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Inside this issue

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Government Oversight Committee Report May Change FTC Case Outcome

The course of an ongoing case, LabMD v. FTC, may be altered considerably as the result of a recently released report issued by the Committee on Oversight and Government Reform (OGR) that has been investigating the activities of Tiversa, Inc., a company the Federal Trade Commission (FTC) relied on heavily in its case against uropathology laboratory LabMD. OGR Chairman Darrell Issa sent a letter to Edith Ramirez, Chairwoman of the FTC concerning the Dec. 1, 2014 OGR report. In the letter, Issa informs Ramirez:

> "The Committee has obtained documents and information indicating Tiversa failed to provide full and complete information about work it performed regarding the inadvertent leak of LabMD data on peer-to-peer computer networks. In fact, it appears that, in responding to an FTC subpoena issued on Sept. 30, 2013, Tiversa withheld responsive information that contradicted other information it did provide about the source and spread of the LabMD data, a billing spreadsheet file."

Background

Briefly, this case concerns an FTC investigation of the security practices of LabMD, no longer operating allegedly as a result of the investigation and the subsequent FTC enforcement action. The investigation was primarily based on a LabMD computer file that contained protected health information (PHI) on over 9,000 people. Tiversa, a company that provides peer-to-peer (P2P) intelligence and security services, supposedly found the file on a P2P network. Tiversa

Continued on page 9

Four-Year-Old Laboratory Kickback Case Forces Government's Hand

The Department of Justice (DOJ) took the unusual step of filing an amicus curiae or "friend of the court" brief in a private lawsuit between two laboratories concerning alleged violations of the physician self-referral (Stark) law and the Anti-Kickback Statute (AKS). According to the Feb. 2 corrected brief, the United States has a substantial interest in the circuit court's proper interpretation of these two statutes because they are "critical tools in the government's ongoing efforts to contain health care costs, reduce conflicts of interests in the provision of health care services, and prevent billing for unnecessary services." Violations of these laws also give rise to False Claims Act liability.

Continued on page 2

Four Year Old Laboratory Kickback Case Forces Government's Hand, *from page 1*

Background

According to the DOJ brief, in *Ameritox Ltd. v. Millennium Laboratories, Inc.*, Ameritox alleged violations of the Lanham Act and various state tort laws, claiming that Millenium engaged in unfair competition and tortiously interfered with Ameritox's business relationships when it provided point-of-care testing cups (POCT cups) at no charge to physicians who referred urine samples to it for testing. Ameritox asserted these specimen collection cups had immunoassay testing strips embedded in the cup and were provided to physicians for free under certain conditions in "cup agreements."

Ameritox prevailed in the jury trial and was awarded damages of almost $10 million. Millennium appealed, claiming, among other things that the court misinterpreted Stark and the AKS. According to the corrected brief, the United States is taking "no position" against Millenium's evidentiary or the state law arguments, instead focusing only on the Stark and AKS issues:

> "[T]he United States submits this amicus brief to correct several erroneous arguments Millennium has made with respect to the Stark Law and the AKS, which rest to a large degree on a flawed understanding of the views held by the principal government entities charged with implementing and enforcing those statutes, the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General for the U.S. Department of Health and Human Services ("OIG")."

The brief addresses three important issues:

1. Did the provision of the POCT cups to some physicians constitute unlawful remuneration under the Stark law?
2. Did the provision of the POCT cups to some physicians constitute unlawful remuneration under the AKS?
3. Do civil claims alleging violations of the AKS require proof by a "preponderance of the evidence," or the "beyond a reasonable doubt" standard applicable in criminal cases?

The DOJ said in the brief it felt compelled to address Millenium's incorrect interpretation of these laws expressed in its appeal and "set the record straight."

Clarification of the AKS and Stark

Millenium asserts that the simple provision of the free POCT cups with the imbedded testing strips does not violate Stark because it falls under the broad category of devices and supplies used solely to collect, transport, process and store specimens, which can be provided under Stark. According to the DOJ, the flaw in this argument is that Millenium does not use the imbedded test strips for any of its own testing purposes. Instead, the physicians use these test strips in the treatment of their patients. Therefore, the DOJ asserts Millenium is providing a value to the physicians beyond simply cups used "solely" for collection, storing, processing and transporting specimens. The issue is the meaning of the term "solely" in the statute. Millenium contends that CMS has construed this carve-out for laboratory supplies to mean "primarily." Of particular concern for laboratory compliance officers, the DOJ says that CMS and the OIG have consistently "reiterated that 'solely' means 'solely' and emphasized in regulations and advisory opinions that items, devices or supplies providing tangible benefits to physicians that are *unrelated to* permissible purposes (*i.e.*, collection, transportation, and

storage for the entity providing the items, devices or supplies) do not fall within the laboratory supplies carve-out, even if the benefits conferred are very small." The brief then cites a variety of statutes and advisory opinions contradicting Millenium's argument that the provision of the POCT cups falls within the supplies carve-out of the statute and supporting CMS's consistent and long held views regarding this carve-out.

