G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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CMS Establishes New 'X' Modifiers For Use With Modifier 59

Laboratories need to be careful how they use modifier 59, Distinct Procedural Service, in 2015 because the Centers for Medicare and Medicaid Services (CMS) is trying a new tactic to ensure proper use of the modifier after several years of warnings and education without effect.

Program transmittal R1442OTN (change request 8863) adds four new Healthcare Common Procedure Coding System (HCPCS) code modifiers that define subsets of the 59 modifier for use beginning on Jan. 1, 2015. CMS estimates the one-year overpayments associated with misuse of modifier 59 are $770 million, more than enough incentive to try this new tactic to bring providers into compliance.

What Is the Problem?

The 59 modifier overrides edits imposed by the Correct Coding Initiative (CCI), including medically unnecessary edits or MUEs, and is the most used modifier. According to the transmittal, "it is also associated with considerable abuse and high levels of manual audit activity, leading to reviews, appeals and even civil fraud and abuse cases." Modifier 59 is supposed to be used only when no other modifier is a better choice.

The most common incorrect use of the modifier is for a distinct service and, unfortunately for laboratories, this is the primary reason a

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HHS Seeks Help From Providers to Resolve Backlog of ALJ Appeals

If you were to appeal your denied claims to the administrative law judge (ALJ) level today, you would have to wait 515 days for a resolution as things currently stand at the Department of Health and Human Services (HHS) Office of Medicare Hearings and Appeals (OMHA), which administers the ALJ level of the appeals process.

This lengthy backlog was revealed by Nancy J. Griswold, the chief administrative law judge at OMHA, during an Oct. 29 Medicare Appellant Forum hosted by OMHA. Griswold also shared other statistics designed to help providers understand the extent of the backlog and extreme delays in adjudicating claims at the ALJ level.

According to presentation materials for the forum, the agency is currently entering requests for ALJ hearings from July 2014 into their computer

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laboratory might use it. Physicians or practitioners often order two CCI tests at the same time. CMS says using modifier 59 to override CCI edits is common and "not infrequently overrides the edit in the exact circumstance for which CMS created the edit in the first place." The options available to labs are either to call the physician or apply the 59 modifier on the assumption that the physician knows what he is ordering.

CMS will continue to accept the 59 modifier, but instructions associated with it state that 59 is to be used only when a more descriptive modifier is not available.

Until now, the latter was a good, but risky, option for the lab because it saved time and money and usually required a post payment review to detect any problems. Going forward, the risk may not be worth the gain because CMS integrity auditors are likely to focus more effort in this area. That means more denials, audits, and medical review scrutiny and potentially whistleblower fraud and abuse cases and lawsuits.

Introducing the 'X' Modifiers

The solution, according to the transmittal, is more precise coding options, provider education, and selective editing. To accomplish this, CMS created four new HCPCS code modifiers to be used in place of the 59 modifier. The new modifiers, referred to by CMS as X{EPSU}, define specific subsets of the 59 modifier and allow contractors to use selective editing when they believe abuse is occurring. The new modifiers identify the reason a service is distinct.

- **XE Separate Encounter**, distinct because it occurred during a separate encounter. For laboratories, an example would be a patient who had an abnormal glucose as part of an organ or disease panel in the morning who was then tested again as a single service in the afternoon after treatment has occurred. The 91 modifier for a repeat test would not be applicable because the two tests have different HCPCS codes.
- **XS Separate Structure**, distinct because it was performed on a separate organ or structure. For labs, this could apply to pathology exams or cultures.
- **XP Separate Practitioner**, distinct because it was performed by a different practitioner. For laboratories, this could be considered not applicable because of the use of the word *performed*. However, if CMS views this as ordered rather than performed it would be applicable to labs in the case of duplicate orders from different practitioners. This can be either legitimate or not. If the tests are duplicates or partially overlapping, the best practice would be to call the practitioner and clarify the orders rather than just adding the modifier and filing the claim.
- **XU Unusual Non-Overlapping Service**, distinct because it does not overlap usual components of the main service. More explanation of the exact nature of this description is needed to determine when a laboratory would use this modifier.

