G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Laboratory Instrument Provider Accused of Health Care Fraud

A North Carolina-based manufacturer and provider of laboratory instruments and reagents, Carolina Liquid Chemistries Corp. (CLC) and its owners, were served with federal search warrants on May 7 seeking chemicals, documents, electronic devices, and communications with its clients as part of a federal investigation into alleged wire and health care fraud.

The case is focused on Phil and Patti Shugart, owners of the company, and may be worth an estimated $135 million. The case involves the Federal Bureau of Investigation, the U.S. Department of Health and Human Services and its Office of Inspector General, the Food and Drug Administration (FDA), and the Department of Defense. No charges have been filed in the case, and documents have been sealed by the court.

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Lessons Learned From Calloway Laboratories Settlement

Calloway Laboratories (Woburn, Mass.), which recently agreed to pay almost $4.7 million to settle fraud allegations, was already under a five-year corporate integrity agreement (CIA) when it discovered it was being investigated for a billing irregularity.

Calloway immediately suspended the questionable billing practice and began cooperating with the government to resolve the matter. The CIA resulted from a settlement agreement signed in March 2012 by the former owners of the laboratory, two of which had pleaded guilty to kickback and bribery allegations.

The suspect billing practice in this new investigation involved billing for urine drug screen testing. Calloway's former owners had been billing for a pathology review service to the West Virginia Medicaid program and to Medicare with every drug screen it performed. The pathology review services were not necessary, according to the allegations in the case, and were not needed or knowingly ordered by the physicians ordering the drug screens (this case was reported in *National Intelligence Report* in the June 6 issue).

As a result of the new allegations, Calloway Laboratories Inc. signed an amended and restated CIA as part of its record $4.675 million settlement with West Virginia Medicaid and the Medicare program.

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Lessons Learned From Calloway Laboratories Settlement, *from page 1*

Had Calloway been found to have materially breached the existing CIA, it faced serious fines and possible exclusion from the Medicare and Medicaid programs. "This settlement ensures that the federal tax dollars that fund Medicare and Medicaid are restored in full to the programs and the people they were intended to serve," said U.S. Attorney Booth Goodwin in announcing the settlement May 21. The settlement also covered the costs of investigating and prosecuting the case, according to Goodwin, as well as the cost of future monitoring of the CIA.

Original CIA

The original CIA covered a 2010 lawsuit that was settled in 2012 alleging kickbacks and the payment of bribes to the managers of group homes for recovering addicts in exchange for referrals to the laboratory. The new settlement concerns billing for services that were not necessary, and in many cases, not performed. It may be this difference in the two cases along with Calloway's voluntary suspension of the suspect billing practices and cooperation in the government investigation that led to the amended CIA instead of a material breach of the existing agreement. This allowed the government to address the new allegations while keeping the majority of requirements from the existing CIA in place for an extended period. Calloway settled both cases with no admission of liability.

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Consequences of Material Breach of a CIA

There are significant financial and administrative penalties for a provider under a CIA if they materially breach the terms of their CIA. The financial penalties include daily accruing penalties between $1,000 and $2,500 for a variety of breaches, which could occur simultaneously. These include failure to appoint a compliance officer or committee, failure to engage and use the services of an independent review organization, failure to submit any required reports, and a failure to comply with any of the provisions of the CIA as determined by the OIG, among others. The highest penalty, $50,000 per occurrence, is for false certification by Calloway, or any entity representing Calloway, of its compliance with any of the terms of the CIA. In addition to the financial penalties, Calloway could face exclusion from doing business with government-funded health care programs.

The CIA also includes provisions that the laboratory may take to resolve alleged breaches of the CIA in any case where there is a dispute concerning the breach allegation by the government.

Carryover From Existing CIA

According to the amended CIA, Calloway is subject to certain of the terms of the old CIA only for its five-year term. For instance, arrangements involving the training provisions, tracking procedures, and review procedures outlined in the existing CIA will expire at the end of its five-year term, essentially March 5, 2017. Those provisions are specific to the allegations brought under the prior case and may not be relevant during the entire term of the new CIA. These include specific requirements that involve the Stark self-referral and anti-kickback laws or regulations and Calloway's policies and procedures pertaining to them.

