G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

January 2015

Inside this issue

www.G2Intelligence.com

Legal Dispute Highlights Contract Terms that Also Raise Compliance Issues

One of the more important functions a compliance officer performs is the review of contractual and non-contractual arrangements between their laboratory and the entities who make referrals to it. In any case where the laboratory is providing remuneration in any form to a referral source, there should be a written agreement detailing the arrangement. When there is remuneration between a laboratory and a referral source, both the Anti-Kickback Statute (AKS) and Stark physician self-referral laws and regulations are implicated. The compliance officer should review these agreements for any language or terms that might implicate Stark and AKS. A recent lawsuit involving a laboratory and its contracted sales and marketing company, involving liability potentially exceeding $200 million highlights the risks of Stark or AKS violations in such agreements. The sales agreement attached to BlueWave's complaint meant to substantiate its claims for unpaid commissions, provides other details that may ultimately prove to work against BlueWave.

HDL and BlueWave Terms

According to court documents filed on Jan. 9, BlueWave Consultants (BlueWave), a sales and marketing company, sued its client, Health Diagnostic Laboratory (HDL), a Richmond, Va.-based cardiac bio-

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Effective Compliance Program Could Have Thwarted Rogue Employees

The plea agreement accepted by Vic Wadhwa of Frederick, Maryland on Dec. 15, 2014, will end court proceedings for Wadhwa in a federal antikickback case that involved multiple pain management clinics, millions of dollars and thousands of urine samples. Wadhwa, the former Chief Financial Officer of a group of pain management clinics, pleaded guilty to soliciting and accepting $459,245 in kickbacks from a New Jersey drug testing laboratory in exchange for referring urine samples to it for drug testing. However, the scheme described in the plea agreement, while serious in its own right, is just part of the entire story. The relevance for laboratories is the need for oversight to ensure individuals don't use their authority within the laboratory for personal benefit, putting the laboratory at risk of serious compliance violations.

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Effective Compliance Program Could Have Thwarted Rogue Employees, *from page 1*

Details of Wadhwa's Participation

Wadhwa's plea agreement describes the details of how the scheme developed and operated and what his role was. According to a Dec. 15, 2014, Department of Justice press release, Wadhwa worked for a physician group that operated pain management clinics in central Maryland known as Advanced Pain Management (APM). APM, like most other pain management clinics, required patients who were being prescribed narcotic pain medications to submit samples for testing to ensure they were taking the medications being prescribed and no others. APM generated hundreds of urine samples each month and referred them to an outside laboratory for testing. The physicians in the groups that made up APM were satisfied with the quality and service provided by their current laboratory provider.

After learning of a laboratory in New Jersey that was willing to pay a kickback for each sample referred, Wadhwa and others at APM switched its referrals to the New Jersey lab, apparently without the knowledge of other members of APM, including the owners. According to a Department of Justice press release, Wadhwa negotiated the agreement with the laboratory which resulted in a kickback that consisted of an amount equal to half of the lab's profits after covering expenses. APM changed laboratory providers in March 2011 and the kickback payments commenced in July 2011. The scheme lasted until July 2012 and during that time the laboratory had paid APM kickbacks in the amount of $1.38 million, of which Wadhwa received approximately $459,245.92. The remainder was paid to others at the clinic, including the Chief Executive Officer who recruited Wadhwa and brought the New Jersey laboratory to his attention. For the laboratory's part in the scheme, it received over $1 million in profit from billing for the urine drug tests.

Wadhwa faces up to five years in prison and a $250,000 fine when sentenced on April 2. The case is ongoing, meaning that there will likely be more court cases or plea agreements as the government pursues others who may be involved in the scheme.

APM Files a Civil Suit Against Employees

On Dec. 5, 2012, APM filed a civil action against Wadhwa and CEO Muhammad Kahn, their spouses and the corporate entities under their control. APM is seeking damages and injunctive relief. The first amended complaint alleges Wadhwa and Kahn took specific actions to gain control over the operations and finances of APM including its computer systems, without the owner physicians' knowledge or consent. The 54-page document provides a detailed description of the defendants' alleged efforts to deceive APM's owners.