Here is how this will work, at least in the near term. CMS will continue to accept the 59 modifier, but instructions associated with it state that 59 is to be used only when a more descriptive modifier is not available. The new HCPCS X{EPSU} modifiers are more descriptive. Essentially, do not use 59 when one of the new modifiers is specific to the circumstances of an individual claim. Do not use both the 59 and one of the X modifiers on the same claim line. CMS is going to encourage a rapid migration to the new X{EPSU} modifiers and has given local contractors the go ahead to start creating edits to that effect. Medicare Administrative Contractors (MACs) may introduce policies or issue notices that require one of the new modifiers for certain HCPCS codes where the MAC has determined that incorrect billing is occurring. Laboratory compliance officers and billing managers should watch for these notices.

Steps Laboratories Need to Take

Billing computers and software need to be revised to allow the use of the new modifiers and to edit for them. If local contractors notify labs that they will be requiring a new modifier in place of the 59 modifier for certain code sets, the software should be set to either drop the claim for review or attach the modifier. In the latter case, laboratories may choose to hard code these so that when the HCPCS codes in question are ordered together, their system will automatically apply the appropriate modifier. Do so with caution. If the contractor requires an X modifier for a specific code pair, it is imperative that the laboratory make certain the case described by the modifier is correct. If a laboratory hard codes the modifier, it should still drop claims for at least a brief review to verify the circumstances before releasing it.

Laboratories will need to educate their staff directly affected by the change, update their policies and procedures to reflect the changes, and modify or update their annual compliance training as necessary. Education of clients is also important, particularly in any case where frequent inappropriate orders occur. Finally, laboratories need to design audits to verify they are applying the 59 and X{EPSU} modifiers correctly.

Takeaway: CMS has focused on the 59 modifier because the agency believes it is commonly used incorrectly. Labs should have the same focus on use of this modifier and the X{EPSU} modifiers.

More Than Meets the Eye: Taking a Deeper Look at 2015 OIG Work Plan Analysis for Laboratories

It is an error to review the single item directly addressed to laboratories in the Health and Human Services Office of Inspector General (OIG) Work Plan for fiscal year 2015 and believe that only independent laboratories are affected.

The brief item titled *Selected independent clinical laboratories billing requirements* (*new*) says the OIG will review Medicare payments for these laboratories for selected billing requirements but does not identify what those requirements are. It also says that prior OIG work has identified areas of Medicare billing compliance risks for laboratories. It is this prior work that laboratories should be concerned about.

Prior OIG Reviews of Part B Laboratory Billing

One of the more likely reviews is the July 2014 report titled *Questionable Billing for Medicare Part B Clinical Laboratory Services*. In this report, the OIG identifies 13 measures describing billing patterns that it regards as questionable. Over 1,000 labs exceeded these measures in five or more of the questionable billing measures, indicating there may be a problem in those labs. This is a good starting point for the OIG. See the July 2014 issue of *G2 Compliance Advisor* for an article on this review and report.

Another report that could be considered by the OIG is the *Comparative Billing Report* on pathology immunohistochemical and special stains. This report identifies 5,000 labs that may have a billing problem. The difference with this case is that the labs identified received a specific and detailed report indicating each laboratory's specific area of risk. For details on this report, see the August 2014 issue of *G2 Compliance Advisor*.

Other Area Identified in the Work Plan That May Affect Laboratories

Not everything that could affect laboratories is identified as an area of risk for laboratories. For instance, there is an item in the Medicaid section that says the OIG will review the Centers for Medicare and Medicaid Services oversight of implementation of the Correct Coding Initiative (CCI) edits by Medicaid contractors. Previously, Medicaid contractors could turn off the edits for reasons that included conflict with state laws or just because the state wasn't ready to implement them. After April 1, 2011, Medicaid

contractors could not use "not ready to implement" as a reason to deactivate the edits. This likely means more emphasis on CCI edits for Medicaid claims and the consequences of that action. In fact, there are a number of Medicaid items in the Work Plan.