Any new or renewed requirements under the amended CIA will be in effect for five years from the date of the final signature on the new CIA, May 15, 2014. That effectively extends the CIA for the majority of its requirements until May 15, 2019.

Lessons Learned From This Case

Calloway avoided a potential material breach of its existing CIA by immediately and voluntarily suspending the suspect billing once the management team became

aware of the government investigation. While the financial penalties were substantial, they were nowhere near as devastating as they would have been had Calloway not taken voluntary measures to correct the problem and cooperated with the government investigation. Any other course could have led to significant consequences for the laboratory and its management team, including possible suspension from the Medicare and Medicaid programs.

It is difficult to understand how this problem was overlooked when Calloway's ownership changed shortly after the previous alleged violations and its settlement agreement in late 2012. Usually, a new owner will conduct a thorough due diligence audit of the previous owner's billing practices and other compliance issues, especially in light of the existing CIA. That notwithstanding, it is important that a thorough billing audit and review be conducted any time the ownership of a laboratory changes, especially when there are previous allegations or disclosures of violations of any laws or regulations.

Takeaway: Calloway avoided significant financial and administrative penalties because it is operating an effective compliance program that allowed it to detect and self-report a billing issue that could have resulted in a material breach of its existing CIA.

Should We Care About *Millennium vs. Ameritox*?

After several years of back-and-forth lawsuits, motions, and court judgments between Millennium Laboratories (ML) and Ameritox in a case that primarily started out as an unfair competition and false advertising case, we may have finally reached a jury verdict that could have relevance for the rest of us working in the lab industry.

A Florida jury on June 16 reached a verdict in the case concerning whether San Diego-based Millennium had provided remuneration that violated the Stark self-referral laws or the anti-kickback laws when it provided free point-of-care urine testing (POCT) cups to its client and potential clients as part of a program known as the "cup agreement" program. The jury ordered ML to pay Baltimore-based Ameritox $14.755 million, including $12 million in punitive damages.

In order to receive the free cups, doctors must agree not to bill anyone for the tests that can be conducted using the POCT cups; not to use the cups for any reason other than to collect urine samples, obtain the preliminary results, and transport the cups to ML for confirmatory testing; and to work with ML to account for the use of the cups and compliance with the cup agreement.

The jury verdict was a result of a motion filed by Ameritox seeking a partial summary judgment in its case against ML that the judge, Susan C. Bucklew, denied in part and allowed in part. ML opposed the motion to no avail.

In the complaint relevant to this motion, Ameritox claims that ML engaged in unfair competition by providing POCT cups to doctors. In order to receive the free cups, doctors must agree not to bill anyone for the tests that can be conducted using the POCT cups; not to use the cups for any reason other than to collect urine samples, obtain the preliminary results, and transport the cups to ML for confirmatory testing; and to work with ML to account for the use of the cups and compliance with the cup agreement.

Ameritox contends that the provision of the free cups violates the anti-kickback and or the Stark laws, while ML contends that is not the case because the physician is not receiving any financial benefit if they do not violate the cup agreement.

Is the Provision of POCT Cups Remuneration?

That is the question that was posed to the jury to decide, and the conclusion they reached is why we should all care about this case. One key element is ML's argument that the POCT cups fall within the Stark exception that allows the provision of items that are used solely to collect, transport, process, and store specimens for the laboratory providing the items. ML also argues that the agreement falls under the exception that allows provision of items that are solely used to communicate the results of tests for the entity providing them. ML contends that what the government meant when it said "solely" was really "primarily" used for these purposes. The court was not convinced because of a statement made by the Centers for Medicare and Medicaid Services in 1998 when it said that "solely" meant exactly that and that a device or item will not meet this requirement if it had any other purpose besides those listed in the statute.

