G2 Compliance Report

INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Palmetto Delays MolDx Implementation, Allows for Alternate Test Identifier

Palmetto GBA has changed the effective date for claim submissions under its new Molecular Diagnostic Services Program (MolDx) from March 1 to May 1 and will give laboratories a choice between applying for the McKesson Z-Code or an alternate test identifier.

The changes were made in response to concerns raised by the laboratory industry over the new program for determining coverage and payment for molecular tests in the J1 region. Currently, most molecular tests are paid through "code stacking," which involves using a series of current procedural terminology codes (CPT) to describe a test that does not have a designated code.

Under Palmetto's MolDx program, announced in November 2011, laboratory service providers will register their molecular diagnostic tests with Palmetto and submit test information and supporting evidence for a coverage and reimbursement determination.

In comments to Palmetto, many in the lab industry expressed concerns about Palmetto's requirement that they obtain a unique Z-Code from

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Quest Diagnostics Sued for Gender Bias

Quest Diagnostics (Madison, N.J.) has been hit with a $100 million federal lawsuit filed by female representatives accusing the company of gender discrimination.

The suit was brought in U.S. District Court in Newark, N.J., by sales managers Erin Beery and Heather Traeger, two employees of the company's AmeriPath division. Beery is currently executive territory manager for AmeriPath in Indianapolis. Traeger is senior executive territory manager for AmeriPath in Bradenton, Fla. They are seeking to have the court extend the lawsuit to other female sales representatives who have been employed by Quest since Feb. 17, 2010.

Beery and Traeger allege a wide range of discriminatory practices by Quest. The complaint details discriminatory practices in the selection, promotion, and advancement of sales reps at Quest and AmeriPath, including discrimination on the basis of pregnancy and caretaking responsibilities in violation of Title VII of the Civil Rights Act of 1964 and other federal statutes.

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Palmetto Delays MolDx Implementation, *from page 1*

McKesson, a consulting company and third-party vendor. Lab groups also opposed the March 1 implementation deadline, saying it did not give them enough time to prepare for the new program.

Palmetto released an update to the MolDx program on Feb. 3 in which it attempts to address these concerns. The carrier says it has revised the license agreement used for the Z-Code application to reduce the administrative burden and also has provided an alternate code application process called the Palmetto Test Indicator (PTI).

For labs unable to implement systems for meeting the MolDx additional information timelines to include this information on their claims, Palmetto has updated its electronic claims fax cover sheet to allow submission of the test identifier via fax "attachment" to an electronic claim. If no test identifier (Z-Code or PTI) has been issued, Palmetto has developed a MolDx test information form. This form may be faxed with each test claim submission to identify the MolDx service provided. This form may be used until Sept. 1, 2012.

The effective date of the MolDx program has been delayed for two months, from March 1 to May 1. Claims received with paid dates of services on and after May 1, 2012, without one of the listed identifiers or a fax with the required information will be rejected for insufficient documentation.

CDC Issues Recommendations on Lab Safety Practices

A blue-ribbon panel of the Centers for Disease Control and Prevention (CDC) has issued a report detailing safety practices that medical diagnostic labs should follow. The 105-page Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories was published Jan. 6 in *Morbidity and Mortality Weekly Report*.

The report offers guidance and recommends biosafety practices specifically for diagnostic laboratories and is intended to supplement the fifth edition of *Biosafety in Microbiological and Biomedical Laboratories*, developed by the CDC and the National Institutes of Health.

According to the CDC, the document was written not to replace existing biosafety guidelines but to (1) improve the safety of activities in clinical diagnostic laboratories, (2) encourage laboratory workers to think about safety issues they might not previously have considered or addressed, and (3) encourage laboratorians to create and foster a culture of safety in their laboratories.

High Infection Rates for Lab Workers

Prior to the panel's creation, several studies found disease infection rates among lab workers were substantially higher than in the general public. Among the research cited in the report was a 2005 CDC study of bacterial meningitis in U.S. lab staff members.

"The attack rate in the general population aged 30-59 years (the estimated age range of the average laboratorian) was 0.3 per 100,000. The attack rate for microbiologists (aged 30-59 years) was 20 per 100,000," the report said.