For example, the complaint alleges that problems with the new laboratory provider commenced from the very beginning and Wadhwa and Kahn promised to correct the problems but never did so. According to the complaint, the defendants created a company called Apex Diagnostic Services and APM started referring the urine drug tests to Apex. APM's owners claim they were not aware that Apex was owned by Wadhwa and Kahn and that when one of the owners asked to meet Apex's laboratory director, the request was simply ignored.

An Effective Compliance Program Would Have Prevented These Rogue Actions

While the actions in this case are extreme, they serve as a warning and an example of what can happen unless you have an effective compliance program that includes oversight of the laboratory's operations and the individuals in charge of those operations. An effective compliance program should be able to prevent—or at least detect early on—efforts of executives such as Wadhwa and Kahn from gaining control of critical systems and taking actions that could create potentially devastating problems for the company. When compliance problems are rooted in upper level management, they are the most difficult to address but that makes

an effective compliance program even more critical. The savings achieved by not spending money on developing and implementing and continually reviewing and updating a compliance program can be lost later in legal fees spent defending the laboratory against alleged compliance violations and rehabilitating the company's reputation.

Takeaway: An effective compliance program is like insurance or routine maintenance that quietly protects a physician group, laboratory or other provider from the potential bad acts of individuals within the entity. G2

Allergy Lab Owner Gets Prison Time for Faking Test Results

Six months after pleading guilty to faking laboratory test results, former allergy lab owner Rahsaan Jackson Garth, also known as R. Jackson Garth, was sentenced to 46 months in prison followed by 3 years supervised release, ordered to pay a fine of $246,536.50 in restitution and perform 100 hours of community service. Garth was the owner of Polaris Allergy Labs, Inc., a laboratory in East Point, Ga. that performed blood tests for food and environmental allergies on patients, many of whom were elderly or were children. According to a Department of Justice press release, Garth directed his employees not to test some of the blood samples in order to save money. He would create fake test results to send back to the doctor. Finally, he would submit insurance claims for the testing to various government and commercial insurance payers, including Medicare and Medicaid.

According to the court record from the case, Garth is not a medical doctor and has no medical training. His wife is a physician.

How Polaris Operated

According to court documents, Polaris would place a phlebotomist in those physicians' offices with which it had established business relationships. The phlebotomists would perform scratch tests when requested by the physician, and read them later. They also collected blood samples to be returned to the lab for testing.

From the perspective of the physician ordering tests from Polaris, the laboratory looked and operated like most other laboratories. The physician would order tests. The Polaris phlebotomist would collect the blood sample, complete the requisition form according to the physician's orders and then package the samples and the form for pickup by a Polaris courier. Polaris phlebotomists performing the scratch tests is one uncommon variable but since this is allergy testing and that was the lab's specialty, it probably seemed like part of the service, and it saved the physician money. A few days later, the physician received a test result. If the physician, or any one else for that matter, visited Polaris, it looked like an operational laboratory.

Details of the Fraud

Garth opened Polaris in 2011 with money borrowed from his wife and some of his friends. In September 2012, with the business not doing well, court documents indicate he directed his laboratory technicians to stop testing some of the samples the laboratory received. The criteria to select the samples that were to go untested, at least initially, were, if the patient was older than 12 years or the scratch tests did not have any highly reactive results. The technician would create a blank report template with the patient's demographics and send it electronically to Garth. Garth would add the fake test results and transmit the completed test result with the fake numbers back to the ordering physician. The sample would be discarded, never having even been processed. Garth would vary the results so they would not appear suspicious.

In some cases, partial tests were actually run. For instance, if the laboratory was out of a particular reagent or reagents, the tests for which there were reagents were performed and then Garth would fill in the blanks with fake results for the ones that were not performed. Sometimes, Garth would override the criteria for selecting which samples would be faked and fake tests for patients under 12 years of age or when there was a highly reactive scratch test.

