G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Court Dismisses Lawsuit Against Millennium Laboratories; Compliance Officers Take Heed

A Massachusetts district court filed an order on Jan. 28 dismissing, for the final time, a 5-year-old whistleblower lawsuit against Millennium Laboratories (ML) in which an employee of a competitor, Robert Cunningham, alleged false claims and conspiracy to commit fraud against both state and federal health care programs.

The dismissal came as a result of motions filed by ML for the second time seeking the dismissal of the original complaint filed in 2009, which it won, but Cunningham appealed. A thorough review of the documents from this case teaches three very important aspects of a compliance officer's day-to-day practices: (1) Never jump to conclusions when presented with a compliance problem, (2) there are many ways to defend against a whistleblower lawsuit, and (3) seek the advice of legal counsel experienced in defending against such suits.

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When Should Labs Fight Overpayment Determinations Based on Extrapolation of Claims?

A recent district court decision on overpayments based on extrapolation of claims contains important lessons for health care providers, including clinical laboratories, on how and when to challenge overpayment requests.

The U.S. District Court of Nebraska on Jan. 22 ruled on an overpayment based on an extrapolation of a sampling of claims. The court denied the plaintiff's assertion that the extrapolation was invalid even though two separate statistical experts opined that it was unreliable and should not be used for extrapolating to the larger universe of claims.

In upholding a motion for summary disposition in favor of the Department of Health and Human Services, the court said, "A court reviewing an agency's adjudicative action should accept the agency's factual findings if those findings are supported by substantial evidence on the record as a whole."

In the case of a clinical laboratory where thousands of patients and tests are often involved, overpayments are most often based on an extrapolation from a relatively small sample.

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When Should Labs Fight Overpayment Determinations, *from page 1*

History of Case

Schuldt Chiropractic Wellness Center (Hasting, Neb.) is a provider of chiropractic services for Medicare beneficiaries. Wisconsin Physician Services (WPS) is a Zone Program Integrity Contractor (ZPIC) that conducted an expanded, postpayment review of claims submitted by Schuldt on 75 Medicare beneficiaries, with dates of service from January 2008 through April 2010. The review was conducted on a statistical sample of claims, a common auditing practice, and caused WPS to conclude that there was a 99.55 percent error rate. Based on that, WPS projected overpayment findings of $126,041.13 extrapolated from the $11,376.14 of actual overpayments in the audit sample.

Schuldt exercised its appeal options of redetermination and reconsideration, to no avail, and requested an administrative law judge (ALJ) hearing. During the Sept. 19, 2011, telephone hearing, ALJ William J. Cowan found that 344 of the 445 services billed were correctly billed based on the issues of coverage, liability, and overpayment waivers and Schuldt should be paid for them. The ALJ also considered the opinions of two statistical experts, Schuldt's and the ALJ's own expert, and concluded that the ZPIC's results "were insufficiently reliable to be used for the purpose of estimating an overpayment to a larger universe than the sample itself."

On Aug. 6, 2012, the Centers for Medicare and Medicaid Services (CMS) filed a referral memorandum with the Medicare Appeals Council (MAC) asserting that the ALJ decision contained an error of law material to the outcome of the claim. Based on the single issue of whether Schuldt met its burden of proving that the statistical sampling methodology was invalid, the MAC reversed the ALJs decision in respect to the validity of the statistical sampling methodology and did not address the ALJs findings with respect to coverage, liability, or overpayment waiver. On Jan. 31, 2013, WPS issued a recalculation of the projected overpayment applying the ALJs findings with respect to coverage, liability, and overpayment waiver to the sample of 445 billed services and came up with a $37,580 overpayment, which Schuldt paid.

Presumption of Validity

Schuldt was not wrong to challenge the sampling and extrapolation, but if its appeal had been based solely on that challenge, it would have failed and the $126,041.13 overpayment would have been upheld.