Lab-acquired infections (LAIs) also include fungal and patristic infections. The most comment agents of laboratory-acquired fungal infections are the dimorphic fungi *Blastomyces*, *Histoplasma*, and *Coccidioides*. Most reported infections were caused by

an inhalation of conidia. Reported parasite-associated LAIs were caused primarily by *Leishmania*, *Plasmodium*, *Toxoplasma*, Chagas disease organisms, and other trypanosomes. Most infected health care workers acquired infections from needle sticks during preparation of blood smears or while drawing blood.

Work on the diagnostic laboratory guide began in 2008 with the CDC convening a blue-ribbon panel of experts experienced in a wide range of laboratory settings, from pathology and blood banks to veterinary diagnostics. The goal was to base recommendations on scientific findings, but the panel found there was little research into some diagnostic laboratory safety issues.

Panel Recommendations

To improve biosafety research, the panel recommended establishing a nationwide, nonpunitive system for reporting incidents and infections. Recommendations are broken down in a number of categories: laboratory design and architectural planning for microbiology; biological risk assessment and biosafety guidelines; fundamental safety practices; tuberculosis laboratory; autopsy/necropsy and surgical pathology; parasitology laboratory; mycology laboratory; virology laboratory; chemistry laboratory; hematology and phlebotomy laboratory; blood bank; veterinary diagnostic laboratory; storing, packaging, and shipping infectious substances; emergency procedures; biosafety education; and quality improvement.

General recommendations include:

- Creating a "culture of safety," encouraging laboratories to promote a systematic assessment to identify risks and implement plans to mitigate risks;
- Using Class IIA2 biological safety cabinets (BSC) that are inspected annually;
- Developing written safety protocols to address the risks of chemicals in the laboratory;
- Using appropriate disinfectants, including 1-to-10 dilutions of household bleach;
- Providing for negative airflow into the laboratory; and
- Establishing areas of the laboratory where use of gloves is optional or is recommended.

Adopting and following the guidelines will be up to laboratories and organizations. While some recommendations refer to the Labor Department's Occupational Safety and Health Administration standards, such as the bloodborne pathogen rule, enforced by OSHA, the overall practices are voluntary. The report is available online at *www.cdc.gov/mmwr/pdf/other/su6101.pdf*.

Myriad Opposes High Court Review on Patents

Myriad Genetics Inc. filed a brief Jan. 13 in opposition to the petition seeking Supreme Court review in a case challenging its patents on isolated DNA (*Association for Molecular Pathology v. Myriad Genetics Inc.*, U.S., No. 11-725).

Myriad, as the exclusive patent licensee, argued that the patent challengers, led by the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT), have posed the question, "Are human genes patentable?"—an issue not considered or decided by the U.S. Court of Appeals for the Federal Circuit.

"Rather, the question correctly answered by the Federal Circuit was whether particular isolated molecules of DNA, which were never available to the public until

humans invented them, and whose utility is clear and unquestioned, were eligible for patenting as 'compositions of matter' under 35 U.S.C. §101," Myriad argued. The brief also claimed that resolving whether any patent challenger had standing is an antecedent requirement that makes this case particularly inappropriate for Supreme Court review.

The case involves a 2009 declaratory judgment challenge initiated by the ACLU and PUBPAT against six patents for which Myriad is the exclusive licensee. The plaintiffs argued that nine composition of matter and six method claims of the patents—on the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer—were ineligible for patenting under Section 101.

"The question correctly answered by the Federal Circuit was whether particular isolated molecules of DNA, which were never available to the public until humans invented them, and whose utility is clear and unquestioned, were eligible for patenting as 'compositions of matter' under 35 U.S.C. §101."

—Myriad

A Federal Circuit panel agreed that only one of the method claims at issue was drawn to patentable subject matter and that claims to cDNA are patent-eligible. They split 2-1, however, as to claims to isolated DNA, with the majority reversing the lower court's ruling against patent eligibility for such claims. Judge Alan D. Lourie wrote the majority opinion; Judge Kimberly A. Moore wrote a concurrence. They agreed at minimum that isolated DNA has "markedly different chemical characteristics" compared to corresponding native DNA in the human body, reciting the court's standard set in *Diamond v. Chakrabarty*.

However, they identified different standards for distinguishing patent-ineligible "products of nature." In dissent, Judge William C. Bryson described yet another approach. The panel rejected both parties' rehearing petitions.

