G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

Issue 13-07 • July 2013

Inside this issue

www.G2Intelligence.com

Note From the Managing Editor:

Effective with the July issue, *G2 Compliance Report* is now *G2 Compliance Advisor*. Also beginning with the current issue, Christopher Young, president of Laboratory Management Support Services, is taking over as editor of the newsletter. *GCA* will continue to bring you the latest compliance developments affecting clinical and anatomic pathology laboratories but will now provide more in-depth analysis as well as tips and strategies on how labs and pathologists can stay in compliance with myriad state and federal laws and regulations. As always, if you have any questions, concerns, or suggestions, e-mail me at kscott@g2intelligence.com.

OIG Looks Unfavorably on Lab Proposal

The Health and Human Services Office of Inspector General (OIG) in a recent advisory opinion expressed concern about a laboratory services arrangement in which a lab management company would help physician groups set up their own labs.

Advisory Opinion 13-03 (posted June 13, 2013) concerns the provision of laboratory services by a laboratory company to the patients of a physician practice not covered by a government payer. In its analysis, the OIG concludes that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute.

The requestor of the opinion is an independent clinical laboratory that proposes to set up a separate new entity that would serve as a management company to contract with physician groups to help them set up their own clinical laboratories. The management company would provide these physician group labs with facility space and laboratory

Continued on page 9

Labs Must Comply With New OSHA Standard

A revised labeling standard issued by the U.S. Department of Occupational Safety and Health Administration (OSHA) has implications for clinical and anatomic pathology laboratories that must certify compliance in order to participate in federal health care programs.

The revised Hazard Communication Standard (HCS) contains two important changes that will affect laboratories. The revised standard changes the labeling elements and the format of the Material Safety Data Sheets, including shortening the name to Safety Data Sheets (SDSs). Implementation will be phased in over several years (Dec. 1, 2013, to June 1, 2016), with the first implementation requirement deadline Dec. 1, 2013.

What does this have to do with laboratory compliance? When a laboratory completes its 855b Medicare Enrollment Application, it certifies that it meets all federal and state requirements for the type of supplier for which the application is being submitted. The clinical laboratory is required to meet OSHA chemical hygiene and OSHA bloodborne pathogen regulations. If the laboratory is not meeting those standards, it could lose its ability to participate in the Medicare program.

Continued on page 2

Labs Must Comply With New OSHA Standard, *from page 1*

The first compliance date for the revised HCS, Dec. 1, 2013, requires that laboratories and other covered parties must have trained their workers on the new label elements in the SDS format. OSHA believes the training should occur early in the transition process because workers are already beginning to see the new labels and the revised SDSs is in their workplace.

In an OSHA fact sheet published in February 2013 the requirements of the training are laid out in a list format. The training focuses on new label elements, which must include information the employees would expect to see on the labels, including product identifier, signal word (hazard alert), and pictograms that describe the nature of the hazard. According to OSHA, the new labels must also include "precautionary statements which describe recommended measures to minimize or prevent adverse effect resulting from exposure. The training should include information on how employees might use the labels to help them properly store chemicals and locate information on first aid. The second part of the training should include information on the new format of SDSs and must include information on the standardized 16 section format and how the information on the new label relates to the information in the SDS."

Specific information on the revised standard, published in March 2012, can be found on the OSHA Web site (*www.OSHA.gov*) by searching for "revised hazard communication." Click on the first item that comes up in the list titled "revised hazard communication standard (aligned with GHS)."

OSHA Compliance and Medicare Enrollment

While many labs focus their compliance efforts on the anti-kickback law, Stark statute, and privacy and security requirements, the fact is that OSHA compliance is just as important. This issue was highlighted recently when LabCorp was cited by OSHA for alleged repeat and serious health violations.

When a laboratory violates OSHA laws and regulations, it is not meeting the certification it attested to in its enrollment form and could have its billing privileges revoked.

An article in the June 11 issue of *National Intelligence Report* describes how the laboratory has been cited more than once for similar violations and how the standard applies to all of the laboratory's locations where federal enforcement standards are in place, even in other states. The violations centered around the company not providing mandatory training for its employees before they were required to participate in job-related duties that exposed them to health and safety risks.