Cooperated With Law Enforcement

During the investigation, Garth cooperated with law enforcement in helping to identify the physicians and patients who had received the fake test results. In pleading mitigating circumstances, Garth said he was embarrassed by the lab's failure to make a lot of money so he took the actions he did to increase profits. That said, patients could have been seriously harmed by the fake test results.

Takeaway: Never underestimate the lengths that normally honest people may go to for a profit even at the expense of patient care.

Serial Relator Ends up Paying Attorney Fees

On Dec. 1, 2014, a motion by defendant Managed Health Care Associates Long Term Care Network (MHA LTC) seeking attorney fees and expenses in a dismissed false claims case was granted by United States District Judge Denise Cotes. In granting the defendant's request, Cotes says that the relator, Fox Rx, Inc. is a serial relator that has brought a half dozen actions against entities with which it had previously worked in its role as a Medicare Plan D sponsor. All of the cases were dismissed.

In her ruling on MHA LTC's motion, Judge Cotes says, "the court finds that the claim ... was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment."

In the original case, Fox had filed its complaint and a first amended complaint against MHA LTC's parent, MHA, alleging two specific illegal practices. Fox alleged that (1) MHA failed to substitute generic drugs for brand-name drugs in states that have laws mandating such substitution, and (2) MHA dispensed drugs after the termination date of a national drug code in states that have laws prohibiting pharmacies from dispensing drugs beyond their shelf-life expiration dates.

MHA arranged a meeting with Fox before it filed the second amended complaint in an attempt to get the relator to withdraw its complaints. At that meeting, MHA presented information that showed that Fox's claims were erroneous and provided a copy of a motion for sanctions it intended to file if Fox persisted. Instead of withdrawing, Fox filed a second amended complaint against MHA LTC rather than the parent. The second amended complaint was dismissed in its entirety on Aug. 12, 2014. MHA LTC filed its motion seeking fees and costs on Aug. 26, 2014 and in a Jan. 13 document, it requested costs and fees in the amount of $168,967.61.

This latest case demonstrates how the law can protect innocent companies facing qui tam complaints. Other cases during 2014 addressed the application of Rule 9(b) of the Federal Rules of Civil Procedure in false claims cases. The district courts are divided on the issue of how much evidence is required to substantiate a false claim but it is encouraging to see a qui tam defendant recover some of the devastating costs of qui tam litigation.

Takeaway: Relators are part of our lives in today's health care environment, and if accused when your laboratory hasn't done anything wrong, you should fight back with every tool that you have.

COMPLIANCE PERSPECTIVES

Coming Changes for Clinical Laboratory Fee Schedule May Create New Compliance Risks

Labs need to brace for more changes in the reimbursement environment as the Centers for Medicare and Medicaid (CMS) is set to initiate a new process for setting the clinical laboratory fee schedule (CLFS). In 2016, certain categories of clinical laboratories, identified as "applicable laboratories" will be required to report every three years the rates they are paid by private insurance companies. This new process will determine updates to the CLFS. There will no longer be annual consumer price index updates, geographic adjustments or any other adjustments to the CLFS. All changes, whether they are increases or reductions, will be a result of the market data laboratories provide at these three year intervals covering the reporting period determined by the Secretary of Health and Human Service (the Secretary).

These new policies and others for improving clinical diagnostic laboratory tests are contained in Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which adds Section 1834A to the Social Security Act. This new section will change the way reimbursements are determined for tests paid under the CLFS. It also affects the way new tests are priced and creates a new designation for so called Advanced Diagnostic Laboratory Tests (ADLT). The tests on the CLFS do not include pathology tests which are paid according to the Medicare physician fee schedule (MPFS), but there are indications in the legislation that laboratories may have to report the rates for these tests also.

The legislation indicates what data will be collected and reported and how to handle reporting different payment rates for the same test for the same or different payers, but it does not provide details about the format and collection process. At this point, there are few details and many questions about which laboratories will have to report data and how data will be reported but that does not mean that laboratories cannot take any action at all. This article will address some compliance risks that may arise out of this new legislation and the actions laboratories should consider taking now to prepare. Although 2015 is just beginning, given the significant work labs will have to do to gear up for this new reporting obligation, January 2016 is not very far away.