Petition Says Structure and Function Must Differ

The ACLU and PUBPAT filed the petition for certiorari Dec. 7, 2011. The question presented as to the isolated DNA patent eligibility holding is simply, "Are human genes patentable?"

The petition, written by the ACLU's Christopher A. Hansen, attacked the Section 101 ruling by the appeals court both on doctrinal and policy grounds. The petition broadened the scope of the challenge to date slightly, focusing on the Section 101 requirement of a "new and useful" composition of matter. The ACLU thus concluded that the "useful" requirement meant that the function of the isolated DNA—not just its chemical structure—must be markedly different from what appears in the human body.

The petition also asked the court to reverse the Federal Circuit's opinion as to the requirements for standing in the case. The appeals court held that only one plaintiff—out of several medical associations, medical researchers, breast cancer counselors, and women diagnosed with or seeking diagnosis—had standing.

Specifically, the panel ruled that Harry Ostrer, a researcher at New York University (NYU) School of Medicine, met the requirements for declaratory judgment standing under the Supreme Court's decision in *MedImmune Inc. v. Genentech Inc.* (2007)—"a substantial controversy . . . of sufficient immediacy and reality" and "meaningful preparation" to conduct potentially infringing activity.

However, just before the Federal Circuit's July 29 decision, Myriad notified the court that Ostrer was planning to leave NYU at the end of August and move to the Montefiore Medical Center at the Albert Einstein College of Medicine, thereby putting his standing in doubt. The cert petition did not address Myriad's concern but instead made a case for standing for two other plaintiffs.

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COMPLIANCE PERSPECTIVES

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Laboratory Issues for Sales and Marketing: Being Compliant and Competitive

In the laboratory industry there are certain areas of risk that are greater than others. Two of the areas of greatest risk are billing and coding of laboratory tests and services and the sales and marketing of those tests and services. The issues of coding and billing have been addressed ad nauseam but the compliance issues surrounding sales and marketing are addressed less frequently. Even though a thoughtful and thorough review of government cases and settlements that appear as billing problems and the fines and recoupment are related to claims filed, the underlying cause in many cases is sales- and marketing-related. Further, the vast majority of government prosecutions of clinical laboratories have been brought by or are a result of whistleblower lawsuits brought by competitive salespeople or the sales employees of the laboratory that gets prosecuted.

Part of the reason for this is there is a huge conflict of interest between what sales employees do and what is required by compliance policies and procedures in the clinical laboratory. Many sales and marketing employees see compliance as a hindrance to them accomplishing their tasks and meeting their goals. Compliance people see the sales and marketing departments as high-risk areas for violations of policy and procedures because of the conflicting interests. These two distinct and different perspectives, coupled with the highest levels of government scrutiny seen in the industry in years and a very competitive marketplace brought about by economic pressures and lowered reimbursement, create a perfect storm for compliance problems.

Sales and Marketing Regulations

The main laws and regulations of concern for sales and marketing departments are the physician self-referral law, commonly referred to as the Stark law, and the long-standing anti-kickback laws. Both of these laws and their regulatory schemes are very complex and have been subject to many changes over the last decade. The most recent changes, the Fraud Enforcement and Recovery Act of 2009 (FERA) and the Patient Protection and Affordable Care Act in 2010 (PPACA), have been instrumental in broadening the scope of these laws by increasing the severity of penalties while making it increasingly easier for federal agencies to find and prosecute offenders.

Even though these laws are complex, many providers and physicians tend to reduce them to a small set of basic issues related to the provision of free services or giving gifts or money in exchange for referrals. Many physicians, and even attorneys who are not thoroughly familiar with these laws, misinterpret them and fail to comply with them as a result. They fail to see the implications of many of the relationships between laboratories and their referral sources that can create problems for both parties even as a result of a relatively simple act, like not getting a written agreement in place or letting a lease expire. Once these laws are violated, all referrals between the parties become "tainted" and all claims filed during that time could be, and often are, considered false claims punishable by fines and potential exclusion from the Medicare or Medicaid programs. In some cases, depending on the circumstances of the case, people go to jail. These are serious offenses and should not be taken lightly.

