G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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All False Claims Act Qui Tam Cases Will Get Criminal Reviews

Under a new Department of Justice (DOJ) process for qui tam complaints, all new civil complaints are reviewed by the criminal division as soon as they are filed to determine if a parallel criminal investigation should also be opened.

Assistant Attorney General for the Criminal Division Leslie R. Caldwell announced the change during his remarks at a recent Taxpayers Against Fraud Education Fund conference. Qui tam relators, commonly known as whistleblowers, have always been a large part of the DOJ's civil fraud-fighting efforts, and this change will allow for criminal investigations to commence immediately if criminal activity is alleged in a False Claims Act (FCA) lawsuit.

For providers such as laboratories, the risk of serious consequences stemming from allegations in a civil FCA whistleblower's lawsuit have just increased considerably. The investigators working in the criminal division are experienced in prosecuting the most complex fraud cases and bring a wealth of practical experience and knowledge, resources, and sophisticated investigatory tools to bear on these cases. For instance, of the 100 attorneys working in the division, 40 are dedicated to the health

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Qui Tam Complaint Alleges Duplicate Testing At the Nation's Largest Laboratories

Government prosecutors are having a hard time deciding whether or not to intervene in a Medicare-Medicaid qui tam lawsuit filed by a former Quest Diagnostics phlebotomist who claims that both Quest and Laboratory Corporation of America (LabCorp) have been conducting duplicative tests and billing for them since at least 2002. The case is filed on behalf of the United States and the state of California by the relator Elisa Martinez, a former Quest phlebotomist, and covers both Medicare and Medicaid beneficiaries.

According to the original complaint filed in the U.S. District Court in the Eastern District of California, both labs routinely conduct duplicate testing on the same patient, on the same date of service, and bill for both sets of tests, when they receive orders from two different physicians. Martinez also alleges that, in some cases, extra

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care fraud unit, making it "the largest and most prolific unit of criminal prosecutors dedicated solely to health care fraud in the country," according to Caldwell's remarks.

Working With Others

One of the most beneficial fraud fighting weapons is cooperation between the various government departments and divisions when investigating fraud cases, as occurs with the Health Care Fraud Prevention and Enforcement Action Team. This DOJ and Health and Human Services (HHS) joint strike force operation has proven to be a very successful endeavor, with a 95 percent conviction rate. The strike force consists of a coordinated team of DOJ investigators and prosecutors, Federal Bureau of Investigation agents, HHS employees, and state and local law enforcement. In 2013, as a result of strike force operations, 345 individuals were charged and 234 entered guilty pleas, while another 46 were convicted in jury trials.

Another high-priority target area, according to Caldwell, are executives at health care provider entities such as hospitals. During 2013, individuals prosecuted faced an average prison time of 52 months. Another action is to freeze assets, which, Caldwell says, prevents criminals from enjoying the proceeds of their schemes. The strike force and other DOJ investigators and prosecutors are using real-time analysis of Centers for Medicare and Medicaid Services data to detect and track criminal activity. Finally, Caldwell says the DOJ wants to step up prosecutions of corporations that commit fraud or abuse against Medicare and other government programs. He said that the department has several ongoing health care fraud investigations and more are coming.

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Both Domestic and Foreign

Many laboratories have found that their products are more easily distributed in foreign markets and often can be reimbursed in those other countries without the cost and hassle of dealing with the risks encountered in America. However, the DOJ has developed mutual legal assistance treaties and runs parallel investigations with foreign agencies. Any laboratory operating globally should be aware of the Foreign Corrupt Practices Act and consider hiring a legal firm from the country in which they intend to promote or sell their products.

Complex Cases Require More Resources

Those involved in criminal conduct and fraud can go to extravagant lengths to hide these activities, and that is where whistleblowers come in. Whistleblowers can provide documentation and clues to the factual circumstances of a case and help investigators uncover fraud and criminal activity more quickly and efficiently. Caldwell told the audience that "Qui tam cases are a vital part of the criminal division's future efforts." He praised qui tam relators, saying they are courageous and "all too often, they have lost their jobs after they raised concerns in their workplace."

