G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Documentation Is Key: Medically Necessary Denials May Have Nothing to Do With Patient Care

When Medicare denies a claim because it is not medically reasonable and necessary, the decision may have nothing to do with whether the test is necessary and effective in the treatment of a patient. Rather, the denial may be due to lack of appropriate documentation for Medicare.

In some cases, the documentation may be present but the laboratory may not fully understand the complexities and nuances of the appeals process and lose the appeal as a consequence. Nowhere is this better illustrated than in the court documentation of a recent federal court decision of an appeal of claims denials filed by Nephropathology Associates, PLC (Little Rock, Ark.).

The case, *Nephropathology Assocs., PLC v. Sebelius*, serves as a warning to all laboratories that incomplete documentation and not paying

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Recovery Auditor Program Effective but Wasteful

Federal efforts to reduce the numbers of improperly paid Medicare claims has resulted in some success but comes at the expense of diverting scarce resources from patient care to audit defense. A balance must be struck between protecting Medicare from fraud and abuse and the burden placed on honest providers to respond to the necessary audits to ensure that outcome. That is the takeaway from a June 25 Senate Finance Committee hearing that examined the efforts of recovery audit contractors (RACs) to stem improper payments in the Medicare program.

The hearings were presided over by Sens. Orrin Hatch (R-Utah) and Max Baucus (D-Mont.), chairman of the Finance Committee, and included the testimony of two different providers and a representative of one of the RACs. Hatch noted that according to Centers for Medicare and Medicaid Services (CMS) estimates, improper payments for Medicare amount to more than $44 billion. CMS's use of private contractors like the RACs has resulted in returning hundreds of millions of dollars to the Medicare program and returned approximately $100 million in overpayments to providers in 2012 alone.

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appropriate and serious attention to the appeals process can create insurmountable obstacles resulting in the loss of an appeal even when the laboratory is in the right. However, being right does not necessarily mean being compliant and does not ensure payment.

In this case, Nephropathology received denials for special stains and electron microscopy services performed on kidney biopsies. The document does not detail the precise nature of these initial denials. Nephropathology requested a redetermination and was granted Medicare payment for some of the services, but not all.

Nephropathology then appealed that decision to the next level and a qualified independent contractor issued a decision that upheld most of the denials, but that decision was based on the billing protocol in a coding manual that was not promulgated until after Nephropathology had rendered and billed for the services at issue.

Nephropathology then appealed this decision to the Office of Medicare Hearings and Appeals, which administers level three of the appeals process, the administrative law judge (ALJ) hearings and decisions. During the ALJ hearing, Patrick Walker, M.D., director of Nephropathology, provided testimony that the services were reasonable and necessary. It is at this point in the appeals process where things took a turn that did not benefit the path lab. The ALJ agreed with Nephropathology that payment could not be denied based on a retroactive application of the coding manual. However, he upheld the denials of Medicare coverage for a different reason.

Nephropathology included in this documentation the date and time of a call to and from a physician's office concerning a specific test and a specific patient. However, the documentation of the phone call apparently did not specifically include an order for the test.

The ALJ found that Nephropathology had not met its burden to show that the services were reasonable and necessary because in order for a laboratory service to be medically necessary, it must be ordered and used promptly by the treating physician. He cited 42 CFR 410.32(a) as the source for his determination. This section of the Code of Federal Regulations states, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary. . . . Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

Nephropathology then appealed to the Medicare Appeals Council (MAC), the last step in the appeals process before taking the appeal to the court. The decision of the MAC constitutes the secretary of Health and Human Services' final decision.

The MAC concluded that Nephropathology did not submit evidence that a physician had ordered the services at issue even though it had provided multiple documents that when viewed in totality and in the context of how Nephropathology believed anatomic pathology tests are ordered clearly indicated that the tests had been ordered and information had been provided that could only have come from the physician's office.

Nephropathology included in this documentation the date and time of a call to and from a physician's office concerning a specific test and a specific patient. However,

the documentation of the phone call apparently did not specifically include an order for the test. In fact, in the MAC's opinion, Nephropathology had not submitted any specific documentation of an order for the tests that had been denied.