Laboratory fees have been reduced or remained the same far more often over the last decade then they have been increased.

Laboratories May End Up Paying for Past Mistakes

Laboratory payments will again be reduced, this year by minus .25 percent. Laboratory fees have been reduced or remained the same far more often over the last decade then they have been increased. When an increase did occur, it was very modest.

A similar trend occurred in the private marketplace where Medicare's CLFS was often a starting point for private payers to negotiate terms for exclusive contracts and discounts. Laboratories of sufficient size, wanting to gain market share and able to survive low payment rates in the near term, would accept deep discounts to reach these marketing goals.

One result of this constant assault on laboratory fees by Medicare and other government payers as well as private payers, and some laboratory's seeming willingness to accept

them, is a condensed market. Smaller labs and specialty labs were acquired by larger laboratories. It is likely that larger labs believed they could increase rates once they controlled more and more of the market, giving them increased leverage when negotiating with payers.

However, other market factors delayed the ability to negotiate higher fees and thus have distorted the market. For example, new entrants into the marketplace (such as hospital outreach programs) gave payers new providers with whom to negotiate lower fees. CMS therefore has an opportunity to again reduce laboratory payments as it bases the CLFS using today's distorted market rates. It will likely take several reporting periods to bring the market back to a place where the fees are appropriate for laboratory tests. The new process, if implemented as described, provides an environment where this can happen.

Recent Fee Schedule Disasters Demonstrate the Need for Change

There are two recent events that underscore the need for some kind of revision to the CLFS and the processes used to update and correct payment rates to reflect current trends in the market. The first was the introduction of the tiered payment system for molecular and genetic tests. This includes the ongoing process CMS and other agencies such as the Food and Drug Administration are struggling with to set appropriate payment rates for newer technologies such as next generation sequencing and algorithmic-based test results.

The other is the massive change devised by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel to the drug testing section of CPT codes. CMS had concerns that the new coding system would result in overpayments and decided at the last minute that it would not include the new codes in the 2015 CLFS. Instead, CMS created new Health Care Common Procedural Coding System (HCPCS) "G" codes. As a result, laboratories have to accommodate two different ways to bill drug tests based on who is paying. For their Medicare patients, they will use the G codes, but for many of their other payers, they will use the new coding system. Now, with the new process being initiated in 2016, it is unclear what process CMS will use to price the new drug codes.

Another problem laboratories experienced in 2014 was how late CMS provided the 2015 CLFS information. The transmittal announcing the 2015 CLFS rates and other update information (R3152CP) was not issued until Dec. 19, 2014 with an effective date of Jan. 1. This made it difficult for laboratories to get their systems updated for the new codes and new payment rates. This is not the first time CMS has been late with the CLFS fee schedule update. CMS often misses its required dates when it comes to regulations and there is no reason to believe that trend will not continue with the legislation related to this fee schedule change, particularly since it is so massive and complicated.

Definitions in PAMA are vague at best and leave many unanswered questions.

PAMA Definitions Related to Data Collection and Reporting

Definitions in PAMA are vague at best and leave many unanswered questions. For instance, whether a laboratory is an "applicable laboratory" is determined based on the Medicare fee schedule from which it derives its revenues. According to PAMA section 216, the term "applicable laboratory" means a laboratory that receives a majority of Medicare revenues under Section 1833(h) (all labs

paid under the CLFS), Section 1834A (created by PAMA) or Section 1848 (lab tests paid under the Medicare physician fee schedule) of the Social Security Act.

The term "applicable laboratory" is a critical definition. There is a large variety of laboratories in the marketplace operating in a variety of settings, which affects a determination of private pay rates. For example, hospital laboratories that currently have the majority of their outpatient tests paid under a bundled payment system, will be excluded from reporting data. This is a recent change that once again has the potential to distort the market when it comes to the private pay rates received. In many cases, these hospital outreach programs may have been receiving higher rates than many independent laboratories. Not including those higher rates in the calculation will result in lower rate calculations for laboratories.