Schuldt got its overpayment amount overturned based on the coverage and liability findings of the ALJ, which reduced the number of claims in error and consequently the amount owed. CMS may have wanted to establish the validity of extrapolation for overpayment purposes using smaller samples for future reference. The court ruling explains that sampling creates a presumption of validity as to the amount of an overpayment. This has the effect of shifting the burden to the provider to disprove the validity of the extrapolation.

The key element is the error rate. Once the error rate is determined to be less than 99.55 percent, the extrapolation calculations change. Effectively, Schuldt most likely could have obtained the reduced overpayment amount based on the reduction in the error rate that changed the number of claims for services that the ALJ found to be actually incorrect based on coverage, liability, and overpayment waivers. One other important message from this case is that the Medicare manual instructions allow the use of smaller samples and less precise results in certain circumstances and notes that 42 C.F.R. 405.1062 requires that ALJs and the MAC give substantial deference to manual instructions.

What We Learned From This Case

What this case really provides that is valuable to laboratory compliance officers

and other health care providers is guidance on what needs to be done to attack the validity of the sampling and extrapolation used by a Medicare auditor, and if that is a feasible approach to get overpayments reduced or overturned.

First, it should be noted that attacking the accuracy of the extrapolation is a difficult endeavor and often fails. A provider would have to present evidence that a different random sample from the universe of claims produces a lower error rate or rate of denials. That would require a new sampling and redetermination of the error rate in the new sample.

Another option would be to review the entire universe of claims from which the sample was taken to establish the validity of the error rate of all of its actual claims to demonstrate that the auditors' projection is factually impossible. Both of these options are onerous and potentially costly. The provider really needs to attack the error rate in the sample. By challenging the errors in the sample based on coverage and other Medicare regulations, the provider can change the overpayment estimation calculation because the error rate is a key element in the extrapolation calculation.

Takeaway: When faced with an overpayment based on an extrapolation of a sample of claims, challenging the statistical correctness of the auditor's methods and sample size should be the challenge of last resort, used only if there are no other options available and the provider has the ability to resample from the universe of claims. G2

Incorporating the 2014 OIG Work Plan Into Your Annual Review Processes

The Health and Human Services Office of Inspector General (OIG) released its 2014 work plan on Jan. 31, an important guide for all health care providers in determining priorities for the year.

The OIG has cited its annual work plan as a resource for monitoring risk areas for a compliance program in virtually all OIG compliance guidance documents since the first one was issued in 1998.

Effective laboratory compliance programs include policies and procedures for monitoring and auditing to ensure compliance with laws and regulations. Those policies should include a review of the annual work plan and provide guidance for incorporating that review into the operation of the laboratory's compliance plan.

What's in it for Labs

In the 2014 work plan, laboratories are specifically mentioned in only one item: "Laboratory tests—Billing characteristics and questionable billing." The OIG is concerned that tests paid for by government programs "are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary."

According to the OIG, Medicare's payments for lab services in 2008 represented an increase of 92 percent over payments in 1998. Much of the growth in lab spending has resulted from the increased volume of ordered services, it says, noting that Medicare should only pay for those lab tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary.

The fact that the OIG is reviewing what it considers questionable billing indicates the OIG believes there are a significant number of tests that were not ordered by the treating physician or were not used in the treatment of a Medicare patient. The key element is documentation. In a post-payment laboratory audit, the laboratory

documentation is often compared to the ordering physician or entity's documentation and, if there is a discrepancy, the lab is determined to have received an overpayment unless it can demonstrate otherwise.

Interestingly, a similar item was included in the 2013 work plan with the exception that it was limited to 2010 and was designated as a work in progress with the expected report identification of OEI-03-11-00730, the same identification used in the 2014 work plan. The same identification code was also used in the 2012 work plan for an item titled, "Trends in Laboratory Utilization." All three work plan items cite the same Code of Federal Regulations section but at this time, no report with this designation has been issued.

The laboratory compliance officer should consider some kind of review to ensure that billing processes are being monitored. If a periodic billing audit is already being conducted, make sure it includes a specific review addressing this risk. For instance, the audit could contain a requirement that a designated number of randomly selected review items include a request to the ordering physician or entity for the patient records related to the test orders for that item.