Sales and marketing employees are the primary point of contact for referral sources and often find themselves being asked for special favors, discounts, and other arrangements that are covered under these laws and regulations. The kinds of things we are talking about are placing computers, printers, and other hardware and devices in physician offices; placing laboratory employees in physician offices; paying rent for space from physicians; giving discounts and special pricing; and other similar issues. Often these requests are accompanied by an explicit or implied referral of tests. It might be structured something like "well, my other lab does this for me and if you want me to change labs you would have to do the same thing."

While the Stark and anti-kickback laws and regulations appear similar, there are some important differences to remember. Both of the laws essentially prohibit giving physicians or other referral sources anything of value in exchange for the referral of services. Each of the laws includes exceptions (Stark) or safe harbors (anti-kickback) that allow certain activities or arrangements that would normally violate the law, but as long as the parties meet the requirements or "criteria" of the exception or safe harbor, they would be safe from prosecution.

Under Stark, all of the criteria must be met to avoid prosecution, while under anti-kickback, not meeting all of the requirements does not trigger an automatic violation—these kinds of issues can be handled on a case-by-case basis. This demonstrates one of the more important differences between the two laws. The Stark law is a strict liability law, which means that you don't have to intentionally violate the law to be prosecuted; you can violate the law just by making an error or mistake.

Compliant Sales and Marketing

So how does the laboratory go about mitigating its risks while remaining competitive? It is important as a first step that the laboratory recognize the risk associated with sales and marketing its testing and services. The best tool that the laboratory can employ is extensive and effective training for its sales and marketing employees and providing for them a written code of conduct and a complete set of policies and procedures to guide them in their everyday job. These policies and procedures and the education and training should include at least a basic review of the Stark and anti-kickback laws and regulations and address those specific areas of risk that these employees face while carrying out their responsibilities.

The Office of Inspector General Compliance Program Guidance for Clinical Laboratories[1] informed laboratories that their marketing and sales techniques should be clear and nondeceptive. They must ensure that the physicians who refer to their laboratory understand the billing and testing consequences of the services they order from the laboratory. Sales and marketing material and verbal sales presentations should always properly represent the testing and services that the laboratory provides and not make any claims for tests that cannot be substantiated by a valid study or some kind of objective third-party peer review. They must never represent a test as doing something outside of what the test manufacturer's claims are for the test.

Any sales proposals that include special pricing and discounting or other service arrangements should comply with company policy and should be approved by the appropriate management before offers are made to clients. Some examples include:

- If the laboratory offers custom profiles and panels of tests or reflex tests it must ensure that its physicians understand how to use the tests and understand how to order the tests in a panel or profile individually when all of the tests

[1] *http://oig.hhs.gov/authorities/docs/cpglab.pdf*

in the panel are not needed. In the case of reflex tests, it must be clear what will happen when the reflex test is ordered and under what circumstances secondary or follow-up testing will occur.

- If the laboratory provides a phlebotomist for the physician's office or places a computer or allows access to the laboratory through the Internet, it must ensure that its clients clearly understand the dos and don'ts allowed in these cases. The best case would be a written agreement signed by both parties that provides the details of the arrangement.

- In terms of providing things of value to the office or to a physician like a gift, or bringing food into the office for the staff or taking a physician and his or her spouse out for dinner, sales representatives must ensure that they follow any company policies or procedures. Most important, they must never imply or implicitly state that the gift or food is being provided conditionally upon the referral of tests. Further, make sure that they track the amount associated with the gift or meal because the Stark law sets a specific dollar limit per year that can be spent.[2]

[2] *The Web site for the Stark limit is* http://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp. *The limit is adjusted annually based on the consumer price index.*

Rules of Conduct for Sales and Marketing

There is a basic set of rules for conduct that laboratories should employ when it comes to their sales and marketing activities.

1. **Always tell the truth.** Telling the truth means more than just accurately describing the tests and services; it also means not hiding problems related to the tests and services. Clearly explain what a test can and can't do and never exaggerate, mislead, or misrepresent a test's capabilities or the benefits of a service.

2. **When using a kit or test that is approved by the Food and Drug Administration, only sell in conformance with the label statements about the test.** If you are performing a laboratory-developed test, make certain you understand the rules and regulations related to performing and billing that test but never sell such a test for a use or purpose that is not substantiated through the results of a properly carried out study or based on information provided in an objective third-party journal.