Conclusion

What does this mean for clinical and anatomic pathology laboratories? The risk of not having an effective compliance program becomes more important than ever before. Facing civil penalties as a health care entity is one thing. Facing criminal charges as owners or senior leaders in health care organizations is quite another.

All laboratories should have a strong policy and procedure related to defending against whistleblowers. The first step of such a program is to listen to what employees have to say and then to conduct an investigation to determine credibility for the complaint or issue. Always work with the idea that whatever the outcome of the investigation, be prepared to do the right thing as far as refunding overpayments, correcting problems and issues, and rewarding employees who bring issues forward. The idea is to make the prerelator a source of discovery so they never become a relator.

Takeaway: All whistleblower cases will be reviewed by agents of the criminal division of the DOJ, who are experienced and expert in investigations and prosecutions. This makes it even more important for laboratories and other providers to do all they can to prevent a whistleblower case from ever being filed. G2

Hunter Labs Loses Its Bid to Keep Entire $241 Million FCA Settlement

Chris Riedel and Hunter Laboratories LLC have lost a motion to dismiss a lawsuit over a breach of contract filed by two former partners in a litigation-sharing agreement that called for a 15 percent share in proceeds from lawsuits filed against various clinical laboratories. The plaintiffs in the case, Fair Laboratory Practices Associates and NPT Associates (referred to as FLPA), were partners with Hunter in the agreement in pending and future lawsuits.

Hunter has refused to pay the partners per the shared litigation agreement until and unless a court authorizes the payment. The money, approximately $6.29 million, has been held in escrow since July 5, 2011.

The first settlement was with Quest Diagnostics in California for which the plaintiff Hunter received a $241 million settlement of a False Claims Act case. According to the agreement, FLPA was entitled to 15 percent of that settlement. The next case was a settlement with Laboratory Corporation of America for which Hunter received $49.5 million and subsequently paid FLPA $1,292,301 under the shared litigation agreement. The next case was filed by FLPA in the Southern District of New York. That case was dismissed because one of the members of FLPA had served as general counsel for one of the defendant labs in the case and therefore would be in breach of his ethical obligations as an attorney.

After the New York case, Hunter informed FLPA that it would not be paying the 15 percent share of the Quest case because the New York court's action prohibits the payment in the Quest case. However, Hunter does not cite any specific language in the court's order to substantiate that assertion. Hunter has refused to pay the partners per the shared litigation agreement until and unless a court authorizes the payment. The money, approximately $6.29 million, has been held in escrow since July 5, 2011.

The Plaintiffs' Claims for Relief

FLPA asserts a breach of contract because it has performed, or offered to perform, all of the acts required of it under the shared litigation agreement. Further, FLPA asserts the breach of the agreement is substantial and the plaintiffs have been damaged and continue to be damaged as a result. FLPA also asserts conversion because it has legal and equitable title to the $6.29 million, which

constitutes its 15 percent share of the Quest settlement. Hunter has converted the funds to an escrow account that it controls, depriving FLPA of its possession and use. Finally, FLPA asserts that Hunter unjustly enriched itself in the amount of $6.29 million by depriving FLPA of the funds owed to it as a result of the Quest settlement.

The plaintiffs are seeking judgment in their favor on all three counts in the lawsuit and seek all damages that have resulted from the defendant's actions. Plaintiffs also seek reasonable attorneys' fees and court costs and any other relief under the law considered appropriate for this case.

Finally, the defendants filed a motion to dismiss for improper venue or to move the case to another venue, specifically the Southern District of New York. The court ruled that the venue was proper and that there is no basis for moving the venue to New York. As a result, the court dismissed the motion, leaving the path open for FLPA to receive its share of the Quest settlement.

Takeaway: Whistleblowers often have to fight for years through complex legal maneuverings and other hardships before they receive their reward. This case illustrates the downside of joining with other whistleblowers in a case.