The Work Plan also includes several items for Medicare and Medicaid managed care entities. One item, *Medicaid managed care entities' identification of fraud and abuse* says that over a quarter of managed care entities surveyed did not report a single case of fraud in 2009.

It is a certainty that these reviews will be the result of data mining independent lab claims using algorithms previously determined to detect areas of risk for noncompliance with Medicare and Medicaid billing requirements. After all, data mining is now an essential tool for fraud-fighting efforts.

Takeaway: Laboratory compliance officers need to conduct a thorough review of the OIG Work Plan in all areas, not just specific to laboratories, to detect the multitude of seemingly unrelated items that may ultimately affect laboratories in 2015.

MACs Receive Instructions to Support Medical Review Decisions

In an effort to ensure or improve the quality of decisions by Medicare Administrative Contractor (MAC) staff concerning claims adjudication and denials, the Centers for Medicare and Medicaid Services (CMS) has issued a program transmittal that requires MACs to support their decisions through the third level of the appeal process.

Transmittal R543PI (change request 8501) requires MACs to assign a physician to participate or take party status at administrative law judge (ALJ) hearings to oversee the hearings. The transmittal takes effect Oct. 27, 2014.

These changes cover decisions made by other Medicare audit contractors, but the MAC is responsible for overseeing the ALJ hearings.

The transmittal also instructs MACs to make sure they are included in the notices of upcoming hearings and to select those hearings to attend and whether they should participate as a party or a participant. There are important differences in what they can do depending on their participation status.

MAC Oversight of ALJ Hearings Likely to Further Erode Provider Mistrust

For many providers, the ALJ hearing is the first opportunity they have for a fair and impartial adjudication of their appeals of claims denials. The first two levels of appeal are already controlled by CMS and its contractors, and providers often are dissatisfied with the result. As with many decisions such as this, there are likely to be unintended consequences for all parties involved.

One outcome that is certain is that both providers and MACs are going to have to make a better case to support their appeal request to overturn a denial or to uphold a denial decision. The most successful appellants or contractors will be those who do a better job of gathering information to support their assertions and the laws or regulations that underpin them. Also, those that understand the process best will be successful more often than those who do not.

It is also likely that legal counsel will get involved more frequently in the appeal process, especially when the amount of money involved is large. This will add cost to the process for all parties involved.

Another potential consequence is a change in the dynamics of the ALJ hearings, which are likely to become more adversarial.

Takeaway: Providers who enter into the appeal process are going to need to be better prepared to make a good medical and legal case to support their assertions that Medicare should cover and pay for the services in question.

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COMPLIANCE PERSPECTIVES

Preparing for the New Year: Lab Review, Audit, and Compliance Strategies

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Laboratory compliance officers have many duties to oversee or perform throughout the calendar year, some more vital than others. It is important to understand which of those should be prioritized over others when it comes to allocating resources. Identifying new risks the laboratory faces in the coming years, both near-term and long-term, are essential to an effective compliance program. The best way to accomplish this is through a standardized process at year's end for review of the year's compliance activities, and then using the results of that review to plan for the coming year.

This does not mean that a compliance officer should wait until the end of the current year to update a lab's programs or evaluate current risks. Laboratory compliance officers should be updating the risk the lab faces throughout the year and making changes to their programs as needed. However, at some point in time, all these changes need to be summarized, discovered compliance problems should be addressed to ensure they have been resolved, and policies and procedures updated to reflect the changing environment. The compliance officer then will use the information to plan for the upcoming year. This implies that a standardized process is in place to make sure these tasks can be efficiently and effectively carried out and that nothing falls through the cracks.

What Should That Process Look Like?