3. **Disclose any problem with a particular test or service as soon as the problems are substantiated.** If the problem appears to have legal consequences, the laboratory should engage knowledgeable counsel and disclose information based on the advice of that counsel. However, don't delay or make excuses to postpone disclosures. Most importantly if a laboratory test is not performing properly stop performing the test, stop selling the test, and stop billing for the test. If the problem persists the laboratory should ensure it continues to communicate the status as appropriate.

4. **Don't buy or pay for referrals.** Paying for referrals of Medicare or Medicaid work is a felony. In many states, paying for referrals of any testing is against the law. You don't necessarily have to be paying for the test with money; you could be paying for the test with gifts and favors or in exchange for other items of value provided by the physician. Furthermore, don't pay anyone else to arrange or recommend referrals to your laboratory.

5. **Don't use sales techniques that emphasize how much a doctor can earn if he uses your laboratory.** There is a difference between discussing how much doctors can save the health care system through the effective and efficient use of laboratory services as opposed to how much money they can put in their pocket as a result of using your laboratory. Don't overemphasize economic benefits to physicians. This is especially important when discussing special pricing or discounts with a physician or other referrals source.

6. **Use care with your requisition forms, test directories, panel and profile offerings, and online test-ordering software.** You should avoid giving the appearance that you are steering test-ordering in any way and make sure that your forms or online service-ordering software clearly disclose what tests are included and how the physician can choose other tests if they want.

- A laboratory can provide free tests to a physician or a clinic in the case where there is some kind of a laboratory error; however, all other cases should be carefully reviewed before the free tests are provided. For instance, a laboratory may want to provide a certain number of free tests to validate its quality and services. This could be done provided that the arrangement is clearly spelled out in writing and both parties sign the document. Also, the physician must not benefit from the free work, meaning that the physician does not bill or file any claims for the work, and, at the conclusion of the demonstration, there is documentation of the outcome.

- The question of discounting comes up often so the laboratory must ensure it has some basic rules in place regarding its discounting and pricing practices. Regardless of the details of the policies and procedures there are two basic concepts that sales and marketing employees must understand. They must never give the physician the idea that the discount is being provided in exchange for referrals of Medicare and Medicaid tests. In other words, a discount should not be given based on physicians referring "all" of their laboratory testing to the laboratory giving the discount. Secondly, a discount should never result in pricing tests and services below the cost to provide the tests and services themselves. Put another way, if the discounted tests were the only work that you are receiving from the physician, the amount paid for the tests would be a good business arrangement for the laboratory.

Summary

There should be no doubt that sales and marketing activities are a high compliance risk area for the laboratory. Labs must ensure that employees are well-trained and well-versed in applicable laws and regulations and how they apply to their day-to-day work. The laboratory also must have clear policies and procedures and guidelines for marketing and sales activities and make sure that any violations of such policies and procedures are met with disciplinary action appropriate for the violation.

A salesperson who sells within the company's policies and procedures and the dictates of laws and regulations is far more valuable than a salesperson who makes a lot of sales but violates laws to accomplish that.

It is equally important that laboratory management and the leadership of the laboratory understand the risks posed by the marketing and sales employees and their activities and support efforts by the compliance department to mitigate those risks on behalf of the laboratory. And finally the laboratory needs to understand the vulnerability posed by sales and marketing employees in the area of whistleblower lawsuits.

So, even though the sales and marketing department is often seen as the department that provides growth for the laboratory it also should not receive special favoritism when it comes to violations of laws and regulations. A salesperson who sells within the company's policies and procedures and the dictates of laws and regulations is far more valuable than a salesperson who makes a lot of sales but violates laws to accomplish that. Performance standards, compensation policies, and rewards should be based on the former and not the latter.

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Quest Diagnostics Sued for Gender Bias, *from page 1*

According to Beery and Traeger, high-ranking company officials within Quest's predominantly male management team foster an environment detrimental to the success and advancement of female employees. They describe "old boys' club" attitudes that pervade the enterprise, including forcing women to work under less favorable circumstances than their male counterparts and denying them the educational and job advancement opportunities afforded men in similar positions.