In the case of the second assertion, the court said that the test strips contained in the POCT cups do not process specimens nor do they communicate results to ML. They communicate results to the physician or specimen collector but not ML. The court also ruled that the provision of the free POCT cups violated the anti-kickback statute for essentially the same reasons it violated the Stark law. The court left it to the jury to determine if the provision of the free cups to doctors who could bill but did not constituted remuneration under the Stark and anti-kickback laws.

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On June 16, the jury rendered its verdict, concluding that provision of the free cups did violate the Stark and anti-kickback laws. The jury awarded $14.755 million in actual and punitive damages for three of the six states involved.

ML's Response to the Verdict

The day after the jury verdict, ML filed a document in the case notifying the court that it was voluntarily suspending the cup agreement program. The June 17 filing says that ML is suspending the program on a nationwide basis even though the jury only made findings in favor of Ameritox in four of the states and awarded damages in only three states. It also says that as a result of the May 5 court ruling granting Ameritox's motion for partial summary judgment, it also promptly canceled 20 analyzer accounts that included cup agreements as well as about 20 legacy accounts that has "split cup" agreements.

The document seeks to avoid any permanent injunctive relief for Ameritox in light of ML's voluntary suspension of these programs and agreements, saying that there is no benefit to such an action since the cup agreements will no longer be used. The document also hints at further appeals in the case when it says that "Millennium has raised complex issues of federal law that it may present to the Eleventh Circuit for determination, and has agreed to suspend the cup agreement program during the pendency of that appeal."

It is here that we may find relevance for the rest of us. As the case continues to move forward, certain questions concerning what is and is not remuneration under the Stark and anti-kickback laws will affect all laboratories.

Takeaway: Laboratories and their compliance officers can only speculate what will happen when a court or jury gets involved in the convoluted and complex laws that govern health care because most things are settled rather than actually adjudicated in a court of law.

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COMPLIANCE PERSPECTIVES

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Implications for Clinical Laboratories In the OIG's Proposal to Expand CMP Authority

There are potentially significant implications for the clinical laboratory industry in a proposed rule published in the *Federal Register* on May 12 that amends and expands the authority of the Office of Inspector General (OIG) for Health and Human Services under the civil monetary penalty (CMP) regulations. The proposed rule codifies the Affordable Care Act's (ACA) expansion of authority to protect federal health care programs from fraud and abuse. In the rule, the OIG proposes to update its regulations to incorporate changes made by the ACA; the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and other statutory authorities, as well as technical changes to clarify and update the CMP regulations.

Specifically, the proposed rule implements ACA changes to the OIG authority to permit new CMPs for conduct in five areas:

- Failure to grant OIG timely access to records;
- Ordering of prescribing while excluded;
- Making false statements, omissions, or misrepresentations in an enrollment application;
- Failure to report and return an overpayment; and
- Making or using a false record or statement that is material to a false or fraudulent claim.

Additionally, the rule proposes a reorganization of the current regulations to make the regulations more accessible and to clarify the regulatory scheme. In the rule, the OIG comments that over time, as changes to the CMP regulations have occurred, the current structure has become cumbersome and confusing.

There is also a proposal for an alternate method to calculate the penalties and assessments for employing excluded individuals in positions not directly related to billing federal programs. There are other changes that are not addressed here that may be important to some laboratories.

The OIG anticipates an increase in collections as a result of the proposals in this rule but tempers that with a remark that it is difficult determine the extent of any increased collections. In calendar years 2004 through 2013, collections totaled $165 million.

Implication for Labs

Taking the proposed rule's additions and changes one at a time may be the best way to determine the impact on clinical laboratories. Several areas addressed in the rule have more significance for laboratories than others. Laboratories are unique within health care in several ways, and operations can vary significantly from lab to lab. It is that uniqueness and individual variance that may affect the impact a rule or regulation has on any individual laboratory supplier.