Compliance guidance documents issued by the Health and Human Services Office of Inspector General (OIG) are useful in the respect that they lay out a foundation for laboratory compliance officers to use in creating a template of the essential elements of a compliance program. However, for laboratories, the section of the document that discusses the compliance risks for laboratories is hopelessly out of date and does not identify compliance risks as they exist today.

One of the essential tasks that laboratory compliance officers must undertake to ensure their compliance program is effective and up-to-date is an annual review of compliance activities and events designed to identify new risks and determine if current risks have been resolved. This should be memorialized in a written policy and procedure that lists the essential elements of such a review, such as a checklist or an electronic tool that helps ensure that everything is covered and nothing is overlooked.

Internal or Outsourced

The compliance officer has the choice to conduct these reviews and evaluations internally or to hire an outside vendor to help accomplish them. If the compliance officer prefers to keep the task internal, here are some guidelines to follow:

- The task should be shared among the members of the compliance committee to better use the human resources and expertise available and spread the work around.

- One of the problems is that laboratories start out with good intentions but soon get bogged down in the day-to-day operational issues and the reviews go undone or are done so poorly in the haste to complete them that they actually create potential risks rather than provide benefit. This is a real problem, so do not take it lightly. Whatever process or tools are used for this should be as easy to use as possible. The goal is to identify potential risks, not necessarily to resolve them at the time they are discovered unless they are high-priority items (see below).

If you can afford it or have budgeted for it, it is very useful to bring in an outside vendor to conduct the reviews, assess the results, and make recommendations for what needs to be done and what are high-priority items for your laboratory. However, pick the vendor carefully and use a request for proposal (RFP) process that allows for more than one vendor to bid on your project.

- To make sure the reviews are conducted by competent people, each compliance committee member should be assigned to carry out the part of the review that covers his or her area of responsibility in the laboratory. In other words, don't have the sales or business manager review the billing department and vice versa. While this may be less objective than another approach, it is often the most efficient.
- One common practice in the health system or hospital setting is for a single department, such as risk management or corporate compliance, to conduct these reviews. While there are some advantages to this approach, many laboratory issues are unique to the laboratory. If an internal department is doing these reviews, it is preferable, even essential, that someone on the review team has current experience with laboratory compliance risks.

Using an outside vendor can have certain benefits, such as objectivity and broad compliance experience, but is usually more expensive than using employees. If you can afford it or have budgeted for it, it is very useful to bring in an outside vendor to conduct the reviews, assess the results, and make recommendations for what needs to be done and what are high-priority items for your laboratory. However, pick the vendor carefully and use a request for proposal (RFP) process that allows for more than one vendor to bid on your project. The compliance committee should be involved in the development of the RFP and selection of the vendor. The more specific the RFP is, the better chance you have of choosing the right vendor and getting the results you desire.

Highest-Priority Compliance Tasks

Life must go on at the laboratory, and compliance problems have a way of poking their heads up at just the wrong time. That said, here are some tips for prioritizing compliance issues on a daily basis.

- The highest priority for any compliance program at any time throughout the year is making sure that identified problems and compliance issues have been resolved, or are on schedule to be resolved, in a timely manner. Federal requirements that any overpayments be reported and refunded within 60 days of when they are discovered raise resolution of overpayment to a high level. In other words, ongoing investigations and audits of any situation where an overpayment refund is involved or suspected is the highest priority for laboratory compliance officers.
- Responding to demands for records or refunds by the Centers for Medicare and Medicaid Services or any of its contractors must be the second-highest priority.

Failing to ensure these demands are met in a timely manner can lead to serious problems for the laboratory. In some cases, neglecting these responsibilities can lead to increased risk for the laboratory in addition to the original issue about which the demands were made.

At first glance, the tasks look overwhelming. If your laboratory does not already have a process in place such as what has been discussed in this article thus far, you should make developing the processes, policies, and procedures to get this implemented a priority for the coming year. This will certainly strengthen your compliance program and increase the probability that you will discover your problems before anyone else does. It also serves to provide evidence of an ongoing and active compliance program.