Repeated violations are often considered neglectful and put the laboratory in the position of being seen as a company that is neglecting its requirements to protect its employees and meet federal and state laws and regulations. In this era of heightened scrutiny on compliance issues and Medicare and Medicaid fraud and abuse concerns, a laboratory could find itself under the microscope because of a violation of a law that it perceives has nothing to do with compliance as described in the various OIG compliance guidance documents. When a laboratory violates OSHA laws and regulations, it is not meeting the certification it attested to in its enrollment form and could have its billing privileges revoked.

Lack of Useful Statistics

The OSHA Web site contains a large variety of statistical information parsed and provided in different ways and formatted in different ways. Even with all of these statistics, it is difficult to find information specific to laboratories about the number

of complaints, inspections, and violations that have occurred so it is impossible to estimate the frequency of OSHA complaints and violations for clinical laboratories. Keep in mind, however, that OSHA laws and regulations exist at both the federal and state levels and this serves to increase the risk. Many OSHA inspections occur as a result of employee complaints and in some cases can come from a disgruntled employee.

Two private industry sectors experienced declines in the rate of injuries and illnesses in 2011 compared to 2010—health care and social assistance (driven by declines both in hospitals and in nursing and residential care facilities). While this bodes well for the health care industry, it is not necessarily helpful for estimating risk associated with OSHA violations in clinical laboratories.

Actions

Laboratory administrators and compliance professionals are responsible for ensuring that these rules are followed. There are two actions that can be taken to minimize risk of the kinds of problems experienced at LabCorp. The compliance officer should include compliance with all mandatory training requirements, including OSHA, in periodic audits and reviews. Most of these trainings occur on an annual basis but others may be conducted as needed when a new requirement is published. At that time, affected employees will need to be trained and the annual training will need to be revised to reflect the new requirement. The compliance officer's responsibility is to make certain the training occurs and the annual training materials are updated.

The second recommended action is to design and conduct an audit prior to the effective date of the new requirement, and at an appropriate interval after the effective date, to ensure compliance has occurred. In this audit, do not vary the critical aspects of the audit, unless absolutely necessary, so results can be compared. If the audit needs redesign, redesign it after the second audit and before it is conducted again.

Billing Update:
Processing Claims Containing G Modifiers

Are you using G modifiers correctly? According to a recent report from the Department of Health and Human Services (HHS), Medicare paid close to $744 million in 2011 for claims that included G modifiers, indicating that the provider submitting the claim expected a denial.

In the May 3, 2013, memorandum report, "Medicare Payments for Part B Claims with G Modifiers," the HHS deputy inspector general for evaluation and inspections explains how contractors process claims with these modifiers. This is a good time to ensure your laboratory is using the G modifiers properly.

Currently there are four G modifiers providers use when there is a need to let the Medicare contractor know that an item may not be reasonable and necessary or that an item or service is not covered by Medicare. Several of these modifiers are associated with the use of advance beneficiary notices (ABN).

Modifier Descriptions and Use

The four G modifiers about which this report is concerned are as follows:

- **GA:** Service or item is not considered reasonable and necessary; ABN is on file.
- **GZ:** Service or item is not considered reasonable and necessary; ABN is not on file.
- **GX:** Service or item is statutorily excluded, and the provider or supplier voluntarily notified the beneficiary with an ABN.
- **GY:** Service or item is statutorily excluded or does not meet the definition of any Medicare benefit; ABN is not required.

GA and GZ modifiers are used in the case where the claim is expected to be denied as not reasonable and necessary. These modifiers are used when a provider may be uncertain about whether a claim should be paid, such as in the case of a frequency-limited laboratory test. These modifiers are also used in circumstances when the provider is certain that the claim should not be paid.

Beginning in January 2002, the use of the GA modifier was mandatory if the provider had obtained a properly executed ABN. At that same time, Medicare required providers and suppliers to use the GZ modifier for claims they expected to be denied but because there is no ABN on file, the beneficiary may not be held liable. As a practical matter, many labs do not use the GZ modifier and simply write off claims in that category. The reimbursement for many lab tests is so low there does not seem to be any reason to spend the money filing claims for which you can never get paid.

Also beginning in January 2002, Medicare allowed providers and suppliers, including laboratories, to use the GY modifier as a way to document that they know the services provided are not covered by reason of statutory exclusion. Beneficiaries are liable for claims in this category whether or not an ABN is obtained; however, the modifier exists for those cases when a beneficiary needs Medicare to deny the claim so it can be submitted to a secondary payer.