The records from the office should be reviewed and compared to the order documents the lab received to determine if there are discrepancies in the documentation or other information that may indicate the order was not proper or was not used for a specific treatment purpose. These kinds of discrepancies are indications that a test is not reasonable and necessary and would be considered part of the medical necessity component of the lab's compliance program. The government has implied that the medical necessity of claims submitted to its contractors for reimbursement will be the subject of future reviews. An improper order is a medical necessity issue.

How to Use the Work Plan

The laboratory compliance officer should have a policy or procedure that provides guidance for reviewing the work plan. This list shows how to identify potential risks for the laboratory that are not specifically identified as laboratory items:

1. Consider who the laboratory does business with and look for items in the work plan that may affect those individuals or entities that are related to their laboratory or diagnostic services usage. For labs, that potentially includes nursing homes, hospices, physician offices, hospitals, end-stage renal disease facilities, and home health agencies;
2. Review items related to other government agencies that have jurisdiction over laboratories like the Food and Drug Administration, the Office for Civil Rights, and the Centers for Disease Control and Prevention; and
3. Review previous work plans for similar items or to identify audit reports that may have been completed.

Once laboratory items are identified, the compliance officer should conduct a review of the laboratory's policies and procedures in the risk area. If the risk cannot be established by this review, the compliance officer should conduct a probe audit to assess the risk and set a baseline. Depending on the outcome of the probe audit, the officer may want to conduct a more extensive audit or review, issue a report, make corrective action recommendations, and assign the project to an appropriate member of the lab's compliance committee.

Takeaway: The laboratory compliance officer can avoid compliance problems and help demonstrate that the laboratory compliance program is effective by having policies and procedures for reviewing the OIG annual work plan and having documentation of audits and reviews, along with their outcomes. G2

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COMPLIANCE PERSPECTIVES

Laboratory Phlebotomists in Physician Offices? States Increasingly Saying 'No'

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A common practice among clinical laboratories is to place laboratory employees, such as phlebotomists, in physicians' offices for the purpose of collecting lab samples. This practice has been allowed, with some restrictions, under federal regulations. Increasingly, however, states are prohibiting this practice through their own anti-kickback and fraud regulations. Because of the far-reaching nature of these provisions, clinical laboratories should be mindful of state regulations before placing phlebotomists in physicians' offices.

Federal Regulations

Federal regulations, including the anti-kickback statute (42 U.S.C. §1320a-7b), the Stark law (42 U.S.C. §1395nn), and Clinical Laboratory Improvement Amendments (CLIA, 42 U.S.C. §263a), have been interpreted to allow clinical laboratories to place phlebotomists in physicians' offices under certain, limited circumstances. In the absence of state regulation, clinical laboratories placing phlebotomists in physician offices must pay fair market value rent for any space the phlebotomist uses and must ensure that the phlebotomist does not perform any additional tasks that are normally the responsibility of the physician's office staff.

The anti-kickback statute prohibits the exchange of anything of value made to induce or reward the referral of federal health care program business. The Office of Inspector General (OIG) in a special fraud alert considered whether the federal anti-kickback statute prohibited the placement of phlebotomists in physicians' offices and gave limited approval to the practice (59 Fed. Reg. 65372, 65377, Dec. 19, 1994). The OIG cautioned, however, that the practice must be permitted by state law and that the anti-kickback statute might be implicated if the phlebotomist also performed tasks that normally were the responsibility of the physician's office staff. The OIG also commented that a contract between the laboratory and the physician prohibiting the phlebotomist from performing additional services alone was in itself insufficient to show compliance; rather, laboratories must carefully monitor the phlebotomist's activities to ensure no usual physician office staff services were performed.