Developing the Process, a Suggested Approach

Anyone who has reviewed or assessed the current state of affairs of compliance programs in the laboratory industry quickly learns that many of these laboratory compliance plans or programs have not been meaningfully reviewed or updated within the last several years. While laboratory compliance officers worry about this state of affairs, very often other tasks take priority. Additionally, it is difficult to see the real benefit of taking on this task during a time when resource constraints are being applied throughout health care to deal with falling reimbursement and increased claims denials. Even without regular updates or reviews, these programs still have benefit for the laboratory. However, if a problem occurs that could have been avoided if the plan was regularly updated, those benefits could quickly disappear. In today's world of data mining and technology that allows for analysis of huge amounts of data quickly and relatively easily, all providers are at risk all of the time.

Let us say that your laboratory is in this situation and you, as the compliance officer, want to fix it and prevent it from happening in the future. Here is one suggested process that can help. This process will take a year to complete the first time, but after it is established it can become a regular part of an end-of-the-year routine process.

A Step-by-Step Process

If the laboratory does not already have an ongoing process in place to keep tabs on compliance events, activities, and policy and procedure changes, this is the first thing that needs to be done. Such a process can be as simple as keeping a file where the raw information collected throughout the year can be kept for review at the beginning of the end-of-the-year compliance program assessment and update process described below. A better option is an electronic tool that tracks compliance activities. This has benefits at the end of the year but requires time throughout the year to compile information. It is sort of a pay-now-or-pay-later concept. The end-of-the-year assessment and update process should begin as early as the beginning of the fourth quarter, but not so late that it cannot be completed by year's end.

If a problem occurs that could have been avoided if the plan was regularly updated, benefits [of a compliance program] could quickly disappear. In today's world of data mining and technology that allows for analysis of huge amounts of data quickly and relatively easily, all providers are at risk all of the time.

Given that the tracking system is put in place in January of the coming year, the foundation is in place to review and update your compliance program annually.

1 The first step is schedule a compliance committee meeting specifically to initiate the assessment and update process. The compliance activity that has been collected throughout the year is reviewed during this meeting. If the compliance officer has decided to outsource the assessment and update process, the vendor should already have been selected and a representative would attend this meeting. That should be included in the RFP.

2 Next, conduct a meaningful review of your compliance program to determine how much needs to be done. This does not need to be a complicated, quantitative review but is better served through the use of a checklist that is easy to use and includes all of the basic elements of the OIG compliance guidance for labs, as well as a current list of laboratory compliance risks specific to your laboratory. Include a review of ongoing or active investigations in the checklist. The checklist could be split up between the members of the compliance committee, or the compliance officer can conduct the review herself depending on preference, resources available, and time constraints. If an outside vendor is going to be doing the review, this step should be included in the RFP.

Regardless of the process, the compliance officer needs to make certain [the annual review] is getting done if she expects to get the benefits a compliance program is supposed to bring her laboratory in the event of a problem.

3 The compliance committee then will review the results and analyze the information. Combine the results of the tracking process with the results of the checklist review, and the compliance officer has a pretty complete picture of what needs to be addressed. These results provide a road map for setting priorities, budgeting, and assigning tasks in the upcoming year. If using an outside vendor, make sure this step is included in the RFP as a point of interface between the vendor and the compliance officer or the entire committee.

4 Create a formal report of the process and include recommendations and priorities. If the review determines that more resources need to be applied to the compliance program, then that should be included in the report. The report can be included in the annual report to the board, leadership, or corporate compliance as is appropriate for your laboratory.

5 Summarize the information and use it to make changes to your training material and annual audit plan as well as plan for the upcoming year's compliance activities.

Conclusion

An annual review and update of the laboratory compliance program is an essential step in keeping the program current and active. There are many ways to accomplish this, and the approach described here is just one way. Regardless of the process, the compliance officer needs to make certain it is getting done if she expects to get the benefits a compliance program is supposed to bring her laboratory in the event of a problem.