It is important to understand that according to this court document, an agency's interpretation of its own regulation is entitled to substantial deference, meaning that it would carry more weight than other interpretations in the eyes of the court. The court goes on to explain that this deference is warranted because Medicare is a complex and highly technical regulatory program within which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.

Basically, unless the agency's interpretation of its own regulations is plainly erroneous or inconsistent with the regulation, it will carry controlling weight. In the case of Medicare regulations, the interpretation of the secretary of Health and Human Services concerning what is reasonable and necessary will stand.

Nephropathology used every argument that it could including that the contractor is required to contact the ordering physician to obtain the order for the test and seeking a remand to the MAC to allow it to submit documentation of physician orders for the services at issue, all to no avail. Ultimately, the court upheld the MAC decision that the tests were not medically reasonable and necessary because there was no specific order for them, and the denials were confirmed.

Documenting Test Orders

There were many things Nephropathology could have done differently or better as it went through the appeals process. Ultimately it did not matter if the interpretations were correct.

The real solution to this problem lies at the very beginning: documentation of the original orders for the tests involved. One of the more disturbing factors in this case is that all the things laboratories thought they understood about documenting orders ultimately may no longer apply. Relying on others to maintain good documentation is risky, particularly when there is no consequence for them if the documentation is not adequate.

A signed requisition may have been helpful; however, if there were no corresponding order in the physician's office even that may not have been sufficient in this case. In the current environment where written orders are critical in determining medical necessity for laboratory tests, labs must ensure they are maintaining documentation of those orders to the best of their ability.

If there is a telephone order or the laboratory telephones the physician office for information concerning the order, clear and concise documentation must be kept on the laboratory side. No longer should a laboratory rely on little notes scribbled on a requisition that include little more than the name or initials of both parties participating in the call. Documentation of such communications should be kept in separate logs or forms linked to the original requisition and include exactly what information was obtained. Laboratories must become more aggressive in enforcing their policies regarding clarity in orders for tests.

The Takeaway: When tests are ordered by phone, both the referring physician and the testing facility must adequately document details of the call. The best way to ensure payment for services performed is for a lab to insist on signed, written orders from the referring physician in place of a phone call. G2

Millennium Laboratories Not Off the Hook Yet

A 2009 whistleblower complaint against Millennium Laboratories (San Diego) that it thought had been resolved has been revived, in part, by the First Circuit Court of Appeals.

The appeal was filed because of a January 2012 dismissal of an amended complaint, *U.S. ex rel. Estate of Robert Cunningham v. Millennium Laboratories of California Inc.*, filed on Feb. 25, 2011, after the original whistleblower, Robert Cunningham, an employee of Millennium competitor Calloway Laboratories, died.

The dismissal, issued by District of Massachusetts Judge Joseph Tauro, was based in part on disclosures made during a suit Millennium had filed against Calloway in the Superior Court of California five days before Cunningham's original whistleblower complaint on Dec. 29, 2009. That suit against Calloway alleged defamation and intentional interference with contractual relations and detailed some of the alleged fraudulent activities Millennium had engaged in upon which the amended whistleblower complaint was based.

According to the written decision by a three-judge panel in the April 12, 2013, court of appeals ruling that revived the whistleblower complaint against Millennium, there were three separate aspects to Millennium's alleged schemes.

Aspects 1 and 3 involved billing multiple times for testing performed using a single test kit (aspect 1) and fraudulent activity related to confirmation testing (aspect 3). The court document provides details of these two aspects of the alleged fraud by Millennium and concludes that disclosures made in the California suit filed by Millennium were sufficient to dismiss based on jurisdictional grounds.

Any laboratory engaged in drug screen testing should have its compliance officer review this case because of the detailed descriptions included in the court document.

However, aspect 2 of the amended complaint alleging excessive and unnecessary testing was not discussed in sufficient detail to be dismissed. The court vacated the earlier court's dismissal with prejudice and remanded the matter to the district court for further consideration. Millennium must wait until that ruling before it will find out if it will be subject to further legal action or not.