Laboratories renting space from physicians for laboratory phlebotomists also must comply with the requirements of the Stark law since laboratory services are designated health services. The Stark law prohibits physician referrals of designated health services for Medicare and Medicaid patients if the physician has a financial relationship with that entity, including compensation arrangements. An exception to the Stark law exists for the rental of office space. To meet this exception, the parties must enter into a written lease identifying the premises to be occupied by the tenant, lasting at least one year, and setting rent at fair market value. The space must be exclusive to the tenant when being used by the tenant and the lease must be commercially reasonable. To be commercially reasonable, the phlebotomist placement must satisfy the same business standards that a clinical laboratory would apply to

any other phlebotomist placement, including performing a sufficient number of draws a day necessary to justify the placement.

CLIA regulations apply to virtually all clinical laboratories, with the exception of those in certain states such as New York that have regulatory programs as stringent as CLIA. The CLIA program, operated by the Centers for Medicare and Medicaid Services, sets standards and issues certifications for clinical laboratory testing. While CLIA is a comprehensive regulatory scheme, it only imposes a duty on laboratories to oversee the proper collection of laboratory samples and does not prohibit placement of phlebotomists in physician offices.

State Regulations

Certain states have prohibited or severely curtailed the practice of placing phlebotomists in physicians' offices. Some of these states have created broad prohibitions through legislation, while other states have limited the practice through administrative agency efforts, including regulations and advisory opinions.

Pennsylvania and Florida

Both Pennsylvania and Florida have enacted legislation in the past two years to explicitly prohibit the placement of paid or unpaid clinical laboratory personnel in physicians' offices. Pennsylvania's 2013 Senate Bill 1042, which amended its Clinical Laboratory Act, and Florida's 2012 Senate Bill 1929, which amended Fla. Stat. §483.245(1), prohibit clinical laboratories from placing in a physician's office paid or unpaid personnel to perform services, regardless of whether fair market value is paid. Similarly, both of these states prohibit clinical laboratories from leasing any space within physicians' offices for any purpose, including establishing a collection station. Pennsylvania also prohibits physicians from procuring clinical laboratory staff to perform any functions, even if the payment is at fair market value. As a result of the recent legislation, clinical laboratories can no longer place their phlebotomists in physicians' offices in either of these states.

Certain states have prohibited or severely curtailed the practice of placing phlebotomists in physicians' offices. Some of these states have created broad prohibitions through legislation, while other states have limited the practice through administrative agency efforts, including regulations and advisory opinions.

The scope of the prohibition in both states is also similar and impacts all clinical laboratories seeking to do business in these states. Senate Bill 1042 applies to clinical laboratories operating in Pennsylvania or testing a specimen collected or accepted in Pennsylvania. Fla. Stat. §483.245 provides for penalties both for clinical laboratories licensed in Florida and clinical laboratories licensed in other states but doing business in Florida. Penalties for clinical laboratories not licensed by the Florida Agency for Health Care Administration (AHCA) include a fine capped at $1,000 for violations of this statute and a recommendation from AHCA to the appropriate licensing board that disciplinary action be taken. Therefore, clinical laboratories operating in neighboring states should be mindful of the recent statutory changes. Clinical laboratories with a national presence should consider enacting compliance procedures to ensure that no phlebotomists are placed with Pennsylvanian or Floridian physicians.

New York

New York regulates the behavior of clinical laboratories operating within its borders through regulations issued by the Wadsworth Center. The Wadsworth Center prohibits placing clinical laboratory collection stations within any part of the practice,

administrative area (as distinct from the office area), office or waiting area of any health services purveyor that refers specimens to the clinical laboratory (10 NYCRR, §34-2.6(c)). Similarly, the Wadsworth Center prohibits clinical laboratories from supplying employees or agents to a referring physician to perform functions and duties in the office of that physician (10 NYCRR, §34-2.7).

Because New York requires any laboratory testing specimens originating in New York to hold a New York clinical laboratory license, the Wadsworth prohibitions will apply to any laboratory that tests New York specimens. Compliance with these regulations is important since operating a collection station or placing staff within a physician's office is deemed consideration for referral of specimens for the performance of clinical laboratory services and is, therefore, prohibited under New York's laboratory-specific anti-kickback statute (N.Y. Pub. Health Law §585-588).