Also, conducting an annual review and update has many benefits, not the least of which is to increase the laboratory's ability to detect its own problems and be able to deal with them on its own terms. The process should be memorialized in a written policy and the necessary supporting procedures, but by taking a year to implement the new process, this task can be spread out over time. Meantime, the compliance office must rely on the existing policies and procedures to help mitigate problems, which is the reason for including the section on prioritizing problems above.

HHS Seeks Help From Providers to Resolve the Backlog of ALJ Appeals, *from page 1*

tracking system. OMHA is assigning cases to ALJs from the third quarter of fiscal year 2013 with 59,000 still to go. These are pretty grim statistics for any laboratory or other provider that currently has appeals in the system awaiting assignment to an ALJ.

What Caused the Problem

OMHA has experienced a recent significant and sustained increase in the number of denials and associated appeals that reach the ALJ level. The office was overwhelmed by the increase and could not meet the legally mandated 90-day time frame for resolution of these appeals. According to forum presentations, the number of denied claims and appeals started increasing significantly in fiscal year 2012, when it received 117,068 appeals requests, almost double the number received the previous fiscal year. As of June 2014, OMHA had already received 395,000 requests for the year. It is easy to see that this is not a simple problem, and it will take a monumental effort and cooperative commitment of resources to resolve.

Forum participants cited several reasons for the increase in requests for ALJ-level appeals. One of the main reasons is the cumulative effect of all of the post-payment audit programs, such as the recovery audit program, referred to as the RAC program, and Zone Program Integrity Contractors. Provider experience with these programs is generally perceived as negative. Providers are typically dissatisfied with the first two levels of the appeals process. These first levels are operated or supported entirely by CMS and its contractors, and rulings often uphold the original denial. It is not until a provider reaches the ALJ level of appeal that it gets an opinion from someone not directly involved in the results of the appeals.

Apparently, the faceless and impersonal nature of the lower levels of appeal create the perception that the adjudicators are not really hearing the arguments that support the provider's appeal.

CMS statistics tend to confirm this, pointing to a much higher probability of getting a favorable decision at the ALJ level. Word travels fast in the provider community, and it didn't take providers long to reach the conclusion that they would have to escalate their appeals to that level to get a perceived fair and impartial review. Coincidentally, the ALJ level is the first opportunity an appellant has to interact directly with the person adjudicating their appeals. Apparently, the faceless and impersonal nature of the lower levels of appeal create the perception that the adjudicators are not really hearing the arguments that support the provider's appeal.

Other reasons cited for the increase in denials and appeals include more active state Medicaid agencies and audit efforts and an increase in the base workload for which OMHA is responsible.

Another reason for the increase is that CMS has implemented changes to monitor claim accuracy that have resulted in increased denials and appeals of those denials. As part of this effort, Medicare Administrative Contractors have initiated a series of focused medical reviews, further contributing to the increase in denials and appeals.

What Are OMHA and HHS Doing About the Problem?

HHS plans to expand OMHA's adjudication capacity through budget increases that will allow the division to open more field offices and hire additional people to adjudicate claims. There are also a number of computer and technology improvements being made that should facilitate the appeals process. One system under development is known as the ALJ Appeal Status Information System Web site, or AASIS. This will enhance both OMHA's and providers' abilities to track the progress of appeals. AASIS is not expected until the end of 2015.

Another technology tool is the Electronic Case Adjudication and Processing Environment (ESCAPE). The ESCAPE system will have the capability to handle such things as case intake and assignment and workflow management. It will also allow for the sharing of files and case records between adjudicators. Unfortunately, phase I of ESCAPE is not expected to be up and running until the summer of 2015 at the earliest. The final phase of the ESCAPE program is not expected until November 2016.

OMHA has launched some pilot projects such as using statistical sampling to help appellants address large volumes of appeals, as well as the settlement conference facilitation pilot program. To date, neither of these pilots has been successful, but OMHA continues to tweak them in the hopes that they will provide a partial solution to the problem.