Reporting and Returning Overpayments

The ACA requires that a person or entity receiving an overpayment must report and return the overpayment by the later of 60 days after the overpayment has been identified or the date an applicable cost report is due. ACA did not define what constitutes identification of an overpayment and that is also not addressed in this proposed rule, so laboratories and other providers are left to their own interpretation of the term.

The new CMP authority does not include a specific penalty amount but uses the default penalty of $10,000 for each item or service for which an overpayment has been received. The OIG has interpreted this, in the proposed rule, to mean that the penalty would be imposed for each day after 60 days that an identified overpayment is not returned as well as for each item.

While the dollar value of the claims involved may be small for labs, this penalty is not necessarily dependent on dollar value but rather on the number of tests that are involved. CMP penalties are imposed in addition to other penalties, and labs submit far more claims than most other kinds of providers.

For laboratories, a simple error like a miscoded test or an erroneous entry in the chargemaster or fee schedule could have a significant liability if the overpayment proposal is adopted because of the sheer volume of claims that labs submit. For even moderate-volume tests, it is not too far out of line to expect that a moderate-sized lab might have as many as 10 per day, and depending on the test and the kind of laboratory involved, 30 percent to 50 percent of those may be from tests provided to Medicare patients. In this scenario, the CMP penalty will reach the hundreds of thousands of dollars in short order.

While the dollar value of the claims involved may be small for labs, this penalty is not necessarily dependent on dollar value but rather on the number of tests that are involved. CMP penalties are imposed in addition to other penalties, and labs submit far more claims than most other kinds of providers. The volume of claims submitted by a laboratory increases the chance of receiving overpayments, which further increases the liability a lab faces under the new CMP penalties proposed in this rule. If the proposed penalty of $10,000 per day, per claim stands, it could have significant implications for laboratories. The OIG is seeking comments on this aspect of the proposed rule, and it would be prudent for labs to comment on the potential impact this proposal could have on them.

Timely Access to Records

The proposed rule aslo adds a penalty of up to $15,000 per day for failing to grant timely access to records upon a reasonable request by the OIG for the purpose of audits, investigations, evaluations, or other statutory functions. According to the rule, the flexibility afforded by using terms like *timely access* and *reasonable request* gives the OIG an opportunity to vary the time within which records must be produced, depending on the circumstances of any given situation.

The rule says that the best approach for the OIG is to make any requests in writing and specify the date records must be produced or access provided. The OIG will consider factors like the circumstances of the request, the volume of material requested, the size and resources available to the provider, and the OIG's need for the material in a timely fashion. The exception is in a case where the OIG believes that requested material is about to be altered or destroyed. In that case, timely access means at the time the request is made.

Laboratories maintain large amounts of records and materials that may be subject to such a request. Sometimes, the requested materials may be remotely located or in the hands of another provider, such as a physician office or a hospital. Laboratories must

make sure they can meet any deadlines imposed in an OIG request for records. One good way to test their capability to do that is to include it as a component of billing audits.

Employing or Contracting With Excluded Parties

This is another area where labs find themselves in difficult circumstances because they do business with a large number of physicians who refer tests to their laboratories, with new ones being identified each week. Labs also deal with a wide variety of vendors that supply instruments, reagents, and other services that support services that are ultimately paid under federal and state health care programs.

The proposed rule discusses this CMP at some length and proposes a new formula for assessing a lab or other provider who employs or contracts with an excluded person depending on the manner in which the items or services are reimbursed. In order to create an alternate method by which to calculate the CMP penalty for failure to comply, the rule adds proposed definitions for "separately billable items or services" and "non-separately billable items or services." This is an attempt to accommodate changes in the way health care providers are reimbursed in the current system and how they may be reimbursed going forward. That means that the new definitions become more relevant as the system moves closer to bundled reimbursement for services.

This section of the rule also restates the OIG's broad view that anyone in the supply chain needs to be checked to verify their exclusion status if they in any way contribute to the service that ends up on a claim to a federal program.

