a practice with the billing physician.

In a letter to CMS Administrator Donald Berwick, M.D., the in-office ancillary services (IOAS) coalition asked that anatomic pathology and certain radiology services be removed from the in-office exception. Coalition members include the College of American Pathology (CAP), the American Clinical Laboratory Association (ACLA), the American Society for Clinical Pathology, and the American College of Radiology.

In separate comments, ACLA said CMS's reluctance to tackle the issues has given the green light for physician specialists to capture more pathology work. "Physician specialists are increasingly taking advantage of gaps in the anti-markup and self-referral rules and entering into business arrangements that

permit them to order, bill, and be paid the full fee schedule rate for anatomic pathology, even though the services are actually furnished by physicians who have little or no relationship with the ordering physician and his or her group." At a minimum, CMS should "emphasize its concerns about these arrangements in the final rule" to deter their proliferation in 2011.

Both ACLA and CAP called on CMS to reinstate the requirements governing "purchased" diagnostic tests that were dropped in 2009. This previous policy prevented physicians from marking up diagnostic tests purchased from an outside supplier.

The Medicare Payment Advisory Commission (MedPAC) has also voiced its concern over volume group and increased Part B spending associated with physician investment in ancillary services, in its June 2010 report to Congress. 🏛️

CMS Considers Withdrawing Proposed Cytology PT Rule

The Centers for Medicare and Medicaid Services (CMS) is considering withdrawal of the proposed rulemaking for gynecologic cytology proficiency testing (PT), published in January 2009, following the Sept. 1-2 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIA).

That proposal, issued under the Clinical Laboratory Improvement Amendments (CLIA) was based on most but not all recommendations from a CLIA work group charged with revising the current PT program and adopted by the committee. In response, the College of American Pathologists (CAP) urged CMS to adopt a continuing medical education alternative.

CAP has long opposed proficiency testing of pathologists and has been critical of the existing program and the 2009 proposal. According to CAP, the cytology PT program fails to measure competency, is not supported by science, and does not improve health outcomes.

In explaining the latest CMS action, Judy Yost, the top CLIA official, told G-2 Reports, "Unfortunately, the current CLIA members were not members at the time that CLIA made the original recommendations to CMS for these proposed changes. Therefore, they were unable to come to agreement about it, even though 77 percent of the comments we received expressed dislike for the rule."

CLIA has recommended more performance analysis and evaluation before taking action to change the current program.

In publishing the PT proposal, CMS said the program has been successful in improving quality and reducing errors, based on PT results from the first three years of nationwide testing since it began in 2005.

"For example, failure rates on the initial test of each annual testing cycle dropped from 33 percent in 2005 to 11 percent in 2007 for pathologists reading slides without the assistance of a cytotechnologist," said the agency. "Nonetheless, given the consequences of false Pap test results, the current level of failure is still of great concern to CMS. During the same period, the failure rates dropped from 10 percent to 3 percent for pathologists reading slides with the assistance of a cytotechnologist, and from 7 percent to 3 percent for cytotechnologists reading slides alone under the supervision of a pathologist." 🏛️