New Jersey

New Jersey originally prohibited the placement of phlebotomists in physicians' offices through its Medicaid regulations. N.J. Admin. Code §10:61-2.4 prohibits the payment of rent by clinical laboratories to physicians as a condition of provider enrollment in Medicaid. Because federal regulations, including the Stark law and the federal anti-kickback statute, require that the clinical laboratory pay fair market value rent for space it uses in a physician's office, this regulation effectively prohibits a clinical laboratory from establishing a collection space in a Medicaid-enrolled physician's office. A ramification of this Medicaid-focused approach was that some providers stopped participating in Medicaid in order to continue to pay and receive rent for clinical laboratory collection stations placed in physicians' offices.

New Jersey has interpreted its state anti-kickback law, N.J. Stat. §45:9-42.42, to prohibit the placement of phlebotomists in non-Medicaid-affiliated physicians' offices. In May 2001 and January 2007, the Department of Health issued advisory opinions stating that the rental of office space by clinical laboratories in physicians' offices violated the state's laboratory anti-kickback law. Because these advisories were not effective in prohibiting clinical laboratories from placing phlebotomists in physicians' offices, the New Jersey Department of Health, in 2010, promulgated regulations prohibiting a laboratory from paying rent on physician office space (*see* N.J. Admin. Code §8:44-2.14). Any payment of monetary or nonmonetary remuneration to a physician to operate a collection station at the physician's office is considered a payment by the laboratory to solicit the physician's patients in violation of the state's laboratory anti-kickback statute.

The regulations provide an exception to the prohibition for freestanding collection stations. The N.J. Admin. Code §8:44-2.14, however, creates stringent requirements that collection stations must meet to be deemed freestanding, including that these stations (1) serve all members of the public, not just patients of one or more specific medical practice; and (2) be accessible through a public access entrance that clearly identifies the name of the laboratory and its days and hours of operation. As a result, it is impossible for a phlebotomist stationed in a physician's office to meet the requirements of a freestanding collection station.

The regulation allows for the placement of staff in physicians' offices so long as the physicians received no compensation. The Public Health and Environmental Laboratories Division of the New Jersey Department of Health explained that the intention was not to prohibit the operation of collection stations entirely but to instead allow in-office collection stations driven by patient need instead of financial incentives. Because N.J. Admin. Code §8:44-2.14 is written more narrowly than the Pennsylvania,

Florida, or New York statutes, laboratories may be able to place phlebotomists in a limited number of physicians' offices, provided that these physicians do not participate in federal health care programs and acquiesce to providing office space for free.

California

While California does not have explicit legislative prohibitions on the placements of phlebotomists in physicians' offices, the Physician Ownership and Referral Act (PORA), California's Stark law, and Cal. Bus. & Prof. Code §650, California's anti-kickback law, have been interpreted to prohibit laboratories from providing phlebotomists in physician offices. In 1980, the California attorney general interpreted these statutes to prohibit the provision of professional courtesy services by clinical laboratories provided as compensation or inducement for referrals to a physician, a physician's family, or patients. The opinion notes that even when there is no money changing hands there may still be improper consideration, which, if connected in any manner to the referral of patients, would violate Cal. Bus. & Prof. Code §650. The payment of rent for collection station space in a physician's office violates Cal. Bus. & Prof. Code §650 as interpreted by the attorney general. Additionally, the attorney general interpreted the statute to prohibit to the provision of staff in physicians' offices.

As evidenced by Pennsylvania and Florida, prohibitions against placing phlebotomists in physicians' offices are generally written broadly. The scope of these regulations will be of particular concern to clinical laboratories located in one state but looking to expand across the border to other states and to clinical laboratories with a national presence.