The rule says that providers may provide items or services in two different ways, and they are represented on claims accordingly. Either the item or service is separately billable, which will result in the ordering or providing person or entity being identified on the claim. This is the group that labs fall into the vast majority of the time. Each lab service is identified on the claim, and the claim includes the identity of the ordering person.

This section of the rule also restates the OIG's broad view that anyone in the supply chain needs to be checked to verify their exclusion status if they in any way contribute to the service that ends up on a claim to a federal program. For example, the rule identifies how a nurse working in a physician office is involved in a claim for evaluation and management services even though the nurse is not identified on the claim. Another example is the pharmacist who fills a prescription. Since the manufacturer, distributor, and wholesaler all have a part in filling that prescription, they would need to be checked for exclusion status. In the case of a laboratory, the number of individuals and entities involved in the provision of a service that is billed to a federal or state payer may be quite substantial.

The proposed rule allows the OIG to assess a penalty of not more than $10,000 for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual plus an assessment of three times the amount billed.

In a case where an excluded individual or entity in the supply chain performs a service that itself is not separately billable, the OIG proposes a penalty based on the number of days the person was employed or entity was contracted with, and assessments would be made based on the total compensation the individual or entity was paid.

There were no lab-specific examples provided in the proposed rule for this part of the proposal, but consider a case where the laboratory employs an excluded individual to perform maintenance on its testing equipment. The maintenance services cannot be tied to a certain number of items or services provided and separately billed, so the second calculation would be substituted for the $10,000 per item assessment under this proposed CMP rule.

A laboratory would be well advised to make certain that its policies and procedures for checking the exclusion status of all of its employees, clients, and other referral

sources and vendors are being followed and working as they should. While this is not necessarily a new CMP, it is expanded and emphasized in this proposed rule and may be a concern for labs and all health care providers.

False Statements

This section of the proposed rule authorizes the OIG to impose a $50,000 penalty for each false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a supplier or provider under any federal health care program. The proposed rule added the word "omission," which was not included in the ACA. CMS says the addition was necessary to give the full effect of the ACA amendment. It is incumbent on labs and other providers to make certain that all of the information on any enrollment forms is accurate and factual.

According to the proposed rule, a loss to the program of $15,000 or more would constitute a substantial or serious loss.

This section could also be troubling next year when the government starts collecting data upon which new fees will be determined for payment for lab services. Labs would be advised to comment on the application of the penalties under this provision of the proposed rule and if or how they would be applicable in that process.

Aggravating and Mitigating Factors

The OIG will consider several aggravating factors when making decisions about penalty assessments. Those factors vary based on the type of violation the CMP assessment is being applied to, but the following list includes more common aggravating factors:

- Length of time the misconduct has been ongoing;
- Whether the conduct is a one-time event or part of a pattern;
- The extent of the misconduct;
- The number and variety of billing codes involved;
- The significance of a false statement, including omissions;
- The number of people involved;
- Harm to patients; and
- Level of intent concerning the conduct.

In another break from the past, the OIG proposes to set an actual amount to denote whether misconduct is "substantial" or not. According to the proposed rule, a loss to the program of $15,000 or more would constitute a substantial or serious loss. The OIG says that by providing an actual dollar threshold it "increases transparency and provides better guidance to the provider community."

Summary

This is a brief summary of the sections of this proposed rule that may affect laboratories. It is not meant to be a comprehensive analysis of the rule. However, laboratory compliance officers should read this rule to make their own determination of whether or not this rule will affect their laboratories and how it will affect them, should the proposal be finalized as it is currently written. It is likely that some changes will be made based on comments received from providers and laboratories. Because some of the issues are unique to the industry, laboratories should seriously consider commenting on the rule, particularly in those areas described in this article. Comments on the rule will be received until July 11.