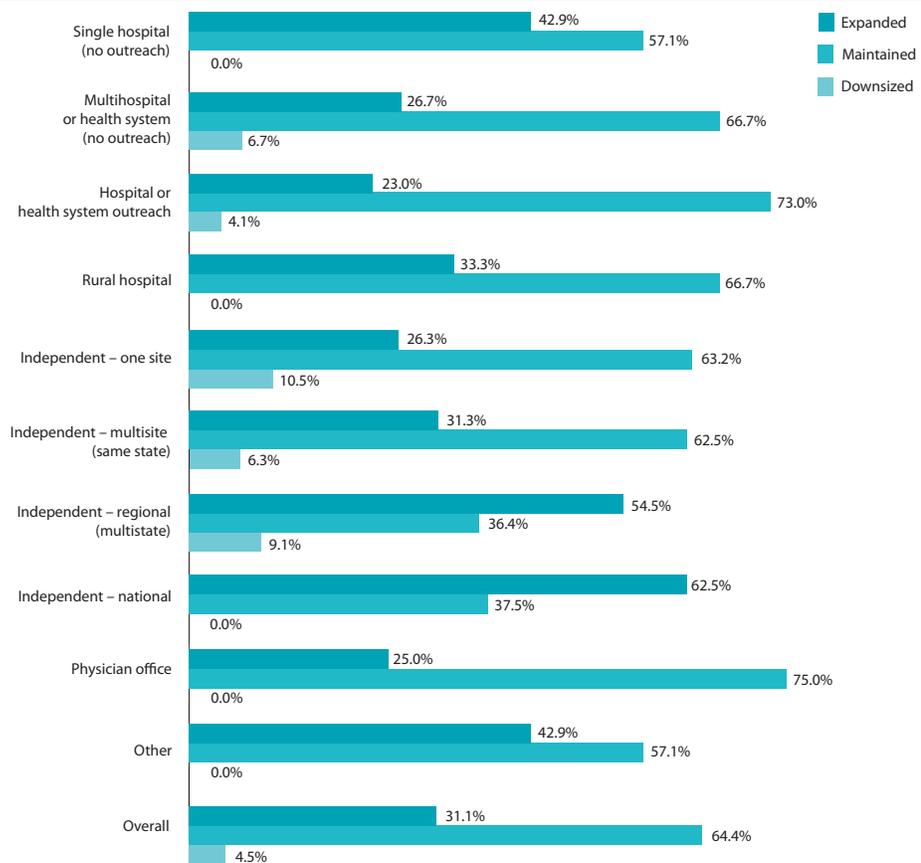
COMPLIANCE PERSPECTIVES

Most Lab Compliance Programs Expanding or Being Maintained

The majority of clinical laboratory compliance programs are either being maintained or expanded, according to a survey of lab compliance officers conducted by Washington G-2 Reports and Laboratory Management Support Services (LMSS) of Phoenix.

Overall, 64.4 percent of respondents say their compliance programs are being maintained, and 31.1 percent say they are being expanded. Independent national labs are more in an expansion mode than other types of labs, with 62.5 percent saying their compliance programs are being expanded and just 35.5 percent reporting their programs are being maintained (see chart).

Is Your Compliance Program Being Expanded, Maintained, or Downized?



Source: G-2 Reports-LMSS Compliance Survey

The survey, conducted in July and August 2010, received 178 responses, with the greatest percentage (42.1 percent) coming from hospital outreach programs. Also responding were independent labs with one site (10.7 percent), independent labs

with multiple sites in the same state (9 percent), hospitals or health systems that don't perform outreach (8.4 percent), single hospitals with no outreach (7.9 percent), independent regional labs (6.2 percent), independent national labs (4.5 percent), physician office labs (2.2 percent), and others (3.9 percent).

The majority of respondents (70.6 percent) reported that their organization's management views compliance as a high-priority area, while 19.8 percent say management sees it as important, but not high priority, and 8.5 percent say compliance is viewed as necessary but not as important as it once was. Surprisingly, 26.7 percent of health systems with no outreach and 22 percent of rural hospitals said compliance is viewed as necessary but not as important as previously. More than 12 percent of independent national labs and 6.7 percent of health systems report that management views compliance as not an important issue.

Compliance Officer Role

When asked about the management level of the compliance officer, responses were divided fairly evenly, with 29.4 percent reporting that the compliance officer is an officer of the company (such as a director, vice president, or chief operating officer), part of the senior management team (28.8 percent), middle management (22 percent), and supervisor or manager (19.8 percent). Independent national labs say that the compliance officer is either an officer of the company (37.5 percent) or part of the senior management team (62.5 percent).

In terms of other duties in addition to compliance duties, 41 percent of respondents report they also are responsible for quality assurance, and 33.1 percent say they are responsible for privacy and security under the Health Insurance Portability and Accountability Act (HIPAA). Other functions cited included safety, billing compliance, point-of-care testing, and risk management. Not surprisingly, compliance officers in physician offices perform multiple roles, with 100 percent saying they are the lab or department director and are also responsible for all quality assurance.