While attorney general advisory opinions are not binding on the courts, the Clinical Laboratory Technology Advisory Committee, the subagency that advises California's Department of Public Health on clinical laboratory matters, has adopted the attorney general's stance and even affirmatively stated that Cal. Bus. & Prof. Code §650 and PORA specifically prohibit the placement of laboratory phlebotomists in physicians' offices. Clinical laboratories operating in California thus should not assume that the absence of any legislative prohibition in California renders this practice permissible.

Conclusion

Clinical laboratories should be mindful of which state regulatory regimes prohibit the placement of phlebotomists in physicians' offices. As evidenced by Pennsylvania and Florida, prohibitions against placing phlebotomists in physicians' offices are generally written broadly. The scope of these regulations will be of particular concern to clinical laboratories located in one state but looking to expand across the border to other states and to clinical laboratories with a national presence.

Clinical laboratories also should consider the impact of regulatory risk on their provider relations. Physicians who run afoul of prohibitions against laboratory staff in their offices may face disciplinary action. Clinical laboratories thus should be mindful of the impact enforcement could have on their relationships with physicians.

Increasingly, states are not content to let federal guidance be the final world regarding placement of phlebotomists in physicians' offices. Concerns about the potential for abuse have sparked a number of recent statutes and regulations severely limiting or prohibiting the practice. Because of the broad scope of this legislation, all clinical laboratories—not just those licensed in these states—should be aware of state compliance requirements.

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Court Dismisses Lawsuit Against Millennium Laboratories, *from page 1*

In this case, the outcome has very little to do with the facts and circumstances of the alleged fraudulent activities but was won based on understanding the technicalities of how the False Claims Act (FCA) works and because the plaintiff did not, in the eyes of the courts, provide any actual evidence to support the allegations.

The Case

The suit was originally filed by Cunningham (now deceased) in December 2009, five days after ML filed a suit against Cunningham's employer, Calloway Laboratories, in California state court. Cunningham was a compliance officer at Calloway, a competitor of ML. Since Cunningham's death, the suit has been carried forward by his estate.

It is the disclosures in the California state court that ultimately resulted in the dismissal of Cunningham's suit. Cunningham's estate filed an amended complaint on Feb. 25, 2011. ML filed a motion to dismiss the amended complaint because, it argued, there was a jurisdictional bar in the FCA that deprived the court of jurisdiction over the subject matter because there was already a public disclosure resulting from the California state lawsuit.

Additionally, the motion argued that Cunningham had not stated a claim upon which relief could be granted and that he failed to plead fraud with the requisite, particularly under the Federal Rules of Civil Procedures, rule 9(b), a rule that has been cited by defendants in several recent whistleblower cases. The court dismissed the case in its entirety and Cunningham appealed.

The original complaint alleged a conspiracy to defraud the United States and 15 individual states by getting false or fraudulent claims allowed or paid. The alleged scheme included ML and John Doe 1-10,000 defendants, who were physicians allegedly involved because they referred to ML. Court documents related to the amended complaint in 2011 and the subsequent motion for dismissal filed by ML indicate the court divided the complaint into three aspects. Aspect 1 alleged multiple billings for the same test kit and aspect 3 concerned confirmation screening. The dismissal of these two aspects was upheld by the court, and they were barred from being filed again.

Aspect 2, which survived the first ML motion to dismiss, alleged the promotion of excessive unnecessary testing and billing and was remanded to the Massachusetts district court. Since the remand, both the defendant and the plaintiff have filed additional documents to support their arguments. ML filed additional documents to support its motion for dismissal and Cunningham responded and moved to file a second amended complaint (SAC).

The Final Order

As part of the appeal of the dismissal of the first complaint, Cunningham asserted that rule 9(b) didn't apply to conspiracy cases as are alleged in the first complaint, but the court disagreed. Citing a precedent, *United States ex rel. Gagne v. City of Worcester*, the court said that is not the law in its circuit. In its circuit, rule 9(b) applies to a conspiracy under the FCA, so it is not sufficient to allege, in general, some of the mechanisms of the fraud. Instead, the plaintiff must plead with particularity.