Takeaway: Laboratories should be aware of proposed changes to regulations governing civil money penalties since labs could be subject to significant penalties based on the sheer volume of claims they submit. G2

Laboratory Instrument Provider Accused of Health Care Fraud, *from page 1*

Part of the complex case involves CLC's alleged practice of selling its instruments, reagents, and testing systems as quantitative drug testing systems when they were only FDA approved as qualitative or semiquantitative systems. Further, CLC tried to convince its clients that they could bill insurance companies, including the Medicare and Medicaid programs and TRICARE, for testing as if it were quantitative, garnering reimbursements as much as five times the amount allowed for screening qualitative or semiquantitative drug tests.

According to a search warrant affidavit, the searches were justified based in part on electronic communications consisting of e-mails between Patti Shugart and a variety of individuals and entities, including a Medicare Administrative Contractor, Palmetto GBA, and several coding, billing, and testing experts. According to the investigator's request for a search warrant, these e-mails and other sources of information, including interviews with employees and experts, provided enough cause to justify the searches at not only the company site but Shugart's home as well.

CLC Says Its Testing System Is an LDT

According to the affidavit, the company told clients that they could seek higher reimbursement from Medicare and other health insurance companies by using billing codes that are set aside for quantitative testing. CLC executives also told clients that there was no need to send drug screens to other labs for confirmation testing because the CLC instruments provided a quantitative result.

In addition, they told clients that the modified testing procedure used by CLC was a highly complex laboratory-developed test and since it provided an actual value as opposed to a positive or negative or a range of values like between 50 and 75 ng/dl, the quantitative 80000 series of codes could be used instead of the Medicare created "G" codes.

Employees of CLC allegedly told prospective instrument purchasers, primarily physicians, that they could make much more money by using CLC's equipment as opposed to other instruments and test systems available on the market. In one case, the investigator in the case was shown a document allegedly provided by CLC to a client that asserted that by using the 80000 series of CPT codes, the physician could get $476.22 per test. This is a significant increase in revenue as opposed to billing using the Medicare G codes, which would allow, at best, about $99 per test.

According to the affidavit, the company told clients that they could seek higher reimbursement from Medicare and other health insurance companies by using billing codes that are set aside for quantitative testing.

In one partially quoted e-mail from Patti Shugart to a person believed to be a billing consultant, in response to a question regarding the testing and the equipment CLC was providing and what codes to use, Shugart said, "If they are using the product 'off-label' and they are using the number off the instrument as their final number and they have developed their own Lab Developed Test (LDT) and the best CPT that describes what they are doing is Quantitative, then use them." This would seem to be a pretty loose determination of what an LDT is and who can claim that status for a test system.

FDA Violations Also Alleged

According to the affidavit, CLC never received any approval from the FDA to market or use its test for urine drug testing. This resulted in the systems sold by CLC to be misbranded and adulterated devices. Since they were sold nationally, the misbranded devices were introduced into interstate commerce, a violation of the Federal Food, Drug, and Cosmetic Act.

Potential Outcomes and Questions Stemming From Case

First, can CLC be prosecuted for causing false claims to be submitted as a result of their actions? The government would have to prove that claims were actually

submitted by a CLC client in order to have a case against CLC for causing the overbilling that may have resulted by any physician who billed as CLC recommended. According to the documents available so far, that may be one of the outcomes resulting from this case. After all, CLC allegedly sold its instruments based on the promise of increased revenue that they could provide for a client as opposed to other testing systems if clients billed as CLC recommended.

Another potential outcome is related to the use of laboratory-developed tests and systems. The first question is, are the CLC test systems really LDTs? That may be a difficult case for the Shugarts and CLC to make. For that to be the case, each of the physicians using the systems may have to make their own adjustments and then verify them according to Clinical Laboratory Improvement Amendments rules and regulations to use the systems for treating patients. If the case could be made, does that allow the providers using the systems to bill the quantitative 80000 drug-specific quantitative codes instead of the Medicare-derived G codes, G0431 and G0434?

Another potential outcome is related to the use of laboratory-developed tests and systems. The first question is, are the CLC test systems really LDTs?