CMS Seeking Help From Provider Community

In a Nov. 5 *Federal Register* information request, CMS is seeking input from the provider community for ideas to help with the problem. According to the information request, OMHA wants input on its current initiatives designed to help resolve the problems. It is also specifically seeking input or asking questions on the following topics:

- Are there suggestions to improve the current initiatives OMHA is undertaking?
- Are there other suggestions outside of the initiatives currently under development?
- Are there any regulations that might be affecting the ability of OMHA to resolve the problem that could be revised to streamline the adjudication process that ensures opportunities for provider participation in the process?

Obviously, the best tip is to avoid submitting claims that are sure to be denied whenever possible. This can be partly accomplished through better training of employees and ordering providers.

Any suggestions for the first two bullets must comply with current statutory authorities and requirements, according to the notice. Comments are due by 5 p.m. Eastern time on Dec. 5, less than a month from the publication of this article.

Tips for Laboratory Providers

This problem will not be resolved easily nor in any reasonably short time frame. Obviously, the best tip is to avoid submitting claims that are sure to be denied whenever possible. This can be partly accomplished through better training of employees and ordering providers. Using tools such as process improvement techniques and the use of data to identify claims denial issues and prioritize the use of limited resources should help.

If denials occur, laboratories must become more familiar with the first two levels in the appeals process and make every effort to get their denial appeals resolved within those appeal levels. There is no real benefit to appealing claims if the resolution is so far in the future that it will make little difference to the laboratory financially.

Finally, participate in OMHA's efforts to resolve the problem by attending any programs they provide, following their efforts to resolve the problem, and commenting on the problem when asked by the government.

Takeaway: Laboratories need to make a concerted effort to submit clean claims and learn the ins and outs of the first two levels of the appeals process or wait nearly two years for their denial appeals to be resolved.

Bio-Rad Will Pay $55 Million to Settle Foreign Bribery Investigations

As more specialty molecular and genetic laboratories look to European and Asian markets to increase sales of their products, they must also become familiar with the Foreign Corrupt Practices Act (FCPA). Bio-Rad, a clinical diagnostic and life science research company based in California, learned this the hard way.

According to the Department of Justice (DOJ) press, Bio-Rad will pay $14.35 million in penalties and $40.7 million in disgorgement and prejudgment interest in connection with the company's sales in Russia, Thailand, and Vietnam. Bio-Rad entered into a nonprosecution agreement with the DOJ that allowed it to avoid criminal charges. "This action demonstrates the benefits of self-disclosure, cooperation, and subsequent remediation by companies," said David Johnson, the Federal Bureau of Investigation special agent in charge.

What They Did

In the admissions in the settlement agreement, Bio-Rad admitted it violated the FCPA by falsifying its books and records and failing to implement adequate internal controls in connection with sales it made in Russia. Bribes were disguised as commissions and other legitimate appearing payments but were designed primarily to influence Russia's Ministry of Health to help the company win government contracts. Similar secret payments were funneled to government officials in Thailand and Vietnam in return for business. Bio-Rad employees paid $7.5 million in bribes and illegitimate payments over a five-year period and received $35 million in business in return.

Other provisions of the settlement agreement include the company making improvements in its internal controls to prevent future situations such as this, continuing to cooperate with the government by reporting its compliance activities for the next two years, and developing an enhanced compliance program.

Lessons for Laboratories

Laboratories that intend to do business in foreign countries must learn the provisions of the FCPA and include a section in their compliance programs to ensure compliance with its requirements. Labs should train their employees about the FCPA, including enhanced training specifically related to the laws and regulations in the countries they will be operating in. It is also beneficial to specially train the employees who will be interacting directly with their foreign partners concerning the culture of the countries where they will be selling their products.

Takeaway: Many laboratories are looking to foreign markets to increase sales of their tests, but it is essential that they understand the laws and regulations in those countries and the requirements of the FCPA.

Compliance Corner

Can a high-complexity CLIA-certified laboratory perform and bill for a test marked as research use only or investigational use only by the manufacturer?