"There is no question that male employees and, in some cases, women without primary childcare responsibilities, have advanced and continue to advance more rapidly to better and higher-paying jobs at Quest," said Sharon Eubanks, a member of the plaintiffs' legal team. "The managers who are maintaining and promoting the current male-dominated management structure have a disproportionate impact on the promotion and compensation decisions that affect female sales reps."

Beery and Traeger are seeking declaratory and injunctive relief; backpay; front pay; compensatory, nominal, and punitive damages; and attorneys' fees and legal expenses for themselves and the class.

Quest denies the allegations and intends to vigorously fight the lawsuit, according to a company spokesperson. "We are committed to equal opportunity for all employees and we take seriously our policies requiring equal treatment regardless of gender," the company says in a statement. "We are proud to be routinely recognized as a top employer in communities around the United States."

Hospital Had No Duty to Inform Patient of Laboratory Test Results, State Court Says

A hospital was not liable to a patient for failing to inform her directly of the results of a test ordered by her physician, a California state appeals court Jan. 12 said in affirming summary judgment for the hospital (*Walker v. Sonora Regional Medical Center*, Cal. Ct. App., No. F060420).

In a partially published opinion, the California Court of Appeal, Fifth District, said that state and federal law precluded Sonora Regional Medical Center (SRMC) from disclosing the test results to anyone other than plaintiff Amber Walker's physician, including Walker herself.

Walker, her husband Adam, and their daughter Payton filed this lawsuit against several defendants, including SRMC, seeking damages resulting from the defendants' negligence in failing to inform Walker that she was a carrier of a genetic mutation for cystic fibrosis. Payton was born with the condition more than a year after a lab test revealed Walker's status as a carrier. Walker claimed that if she had known the results of the test she would not have conceived a child.

Hospital's Duty

Walker's obstetrician/gynecologist, Donovan Teel, M.D., recommended that Walker have a cystic fibrosis test during a previous pregnancy. Walker went to SRMC's outpatient laboratory, where a blood specimen was taken. The hospital sent the specimen to an outside testing agency, which confirmed that Walker was a carrier of cystic fibrosis.

The outside laboratory sent a report to SRMC detailing the results of the test. SRMC electronically transmitted the report to Teel, who made a note on Walker's chart to

discuss the results. By that time, Walker had miscarried, and Teel failed to inform her of the test results even though he treated her throughout her subsequent pregnancy with Payton.

In their lawsuit against SRMC, the plaintiffs alleged that the hospital had a duty to inform Walker directly of the test results. The trial court, finding no such duty, granted summary judgment for SRMC, and the plaintiffs appealed. Although the appeals court recognized that a hospital has a duty to exercise reasonable care to protect its patients, it found that under the circumstances, SRMC had a duty to send the test results to Teel only.

The court found that there are legal limitations under both federal and state law that govern a laboratory's release of a patient's test results. Federal regulations governing clinical laboratories, such as SRMC's, require that medical test results are to be released "only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test," 42 C.F.R. §493.1291(f). The regulations, at Section 493.2, define an "authorized person" as "an individual authorized under State law to order tests or receive tests, or both."

California law, specifically Cal. Bus. & Prof. Code §1288, provides that a clinical laboratory "may accept assignments for tests only from and make reports only to" licensed medical professionals. In other words, the court said, the statute establishes that clinical laboratory results are to be reported to the physician who ordered the test, not to the patient.

The court concluded that since SRMC provided only clinical laboratory testing services to Walker, it owed a duty of care to send the results to Teel only. "That is," it said, "the hospital had no affirmative duty to release the laboratory results directly to Amber [Walker] or to counsel her regarding the same." SRMC fulfilled its duty by reporting the results to Teel, the court said.

The court added that SRMC's act of "performing a single discrete outpatient lab test . . . [did] not invoke the full panoply of hospital duties regarding every aspect of [Walker's] health care treatment."

HCCA Survey Questions Handling of RAC Audits By Health Care Providers

One-third of health care providers are not handling Recovery Audit Contractor (RAC) audits through their compliance departments, according to a survey from the Health Care Compliance Association (HCCA) released Jan. 18 and conducted in September and October 2011.

Compliance staff at the remaining two-thirds of health care providers surveyed are responsible for RAC audits, the survey said.

"While most companies have placed RAC audits under the compliance program, one-third of the respondents indicated that the RAC audits are not their responsibility, leaving the questions of who is managing the process and whether compliance is involved at all," the *RAC Audit Survey* said.