Lessons for Other Laboratories

Any laboratory engaged in drug screen testing should have its compliance officer review this case because of the detailed descriptions included in the court document written by the three-judge panel.

The details revealed therein concerning the allegations against Millennium, even though they are no more than allegations at this time, are revealing in that they illustrate how long a company can survive and continue to function even under the relatively severe charges leveled against it by competitors or even regulators.

That said, the risk associated with public disclosures made in these various lawsuits can damage a company's reputation beyond repair, and even though it may survive the legal challenge, it may not survive the reputational damage.

The Takeaway: Ongoing litigation can damage a lab's reputation beyond repair. When involved in a legal battle, resolve the issues as quickly as possible.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Anatomy of a Physician Referral Relationship: Dissecting the Risk Areas and Ensuring Compliance

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Relationships between health care providers and their physician referral sources are facing an unprecedented level of government scrutiny for potential fraud and abuse in these relationships. With a renewed focus on target areas of enforcement such as quality-of-care issues and mandates for increased levels of accountability from the governance and leadership of health care organizations, the federal government will continue its relentless pursuit to eradicate fraud, waste, and abuse. The recent arrests on federal charges of a physician and executives of New Jersey-based Biodiagnostic Laboratory Services LLC for an alleged scheme to bribe physicians for patient referrals demonstrate that laboratories are not immune from this scrutiny.

Seemingly innocent business arrangements between laboratories and potential referral sources, such as employment agreements, medical directorships, and space or equipment leases, may provide an easy enforcement target if not structured appropriately. Additionally, in today's challenging global economy, business opportunities and regulatory risks are constantly changing. Therefore, it is imperative that laboratories understand the legal framework and remain vigilant in navigating this dynamic, yet unstable, regulatory landscape they confront each day.

Legal Framework

Laboratories considering a potential arrangement with referral sources should familiarize themselves with the potential regulatory requirements in structuring these arrangements in a compliant manner. Two key laws that should be considered are the physician self-referral law, also known as the Stark law, and the anti-kickback statute.

Physician Self-Referral Law. The physician self-referral law generally prohibits physicians and immediate family members with a direct or indirect financial interest in an entity, such as a laboratory, from referring Medicare patients to that entity for "designated health services," which include clinical laboratory, radiology, and other imaging services, unless one of the many exceptions applies.[1] These exceptions include equipment and space leases, employment, and personal services. Each exception has specific requirements that must be met.

For example, if a laboratory wishes to engage a medical director, the laboratory may look to structure the arrangement to comply with the personal services exception. This exception requires, among other things, a written agreement with a term of at least one year that is signed by the parties and specifies the services covered by the arrangement, which do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The arrangement also cannot involve the counseling or promotion of a business arrangement or other activity that violates any law. Additionally, the personal services exception requires that the compensation paid under a medical director agreement must be set in advance, not exceed fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the physician and the laboratory.

1. 42 U.S.C. § 1395nn(a).

The Stark law's purpose is to prevent a potential conflict of interest that may arise for a physician who can benefit financially from making referrals that may not be medically necessary or appropriate. Importantly, the Stark law is a strict liability statute, which means that proof of intent to violate the law is not required—physicians may be liable even if the violation was "technical" and not intentional. Penalties for this strict liability law include denial of payment, refunds of billed amounts, and civil monetary penalties of up to $15,000 per prohibited referral.

Anti-Kickback Statute. The anti-kickback statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs.[2] Remuneration can involve anything of value, including cash, free rent, hotel stays and meals, excessive compensation, or other "perks" related to referrals.

The AKS is intent-based, which means that a violation cannot occur unless the parties possess the requisite level of intent. The Office of Inspector General (OIG) has taken an expansive view of what constitutes the requisite intent, and the AKS's intent standard has been interpreted to have been met if any one purpose is to induce referral or generation of federal health care program business.[3] Moreover, the 2010 Patient Protection and Affordable Care Act revised the intent requirement such that actual knowledge of or specific intent to violate the AKS is not required. Merely the intent to induce the referral or purchase of items or services for which payment may be made, in whole or in part, by a federal or state health care program is sufficient.