Effective Compliance Program Leads To Self-Disclosure for New York Hospital

The benefits of an effective compliance program and self-disclosure are demonstrated by a case involving Our Lady of Lourdes Memorial Hospital, a 242-bed hospital located in Binghampton, N.Y.

Lourdes paid the government $3.38 million after it discovered that it had been overpaid by Medicare for hyperbaric oxygen therapy services from February 2008 through September 2013, according to an Oct. 16 announcement by the Department of Justice. Lourdes claimed the services as if they were performed as provider-based even though they did not qualify for that under Medicare regulations.

The improper billing was found as a result of Lourdes's internal auditing program, part of its compliance program, and was immediately corrected and then reported to the government. Because Lourdes took the action it did and then cooperated with the government investigation, it was required to pay far less than the treble damages and other monetary penalties that government prosecutors could have imposed. In addition, Lourdes was not required to enter into a corporate integrity agreement or comply with other onerous compliance measures.

There were never any allegations that patient care was compromised in any way. Lourdes President David J. Patak said in a statement, "Lourdes has always been dedicated to enhancing the health and well-being of this community and we hold ourselves accountable to the highest standards of integrity."

"Today's settlement is an excellent example of how voluntary self-disclosure benefits both the integrity of health care programs and providers who discover and report evidence of improper billing in their organization. Lourdes should be commended for the manner in which it handled the disclosure" said U.S. Attorney Richard S. Hartunian.

Takeaway: This case demonstrates the real financial and reputational benefits of an effective compliance program when a compliance issue is discovered.

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COMPLIANCE PERSPECTIVES

Dennis L. Padget, MBA, CPA, FHFMA, is the lead consultant with PathConsulting (an APF company).

Defending the Medical Necessity of Anatomic, Clinical Pathology Services

"Thou shalt bill only *medically* necessary services." Even though the term *medical necessity* appears in nearly every coverage policy issued by payers and insurers, its precise meaning remains elusive. Taking it into account when writing an internal medical protocol or dictating a patient report is often difficult. Nonetheless, we are charged with that responsibility under various state and federal laws as well as participation agreements with payers.

Government payers and private insurers have invested heavily the past 20 years in ways to monitor the medical necessity and clinical efficacy of health care services. Pathologists and laboratories should anticipate more aggressive demands for demonstration of clinical utility in the next five years. The information in this article will help you prepare.

Definition of Medical Necessity

There is no universal definition of *medical necessity*. Guidance from several authorities has been massaged to yield the following working definition, first published in version 14.3 (July 1, 2014) of *Pathology Service Coding Handbook* (American Pathology Foundation):

A medically necessary service is one that a prudent pathologist would provide to a patient for the purpose of diagnosing an illness, disease, condition, or symptom. Prudence means the service is clinically appropriate considering the patient's history, the current clinical circumstances, and generally accepted standards of medical practice. It's imprudent to conduct a service primarily for the convenience of the patient, the ordering physician, or the examining pathologist.

Interest in the definition for purposes of this article is limited to its implications for billable versus nonbillable medical activities. It may be prudent, for example, to run a validity test on a urine sample prior to performing a quantitative toxicology assay for opiates, but to the extent the validity test represents a quality control measure instead of providing significant, independent diagnostic information, some payers will not permit a separate charge (i.e., the cost of the validity test is built into the payment for the toxicology assay).

Note that clinical appropriateness from the standpoint of payment determination is driven largely by the medical facts and circumstances surrounding each patient case. For example, a pathologist at a community hospital sends a tumor tissue block to a reference lab for a fluorescence in situ hybridization (FISH) test. Although she's confident of her invasive ductal carcinoma diagnosis and orders only the FISH test, the pathologist at the reference lab orders a hematoxylin and eosin (H&E) section from the block to confirm the original diagnosis and ensure the appropriateness of the tissue for the ordered test. Even if the reference lab's report includes commentary on the light microscopy exam in addition to the FISH interpretation, it cannot properly bill a consultation fee (e.g., 88323) for that work, because the referring pathologist had no need for and did not order the consult.