The DOJ's brief also argues Millenium's assertion that its conduct does not violate the AKS fails for the same reason that its Stark interpretation fails—the embedded test strips are not provided for collection, transport or storage but are instead used by the physicians. The government entity that enforces the AKS, the OIG, has consistently interpreted the statute to apply when an entity provides items for free or below fair market value if the item has any benefit for the physician or other referral source receiving it. Even though the AKS has no specific carve-out for free supplies, both the CMS and the OIG have construed the carve-out in Stark to apply similarly in the AKS.

Standard of Proof

Finally, regarding the standard of proof required to find a violation, Millenium asserts that the district court improperly instructed the jury using the preponderance of the evidence standard instead of the higher reasonable doubt standard. The DOJ urged the court to reject the higher standard in the context of this case.

The Cup Agreements

The cup agreements allegedly prohibited the physicians receiving the free POCT cups from billing anyone for the cups, including government agencies like Medicare and Medicaid. Further, the physicians had to return the cups to Millenium for testing, and if they did not, Millenium would bill them for the cups. The DOJ contends this arrangement is an inducement and creates a financial relationship between the parties—precisely what Stark and the AKS are designed to prevent.

Analysis and Comment

The amicus brief should be required reading for all laboratory compliance officers. The DOJ asserts that the plain meaning of remuneration within both Stark and the AKS and the carve-out for collection supplies are clear and unequivocal.

According to the DOJ, if the court accepts Millenium's arguments it would create a huge loophole in the Stark law. Using Millenium's logic, the DOJ asserts a laboratory potentially could funnel valuable items to its referral sources by simply attaching them to or putting them inside of a permissible item like a urine cup. For example, the DOJ argues that Millenium's theory would allow a laboratory to place a five dollar bill in such a cup and it would be included in the carve-out for supplies.

The fact that the government felt that the amicus curiae brief was necessary to instruct the court on the interpretation of these laws is also informative. It signals the potential that the DOJ will intervene in cases to which it is not a party, if it is concerned that a court might not interpret these laws consistent with how the government has historically applied them or if the parties assert what the government considers incorrect interpretations of these laws.

Takeaway: Laboratory compliance officers can use the information provided in the DOJ's brief to help make better decisions when auditing and reviewing contracts and agreements for potential Stark and AKS violations.

Class Action Suit Alleges Quest Diagnostics is a Monopoly

A class action lawsuit filed in the northern district of California on Jan. 29, includes accusations that Quest Diagnostics, Inc. (Quest) colluded with Aetna and Blue Shield of California to exclude competitors and charge above fair market prices, achieving a monopoly in clinical diagnostic testing in northern California.

Alleged Anti-competitive Conduct

The class action complaint asserts that Quest dominates two markets—namely, markets for testing billed directly to outpatients and health plans and testing billed directly to medical providers, such as physicians. The complaint alleges that Quest gained control of these markets by providing significant discounts to physicians it billed directly for testing services and to insurance companies to gain exclusive contracts and exclude competitors so they could overcharge patients and obtain more lucrative "pull through" business. Quest also aggressively acquires its competitors, according to the class action lawsuit.

The 36-page complaint lists four counts against Quest and cites what it claims is direct and circumstantial evidence of Quest's market power and a monopoly. The plaintiffs allege that Quest charged in excess of competitive pricing yet provided "inferior quality service"—and claim Quest's ability to do this demonstrates market control. Other circumstantial evidence plaintiffs allege includes Quest's economies of scale that allow it to offer managed care contracts at substantially lower prices than competitors in the northern California market which results in exclusive capitated contracts between Quest and the largest insurance companies in the market.