As long as the laboratory meets the CLIA validation requirements at 42 C.F.R. 493.1253, it can perform the test. That does not mean payers must pay for the test. For instance, Medicare does not pay for tests it considers not reasonable and necessary to diagnose or treat a Medicare beneficiary, according to Section 1862(a)(1) of the Social Security Act. One of the things that makes a test not reasonable and necessary is that it is considered investigational or for research use only. One reason labs get confused about this is that it is not specifically articulated anywhere except in the Medicare claims processing manual in Chapter 30, Section 40.3.6.4 and Section 50.3.1, where it says, "When Medicare considers an item or service experimental (e.g., a 'Research Use Only' or 'Investigational Use Only' laboratory test), payment for the experimental item or service is denied under §1862(a)(1) of the act as not reasonable and necessary." Commercial or private payers may or may not pay depending on their coverage policies, and labs should check with the payer before performing the test.

News-At-A-Glance

ANOTHER *WSJ* STORY IMPLICATING LABORATORIES: Once again, the *Wall Street Journal* (*WSJ*) has published an article based on data from the April data dump by the Centers for Medicare and Medicaid Services. This article, published in mid-November, addresses testing seniors for drugs, both legal and illegal, by physicians who the article alleges are doing it for the money because the drugs being tested would likely never be used by seniors. Tests for drugs such as heroin, cocaine, and angel dust, the street name for phencyclidine (PCP), are rarely, if ever, positive in samples from seniors. According to the article, this is an unintended consequence of the war on pain killer addiction. The numbers are staggering. Medicare paid $445 million in 2012 alone, which represents a 1,423 percent increase in just five years. According to the article, doctors have established drug testing labs, rather than refer drug tests to an outside lab, because they cannot bill Medicare if they do not do the tests themselves. When Medicare cracked down on payments for waived versions of these drug tests, some physicians added gas chromatography equipment to perform more sophisticated tests for which they were getting paid for each individual test. They also use panels of tests to increase volume. Medicare and its contractors are taking steps to curb this kind of abuse, but regardless of the outcome, honest laboratories likely will suffer more restrictive policies related to drug testing before Medicare corrects this problem.

HIPAA PRIVACY IN EMERGENCIES: In a November bulletin in response to the Ebola outbreak, the Office for Civil Rights (OCR) is seeking to ensure that violations of the Health Insurance Portability and Accountability Act (HIPAA) do not occur during emergency situations. The bulletin reminds providers that HIPAA is not set aside during such an emergency and explains the requirements and exceptions that could apply during an emergency. The bulletin should be required reading for privacy and security compliance officers. Emergency situations such as Ebola may cause breaches of HIPAA because of the personal beliefs of an employee or overzealous members of the media looking for a story. Compliance professionals should re-educate employees about the privacy rule provisions and what exceptions may apply in their institution. This can help reduce the potential for a breach. The bulletin and other information about HIPAA in emergency situations can be found on the OCR Web site at *http://www.hhs.gov/ocr/office/index.html*.

LABMD VS. FTC UPDATE: One more step has been taken toward a resolution in this ongoing HIPAA security case where LabMD, a cancer screening laboratory that is now out of business, has challenged the Federal Trade Commission's (FTC) authority to enforce the HIPAA security rule. The case is interesting to laboratories because it involves a relatively small laboratory that was the target of the FTC based on evidence provided by a third party with a conflict of interest in the case. Tiversa, a security firm specializing in peer-to-peer file searches, obtained a file that belonged to LabMD, allegedly on a public site called LimeWire. That file, which contained protected health information, is the centerpiece of the FTC's case, but the circumstances under which it was obtained are questionable. One of the main witnesses in the case, Rick Wallace, an employee at Tiversa, was recently granted immunity in exchange for his testimony. LabMD was ready to move forward with the case, but it has been delayed again. In a court document, Tiversa says that Wallace is not a trustworthy witness. Laboratories should follow developments in this case because the implications, should the FTC lose, could be significant.

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