Failure to comply with a safe harbor does not mean that an arrangement is per se illegal, and such arrangements must be analyzed on a case-by-case basis to determine risk under the AKS.

The OIG has established certain "safe harbors" that protect remuneration that could otherwise be considered suspect under the AKS. While compliance with a safe harbor is not mandatory, such compliance creates a presumption that the parties are meeting the statutory requirements of the AKS. These safe harbors include space rentals, equipment rentals, and personal services and management contracts.

Using the medical director example described above, the personal services and management contracts safe harbor has similar requirements as the Stark personal services exception. These requirements include a written agreement with a term of at least one year that is signed by the parties and covers all of the arrangement's services. The arrangement also cannot involve the counseling or promotion of a business arrangement or other activity that violates any law. The aggregate compensation must also be set in advance, consistent with fair market value in an arm's-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties for which payment may be made by federal health care programs.

Failure to comply with a safe harbor does not mean that an arrangement is *per se* illegal, and such arrangements must be analyzed on a case-by-case basis to determine risk under the AKS. Conversely, even if an arrangement complies with all of the applicable safe harbor requirements, the OIG maintains that a safe harbor still may not protect the arrangement if the intent or purpose of the arrangement is to

2. 42 U.S.C. § 1320a-7b(b).

3. *See United Sates v. LaHue*, 261 F. 3d 993 (10th Cir. 2001); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985). *But see United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000), in which the 10th Circuit Court of Appeals stated that the mere hope for or expectation of referrals collateral to a legitimate motive for the financial arrangement does not rise to the level of an improper purpose.

provide a referral source with the opportunity to generate or retain a profit from the referral source's referrals.

The AKS covers both the payers and recipients of kickbacks with penalties including fines of up to $50,000 per kickback plus three times the amount of the remuneration and imprisonment up to five years.[4] Conviction may also lead to exclusion from participation in federal health care programs.

False Claims Act. Where the government has found violations of the AKS or the Stark law, the False Claims Act (FCA) may create additional civil and criminal liability for laboratories.[5] Where a claim to Medicare or Medicaid has resulted from a kickback or is made in violation of the Stark law, it may be rendered "false or fraudulent," creating liability for up to three times the program's loss plus $11,000 per claim filed. The FCA also can subject a laboratory to criminal liability.

Questions to Ask in Structuring Arrangements With Referral Sources

When applying the regulatory framework to their operations, laboratories should apply several basic principles in evaluating whether to enter into a particular business arrangement or opportunity. Laboratories should consider the following questions prior to entering into relationships with potential referral sources to ensure that the relationship is appropriate:

1. Does the arrangement or practice have a potential to interfere with, or skew, clinical decisionmaking?
2. Does the arrangement or practice have a potential to increase costs to federal health care programs?
3. Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization of laboratory services?
4. Does the arrangement or practice raise patient safety or quality of care concerns?

In addition to these questions, laboratories should consider the following to assist with monitoring and maintaining compliance:

Remember the Stark law's basic purposes.

Federal regulators believe that the successful and efficient delivery of quality health care is driven by sound clinical judgment that is free from potential conflicts of interest. Therefore, laboratories should examine potential arrangements with referral sources and avoid potentially conflicted medical decisionmaking, which can ultimately result in overutilization, increased program costs, and unfair competition.

Meet a Stark exception and hug a safe harbor or advisory opinion as closely as possible. Remember, the Stark law is a strict liability statute so intent is not required, and an exception *must* be met if the Stark law applies. On the contrary, not falling directly within a safe harbor under the AKS does not mean you are in violation of the law. However, it does mean that there may be a significant component of risk present. It is optimal to meet a safe harbor or structure the arrangements to come as close to compliance with the safe harbor as possible. Always review and evaluate OIG guidance and advisory opinions. More importantly, document reasons why full compliance with an applicable safe harbor may not be possible.

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4. *Id.*
5. 31 U.S.C. §§ 3729-3733.