Regarding aspect 2 of the complaint, excessive billing, the plaintiff provided details of a program, the physician billing model (PBM), allegedly used by ML representatives, which showed a physician how much money the physician could earn by using the PBM.

Cunningham alleges that the PBM is designed to cause false claims to be submitted by encouraging physicians to perform excessive unnecessary tests but provided no details of the use of the PBM by any physician. Further, no physicians were specifically identified and the allegations are based entirely on "information and belief," a standard phrase used in legal pleadings that means the statements made are based on secondhand knowledge but the person presenting the information believes them to be true.

Concerning the conspiracy allegation, Cunningham provided no specific evidence showing a conspiracy, and in its proposed SAC, the court ruled that it did not meet the promised information detailing the fraud and conspiracy alleged by the plaintiff. It also introduced new allegations that should have been filed under seal. As a result, the defendant's motion to dismiss the first amended complaint was allowed and the plaintiff's motion for leave to file an SAC was denied. This essentially concludes this case as the whistleblower suit is dismissed.

Lessons Learned

The documents and exhibits associated with this case could represent the kind of information and documents provided to a compliance officer by an employee seeking some kind of action against a competitor. A compliance officer might be tempted to take some kind of action based on these documents but he or she should carefully consider the facts before acting. As far as the compliance officer is concerned, these are allegations and even if the employee believes the documents prove some kind of violation of law or regulation, they may not.

Compliance officers must always rely on fact and data. In the laboratory field, compliance officers are not usually lawyers and generally do not have a background in legal training. The nuances of laws and regulations are complex and best left to experts. Compliance officers should not jump to any conclusions and should avoid leading employees down a path of having any expectation that an action might be taken in light of their belief that a competitor is violating any laws or regulations.

Takeaway: Compliance officers must be the voice of reason when faced with accusations of violations of laws and regulations by competitors or persons within the laboratory and take a conservative approach of seeking facts before considering taking any kind of action, legal or otherwise, against a competitor or an employee.

More Trouble in the Toxicology Laboratory Marketplace

A chain of opiate addiction recovery clinics, a laboratory that performed toxicology testing for the clinics, and the two physician owners of both entities have agreed to pay the government $15.75 million to settle civil allegations of fraudulently billing Medicare and Kentucky Medicaid for unnecessary and excessive toxicology tests.

The settlement agreement, announced Feb. 10 by the U.S. Attorney's Office for the Eastern District of Kentucky, requires PremierTox to enter into a corporate integrity agreement (CIA) imposed by the Department of Health and Human Services

Office of Inspector General. The CIA obligates PremierTox to institute an internal compliance program and allow a third-party review of its claims for the next five years. The settlement agreement also resolves allegations of violations of the Stark law, which prohibits referrals by a physician to an entity in which it has a financial ownership.

The settlement involves SelfRefined, a chain of addition clinics; PremierTox LLC, a clinical lab that performs urine drug testing; and Bryan Wood and Robin Peavler, physician owners of both entities who allegedly violated the False Claims Act by submitting claims to the Medicare and Medicaid programs for unnecessary urine drug tests at a frequency that is unnecessary for treatment purposes.

According to the settlement agreement, after Wood and Peavler became part owners of the laboratory, they instituted a policy that required that urine samples be automatically referred to PremierTox for additional comprehensive urine testing, including confirmation tests. Prior to the physician ownership, the addiction clinics did not automatically refer the urine samples for the extra tests.

The urine samples were frozen and held for testing at a later date because the lab did not have the equipment necessary to test the large volume of referrals it was receiving. By the time the samples were tested, many months later, they were unnecessary for patient treatment use but the lab allegedly billed them to the government programs anyway. In addition, the test were allegedly upcoded so that the fees charged were many times more expensive than other suitable alternative tests would have been.

"Billing Medicare and Medicaid for laboratory tests that are not necessary contributes to the soaring costs of health care," said Assistant Attorney General for the Civil Division Stuart F. Delery. "Providers will be aggressively investigated and held accountable for falsely billing federal health care programs."