Pathologists properly strive to minimize the turnaround times of their cases. This sometimes is achieved via standing orders for a special stain (e.g., giemsa) during the routine processing stage whenever a particular type of tissue (e.g., gastric) is received in the lab. It's not relevant whether one views the advance ordering of a special stain (i.e., prior to examining the H&E sections) to be for the convenience of the referring physician or the pathologist: From the standpoint of an insurer, the special stain is medically necessary only if the routine sections support its need.

Expect More Aggressive Demands for Proof

It may simply be that news travels so much faster and wider these days with the growth of Twitter, Facebook, blogs, and other social media, but perception suggests that pathologists at large only very recently have taken notice of the trend by Medicare contractors and private insurers to issue benefit coverage (i.e., payment) guidelines that directly implicate the usual way pathologists approach their medical cases.

Pathologists by and large have failed to take payer coverage guidelines into account in their daily practice, even at such a fundamental level as the content of their medical reports.

Payer coverage guidelines have, of course, been around for many years. In terms of modern history, Medicare launched its National Correct Coding Initiative (NCCI) in the late 1990s. That was closely followed by the advent of local coverage determinations published by individual Medicare administrative contractors, which were first authorized by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. National coverage determinations by the central Medicare office in Baltimore must also be taken into account. To greater or lesser extent, all these guidelines focus on establishing the clinical parameters under which Medicare deems physician, laboratory, and other health care provider services to be medically necessary and thereby payable on behalf of Medicare beneficiaries.

Experience indicates that, until very recently, the problem has been that pathology practice administrators, laboratory managers, coders, and billers have been the ones taking note of the coverage guidelines issued on a regular basis by Medicare, its contractors, and private insurers. Pathologists by and large have failed to take payer coverage guidelines into account in their daily practice, even at such a fundamental level as the content of their medical reports.

A good example of pathologist inaction is drawn from the bone marrow case arena. Quite frequently such cases require both immunohistochemistry (IHC) and immunophenotyping by flow cytometry for thorough diagnostic evaluation. But Medicare via its NCCI policy manual since at least 2004 has said that testing by those two methods of several or many overlapping antibodies is *duplicate testing* unless "the initial method [is nondiagnostic or] does not explain all the light microscopic findings." Nonetheless, broad-based sampling indicates that many pathologists even today fail to include a simple declarative sentence (e.g., "IHC stains were evaluated to subtype the B-cell lymphoma identified by flow cytometry") in their bone marrow reports that explains why both IHC and flow were medically indicated for a particular patient case. Without that type of defense in the report, the IHC charges are at risk of summary denial by a Medicare or private insurer auditor.

The profession's attention to the implications of payer coverage guidelines on the workaday practice of pathology seemingly came into sharp focus this past May when Palmetto GBA, the Medicare Administrative Contractor for Jurisdiction 11 (North and South Carolina, Virginia, and West Virginia), posted a policy to its Web site related to special stains and IHC for Helicobacter pylori in conjunction with gastric biopsies. The policy observed that cited professional literature indicates that a special stain or IHC is medically indicated for the evaluation of H. pylori with only about 20 percent of gastric biopsies (i.e., the H&E sections alone are sufficient for most biopsies). The

policy intimated that a pathologist whose special stain utilization rate for gastric biopsies exceeded 20 percent might be subject to some type of sanction.

Heavy pushback from the College of American Pathologists and practitioners in J11 resulted in Palmetto GBA rescinding the gastric biopsy policy in late July or early August. However, it's important to note that procedural grounds played the biggest role in the reversal: Palmetto did not publish the policy as a proposed rule for public comment as it should have. The principal foundation of the policy, that Medicare's medical necessity standards suggest that the decision to order a special stain for a case should be based on clinical criteria such as examination of the H&E sections, was in many ways sound and reasonably supported.