"Everyone is doing it" is not an absolute defense. A laboratory's compliance obligations will never be viewed by regulators in the context of "what everyone else is doing." It really shouldn't and doesn't matter. Laboratories should avoid becoming the next "national project" and be particularly sensitive to areas of heightened scrutiny. Laboratories should stay up to date on government enforcement trends by reviewing the Health and Human Services OIG work plan, recent government settlements, and any other guidance that may be applicable to their operations.

Greed is not good. Optimization of revenue and achieving compliance is possible, but laboratories should remain vigilant to ensure that the two are not mutually exclusive. Laboratories should look for potential red flags to investigators, such as excessive return on investments and excessive compensation. A laboratory's return on investment, compensation structure, and operational expenditures should be demonstrative of its commitment to compliance.

Fair market value is your best friend. Facilitating business arrangements in today's complex regulatory landscape is sufficiently challenging without having to worry about implicating Stark and AKS. Minimize some of the frustration by relying on outside valuators and respected independent industry resources to justify potential services and investments. A key question to ask is if a reasonable commercial entity would undertake the arrangement absent a potential for referrals. Anytime a health care business offers something to a referral source for free or at below fair market value, the question should be "Why?" To further ensure that an arrangement falls within fair market value, a laboratory can consider obtaining an outside valuation of the compensation from an independent third party.

Document! Document! Document! A regulator may take the position that if something is not documented, then it does not exist. In certain instances, a lack of documentation may equal a regulatory violation. Laboratories must document all legitimate business purposes for its arrangements with referral services, fair market value assessments, and all services to be provided and the time spent providing them. But documentation is discoverable, so accuracy is of the upmost importance.

Review compliance on an ongoing basis. Compliance programs are more than a "trophy document" or annual training. Laboratories should continually reassess to be certain that deals are properly implemented, parties are fulfilling substantive responsibilities, and ongoing documentation is properly maintained. Be sure to integrate best practices into your organization's culture and reflect these best practices in *all* business practices.

Look for the big picture. When evaluating an issue or potential violation, gain a full understanding of every angle of the layered, interconnected network of facts and the risk impact to your organization's business. Do not review issues as isolated incidents, especially when the stakes are high. Managing your compliance programs using an enterprise risk management approach can never hurt, since it compels everyone to be proactively engaged in the process.

The Takeaway: Business arrangements between laboratories and potential referral sources can be risky if not structured properly. In setting up agreements, labs must review key laws and ask key questions regarding the intent and appearance of the arrangements.

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Recovery Auditor Program Effective but Wasteful, *from page 1*

Even though RACs have reviewed less than 1 percent of claims nationwide, their efforts can be burdensome to providers caring for sick patients, Hatch acknowledged. Baucus added that while RAC audits play a key role in recovering improper payments, it should not be necessary to overburden legitimate providers, who play by the rules, with unnecessary red tape.

Baucus called for balance in RAC audits, citing the case of a small hospital in Montana—Kalispell Regional Medical Center. According to the hospital, it has spent nearly $1 million and hired three new full-time staff just to deal with audits. Kalispell Regional has won its appeals in 53 percent of cases, say hospital officials.

Provider's Testimony

Susie Draper, vice president of business ethics and compliance for Intermountain Health Care (IHC, Salt Lake City) testified about IHC's experience with RAC audits. Draper described how IHC had prepared for the implementation of the RAC program and what benefits it believed the health system had gained as a result of that preparation and implementation once the audits began.

Draper included specific data about the audits, including number of claims requested, and reviewed and the outcome, including net Medicare gain or loss. According to Draper, resources spent on responding to RAC audits could have been used for patient care and quality projects. According to her testimony, IHC added 22 full-time employees primarily in the appeals unit. She said IHC data showed that after RAC reviews of approximately $120 million in claims, Medicare recovered a net of about $16,000 after tallying underpayments and overpayments.

Jennifer Carmody from Billings Clinic in Montana discussed the same kinds of issues and problems as Draper expressed. She also highlighted the number of claims that are hung up somewhere in the appeals process awaiting final decision. According to Carmody, Billings has been successful in 84 percent of its appeals.