Various newsletters have reported that a Quest spokesperson has denied the allegations, vowed to vigorously defend itself, and claimed Quest obtained a dismissal recently in a similar antitrust case. In that other case, the judge dismissed claims related to competition but, according to a Feb. 2 article in the Internet publication Top Class Actions, other aspects of the case are still ongoing.

Plaintiffs seek a declaration that Quest violated federal and state laws regarding competition, an injunction prohibiting Quest from engaging in the conduct described in the complaint, and an award of damages, restitution, disgorgement, attorneys fees and costs, and pre- and post-judgment interest.

Analysis and Summary

Other lawsuits similar to this one have been filed unsuccessfully against the two largest laboratories, Quest Diagnostics and Laboratory Corporation of America. The government has obtained vast numbers of documents through the various court cases and settlements occurring as a result of these lawsuits. Yet, no meaningful government action has been taken in response to the allegations made in these complaints. It remains to be seen whether this lawsuit will suffer the same fate—a slow and costly demise, as all those that went before it.

Takeaway: Even despite a lack of success in these lawsuits, laboratory compliance officers should still be alert for potentially anti-competitive activity and not consider these outcomes as a license to allow their laboratories to engage in anticompetitive practices.

Stark and Anti-Kickback Issues Expected to Increase for Laboratories in 2015

Health care experts and attorneys predict 2015 will be a significant year for Health and Human Services Office of Inspector General (OIG) investigations of physician self-referral (Stark) and Anti-Kickback Statute (AKS) violations. The primary drivers of these cases are the significant False Claims Act and Civil Monetary Penalty awards that can be achieved by the government either in court or at the settlement table.

Laboratories and other providers are at a significantly greater risk today than ever before…

Recently, private health insurance giants Aetna and Cigna have entered the fray by filing lawsuits against some laboratories claiming Stark and AKS violations, seeking the return of millions of dollars in alleged overpayments. The lawsuits assert overpayments were caused by referrals that were allegedly induced though kickbacks in the form of bribes or sham agreements. Experts also expect Medicaid and Medicare managed care organizations will join the party. Aetna Health Inc. and Aetna Life Insurance Co. recently filed a civil complaint in New Jersey's Camden County Superior Court against Biodiagnostic Laboratory Services, three of its owners, and several physicians. As we have reported here in *G2 Compliance Advisor* and other G2 publications, various individuals have admitted in guilty pleas that they received bribes in exchange for referring specimens to the lab and ordering unnecessary tests. In fact, the Department of Justice just announced as we went to press a 36th guilty plea relating to this case.

In another case, Health Diagnostic Laboratory, Inc.. is being sued by Cigna Health and Life Insurance for $84 million. HDL is under a federal investigation for allegedly paying physicians to refer tests via specimen handling and collection fees. In Cigna's suit, HDL is accused of "gaming the healthcare system by submitting grossly inflated, phantom 'charges' to Cigna that do not reflect the actual amount HDL bills patients."

The media has also entered the arena. Fed by a massive release of Medicare claims data by the Centers for Medicare and Medicaid Services (CMS) last April, the *Wall Street Journal* has reported front page stories about seemingly outrageous payments to physicians and others.

Laboratories have numerous interactions with physicians who refer tests to them. Many of these interactions have both Stark and AKS implications. Laboratories and other providers are at a significantly greater risk today than ever before for legal problems related to a Stark and AKS violation, and the false claims that can stem from such violations.

Laboratories Can Defend Themselves

Laboratories have complicated relationships with their referral sources that have Stark and AKS implications. The relationships with the laboratory's referral sources are chiefly the domain of the sales and marketing departments and business development. The medical director and other technical laboratory staff may be involved but the efforts are most often driven by sales and marketing. Compliance officers need to monitor these relationships.

The laboratory risk areas related to Stark and AKS include:

- Lease or rental of space from a physician or other entity;

COMPLIANCE PERSPECTIVES

If the compliance officer believes the laboratory may be involved in a situation implicating this risk area, it is critical that the situation is reviewed by a person with a thorough understanding of Stark and Anti-Kickback laws and regulations.

- Lease or rental of equipment from a physician, particularly if the physician uses the equipment to provide a service for which they receive a financial benefit or direct payment;
- Providing computers, printers, or fax machines in a physician office or paying for an interface for that equipment;
- Placing employees to perform phlebotomy services in a physician office;
- Contracting for a professional or personal service with a physician;
- Providing certain supplies for free to physicians offices or other referral sources;
- Providing education and training for physicians or other referral sources if the education is not regarding compliance or regulatory information, particularly if the education benefits the physician in some way;
- Providing nonmonetary gifts or items of value to a physician;
- Providing electronic test results or interfaces for the physician's electronic health record.