In April 2010, Medicare created and established the GX modifier. This is a documentation modifier meant to inform the contractor or payer that the lab knows the items or services provided are statutorily excluded and that the lab voluntarily informed the beneficiary of that fact through the use of an ABN.

Contractors Inconsistently Apply Rules

The evaluations and inspections study (OEI–02–01–00160), conducted on all Part B claims that contained one of the four G modifiers processed during calendar year 2011, revealed that Medicare paid for 16.5 million claims containing one of these modifiers. That equals nearly $744 million paid to providers for claims they expected to be denied. The vast majority, 98 percent, were claims that contained a GA modifier. Another 2 percent were submitted with GZ modifiers. In these two categories of claims, 51 percent of the paid claims with a GA modifier and about three-quarters of the paid claims with GZ modifiers were for laboratory tests. This may be a function of the sheer volume of claims submitted by laboratories.

In July 2011, the Centers for Medicare and Medicaid Services (CMS) required contractors to automatically deny claims with GZ modifiers; however, some contractors did not follow that requirement. Also, contractors do not always consider a modifier submitted on a claim. The study pointed out that this was the case for GY modifiers. For the GX modifier, established in April 2010 on Part A claims, Medicare has never issued instructions to contractors on how they should process this modifier on Part B claims. Medicare paid for 11 percent of claims submitted with GX modifiers, totaling about $1.3 million. Approximately 21 percent of those claims were for laboratory tests.

Contractor Error, Provider Refunds

The report outlines steps that CMS should take to correct these vulnerabilities including ensuring that contractors are following instructions provided by CMS. However, in a situation where a claim should have been denied and was not, the provider who submitted the claim is still liable for the overpayment. Laboratories should have audits and monitors in place to detect these inappropriate payments and ensure that, where appropriate, erroneous payments are returned to the contractor. Further, since the Office of Inspector General work plan has contained items related to claims that include G modifiers, the issuance of this report may signal an increase in denials for these claims. Laboratory compliance officers and administrators should review lab policies and procedures related to these claims to ensure they are being used appropriately.

Hospitals Report Burden of RAC Audits

A majority of hospitals (63 percent) reported spending more than $10,000 in the first quarter of 2013 to handle Recovery Audit Contractor (RAC) requests, with 46 percent spending more than $25,000, and 10 percent spending over $100,000, according to the latest American Hospital Association RACTrac report.

The report found some of the hospital RAC spending resulted from working with outside consultants. For example, 53 percent of hospitals reported working with an external utilization management consultant to handle RAC issues, at an average cost of $58,000 per hospital, and 11 percent reported working with an external legal counsel, at an average cost of $33,000 per hospital.

A total of 1,324 hospitals participated in the RACTrac report during the first quarter of 2013. Overall, 2,380 hospitals have taken part in RACTrac through March 2013. In addition to the administrative burden, hospitals reported an uptick in the number of appeals filed against RAC claim denials. The report, which includes cumulative hospital RAC data from January 2010 through March 2013, found that hospitals have appealed 44 percent of the 428,000 RAC denials issued over that time frame, an increase from the 40 percent reported in the RACTrac report from the fourth quarter of 2012.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Christopher Young, the new editor of G2 Compliance Advisor, *is also president of Laboratory Management Support Services in Phoenix.*

Whistleblowers Can Be Your Best Friend

No matter how you feel about Edward Snowden, his story is one of the hottest going in the world today. Snowden is a whistleblower who felt compelled to publicly disclose information he had concerning actions by the U.S. government. The saga of Snowden, who is now an international fugitive, has been in newspapers and media news stories constantly in recent weeks.

What does this have to do with laboratory compliance? Many laboratory compliance officers and administrators worry that a whistleblower may be working in their facility, copying files and documents to use against the laboratory in a legal action, and if they aren't worried, they should be. Many people view whistleblowers in a negative way. However, statistics show that many health care whistleblowers are conscientious people who feel that if they don't speak out patients at their facility may be harmed in some way. The percentage of False Claims Act (FCA) actions that are either a result of a whistleblower suit or were initiated by a whistleblower suit is in the high 90 percent range.