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Carmody's estimate of the impact of the burden for the clinic is approximately 8,600 work hours and approximately $240,000 per year to manage audits and appeals, not including the $45,000 a month the clinic pays an outside contractor to help with medical necessity reviews.

Carmody urged CMS to remedy the adversarial nature of the RAC program and its auditors. She also called on CMS to issue clear and concise guidelines that are not subject to multiple interpretations, limit the number of record requests RACs are allowed to make, stop RAC auditing of claims that have a low error rate over time, and provide sufficient oversight to ensure RAC and other government contractors meet their deadlines throughout the appeals process.

CGI Testimony

Robert Rolf, a vice president of CGI Federal Inc. provided testimony at the hearing about CGI's experience as a RAC contractor. Through a series of generalized statements, Rolf described those aspects of the RAC program designed to ensure accuracy and enhance communication between the RACs and the providers they audit.

One interesting section of Rolf's testimony touched on the issue of accuracy of the claim reviews. He stated that in the latest set of cumulative annual data published by CMS, all four recovery auditors received accuracy scores of greater than 90 percent.

On the surface this would appear to conflict with the testimony of the two providers; however when G2 Intelligence looked at the report Rolf was citing, the accuracy scores have less to do with claims overturned on appeal and more to do with the accuracy of the interpretation of the specific information on a claim against a regulation or program policy. That same report includes a table that shows that 43.6 percent of appealed claims were overturned.

RACs Are Not Going Away

It is unlikely that any immediate changes will occur to the RAC program as a result of these hearings. Hatch noted that CMS is currently reviewing bids for new contracts for the RACs for the coming years and said he would like to see CMS take more consideration concerning the balance between program integrity issues and the administrative burdens that are placed on honest providers.

Hatch added that even though the RAC program is an important component of recovering improper payments, Congress is responsible for making sure it is being administered as intended by Congress. To that end, CMS must work to continually improve the program based on input from both providers and RACs, seeking that balance.

Laboratories and other health care providers should realize RACs are now part of their daily operations and develop programs that help them efficiently and effectively deal with the program and the administrative burden resulting from its audits. The existence of RACs is changing provider behavior and the cost of dealing with them is being absorbed to the detriment of other provider concerns like patient care, quality and efficiency, and overall improvement in the health care system.

Unfortunately, whether or not the balance sheet ultimately shows that the RAC program is actually recovering enough money to justify its existence is almost moot—they likely will just add to the cost of health care with little real benefit to patients.

The Takeaway: While recovery audit contractors may provide little real benefit to the Medicare program, laboratories and other health care providers must develop programs to effectively deal with RAC audits. G2

Caris Life Sciences Seeks Dismissal of Whistleblower Lawsuit

A whistleblower case against Caris Life Sciences Inc. may be dismissed based on legal technicalities without the court ever addressing the allegations made by the relators.

In a motion to dismiss filed June 17, attorneys for Caris seek dismissal of all counts of the whistleblower's April 16, 2013, complaint because the relators do not meet certain stringent requirements under the Federal Rules of Civil Procedures (in particular, rule 9(b) regarding pleading special matters).

Because False Claims Act (FCA) liability attaches only to a specific claim actually presented to the government for payment, rule 9(b) requires that some example of

reliability, such as a specific claim, must be provided in the complaint to support the allegation that an actual false claim was presented to the government.

Caris's attorneys argue that allegations made by the relators are conclusory and speculative and do not state how the conduct they allegedly witnessed resulted in filing false claims. The attorneys argue that the allegations are so broad and generalized that they do not meet the pleading requirements of rule 9(b).

Regardless of the defendant attorney's arguments, the allegations made by the whistleblowers include a long list of what appear to be serious matters concerning the quality of testing, FCA violations, billing fraud, and violations of the anti-kickback statute. The complaint includes a list of repeated violations alleged by the relators, including:

- Waving the technical component fees of its Target Now testing on Medicare beneficiaries;
- Promoting Target Now testing for uses that were not reasonable and necessary;
- Knowingly billing Medicare for hematology specimens that were not viable due to heat exposure;
- Offering kickbacks to providers to induce referral of Medicare patients;
- Unbundling and double billing to the Medicare program;
- Upcoding of certain procedures to obtain a higher level of reimbursement; and
- Retaliating against one of the relators for reporting the FCA violations.