If the compliance officer believes the laboratory may be involved in a situation implicating this risk area, it is critical that the situation is reviewed by a person with a thorough understanding of Stark and Anti-Kickback laws and regulations.

Lease or Rental of Space and/or Equipment

Lease or rental of space from a physician directly, or in a building that is owned by physicians is most often space primarily used to provide phlebotomy services. If the space leased or rented is owned by physicians or another entity that may refer to, or control referrals to, the laboratory, the compliance officer must make certain the arrangement complies with the appropriate criteria of an AKS safe harbor and, if applicable, the Stark exception. Generally, these criteria require a written agreement for at least one year, payment set at fair market value without adjustment for value or volume of referrals, and the arrangement must be commercially reasonable. A lease or rental of equipment must meet the same general requirements.

Placing Computers in Physician Offices

Placing items such as computers, printers, or fax machines in a physician office for free is allowed as long as the computer, printer, or fax machine is used solely for ordering laboratory tests or receiving laboratory results from the laboratory that placed it. The laboratory may pay for an interface to the office as long as the payment is not made directly to the physician or to an entity the physician owns. The contract and all payments should be made to an independent vendor and the relationship should be with the laboratory, not the physician or entity involved.

Laboratory Employees in a Physician Office

Laboratories can place employees in a physician office to perform phlebotomy services for the patients of that physician or group as long as the laboratory employee does not perform

any duties that normally would be performed by the physician's office staff. If the laboratory pays rent for the space the phlebotomist uses, the Stark exception and/or the AKS safe harbor for rental of space would apply. One important criterion is that the arrangement must be commercially reasonable even if no referrals are received from that physician.

Personal or Professional Services

Laboratories might pay a physician to perform a service or services on their behalf, such as providing oversight of a stat lab, participating in a registry, completing a services survey or providing education for other physicians about using a laboratory service or test. If they are a referring physician, the arrangement must meet another AKS safe harbor or Stark exception for personal services, which imposes many of the same criteria as mentioned above for space and equipment rentals. For example, there must be a written agreement for at least one year, payment at fair market value without adjustment for value or volume of referrals, and the arrangement must be commercially reasonable. Note that the laboratory must monitor the activity to ensure the physician is actually performing the contracted services.

Providing Free Blood Collection Supplies

A laboratory is allowed to provide supplies that are used solely to collect, process, store, and transport samples to the laboratory that provided the supplies. The laboratory should avoid providing supplies that have multiple uses, particularly if one of the multiple uses benefits the physician, such as sharps containers and needles and syringes because it is too difficult to make certain they will only be used for lab purposes. The lab should not provide free surgical supplies or other items that might be included in a bundled payment, such as an evaluation and management (E & M) service or the composite payment for end-stage renal disease facilities.

Providing Education and Training for Physicians

Laboratories should only provide education and training to a physician office staff if it is specific to the services provided by the laboratory. It should not provide training or education for something that benefits the physician in any way, such as coding for E & M services. The laboratory may provide compliance-related training and education as long as the training meets the requirements of the Stark exception for such training. Training that physicians normally would have to pay for and would receive continuing education credit for under state licensing rules is not considered compliance training.

Nonmonetary Gifts or Entertainment

Valuable items or gifts should never be provided to a physician if they are provided in exchange for the referral of laboratory tests. In addition, the Stark regulations set a specific dollar amount on the value of such nonmonetary gifts or entertainment starting with $300.00 and increasing yearly based on an inflation factor for the Consumer Price Index. The laboratory must track the provision of such items and make certain it does not exceed the amount allowed. If the laboratory does accidently exceed the allowance, it may remedy the situation by having the physician return the nonmonetary item within a prescribed time period. If the laboratory fails to remedy, it is not permitted to file claims for tests ordered by the physician and it must return any reimbursements received during the period the violation existed. Cash and cash equivalents such as gift certificates are never allowed.

Reducing the Risk

Laboratories can take steps to reduce the risk associated with financial arrangements with its physicians and referral sources. Here is a list of steps a lab can take to help mitigate those risks:

Counsel must be familiar not only with these federal laws but also the statutes in the states where a laboratory does business, because states can have their own self-referral and kickback laws.