When asked how many employees, in addition to the compliance officer, are assigned to support the compliance program, responses were mixed, with 32 percent reporting none, 24.2 percent reporting one, 18 percent reporting two, 6.2 percent reporting three, and 19.7 percent reporting four or more. The majority (86.6 percent) of respondents say the compliance officer has access to legal counsel expert in laboratory issues, with only 8.4 percent reporting that there is no such access (5.1 percent say they don't know).

Compliance officers have longevity on their side, with 41.6 percent reporting that they have been in place for more than six years. About 10 percent of respondents say they have been in their position for less than one year, 16.9 percent for one to two years, 17.4 percent for three to four years, and 13.5 percent for five to six years.

Training

Almost all (95.5 percent) of respondents say that compliance training is mandatory for all employees. Of those, 86 percent say employees receive annual general compliance update training, 45.5 percent provide additional training for employees working in areas considered high risk (such as billing and sales), and 30.9 percent provide training for temporary and contracted employees (many do all three).

In about three-quarters of instances (76.4 percent), HIPAA training is separate from regular compliance training, say respondents. Half (50 percent) spend one to three hours in compliance training, not including HIPAA, while 40.4 percent spend one hour or less. A much smaller percentage (4.5 percent) spend three to five hours on training, and 2.8 percent report that employees receive more than five hours of training (*see chart on p. 7*).

How Many Hours a Year Do Most Employees Spend in Compliance Training, Not Including HIPAA if Separate?					
	One hour or less	1 to 3 hours	3 to 5 hours	More than 5 hours	Don't know
Single hospital (no outreach)	50.0%	35.7%	7.1%	0.0%	7.1%
Multihospital or health system (no outreach)	40.0	53.3	6.7	0.0	0.0
Hospital or health system outreach	44.0	50.7	1.3	1.3	2.7
Rural hospital	66.7	33.3	0.0	0.0	0.0
Independent – one site	36.8	42.1	10.5	10.5	0.0
Independent – multisite (same state)	12.5	87.5	0.0	0.0	0.0
Independent – regional (multistate)	27.3	54.5	0.0	9.1	9.1
Independent – national	50.0	37.5	12.5	0.0	0.0
Physician office	50.0	50.0	0.0	0.0	0.0
Other	28.6	28.6	28.6	14.3	0.0
Overall	40.4	50.0	4.5	2.8	2.2

Source: G-2 Reports-LMSS Compliance Survey

When asked about the primary method of training employees for compliance, the majority (58.4 percent) say they use computer-based or Web-based training, 18.5 percent use instructor-led classroom training by the compliance officer, 6.7 percent use instructor-led training by someone other than the compliance officer, 10.7 percent use self-study written modules, and 1.7 percent use video training.

Compliance Committee and Budget

More than half (54.5 percent) of respondents say their laboratory has a compliance committee, which is down from 65 percent in last G-2-LMSS compliance survey, conducted in 2008. Not surprisingly, the smaller the lab, the less likely it is to have a compliance committee. The compliance committee is specifically referred to in all OIG compliance guidance documents. Almost all (95.9 percent) say the compliance committee has sufficient authority to make decisions, although this figure is down slightly from 2008, when it was 98 percent.

Christopher Young, president of LMSS, notes that the compliance committee is an important tool in the compliance officer's arsenal and that the absence of a committee likely would be considered a negative in terms of evaluation of the effectiveness of the program. "Labs that do not have active committees should seriously consider forming one even if the meetings are only quarterly, semiannually, or as needed," says Young.

Only about 14 percent of respondents say they have a specific compliance budget although 64 percent believe the budget is adequate. Interestingly, when asked if the number of compliance-specific programs or audio conferences attended by the compliance officer was restricted by budget issues, almost 63 percent said yes. The presence or absence of a line-item compliance budget has been cited by government representatives as an element used to assess program effectiveness.