A whistleblower is a private person who brings a qui tam action, a lawsuit, against another who has defrauded the federal government by knowingly presenting a false claim for payment. Qui tam actions are part of the FCA. In 1986, Congress amended the FCA to make it more lucrative to file a suit and added other provisions to protect whistleblowers, known as qui tam relators, from retaliation by the person or entity against whom the suit was filed. Whistleblowers often are employees of the company; however, they can be a competitor, a customer, a government employee, or a variety of other private individuals and groups. In other words, pretty much anyone who interacts with a laboratory could be a whistleblower.

These qui tam lawsuits are filed under seal, which gives the government an opportunity to join the suit. If the government chooses not to join the lawsuit, the whistleblower may continue on his or her own. Whistleblowers who win their lawsuits are entitled to 15 percent to 30 percent of the recovered funds and other costs and attorneys' fees. In the past, if the government chose to not intervene in the lawsuit, the whistleblower might just give up. Even if the government believes a whistleblower action has merit, its own limited resources may prevent it from intervening in the case. In the current environment, many private individuals go forward with their cases even if the government decides not to intervene. There are plenty of resources available to them to guide them and improve their chances of winning their case. If you doubt that, do an Internet search using the terms "whistleblower attorney support."

Many laboratory compliance officers and administrators worry that a whistleblower may be working in their facility, copying files and documents to use against the laboratory in a legal action, and if they aren't worried, they should be.

According to statistics from Taxpayers Against Fraud Education Fund (TAF), fiscal year 2012 was a record year for FCA recoveries. Last year also saw an increase

in state FCA recoveries. Thirty states have false claims acts of their own. Eight are Medicaid-only false claims acts, and 13 states laws provide an additional 20 percent to 35 percent reward. According to TAF, the bulk of FCA cases currently are in health care at both the state and federal level. A chart on the TAF Web site lists the top 30 FCA actions in 2012, of which 28 were initiated by whistleblowers. There is no doubt that federal prosecutors believe that investing in whistleblowers is an important tool in their arsenal in the fight against Medicare and Medicaid fraud and abuse.

Retaliation Can Be Costly

To underscore the importance the government and juries place on protecting whistleblowers, take a look at *Doculan v. Bayonne Medical Center*. In this case, a hematology technician who was a 20-year employee of the medical center reported to his supervisors, human resources, and upper management that he believed the staffing practices in the blood bank did not meet the requisite credentials set forth in the New Jersey State Sanitary Code and other regulations that govern the laboratory. Most of his complaints went unanswered or unresponded to and eventually Doculan became the subject of repeated disciplinary events as a result of actions by the blood bank supervisor against him. His complaints were focused on her department. Eventually he was fired.

After a six-day trial, an eight-member jury unanimously awarded the plaintiff $80,640 in lost wages, $60,000 for pain and suffering, and $2 million in punitive damages totaling $2.14 million. An effective plan to address whistleblowers would have prevented this action.

After his termination, Doculan contacted the New Jersey Department of Health, which subsequently investigated the laboratory, substantiated his allegations, and directed the hospital to create an acceptable plan of correction. For our purpose, the details in the court documents are not as important as the result. After a six-day trial, an eight-member jury unanimously awarded the plaintiff $80,640 in lost wages, $60,000 for pain and suffering, and $2 million in punitive damages totaling $2.14 million. An effective plan to address whistleblowers would have prevented this action.

Whistleblower: Friend or Foe?

Some laboratories have set up programs designed to avoid whistleblower lawsuits. These programs encourage employees who have complaints or who think that they have found a problem at the laboratory or the hospital to report them. Many companies encourage employees to report problems but then don't follow up or provide feedback to the reporting employee.

Many complaints and problems are a result of employees, competitors, customers, or others not understanding either the laws and regulations or company policy concerning whatever their complaint is about. In some cases they have been misinformed about an incident or misunderstood something they saw or heard. If ignored, these things have a way of festering, particularly if they are reported in good faith and no one has responded to them, which was precisely the case with the hematology technician in New Jersey. Laboratories that see whistleblower reports as an opportunity to detect and correct problems within their laboratories and hospitals are actually strengthening their compliance programs and reducing the risk of small problems becoming large problems, as well as reducing the risk of a whistleblower action against their laboratory.