Another issue in this complex case is that the communications between the Medicare contractor and CLC may have provided the evidence that CLC executives did not stop marketing the test systems even in the face of very specific instructions that what they were doing was not correct. A more prudent course of action may have been to stop the practice while they sought the appropriate approval for their instruments and test systems. Even in that case, since they were not actually filing the claims, would they have to take some action to inform their clients to change the way they were billing until the issue is resolved? And finally, what liability exists for physicians who followed CLC's billing recommendations?

Implications for Laboratory Compliance Professionals

Since no charges have been filed yet, compliance officers will have to wait for further developments in the case to gain a full understanding of what laws the government thinks have been violated. Investigators will have to sift through the materials collected during the search and seizure at the CLC facility and the Shugarts' residence.

There is no doubt that electronic communications, mainly e-mails, played a large role so far in this case. Also, there are important implications for instrument and reagent manufacturers that make coding and billing recommendations to their clients, particularly when those recommendations are based on demonstrating that increased revenues can be achieved by the purchaser if they follow the company's advice. Compliance officers in both labs and instrument companies may want to review their policies and procedures concerning e-mails and coding recommendations by instrument manufacturers in light of this case as it develops.

Takeaway: Manufacturers should be careful about making recommendations for the coding and billing of their tests based on potential increases in revenue. Laboratories and other providers should always make their own coding and billing determinations.

LabMD vs. FTC Trial Delayed Amid Dramatic Twists and Turns

The highly anticipated trial of LabMD versus the Federal Trade Commission (FTC) has been interrupted by a related investigation by the House Committee on Oversight and Government Reform.

The committee recently disclosed via a letter to the chairwoman of the FTC that testimony it had relied upon in its case against LabMD may not have been truthful. The letter addressed to Chairwoman Edith Ramirez says that key information provided to the FTC upon which the initial complaint against LabMD is based is "incomplete and inaccurate."

Unofficial court documents related to the *LabMD vs. FTC* case lay out some, but not all, of the details related to whatever the committee is investigating, which has resulted in witnesses exercising their Fifth Amendment right against self-incrimination and at least two trial delays. The trial is currently in a recess of undetermined length while the court awaits information from the congressional oversight committee and decision concerning a grant of immunity to a key witness in the case, Robert Wallace.

Central to the case and the committee investigation is a file known as the 1718 file. This is the file that the FTC claims was "found" on a peer-to-peer Web site by Tiversa (a "cyberintelligence" company) that contained protected information and is the reason for the three-year investigation of LabMD. According court documents, the source of this file is in question. Sometime in 2009, FTC and Tiversa "cut a deal under which Tiversa funneled the 1718 file to FTC after FTC sent a civil investigative demand to Tiversa's sham corporation, 'The Privacy Institute'."

According to a motion to admit an exhibit, known as RX-542, which is the letter from Darrell Issa (R-Calif.) of the Government Oversight Committee mentioned previously, the source of this document is now in question. The FTC allegedly never attempted to verify the source of the file by any outside company or expert, accepting the source as stated by Tiversa.

According to the motion to admit the congressional oversight committee's letter, Wallace may have been the author of the 1718 file or the file was obtained illegally by Tiversa. The same motion also states that Tiversa CEO Robert Boback has testified inconsistently about the origins of the file. It seems that the FTC case may be relying on a document that was obtained illegally by Tiversa, which would be criminal if true and a lie about the origin of the file. Ultimately, the court ruled that the RX-542 document is admissible.

Saga Far From Over

LabMD has all but shut down operations because of the FTC pursuit of what it considered security lapses serious enough to warrant a three-year investigation and severe penalties for LabMD. Now, it seems that at least some of the parties to this civil action have been less than truthful about the foundational evidence in this matter, resulting in action by a congressional oversight committee into the actions of the FTC.

There may also be repercussions for other FTC cases that involve Tiversa. LabMD may not survive, but its unwillingness to give in to the FTC's relentless pursuit may benefit others in the laboratory and health care community. We will just have to wait for the next episode in this surprising and ever more interesting case.

Takeaway: Compliance officers need to be on the lookout for any and all cases concerning compliance and privacy issues so they are aware of the latest developments in laws and regulations should they ever find their company is the target of such an investigation.