What to Do *Now* to Avoid Compliance Risks Later

With so many aspects of the new process as yet unclear and so many unanswered questions about the details of the implementation process, it may seem like there isn't much labs can do now to prepare. However, barring a complete repeal of this new process, which seems unlikely, laboratories should begin preparing by examining the new law closely, looking to the text of the legislation and the upcoming regulation and highlight the sections that pertain to their laboratory. Then, to help you prepare for the reporting obligation, here are two critical steps you need to start now:

Failing to report data when your laboratory should, or reporting incomplete or inaccurate data can lead to fines and penalties that can be significant.

#1: Understand What Data Will Be Reported

One aspect of PAMA that all laboratories are going to have to address in some fashion is the data reporting, beginning possibly as soon as 2016. This presents the biggest compliance risk. Failing to report data when your laboratory should, or reporting incomplete or inaccurate data can lead to fines and penalties that can be significant. In order to ensure accurate reporting of rates, an officer of the company will be required to certify the accuracy and completeness of the information reported. The penalty for not reporting, reporting inaccurate or incomplete information or omitting data, is a per day penalty of up to $10,000.

Even without the details, PAMA provides enough information to know that the reporting aspect is going to be a difficult task for any laboratory. PAMA defines "applicable information" and the parameters for reporting as follows:

- For each laboratory test, for each data reporting period:
  - Report the rate paid by each private payer for each test
  - Report the volume of each test for each reported payer
  - Exclude tests paid on a capitated or similar basis
  - Note the data collection period will be defined by the Secretary
  - Include in payment rates all discounts in any form
  - When different rates for the same test from the same payer exist, or different rates from different payers for the same test exist, report each separate one with its volume.

When determining what to report, consider that the legislation defines private payer to mean a health insurer, a group health plan, a Medicare advantage plan and a Medicaid managed care organization.

Note: Once the new rates are established, they are applicable to hospital tests that are separately paid—in other words, not paid as part of a bundled payment. This means these rates will apply to hospital non-patients even though the private payer data from these hospitals, as the legislation is currently written, would not be included.

Laboratory compliance officers and administrators need to determine their information systems' ability to generate the data being requested.

#2: Test Your System's Capabilities

Laboratory compliance officers and administrators need to determine their information systems' ability to generate the data being requested. CMS is very likely to want to receive the information in an electronic format. It is going to require some sophisticated programming to extract the data and organize it so that it can be reported in a format acceptable by CMS. This will be an ongoing process so it will require some staffing and other resources. In some cases it may require new computer hardware or software. So when devising budgets for 2016 and even budget adjustments for 2015, that potential cost should be accounted for.

Laboratories may also want to run some tests on real data to determine what the data is going to show CMS so they can be prepared to answer questions about variations in prices for the same test when paid by the same payer or other odd data. These tests might also detect errors or omissions in the data because of some problem with the software, so the resulting data should be tested for accuracy and completeness by a second objective test, like a manual audit.

Advisory: As with all compliance issues in health care, laboratories need to be aware of the potential for whistleblowers to bring claims related to the data reporting required for this new process. So, review your compliance policies for dealing with whistleblowers and ensure you are encouraging staff to report compliance concerns or questions before they give rise to problems that can lead to whistleblower claims and other liability.

Summary

These changes to the creation of the CLFS are a section of the PAMA requirements that carry significant and imminent compliance risks for laboratories. At $10,000 per day, a reporting error made in 2016 that is discovered in 2019 can result in a very large fine.

Note too that there are many other aspects to the PAMA legislation that have been, or will be, explored in this and other G2 Intelligence newsletters, as the implementation process moves forward. So stay tuned.

Takeaway: The changes PAMA will bring to the laboratory industry seemingly impact areas other than compliance—such as revenue. However, the obligations created by PAMA's data reporting requirements and the tasks necessary to comply with them give rise to potential compliance problems that laboratory compliance officers need to be considering and preparing for now.