- Written policies and procedures that cover each of the risk areas discussed in this article are necessary and should be in plain language and sufficient detail to avoid misunderstandings.
- All employees who are authorized to discuss or negotiate the types of arrangements discussed above, and all supervisor and executive-level employees, should be thoroughly trained on the laws and regulations specifically as they apply to the laboratory.
- All arrangements in which payment is made to a physician or referral source must have a written agreement that meets the requirements of the Stark law or the AKS and must be evaluated against an objective measure to determine fair market value.
- Monetary payments to a physician or referral source must be approved by the compliance officer or an officer of the company other than the individual responsible for the arrangement or relationship.
- The laboratory must have a system in place to track the amount of nonmonetary compensation spent on physicians for gifts and entertainment.
- When a question arises concerning these laws and regulations, the compliance officer should provide a written response to ensure there is no misunderstanding. If the compliance officer is not sure how to answer the question, he or she should seek competent consulting or legal advice before answering.
- The laboratory must set up a system of audits and monitors specifically for the laboratory's relationships with its referral sources.

Conclusions

The requirements of Stark and the AKS are complex. It is imperative that the laboratory compliance officer maintain a current understanding of these laws and their regulations as well as current compliance guidance or make sure he or she has direct access to legal counsel. That counsel must be familiar not only with these federal laws but also the statutes in the states where a laboratory does business, because states can have their own self-referral and kickback laws.

Compliance officers also need to audit all contractual arrangements with physicians and make sure all leases and other contracts are current and are being implemented as drafted. Remember, for Stark, letting a contract expire by accident can be as big a problem as if the contract was intentionally not renewed. As part of the audit, review all policies that govern arrangements such as placement of computers and employees in physician offices. Check to make sure the laboratory's nonmonetary compensation program is up to date and operating as it should. Finally, it would not be inappropriate to create a new training program specifically using recent cases involving laboratories for all executives, directors, managers, and supervisors.

Legal Dispute Highlights Contract Terms, *from page 1*

provided the file to the FTC after it had informed LabMD that it found the file. Tiversa offered remediation services to help LabMD prevent future security issues. LabMD refused to contract with Tiversa.

Lawsuits ensued and the case went to court. After several twists and turns, the court proceedings were stayed because of an OGR inquiry into the relationship between Tiversa and the FTC. In an additional twist concerning the investigation of Tiversa, a former employee of Tiversa, Richard Wallace, scheduled to testify in the case, refused unless he received immunity from prosecution. We wrote about this case in the June 2014 issue of *G2 Compliance Advisor*. Eventually, Wallace got his immunity and the trial is scheduled to resume on March 3.

The OGR Report

The main concerns for the OGR in the Dec. 1, 2014 report are the differences in the details of important information provided by Tiversa to the FTC and the OGR, such as the dates files were first retrieved, the IP addresses on which the LabMD file (known as the 1718 file) was found, and similar information. According to the report:

- Tiversa provided only "summary information" in response to a broad subpoena served by the FTC about its knowledge of the source and spread of the LabMD file containing the PHI.
- Tiversa withheld documents from the FTC it should have provided as a response to a September 2013 subpoena and these documents contradict Tiversa CEO Robert Boback's account to the FTC.
- A forensic report created in June 2014 is the only report provided to the OGR that substantiates Boback's claims.
- "Tiversa did not make a full and complete production of documents to this Committee. It is likely that Tiversa withheld additional documents from both this Committee and the FTC."

Issa closed the letter to Ramirez with this comment: "In the Committee's estimation, the FTC should no longer consider Tiversa to be a cooperating witness. Should the FTC request any further documents from Tiversa, the Commission should take all possible steps to ensure that Tiversa does not withhold additional documents relevant to the proceeding."

Analysis and Comment

The underlying issue in this case, at the start, was whether the FTC has the authority under Section 5: Unfair or Deceptive Acts or Practices, to investigate and enforce security breach cases. For this reason alone, it is being closely watched by a number of companies, legal firms, and others. As reported previously, the enforcement actions taken by the FTC in these cases can be quite onerous.

If the FTC wins, laboratories and other health care companies which experience a breach face a sort of double jeopardy because they can be punished by the government agencies enforcing the Health Insurance Portability and Accountability Act violations as well as the FTC. Additionally, as previously reported, the FTC has given little data security guidance for providers to follow.