Compliance Officer Training

The vast majority (80.3 percent) of respondents say the compliance officer is self-trained by attending seminars and conferences, reading newsletters, and networking with other laboratory compliance officers. A relatively small percentage (15.7



Christopher Young

percent) received formal training through an accredited school or association, and 17.4 percent say they were trained by the previous compliance officer.

Most compliance officers (79.3 percent) responding to the survey say they are not certified by a formal certification agency, although 6.9 percent are certified by the Health Care Compliance Association, 1.7 percent are certified as a clinical laboratory compliance professional, and 5.2 percent are accredited by the American Society for Clinical Pathology (ASCP) as qualified in laboratory compliance (QLC).

Our survey found that compliance officers have mixed feelings about their training and expertise. Almost half (45.5 percent) say they are well-schooled in the basics of compliance but need additional training or support for complex or specialized compliance problems. Over a quarter (26.6 percent) say they know enough to recognize a compliance problem but usually need support to make a decision about the problem. Less than 20 percent (19.5 percent) say they are fully trained and need only to maintain and update their knowledge.

Audits

By and large, audits are conducted on a regular basis, report respondents, with half saying they conducted audits a mix of monthly, quarterly, semiannually, and annually. About a fifth (19.2 percent) say they conduct audits quarterly, 12.3 percent conduct them monthly, 10.8 percent conduct them annually, and 7.7 percent conduct them semiannually.

The most common types of audits, according to our survey, are billing and coding (excluding chargemaster) 69.6 percent, chargemaster audits (53.2 percent), compliance program effectiveness (41.8 percent), training and education effectiveness (31.6 percent), Stark and anti-kickback (29.7 percent), and sales and marketing practices (20.9 percent). Less than a third (28.5 percent) report conducting an annual audit of all areas of compliance.

According to Young, the best practice is to have some kind of comprehensive annual audit plan that addresses audits for all critical areas of the compliance program ensuring that all areas that should be audited are covered and that annually analyzes the effectiveness and frequency of individual audits. "If all audits are done by employees, even if the compliance officer is doing them or overseeing them, it is also important that periodically the program is reviewed by an outside reviewer," he adds.

Challenges and Goals

The greatest challenges faced by compliance officers responding to our survey are similar to those cited in the 2008 survey: budget constraints and lack of resources, pressure from business development and sales and marketing because they believe the compliance program is stricter than competitors' programs, and billing issues. Time constraint was cited by a number of respondents, as was the challenge in keeping up with constant changes in the regulatory environment. This is one area where a compliance committee can add value, notes Young. Members of the committee can be responsible for monitoring their area of responsibility.

When asked to rank major goals for improvement for the next 12 to 18 months, respondents list billing and coding, auditing and monitoring, and training and education as their top priorities, followed by reviewing and revising the compliance program or code of conduct, HIPAA, and conducting a risk assessment.

Benchmarking is an important part of compliance program analysis, notes Young. If the government looks at an individual compliance program, one way to assess effectiveness is to compare programs. It is important, in that context, to be able to compare your program to others, he says. 🏛️

Opposition Grows Against Physician Signature Proposal, *from page 1*

tion exists in an alternate form. For example, the physician may document the ordering of specific services and their medical necessity in the patient's medical record.

Signatories to Letter to CMS Chief

- ❖ American Association of Bioanalysts
- ❖ American Association for Clinical Chemistry
- ❖ American Clinical Laboratory Association
- ❖ American Medical Technologists
- ❖ American Society for Clinical Laboratory Science
- ❖ American Society for Clinical Pathology
- ❖ American Society for Microbiology
- ❖ Clinical Laboratory Management Association
- ❖ College of American Pathologists
- ❖ National Independent Laboratory Association
- ❖ American Hospital Association
- ❖ Laboratory Corporation of America Holdings
- ❖ Quest Diagnostics Incorporated

CMS said the new policy would create less confusion by eliminating any uncertainty over whether the documentation is a requisition or an order, since signatures would be required on both. But the organizations countered that any uncertainty is rooted in confusing language in CMS manuals and can be resolved "without adding the extra and repetitive step of requiring a physician's signature on all requisitions." They then presented Berwick with examples of the new administrative burdens and the potential harm to patients:

- ❖ There will be duplication of recordkeeping since the physician would need to sign the requisition and the patient's chart. Many labs cite a situation in which either of these two is not signed or they differ in some way. The decision as to which is the final order would then be at the lab's discretion.
- ❖ There is no incentive for physicians to comply with the proposed requirement or any consequences for not complying. Many physicians collect lab specimens in their offices, and in this case, requiring a signature for specimens collected by office staff, based on the doctor's order, adds another redundant process to the implied consent found in the use of preprinted requisitions and office collections.
- ❖ Medicare will be one of the few programs with a physician signature rule. Only three state Medicaid programs and no private insurance companies require signatures on clinical lab requisitions.

- ❖ What should a lab do if a signature is missing? Standard practice is to perform the test when the specimen arrives because this is in the best interest of the patient. Is it the lab's function to hold all tests until the physician complies with the regulations? Timely testing is often essential to patient care. In the skilled nursing home environment, obtaining a physician signature for daily lab orders and stat requests creates additional documentation requirements without any improvement in the order validation process. 🏠

FDA, CDC Issue Warning on Use of Fingertick Devices

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have issued a new alert for laboratory personnel, phlebotomists, and all who perform blood testing about the use of fingertick devices on more than one person and the risk this poses for transmitting blood-borne pathogens.

In an Aug. 26 initial communication, the FDA and the CDC noted a progressive

The warning targets reusable fingerstick (blood lancing) devices and point-of-care blood testing devices (for example, blood glucose meters, PT/INR anti-coagulation meters, cholesterol testing devices, etc.).

increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of fingerstick and point-of-care (POC) blood testing devices.

While the infections occur in a variety of health care settings, the agencies noted “a significant increase in hepatitis B virus infection outbreaks related to the shared use of multiuse fingerstick devices and POC blood testing devices in long term care and assisted living settings. Unclear labeling and ineffective cleaning and disinfection instructions may have contributed to these outbreaks.”

Precautions Advised

The FDA and the CDC recommend that health care professionals and patients take the following immediate precautions:

- ❖ Fingerstick devices should never be used for more than one person.
- ❖ Auto-disabling, single-use fingerstick devices should be used for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped, or otherwise made unusable. These may also be called “safety” lancets.
- ❖ Whenever possible, POC blood testing devices, such as blood glucose meters and prothrombin time (PT)/international normalized ratio (INR) anti-coagulation meters, should be used only on one patient and not shared. If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.
- ❖ Change gloves between patients, even when patient-dedicated POC blood testing devices and single-use, self-disabling fingerstick devices are used by health care personnel.

Policy Change Planned

In the past, FDA has cleared multiple-use fingerstick devices both for use in multiple patients and in single patients. But now, the agency has determined that fingerstick and POC blood testing devices used on more than one patient may not be safe for several reasons.

“Improper use or device malfunction can lead to the use of the contaminated lancet blade on more than one patient. Furthermore, it is difficult for healthcare staff to ensure that all blood has been removed from POC blood testing devices and the reusable portions of the fingerstick device. If POC blood testing devices are used on multiple patients and are not cleaned and disinfected correctly and thoroughly between each patient, contaminated blood left on them could result in bloodborne pathogen transmission among patients.”

Some legally marketed fingerstick devices have been cleared for use on more than one patient. Shortly, the FDA said, it will issue a separate communication describing the actions it will take to ensure that these devices are labeled for use on only one patient to reduce the risk of bloodborne infection transmission. 🏛️

CMS Approves First Medical Necessity Review Audits for Recovery Audit Contractors

The Centers for Medicare and Medicaid Services (CMS) has approved the first medical necessity review audits for the recovery audit contractor (RAC) program.

The new audits, approved Aug. 6 by the CMS New Issue Review Board, include 18 focused on inpatient claims issues and one focused on durable medical equipment claims and have already been posted on CGI Technologies and Solutions Inc.'s Web site, the RAC responsible for Region B, which includes Minnesota, Wisconsin, Michigan, Indiana, Ohio, Kentucky, and Illinois.