Legal Dispute Highlights Contract Terms, *from page 1*

HDL Already In Trouble

As previously reported here in the September, October and December issues of *G2 Compliance Advisor*, the federal government is investigating HDL for, among other claims, allegedly paying kickbacks disguised as specimen collection fees to physicians and other laboratories in return for referrals and inducing physicians to order unnecessary tests through the use of panels rather than individual tests. HDL disputes the allegations, saying the fees are paid to cover the costs of drawing and processing specimens for HDL and argues the testing is ordered by physicians, is necessary and improves patient care. According to a Jan. 12 story in the *Wall Street Journal*, HDL is currently negotiating a settlement related to these and other allegations.

In a separate complaint filed by Connecticut General Life Insurance Co (Cigna), reported in the December issue of *G2 Compliance Advisor*, HDL is being sued for $84 million for allegedly operating a scheme to forgive patient copays and deductibles if they use HDL. Cigna also alleges the same kickback scheme the federal government is pursuing related to the payment of specimen collection fees. HDL denies the allegations and has filed a motion to dismiss the lawsuit. That case is winding its way through the courts. In September, Tonya Mallory resigned and was replaced by the chief laboratory officer Joe McConnell.

marker laboratory, for about $205 million on the same day HDL cancelled the marketer's contract. BlueWave, an Alabama corporation, had a Sales Agreement with HDL, which stipulated BlueWave receive payment in a tiered base amount for the first five years of the agreement plus a commission ranging from 13.8 to 19.8 percent of HDL's revenue in the sales territory covered by BlueWave. In addition to the compensation outlined above, the two founders of BlueWave, F. Calhoun Dent, III and Robert Bradford Johnson each received 29.4 shares of the outstanding common stock of HDL.

BlueWave Contends HDL Owes Compensation for Entire Period of the Agreement

BlueWave's Jan. 9 complaint filed in the Northern District of Alabama alleges that HDL owes it $3.1 million in commissions due Dec. 15, 2014, for work already done. BlueWave claims HDL also owes it another $2.7 million in commissions due Jan. 15, 2015, and an additional $19 million for sales activity for which HDL allegedly has failed to account.

Finally, BlueWave's complaint contends that HDL owes it for the loss of approximately $3 million a month over the 60 months remaining in the life of the agreement, amounting to approximately $180 million. The complaint argues that, regardless of the $180 million, HDL should be ordered to pay BlueWave at least $24.8 million for interest, fees and costs relating to the work BlueWave already performed.

Additionally, BlueWave claims that HDL violated the agreement's terms for termination of the agreement. BlueWave's complaint also alleges that HDL is responsible to report to BlueWave the amount of revenue collected as a result of its sales activities and to accurately calculate commissions owed to BlueWave. BlueWave contends that the accounting is overly complex and that it does not have access to HDL records to allow for a full accounting of what it is owed. Therefore, BlueWave's complaint includes a demand for a full accounting for the entire period of the agreement.

Specimen Collection Fees Required by Sales Agreement

The agreement between BlueWave and HDL shows that BlueWave required, and HDL agreed to pay specimen fees. Section 3(b) of the agreement says HDL shall, "provide processing and handling fees to physicians in the range of eighteen to twenty-one dollars ($18.00 - $21.00) and processing and handling fees to outside labs in the range of eighteen dollars to twenty-five dollars ($18.00 - $25.00), provided that, any fee change shall be mutually agreed upon by the Parties unless required by any state or federal laws or regulations." Any payment paid per item or service should raise a flag for further evaluation under AKS and Stark laws. In fact, these are the kinds of fee payments that the OIG has expressed concern about in a 2014 Fraud Alert.

At least one other provision in this section of the agreement presents a potential risk for violations of federal or state laws and regulations. Section 3(e) says in part that HDL shall "provide zero balance billing for Medicare, PPOs, POSs and Medicaid" in its territory. Generally, balance billing is illegal in most states. Specifying that HDL cannot do it for these specific payers may imply that HDL balance bills other payers and patients.

A compliance officer reviewing these or similar terms should determine if a potential violation of AKS or Stark exists and if so, seek modification or deletion of the terms. If such revision had been undertaken when the agreement was first proposed, it could have saved HDL from the current legal problems that now plague it.