Mitigating Whistleblower Risk

The most important whistleblower prevention tool in the laboratory's arsenal is communication. Make sure that lines of communication between employees and management, and communication between members of the management team, are always open and always receptive. Encouraging employees to report problems and then not providing positive feedback may do more damage than good. Active listening, good eye contact, taking notes, and other demonstrations of serious interest are all good ways to encourage employees to report problems.

Make sure that the supervisory staff, including the management team, understands the importance of keeping promises that they make to employees, including the promise, "I'll get back to you and let you know what happened with this." Whether the management team's interview with an employee is positive or negative, it will be discussed among employees and the tone will be set, so be careful when communicating with employees.

Managers and supervisors should be very aware of security procedures in the laboratory. They should not leave confidential documents lying around on their desk when they are not in their office. They should make sure that filing cabinets are locked and passwords are kept secure.

There are a number of things that the management team must be paying attention to as well. There should be policies and procedures regarding how complaints are handled and some kind of guidance or criteria that is used to determine if the complaint has a compliance implication. If the employee who receives the complaint is uncertain of its compliance implication, he or she should seek the compliance officer's guidance or opinion.

Managers and supervisors should be very aware of security procedures in the laboratory. They should not leave confidential documents lying around on their desk when they are not in their office. They should make sure that filing cabinets are locked and passwords are kept secure.

The laboratory should also have policies and procedures in place to ask about compliance problems and issues during performance reviews and any other opportunity where interaction with employees occurs. This is especially true for interactions involving disciplinary problems. The laboratory should also conduct exit interviews, part of which should be addressing any known compliance problems or issues that the employee would like to report.

One important aspect of preventing whistleblowers is to identify potential whistleblowers as early as possible. One of the things to look for during the hiring process is to be aware of potential employees who change jobs often. Be particularly aware of sales and marketing employees and experienced billing employees. Make sure to check references to the extent possible. During early employment watch for employees who complain often about compliance issues or other kinds of issues. Always follow up with these employees. Train supervisors to be aware of aberrant behavior like an excess of questions about things like billing and other compliance problems and issues. Be aware of employees who stay late after work or come in on off times but seek no additional pay. Make it a point to do three-month evaluations and ask if the employee has noticed any kinds of compliance issues or is aware of any.

Just remember: Whistleblowers can be a serious risk or a great opportunity depending on how your laboratory chooses to deal with them.

Christopher Young, CHC, president of Laboratory Management Support Services, can be reached at cpyoung@cox.net.

OIG Looks Unfavorably on Lab Proposal, *from page 1*

management and support services and would offer to lease them personnel, equipment, and licenses to use certain proprietary methods of operation owned by the parent clinical laboratory. Each physician group laboratory would operate under its own Clinical Laboratory Improvement Amendments certificate and would be responsible for its own quality-control process and its own billing.

Important to the facts, from the requester's point of view, is that the physician groups would commit to provide testing only for patients who are not federal health care program beneficiaries. For those patients, the physician group laboratories would refer specimens to another laboratory along with any esoteric testing or testing they could not perform in their own laboratories. While this other laboratory could be the parent laboratory, the requester certified that it would not require, pressure, or induce the physician office laboratories to refer any testing to it or to any other health care entity owned by or affiliated with it.

Imagine a medical building filled with physician group laboratories, each separate except for the common relationship with a parent laboratory.

From the description of the proposed arrangement in the advisory opinion, each physician group laboratory would lease space from the management company in a building operated by the management company. This would be a separate laboratory suite used exclusively by each physician group laboratory. The lease agreement would meet the requirements of the anti-kickback statute safe harbor for lease and rental of space. If the physician group laboratories procured any services from the management company, there would be a written agreement and any payments would be consistent with fair market value and not related to any referrals between the parties, according to the proposal. Imagine a medical building filled with physician group laboratories, each separate except for the common relationship with a parent laboratory.

The Analysis

The OIG's analysis started with a concern about any arrangements that carve out federal health care beneficiaries and business from otherwise "questionable financial arrangements." Such arrangements can be used to disguise remuneration in return for federal health care program business through the payment of amounts purportedly related to nonfederal health care program business. Remuneration could come in the form of allowing the physician group to expand into the clinical laboratory business with little or no business risk.