There may be other unanticipated legal consequences resulting from testimony yet to be received in the case, as well as the report of the investigation conducted by Issa's committee. What happens to other FTC cases that have been based on information

provided by Tiversa? The report calls Tiversa credibility into question in the LabMD case; so can it be relied on in other cases? Finally, is there any culpability for the FTC because it did not question information Tiversa provided even in the face of somewhat obvious problems with the information?

Takeaway: As part of its security audits and reviews, laboratories and other companies should include a review of any public promise to protect consumer information and make sure the company is doing everything it says to protect such information. G2

Device Maker Pays $2.8 Million to Settle False Claims Allegations

Even though Medtronic Inc. does not bill Medicare, the Department of Justice (DOJ) alleges it caused others to submit claims based on coding and billing information it provided for a procedure that was experimental and not reimbursable. In a Feb. 6 DOJ press release, the Minnesota-based device manufacturer is accused of off-label marketing of a procedure known as SubQ Stimulation in order to increase its sales of various related products used to perform the procedure.

The initial lawsuit was brought by a whistleblower, former sales representative Jason Nickell, who claims in the complaint to have witnessed and participated in the improper promotion of the procedure. Medtronic denied any wrong doing as part of the settlement agreement.

Complicated Scheme

In a complicated arrangement involving 20 different states and dozens of physicians and health care entities, Medtronic is alleged to have used a variety of inducements to persuade physicians to use its spinal cord and nerve stimulation devices in an off-label manner and bill for it using an improper Current Procedural Terminology (CPT) code. The Food and Drug Administration (FDA) approved uses for Medtronic's products involved placing epidural leads directly on nerves or in the spine itself. SubQ stimulation is a procedure where leads are placed just under the skin, a much simpler and easier procedure that takes about 15 minutes to perform but is not considered safe and effective for chronic pain. Physicians were reimbursed thousands of dollars for performing the procedures and Medtronic sold thousand of dollars of the products it provided for physicians performing the procedure.

SubQ stimulation is part of a rapidly growing and evolving medical science known as neuromodulation. Neuromodulation involves the bionic implantation of electrical devices that deliver low-voltage electrical stimulation to different parts of the nervous system and is being touted as a potential treatment for many neurological and emotional conditions. In addition to chronic pain, neuromodulation may be used for treating conditions such as Parkinson's disease, Alzheimer's disease, migraine headaches, epilepsy, depression, obsessive-compulsive disorder, obesity and sexual dysfunction, among others. Medtronic is a neuromodulation industry leader.

According to the complaint, the suggested CPT code is not the correct code for this procedure. Since the procedure is not FDA-approved for use in this manner, the correct code would be an unlisted procedure code. Most unlisted codes, codes ending in "-99," are not reimbursable under the Medicare and Medicaid programs.

The physician could profit if they followed instructions Medtronic provided. Physician were allegedly instructed on how to use the Medtronic products in trial proce-

dures supposedly to insure the SubQ Stimulation was appropriate for particular patients before referring the patient to other facilities for permanent implantation. Some physicians were also allegedly paid to allow other physicians to watch them perform the procedure. According to the court documents, the procedure took 5 to 15 minutes for which the physician could reap profits of $10,000 or more.

In the Laboratory Industry, Innovation is the Word of the Day

This case is important for the laboratory compliance officer as the laboratory industry evolves and reimbursement amounts and coverage policies change. More routine laboratories and some specialty laboratories are developing new tests, or novel uses for existing tests or combinations of tests, to garner referrals. This can also be the case for laboratory developed tests or genetic tests designed for screening purposes for which Medicare will not reimburse. It can be difficult to get physicians to order new tests, or test combinations, if there is little peer review evidence that they are medically necessary for the treatment or diagnosis of their patients.

Some laboratories may turn to sales and marketing techniques to promote these new services. But some sales and marketing strategies can raise questions concerning medical necessity and Anti-Kickback issues. If carried out in a manner consistent with the requirements of the Anti-Kickback and Stark statutes, these techniques may be legal. If not, the referrals that result from them are false claims waiting to be discovered.

We have already seen allegations that physicians were paid for collection and handling of specimens as a means to induce referral of tests having dubious medical necessity value (see the September 2014 issue of *G2 Compliance Advisor*).