Of the $15.75 million plus interest, the commonwealth of Kentucky will receive $2.74 million, which represents its share of the government's recovery of Medicaid funds. The claims settled by the agreements in this case are allegations only and there has been no determination of liability.

Takeaway: As this case may increase government scrutiny of toxicology labs, all labs performing drug testing must ensure they have a strong and effective compliance program.

Compliance Corner

Pennsylvania recently passed a law prohibiting leasing or renting space in a physician office or placing phlebotomists in an office. Can a lab lease or rent space from a physician in other states specifically for placing a phlebotomist in the office?

The federal physician self-referral law, also known as the Stark law, and the anti-kickback statute include exceptions or safe harbors for renting space from physicians or other referral sources. Many states now also have laws or regulations covering the same situation, but each state law may have different criteria (*see the Perspectives article beginning on page 5*). In the case of placing a phlebotomist, as opposed to setting up a new drawing station, Stark presents the more problematic exception criteria because it includes a criterion that says the agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor, in addition to all of the usual requirements such as a written agreement, fair market value of the lease payment, and value or volume of referrals.

If the phlebotomist is only drawing specimens for the physician leasing the space to the laboratory, and the physician stops referring specimens, it is unlikely that this criterion would be met. The test of other referrals would include more than cosmetic representations that patients from other physicians use the draw site; it would require proof of those referrals and the draw site would have to meet any criteria the lab uses to financially justify the cost of the space in any other situation. Under Stark, the requirements of all the criteria must be met in order for the exception to apply.

News-At-A-Glance

LAWSUIT CHALLENGING OIG SPECIAL FRAUD ALERT DISMISSED: A California court Feb. 5 dismissed a lawsuit challenging the Health and Human Services Office of Inspector General's Special Fraud Alert (SFA) concerning physician-owned distributorships (PODs). In dismissing the case, the court stated that even if it had subject matter jurisdiction in the case, it would decline to exercise it. Reliance Medical Systems LLC filed the suit on Oct. 8, 2013, in the U.S. District Court in the Central District of California alleging that the SFA violated its First Amendment right of speech, its rights to due process under the Fifth and 14th Amendments, and the Administrative Procedure Act. Reliance said in the complaint that the SFA chilled any discussions of a POD with any other party. The court dismissed the complaint saying that Reliance had no standing because it had not suffered an injury-in-fact and because there has been no concrete action applying the SFA, and as a result, the components of the controversy are as yet not in focus. Reliance filed the suit because it had previously included physician owners and was considering returning to the POD business model.

LOUISIANA SUPREME COURT REVERSES $330 MILLION JUDGMENT: Johnson & Johnson and it subsidiary Janssen Pharmaceuticals were pleased to hear the results of the Jan. 28 ruling that overturned the large judgment against them based on allegations that they violated Louisiana's Medical Assistance Programs Integrity Law (MAPIL) by misrepresenting the potential risks and side effects of the anti-psychotic drug Risperdal through off-label statements. Even though J&J had complied with the Food and Drug Administration's instructions to issue letters to providers and amend its product labeling, the Louisiana attorney general brought the suit. In its dismissal of the suit, the high court said it found no evidence that any defendant made or attempted to make a fraudulent claim for payment against the MAPIL program. The reversal relieves J&J of the penalty that consisted of a $258 million fine, $70 million in attorneys' fees, and $3 million in costs.

NEW YORK GOVERNOR CLAIMS HIS STATE LEADS NATION IN FIGHTING FRAUD: New York Gov. Andrew Cuomo is touting a record $851 million recovered from Medicaid providers due to fraud, abuse, and waste. In a Feb. 3 announcement, Cuomo stated, "New York is truly leading the nation in fighting fraud and protecting taxpayer dollars." The governor gave credit to the Office of the Medicaid Inspector General (OMIG), saying that the "OMIG's efforts serve as a role model for other states to follow." OMIG works to eliminate fraud by responding to allegations and conducting specialized reviews of home health claims and inventory reports. As a result, more than $1.73 billion has been recovered over three years.

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