Even though the physician group laboratories would only bill private-pay services, the OIG notes there is a likelihood that the group laboratories would refer federally funded business to the parent independent laboratory as a matter of convenience, to show loyalty, or simply as a way to get better pricing from the parent laboratory for the test they refer. The OIG feels this provides a "nexus" between the potential profits physician groups may generate from the private-pay clinical laboratory business on one hand axnd orders of the parent laboratory services for federally insured patients on the other. The term "nexus" was used in a 1999 advisory opinion that also received a negative ruling concerning discount pricing for referral sources of an independent clinical laboratory.

Finally, the OIG expressed a concern that the financial incentives resulting from this arrangement are likely to affect the physician's decisionmaking with respect

to all of his or her patients who are federally funded health care beneficiaries, as well as private beneficiaries, potentially resulting in the overutilization of laboratory services generally.

Hanlester and Other Issues

This proposal has eerie similarities to a 1995 case involving joint venture laboratories created as part of an arrangement between physician and physician groups and a large clinical laboratory. In this case, known as *The Hanlester Network v. Shalala*, the physicians and the laboratory were sanctioned under the anti-kickback statute, including fines and exclusions from the Medicare program. *Hanlester* was an important case, and all laboratory compliance officers should become familiar with it and the legal analysis associated with it. In addition, laboratory compliance officers should review advisory opinions even not directly concerning laboratories because of the ability to learn about government thinking concerning fraud and abuse and interpretations of the various statutes that govern the industry. G2

Are There Lessons to Be Learned From Biodiagnostic Laboratory Services?

The president of Parsippany, N.J.-based Biodiagnostic Laboratory Services LLC (BLS), three employees, and three associates in June admitted to a conspiracy in which millions of dollars in bribes were paid to physicians in exchange for blood testing referrals.

The admission comes after the president of Biodiagnostic, David Nicoll, and several senior employees were arrested in April on charges they participated in a long-running cash-for-referral scheme (*GCR, May 2013, p. 1*). According to the U.S. Attorney's Office for the District of New Jersey, the referrals were worth more than $100 million to the company.

U.S. Attorney Paul J. Fishman has indicated that there could be more arrests to come as a result of this case. One physician has already been arrested, and charges are pending against him. Considering the time span that the conspiracy existed, 2006 through April 2013, it would seem likely that more physicians were involved. Typically we do not see physicians prosecuted in cases like this; however, as this plays out, we may yet see just that. (Details about the arrests and subsequent admission of guilt can be found at *http://www.fbi.gov/newark/*).

After reviewing the complaint from the U.S. District Court in New Jersey and reading the plethora of articles and commentary about this case, it is difficult to distill worthwhile lessons for honest providers. Now that some of the individuals and the president of the company have confessed to their crimes, it seems like an open-and-shut case in which these people sought to enrich themselves at the expense of the government and various insurance companies. The admission of guilt to the egregious allegations seems to confirm that the parties involved, including at least one physician who received kickbacks, were not honest providers. After all, what honest provider would knowingly commit these kinds of crimes? In that light, what lessons can we glean from this, if any?

Compliance Point of View

From a compliance perspective, there were a number of interesting disclosures in the details of the complaint against BLS that may have bearing on how compliance officers think about questions or problems they receive for review. We read

lots of articles and hear from attorneys that we should be careful what we put in e-mails and text messages. In the complaint, e-mails and text messages are used to provide evidence of incriminating activity by the parties involved that would seem to confirm that we should take that message seriously.

Another interesting item in this case is the use of the federal Travel Act as a complementary statute. The Travel Act is a criminal statute that prohibits the use of the U.S. mail, or interstate or foreign travel, for the purpose of engaging in certain specified criminal acts. According to the Travel Act, bribery is within the criminal acts covered by this law. It is possible, even likely, that we will see the Travel Act used in future cases of anti-kickback and false claims allegations.

From a compliance perspective, there were a number of interesting disclosures in the details of the complaint against BLS that may have bearing on how compliance officers think about questions or problems they receive for review.

As it turns out, BLS has been in trouble before for issues like those involved in this current case. In June 2009 a civil suit was filed against BLS by Horizon Blue Cross Blue Shield of New Jersey. *G2 Compliance Report* published an article in September 2009 describing the suit against BLS. In that case Horizon alleged that BLS had received in excess of $14 million based on fraudulent insurance claims.