Additionally, a majority of providers (57 percent) reported having just one full-time employee (FTE) dedicated to RAC audits, the survey said. Twenty-seven percent reported having two FTEs, 11 percent reported having four to six, 3 percent reported having seven to 10, and 3 percent reported having 11 or more.

RAC Staffing

A majority of providers said their RAC staffing levels were in line with existing staffing in their organization dedicated to responding to other government program requests. Fifty-six percent reported having only one FTE assigned to handle requests from Medicaid Integrity Contractors, Zone Program Integrity Contractors, and other government health care contractors.

The RAC program is designed to detect and recover improper Medicare payments and was created by Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The law authorized a three-year, six-state demonstration program, covering Medicare Part A and Part B claims, that began in 2005. Section 302 of the Tax Relief and Healthcare Act of 2006 permanently authorized a nationwide Medicare RAC program, which began in fiscal year 2010.

The Patient Protection and Affordable Care Act expanded the RAC model into Medicare Part C and Part D, as well as Medicaid. The Centers for Medicare and Medicaid Services (CMS) published a final rule in the Sept. 16, 2011, *Federal Register* that required all states to have a signed contract with a Medicaid RAC vendor by Jan. 1 unless an exception was granted by CMS. Medicare Part C and Part D RACs have yet to be implemented.

Survey Participants and Results

The HCCA survey received Internet-based responses from 418 health care providers and was designed to determine how providers are responding to RAC audits. Organizations of all sizes participated, including:

- Companies with one to 250 employees (18 percent of the responses);
- Companies with 251 to 1,000 employees (23 percent of the responses);
- Companies with 1,001 to 5,000 employees (34 percent of the responses); and
- Companies with more than 5,001 employees (25 percent of the responses).

Only 10 percent of providers reported increasing their current fiscal year compliance budget to handle government requests such as RAC audits, the study found, while 50 percent reported no change at all and 5 percent reported a budget decrease. Thirty-four percent reported that their compliance budget had increased "somewhat."

Survey responses were consistent for the most part across all organization sizes, with the exception of responses to a question about the use of outside consultants during the RAC appeal process. Seventy-seven percent of organizations with one to 250 employees said they had never used outside consultants, while only 40 percent of organizations with more than 5,001 employees said they had never used outside consultants.

News-At-A-Glance

ROMNEY'S ROLE AT DAMON: Mitt Romney is taking a lashing for his role at Damon Corp., a medical testing company that was hit with more than $119 million in criminal and civil fines related to Medicare fraud while he served on the board. Democratic National Committee Chairwoman Debbie Wasserman Schultz, in a memo shared with *Politico*, says Romney must "answer troubling questions about his time as a board member at Damon . . . and his debunked story about his role in uncovering and reporting the fraud to federal investigators." According to Wasserman Schultz, Romney's experience with Damon "underscores troubling questions about Romney's record of seeking profits at any cost and saying anything to get elected." Democrats aren't the only ones raising the issue. "Mitt's Blood Money," a new minidocumentary released by Winning Our Future, a super-PAC friendly to Newt Gingrich, also questions Romney's involvement with Damon, saying that Romney sits at the center of one of the top 15 corporate crimes of the 1990s.

KARYOTYPING SETTLEMENT: A New Jersey company that provides laboratory testing services for diagnosis of cancer has agreed to pay $1 million to the federal government to settle allegations that it improperly submitted claims to Medicare for chromosome karyotyping studies, U.S. Attorney for Massachusetts Carmen M. Ortiz said Jan. 19. The payment by Cancer Genetics Inc. will resolve allegations that it billed Medicare for tests that were not medically necessary from July 2003 to March 2005. The company previously operated a laboratory in Massachusetts. Chromosome karyotyping studies are used in the diagnosis of various types of cancer. A karyotype is an arrangement of the chromosomes of a single cell for chromosome analysis. The government's investigation found that the company billed Medicare for studies using 20 karyotypes when only two or three karyotypes were medically necessary and thus received a higher amount of reimbursement than was authorized. Panna L. Sharma, president and chief executive officer of the company, says the activity "had nothing to do with the current company" and that there is no employee in the company today who worked for Cancer Genetics when the alleged activity occurred. The company did not admit to any liability.

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