Bogus clinical trial registries and unsanctioned test trials are another activity that can give rise to liability. In these cases, a provider or supplier such as a laboratory, pays the referring physician to report allegedly medically useful information on the tests they refer. The government addressed this kind of activity in a special fraud alert (see OIG, Special Fraud Alert: Laboratory Payments to Referring Physicians, June 25, 2014). For a review of this fraud alert, see the July issue of *G2 Compliance Advisor*.

Another suspect strategy is using speaker bureaus and paying thought leaders to promote their tests or services at educational events. If the cost for travel and lodging for attendees of these seminars or workshops are paid by the company, the events are held in exotic locations or as a supplement to an expensive dinner, they could be deemed improper inducements to physicians to order their tests or services.

Laboratories need to carefully evaluate sales techniques and ensure they understand the laws and regulations governing them or they may find themselves the subject of a government investigation or false claims case.

Takeaway: Laboratories must ensure they employ sales and marketing techniques and programs that do not result in violations of Stark and Anti-Kickback laws. G2

G2 Compliance Corner

Medicare issued an emergency update to correct technical errors in certain elements of the 2015 Medicare physician fee schedule. For the most part, these corrections have little effect on laboratory fees paid on the Medicare physician fee schedule but it is important to be aware of the errors in order to assess their impact on your laboratory. First, the conversion factor was lowered from 35.8013 to 35.7547, a change of -0.0466. Unless a test uses many multiples of the conversion factor, the impact may be not significant. However, according to an article published on Feb. 2, on the Supercoder.com website, there is one laboratory procedure that benefited because of a technical change to a relative value unit (RVU). According to the article, a revision to the RVUs for CPT 88348 (*Electron microscopy, diagnostic*) raised the value from 5.88 to 9.70. That means you can now expect $346.82 for the global electron microscopy service instead of $210.51 under the originally-published fee schedule.

News at a Glance

CMS Extends Deadline for 60-Day Final Rule: The Centers for Medicare and Medicaid Services (CMS) announced the extension of the timeline for publication of a final rule concerning reporting and returning of overpayments in a Feb. 17 Federal Register notice. The timeline for the publication of the final rule is extended one year. This rule concerns changes brought about by Section 6402(a) of the Affordable Care Act which established a new SSA section 1128J(d)(1) regarding overpayments. Section 1128J(d)(1) requires a person who has received an overpayment to return it along with a written explanation of the reason the overpayment occurred, within 60 days of its identification. On day 61, the overpayment becomes an "obligation" under the statute, which essentially means it becomes a false claims liability. The notice reminds providers that even without the publication of a final rule, they are still subject to the statutory requirement to report and return overpayments.

In-Office Drug Testing Improper Coding Case Settled: Whether or not drug tests are performed in a physician office or a national reference laboratory, the rules for coding and claims submission remain the same, as Georgia physician Dennis Conrad Harper learned. Harper entered into a $308,168.54 settlement agreement with the Health and Human Services Office of Inspector General (OIG) according to a notice posted on the OIG website on Jan. 20. The notice says Harper allegedly submitted claims for "low and moderate complexity urine drug tests exceeding the number of units allowed by Medicare by using an inappropriate code to bypass computer programming that would have otherwise rejected such claims." The OIG also alleged that Harper "submitted claims for high complexity drug tests when he performed less-expensive low or moderate complexity drug tests."

Health Care Executives and Medical Directors Beware: A recent court ruling could signal tougher sentences for those in positions of power or authority if they are convicted of an Anti-Kickback violation. Dr. Ashokkumar R. Babaria, a licensed radiologist and the medical director and manager of Orange Community MRI, LLC (Orange), plead guilty to making and supervising illegal payments to referring physicians. During his sentencing hearing, the court applied a two-level upward adjustment to the regular sentencing guidelines' prescribed sentence because he was in a position of trust and abused that trust. He also received a four-level upward adjustment for having an aggravating role in the violation.

Babaria appealed his sentence, arguing that the two-level upward adjustment was unwarranted because he neither occupied nor abused a position of trust at Orange. The court rejected this argument, saying that Babaria had sufficient authority and flexibility, and wasn't subject to supervision. He also unsuccessfully appealed the four-level adjustment because, the court said, he admitted a leadership role in supervising referral payments. Babaria lost the appeal and was sentenced to 46 months in prison, a fine of $25,000, and forfeiture of the $2,014,600.85 Orange received as a result of the scheme.

(*United States v. Ashokkumar Babaria, M.D.*, No. 14-2694, 3rd Cir. Court of Appeals, 12/31/14).

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