Compliance at HDL

HDL currently includes a section titled Compliance on its website under a tab titled "About HDL, Inc" which includes a document titled Code of Conduct and Business Ethics, dated September 2013. That date falls after the execution of the Agreement, after HDL was aware of the problems with the collection fee and before the problems with the government first became public. It includes an appendix A, *Compliance Guide for Interactions with Health Care Professionals* which provides information and guidance instructing HDL employees and agents on how they should interact with referral sources. Even though the specimen processing fee issue had been raised by both customers and employees at that point and by the OIG in 2014, the document doesn't specifically address such fees in the Code of Conduct.

Takeaway: While the lawsuit brought by BlueWave alleges HDL's contract duties were not satisfied, the lawsuit highlights an agreement whose terms could implicate Antikickback and Stark laws. Compliance officers must always be given the opportunity to review such agreements and they should be alert for such terms to avoid the potential legal impact they may have on the laboratory. G2

LabMD versus the FTC Will Finally Move Forward

An important security case pitting the Federal Trade Commission (FTC) against LabMD, a former laboratory testing company forced to cease operations because of the FTC's action, will finally be moving forward again after being stalled indefinitely since last May. According to a January 12 blog entry by Kathryn M. Sylva of Nixon Peabody, an international law firm, on January 5, Chief Administrative Law Judge, D. Michael Chappell lifted the stay on the case, granted immunity to a key witness, Richard Wallace, a former employee of Tiversa, Inc. and granted an FTC request to resume evidentiary hearings on March 3. The FTC is to receive and review additional discovery prior to the March 3 hearing.

Wallace is an important witness in the case because he is the source of a fundamental piece of evidence supporting the FTC case known as the "1718 file." The origin of the file is controversial because the testimony Wallace will supposedly provide when the hearings resume will contradict previous sworn testimony. According to a court document filed Dec. 23, 2014, in which LabMD motions for admission of a series of letters and documents labeled RX 543 through RX 548, the FTC and its experts relied unquestionably on Tiversa's claim that the 1718 file was first downloaded from a peer-to-peer network originating at an IP Address in San Diego. It was this file that

triggered the FTC investigation of LabMD. According to the document, the FTC took no steps to verify Tiversa's claim. Further, it ignored LabMD's protests that the file was taken in violation of Georgia law.

Contradictory Statements and an Ongoing Government Probe

Wallace is expected to testify that he gave false information to an FTC attorney regarding the source of the 1718 file, which would contradict the complaint against LabMD for its lax security practices.

The RX letters and documents that LabMD seeks to have admitted are related to an ongoing House of Representatives Committee on Oversight and Government Reform's (OGR) ongoing probe into the relationship between Tiversa and the FTC. The FTC opposed the admission of this evidence in a document filed on January 2, where it states that these documents are inadmissible hearsay and are being used by LabMD to divert attention from the underlying issue that it failed to take reasonable and appropriate measures to prevent unauthorized access to consumers' personal information.

Underlying Importance of This Case

If the court finds in favor of the FTC, it will continue to pursue cases against health care and other companies under Section 5 of the FTC Act for unfair and deceptive practices without having to publish any guidance as to what constitutes unfair and deceptive practices. In that world, labs and other health care companies will have to potentially face enforcement actions any time there is a data breach. If LabMD wins, the FTC may be forced to codify standards for the data security practices it seeks to prevent so that companies know what they are supposed to do to comply with Section 5.

Conclusion

This case and one other involving Wyndham Worldwide will be among the most watched cases in 2015 when it comes to data security practices. Depending on the outcome, labs and other providers and companies will either have to add one more government agency to their watch and monitor compliance list, or they can breathe a sigh of relief knowing they won't have to comply with FTC secret rules concerning data security.

The other interesting aspect of this case is the OGR investigation concerning the relationship between FTC and Tiversa. While this issue is separate and unrelated to the FTC's Section 5 allegations, the OGR investigation would not have occurred but for the LabMD case.