Each item on the list is discussed in detail in the court documents. However, the defense attorney's motion to dismiss concludes that while there is detail, there is no specific evidence to support that false claims were actually presented to the government for payment nor evidence to support that remunerations alleged are actually linked to any referrals.

Allegations and Violations

A reading of the first amended complaint seems to refute the idea that the complaint does not contain specific examples of the allegations made by the whistleblowers. Whether or not the complaints are valid and what the consequences for Caris might be will only be revealed if the case goes forward beyond the dismissal. Until the final settlement, after all appeals are exhausted, no conclusion should be drawn from the current court documents.

Whether or not the complaints are valid and what the consequences for Caris might be will only be revealed if the case goes forward beyond the dismissal.

However, there are a number of issues in this case that could benefit all laboratories and certain other health care providers or suppliers if the case proceeds to the point where interpretation or comment by the court is an end result. Laboratories should put this case on their watch list because of the nature of the allegations, the potential impact on Caris, and the lessons that can be learned from the court's final ruling.

The Takeaway: Despite how a court rules on a whistleblower case lodged against Caris Life Science, labs should pay attention to the specific allegations related to false claims, waiver of fees, and kickbacks.

News-At-A-Glance

SELF-DISCLOSURE EASIER THAN EVER BUT STILL RISKY: Health care providers who would like to voluntarily disclose self-discovered evidence of potential fraud may now do so online through the Health and Human Services Office of Inspector General Web site (*www.oig.hhs.gov*). The new online process was included in an April 17, 2013, update to the self-disclosure protocol (SDP), which revises the protocol entirely and incorporates and replaces all prior updates and open letters the OIG may have issued since the SDP was created in 1998. While the updated SDP does not fundamentally change the system, it does include important new elements that will affect providers who are deciding whether to use the protocol. Some of those new elements include a minimum multiplier of 1.5 times the claim damages, acknowledgment of the potential violation in the case of violations involving the anti-kickback and physician self-referral statutes, and a certification that any internal investigations not completed prior to the disclosure will be completed within 90 days. Generally, the updated protocol includes more specific instructions for certain kinds of disclosures and adds minimum settlement amounts. Anyone considering making a disclosure through the SDP should discuss the benefits and risks of using the SDP with legal counsel before invoking the process. Laboratory compliance officers should become familiar with the SDP so they can properly advise the laboratory administration concerning SDP disclosures.

CMS UPDATES INTERNET-ONLY MANUAL FOR PATHOLOGY BILLING: A new program transmittal from the Centers for Medicare and Medicaid Services updates the Internet-only manual instructions regarding how the technical component (TC) of pathology services should be billed for hospital inpatients and outpatients. Program transmittal R2714CP communicates revisions to chapters 12 and 16 of the Medicare Claims Processing Manual to update billing and claims processing instructions contained in the manual for billing the TC and professional component (PC) of physician pathology services furnished to hospital patients. Specifically, the transmittal makes it clear that an independent laboratory may not bill Medicare contractors directly for the TC of a physician pathology service furnished to a hospital inpatient or outpatient; it must bill such services to the hospital. The transmittal comes almost one year after its effective date, July 1, 2012. The effect of the transmittal may be that it effectively eliminates global billing for these services for Medicare patients. Anatomic pathology laboratories frequently misunderstand the principles governing global billing and file claims incorrectly. It is important to remember that if a modifier is not used when submitting claims for the separate TC and PC services of anatomic pathology claims, the services will be considered a global service. Global billing essentially means filing a single claim for a service that includes both its TC and PC. Billing globally for anatomic pathology services is only possible when both components are furnished by the same physician or supplier entity. If the TC and PC are provided in different locations, they must be billed separately and must include the appropriate modifier for each service. Anatomic pathology laboratories and hospital laboratories should review their billing processes to ensure they are billing appropriately. The new manual instructions are a good reminder that merely applying the same place of service code does not permit global billing.

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