Compliance Corner

My pathologists believe that the tests listed on the Medicare Clinical Laboratory Fee Schedule that also allow for a professional component (PC) to be billed in certain circumstances can be billed every time as long as the required criteria are met. Is that a correct interpretation?

Yes and no. The three criteria that must be met are as follows:

1. The interpretation must be specifically ordered by the treating physician;
2. The pathologist must document the interpretive findings in the report for the test; and
3. The interpretation must require the exercise of medical judgment by the pathologist.

Technically speaking, as long as these criteria are met, the pathologist can bill for the PC by appending a 26 modifier to the code for the technical part of the test and billing it on a separate line on the claim. However, caution should be exercised if your lab bills this every time in light of Medicare's use of data mining techniques to scrutinize billing practices. If your lab's claims for the PC are significantly higher in number than other similar labs', it may find itself under scrutiny by a Medicare audit contractor and asked to provide documentation that the criteria were actually met.

News-At-A-Glance

CMS RELEASES NEW DATA FOR HOSPITALS: On June 2, the Centers for Medicare and Medicaid Services (CMS) released its first annual update to Medicare hospital charge data, which includes data from 2012. The update includes data comparing the amount a hospital bills for similar inpatient and outpatient services. CMS announced the release of the data and other tools to support its efforts to increase transparency concerning Medicare payments at its annual Datapalooza conference in Washington, D.C. The hospital charge data include the average charge for the 100 most common Medicare inpatient stays for over 3,000 hospitals in all 50 states, according to the announcement. Also released is new and updated information on chronic conditions and geographic variation at the state and county levels and a variety of dashboards and data warehouses. The Food and Drug Administration also announced a new initiative, OpenFDA, that will provide massive amounts of data in a structured, computer readable format. To find out more about these exciting initiatives and to access the data, go to the CMS Web site in the section for research, statistics, data, and systems.

SENIOR MEDICARE PATROL REPORT: On June 13, the Office of Inspector General for Health and Human Services released a report detailing performance data for the Senior Medicare Patrol (SMP) program for 2013. The projects are funded by grants from the Administration for Community Living. The SMPs recruit and train retired professionals and other senior citizens to recognize and report instances or patterns of health care fraud. The report covers certain SMP performance measures that include actual savings to beneficiaries and others attributable to the SMP projects and cost-avoidance issues. According to the report, there are a total of 54 SMP projects and 5,406 active volunteers, which constitute a 5 percent increase from 2012. These volunteers conducted 148,235 one-on-one counseling sessions, a 341 percent increase over 2012, and 14,924 group sessions, also an increase from the 14,748 conducted in 2012. There were $9.1 million in recoveries attributable to the program, an increase of 50 percent over 2012. However, savings to Medicare beneficiaries and others of $41,718 in 2013 represents a decrease over 2012. The report emphasizes that it is not always easy to track referrals to Medicare contractors or law enforcement from the efforts of the SMP program, which means the program may not be receiving full credit for the work.

CMS PROPOSES NEW METROPOLITAN AREAS: The Centers for Medicare and Medicaid Services (CMS) has proposed to implement new metropolitan areas (MAs) in the Inpatient Prospective Payment System Proposed Rule published in the *Federal Register* on April 30. The new MAs would, if adopted as proposed, profoundly affect many aspects of Medicare hospital payments, according to an article published in the *National Law Review* May 28. According to the article, the new MAs were approved by the Office of Management and Budget in February 2013 and are based on 2010 census data. These MAs are used by a wide variety of federal programs, including Medicare and Medicaid, for various purposes including payment decisions. CMS classifies counties into urban or rural areas based on the MA information. Many providers, including hospitals, receive payments based on whether they are in an urban or rural MA. If the proposed rule is finalized, the new MAs would take effect Oct. 1, 2015. Hospitals and other providers, including hospital laboratories, should carefully examine the new proposed MAs and prepare for the effects of their implementation.

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