Takeaway: The number and diversity of government agencies scrutinizing laboratories continues to grow making it necessary for compliance officers to continually expand and grow their knowledge and resources. G2

G2 Compliance Corner

A recent Centers for Medicare and Medicaid Services (CMS) program transmittal concerning the jurisdiction for certain laboratory claims created some confusion among laboratory providers. Transmittal R3071CP says it updates Medicare manuals to clarify existing policies but no change in claims processing should result. However, the transmittal does appear to change claims submittals for reference laboratories for specimen collection and travel allowance claims in some cases. The basic "clarification" is that the collection fee or travel allowance is now filed in the jurisdiction where the test is performed, not where the sample is actually collected.

According to some laboratories, this represents a change in current billing policy and they will have to change their processes and policies to accommodate this clarification. Further, this clarification directly conflicts with Chapter 16, Section 60.1 of the Claims Processing Manual (Pub. 100-04), which states the following with regard to collection fees: "This fee will not be paid to anyone who has not extracted the specimen."

Providers may experience denials for collection or travel allowance claims and should monitor those claims. If they receive denials, they should identify the reason and remark codes accompanying the denials and contact their Medicare Administrative Contractor to ask about the denials.

News at a Glance

Review and Update Non-Monetary Compensation: Laboratories need to review and update many compliance issues at the beginning of each calendar year. Often overlooked is the update to the amount allowed under the Stark non-monetary compensation and medical staff incidental benefits provisions. Non-monetary compensation includes items such as gifts, entertainment, dinners, in-office luncheons etc.—anything but cash or cash equivalents such as gift cards. Medical staff incidental benefits include meals, parking and other items that are used while the physician is on the hospital's campus. The allowed amount is updated annually to reflect changes in the Consumer Price Index-Urban (CPI-U) which was +1.7 percent for the fiscal year ending Sept. 30, 2014. The result of the annual update is $392 for non-monetary compensation and less than $33 per occurrence for the medical staff incidentals.

Laboratories should have a tool or tracking system to monitor the money spent on non-monetary items they have provided during the calendar year, particularly if they give a lot of gifts or they are a department of the hospital and must share the allowance with other hospital departments. For more information, see the Federal regulations at 42 CFR 411.357.

Congressman Eric Paulsen (R–MN) Introduces Medical Device Tax Repeal: A bill titled *Protect Medical Innovation Act of 2015* introduced in the House of Representatives on Jan. 6 would repeal a medical device tax. The bill is similar to a 2013 bill that died in the Democrat-controlled Senate. The tax, enacted by the *Health Care and Education Reconciliation Act of 2010*, took effect Jan. 1, 2013, and imposes a 2.3 percent excise tax on the sale of certain "taxable medical devices." Taxable medical devices are defined as any devices that are intended for humans. Excluded items would include devices such as eyeglasses, contact lenses, hearing aids, and medical devices generally purchased by the general public at retail for individual use. The bill to repeal that tax has received support from more than 250 co-sponsors including 17 Democrats. Repeal of the tax is a legislative priority for Republicans. Laboratories are unlikely to see any benefit from the repeal of the tax, however, because device manufacturers are not expected to pass any savings on to their customers.

CMS Transmittal Updates Reason and Remark Codes: Program transmittal R3161CP, Change Request 9004, updates the Claims Adjustment Reason Code (CARC) and Remittance Advice Remark Code (RARC) lists. Reason and remark codes must be used along with a group code to report payment adjustments and denials and provide information to explain the adjustments or denials to the entity submitting the claim. According to the transmittal, there are seven new CARC codes and two codes with modified narratives. There were no deactivated CARC codes.

The RARC list includes six new codes, three codes with modified narratives and two codes that were deactivated. The transmittal has an effective date of April 1. However, effective dates for individual code changes may be different because the lists are updated only three times a year. The Centers for Medicare and Medicaid Services updates its computer software four times a year. Medicare Administrative Contractors are responsible to make sure that the individual codes are not activated until the appropriate date as provided in this transmittal. A complete list of CARC and RARC codes can be found on the Washington Publishing Company website at http://www.wpc-edi.com.

 G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLC, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 or Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

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