Medical necessity reviews are designed to determine if specific procedures in a Medicare paid claim were medically necessary for a patient's health. One of the approved audits, for example, focuses on red blood cell disorders associated with diagnosis-related group (DRG) code 811, while another is centered on atherosclerosis associated with DRG code 302.

The remainder of the RAC Web sites are expected to post the new review audits shortly, according to a CMS spokesman, who noted that the approved medical necessity reviews were standard and had been reviewed during the initial RAC demonstration program, which ran from 2005 through March 2008.

The RAC program was created to detect and correct improper Medicare payments and was expanded to cover the entire country after the completion of the demonstration. CMS created four geographic regions, each with its own RAC.

RACs conduct two types of reviews—automated reviews that require no additional documentation and complex reviews, which involve documentation requests.

CGI's list of CMS-approved review audits is available at <http://racb.cgi.com/Issues.aspx>. 🏠

Aetna Files Lawsuit Against LabCorp

Health insurer Aetna has filed a lawsuit against Laboratory Corporation of America alleging unfair competition, misrepresentation, interference, breach of contract, and violation of trade secret laws. LabCorp announced the lawsuit Aug. 26 in a Form 8K filing with the Securities and Exchange Commission.

Although few details were provided in the filing, some industry analysts suspect the lawsuit is likely related to LabCorp's relationship with Aetna as an out-of-network provider and potentially continued leakage of some Aetna test volume to LabCorp. Aetna is seeking unspecified monetary damages and relief.

Aetna terminated its national contract with LabCorp effective July 1, 2007, and established Quest as its preferred network provider for a five-year period. LabCorp currently is an out-of-network provider for Aetna. 🏠

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Featured Speaker: Christopher Young
President, Laboratory Management Support Services

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FCA INVESTIGATIONS: A number of False Claims Act investigations are being opened based on alleged Medicare billing errors and mistakes, which was not the intent of the legislation, according to a Sept. 7 letter from the American Hospital Association (AHA). "The AHA is concerned that aggressive FCA investigations are being initiated upon the discovery of evidence of a mistake or overutilization, making FCA enforcement through negotiated 'settlement' a self-fulfilling prophecy," said the letter, addressed to Attorney General Eric Holder and Department of Health and Human Services Secretary Kathleen Sebelius. While recent amendments to the FCA have given the Department of Justice more authority to investigate possible violations, the letter said that the FCA did not apply to billing errors or mistakes. The letter recommended that the Health Care Fraud Prevention and Enforcement Action Team begin a policy review of ongoing investigations and provide more clarity on oversight authority, and also requested a meeting between Holder, Sebelius, and Rich Umdenstock, president and chief executive officer of the AHA. 🏛️

MEDICARE OVERPAYMENTS: Medicare in 2007 overpaid physicians by an estimated \$14 million because claims contained incorrect place-of-service codes, according to an Aug. 12 report from the Department of Health and Human Services Office of Inspector General (OIG). The place-of-service code identifies whether a physician performed a service in a facility setting, such as a hospital or an ambulatory surgical center (ASC), or a nonfacility setting, such as a physician office or independent clinic. Medicare reimburses physicians at a higher rate for performing services in a nonfacility setting. The higher rate covers a physician's overhead expenses. The OIG report, *Review of Place-of-Service Coding for Physician Services Processed by Medicare Part B Carriers During Calendar Year 2007* (A-01-09-00503), examined 484,000 nonfacility coded service claims that had a value of \$42 million and selected a random sample of 100 paid service claims out of that number for further review. Out of the 100 claims, 10 were correctly coded, while the remaining 90 had nonfacility codes even though the services were performed in a hospital or ASC. The 90 claims resulted in overpayments of \$5,000, from which the OIG based its \$14 million estimate. The report is available at <http://oig.hhs.gov/oas/reports/region1/10900503.pdf>. 🏛️

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