That case also involved kickbacks to physicians as well as a variety of other billing violations. One of the areas of focus for this lawsuit was a practice BLS had at the time of providing out-of-network services and writing off the penalty and balances the patient paid because they went out of network. BLS employees told physicians and patients that if the patient used their laboratory, even though it was out of network, the patient would pay no more than if they used an in-network laboratory. The laboratory industry still struggles with this issue today.

The Lessons Learned

Perhaps one lesson we can learn from a case like this is to get a better perspective on why government agents and contractors have such a negative view of laboratories and other health care entities and often approach investigations with a guilty-first-and-prove-innocence-after attitude. Another lesson learned concerns the length of time obvious schemes and frauds can continue before prosecution occurs. During this lengthy period, the guilty lab's competitors must deal with the impact of these activities on the local market, sometimes resulting in their engaging in risky behavior to effectively compete.

Compliance officers should make it a practice to thoroughly investigate or research cases like the BLS prosecution because you never know what may be gleaned that could be applicable to current issues and problems you might be facing now or in the near future. The most effective compliance officer is one who has a broad scope of understanding of laws and regulations and how they are applied in actual cases. This requires compliance officers to read case details and research cases so they thoroughly understand the legal theories behind them. In this way they get a better understanding of how state and government prosecutors and agents are interpreting and applying the laws and regulations. It will serve both the compliance officer and the company well should they get into trouble with the government.

News-At-A-Glance

CMS REDESIGNS SUMMARY NOTICES: The Centers for Medicare and Medicaid Services (CMS) has redesigned its Medicare Summary Notice to help seniors and people with disabilities spot potential fraudulent claims. According to CMS, the new notice will make it easier for Medicare beneficiaries to understand their benefits and how to file an appeal when a claim is denied. It will also help them spot claims for services that they never received. The new notices will be sent to beneficiaries on a quarterly basis with the first of the new notices going out in the coming quarter. "A beneficiary's best defense against fraud is to check their Medicare Summary Notices for accuracy and to diligently protect their health information for privacy," said Peter Budetti, CMS deputy administrator for program integrity, who adds that Medicare beneficiaries and caregivers are critical partners in the fight against fraud.

DOC ADMITS TO KICKBACKS: Padma Siripurapu, M.D., of Belle Mead, N.J., has admitted to receiving cash kickbacks for patient referrals. According to prosecutors, between from 2009 and 2011 Siripurapu had an arrangement with Orange Community MRI LLC (Orange MRI) that it would pay her a set amount of cash for every MRI, CT scan, ultrasound, echocardiogram, and DEXA scan she referred. During that period she referred thousands of patients for these tests. The investigation revealed that she received $3,600 in cash from a government informant as payment for some of those referrals. On Nov. 17, 2011, Siripurapu received another kickback for patient referrals, this time in the amount of $3,450 in cash. She was not alone. Siripurapu is the 12th person pleading guilty in the government's investigation of Orange MRI. The penalty associated with a violation of the anti-kickback statute is a maximum of five years in prison and a minimum $250,000 fine or twice the gain or loss caused by the offense. This is just another reminder that when it comes to investigating fraud and abuse in Medicare, agents use all of the tools in their box including acting as patients or other providers.

OIG BOOSTS RECOVERIES: The Department of Health and Human Services Office of Inspector General (OIG) said expected recoveries for the first half of fiscal year 2013 would reach roughly $4 billion, nearly four times the expected recoveries from the first half of FY 2012 ($1 billion), according to the agency's *Semiannual Report to Congress*, released May 30. OIG said it also excluded 1,661 individuals and entities from participating in federal health care programs, initiated 484 criminal actions, and initiated 240 civil actions, including False Claims Act cases and administrative recoveries associated with provider self-disclosures. Much of OIG's results from the first half of FY 2013 have been the result of partnering with other agencies, OIG Inspector General Daniel R. Levinson said in the report's introduction. For example, Levinson highlighted the work of the Medicare Fraud Strike Force, which has "resulted in over $887 million in investigative receivables and over 800 criminal actions" from 2007 through the first half of FY 2013. During the first six months of FY 2013, the strike force work led to charges being filed against 148 individuals or entities, helped initiate 139 criminal actions, and resulted in $194 million in investigative receivables, OIG said. The $194 million in receivables was almost four times the amount recovered by the strike force in the first half of FY 2012. Strike force efforts in October 2012 resulted in 91 people being charged with fraud involving $429 million in false billings.