The primary takeaways from the NCCI and Palmetto anecdotes are twofold: (1) Pathologists should incorporate payer benefit coverage guidelines into their daily practice protocols, assuming the guidelines are reasonably consistent with the sound practice of medicine, and (2) pathologists and laboratories should anticipate and prepare for many more coverage guidelines being issued by government payers and private insurers in the next three to five years. Targets for near-term coverage guideline expansion almost certainly will include the following:

- Ongoing growth in the volume of special stains, immunohistochemistry, and in situ hybridization testing will prompt payers to closely monitor their clinical utility;
- Continued significant increase in the annual volume of toxicology tests will cause insurers to come to terms with sound medical necessity and coverage standards;
- The ever-increasing availability of molecular tests and expanded ordering practices will lead payers to strengthen their coverage guidelines; and
- "Next-generation" molecular panels have matured to the point that they're set out separately in *CPT-2015*, but medical necessity-type questions remain (e.g., screening versus diagnostic; inclusion of genes with no known clinical significance vis-à-vis the tumor of interest; running an entire panel when only two or three genes are of dominant interest) that will motivate insurers to develop methods of monitoring for abuse.

Common prepayment claim edits focus on detecting duplicate services, excess units of service, suspect combinations of services, and medically unnecessary services.

Learning to Defend Your Orders

Your claims for medical services are already carefully scrutinized by government payers and private insurers. Common prepayment claim edits focus on detecting duplicate services, excess units of service, suspect combinations of services, and medically unnecessary services (e.g., a particular CPT code is covered only when accompanied on the claim with one of a predefined, limited list of ICD diagnosis codes).

Recent trends indicate that payers and insurers are working hard to make their pre- and post-payment claim review processes even more robust and comprehensive. You can minimize the impact of those future initiatives on your practice by taking steps now to better defend your internal medical policies and the case-by-case diagnostic decisions that you make. Following are some of the key actions you should consider near-term:

- Base all of your internal medical policies and protocols on generally accepted standards of practice, particularly as are evidenced by material published by pathology and laboratory professional organizations and in peer-reviewed literature. Resist policies and practices that are encouraged by referring physicians but are nonetheless of questionable clinical utility. Never decide to do something merely

because it's billable or pays more than an alternate procedure. Once you and your practice associates make an internal medical policy, practice, or protocol decision, everyone should religiously adhere to the group decision—even one nonconformist can cause an outsider to view the group decision with suspicion.

- Always remember that government regulators and insurance auditors are as much a target audience for your medical report communications as are your referring physician clients. Use CPT-based key words and terminology to the maximum extent possible (e.g., biopsy, resection, quantitative, single versus multiplex). Don't fail to state the obvious in relation to billable procedures (e.g., decalcification, frozen section block, microscopic exam was performed). Highlight important ancillary procedures in their own section of the report (e.g., intraoperative consultations, FNA adequacy examinations, special stains).
- Restrict standing orders for special stains and other ancillary procedures to clinical situations of unquestioned prudence vis-à-vis generally accepted practice standards, for example, a limited, defined battery of histologic and immunofluorescence stains with renal biopsies or enzyme histochemistry stains with muscle biopsies. Otherwise, base your decision to order a special stain, IHC stain, or other ancillary procedure on your findings from the microscopic examination of the routine tissue sections or smears or on the patient's pertinent medical history. Document in your report the reason each special procedure was ordered as well as the medical conclusion you reached in respect of it; for example:

Restrict standing orders for special stains and other ancillary procedures to clinical situations of unquestioned prudence vis-à-vis generally accepted practice standards.

Final Diagnosis: Gastric biopsy showing chronic gastritis with mild atrophy and intestinal metaplasia, suggestive of autoimmune gastritis (see comment).

Comment: Gastrin immunohistochemical stain confirms the presence of antral and body-type mucosa. Within the body-type mucosa, synaptophysin IHC stain highlights linear and nodular neuroendocrine hyperplasia, supporting the above diagnosis.

- Monitor the coverage policy bulletins and pronouncements of your regional Medicare Part B administrative contractor and the major private insurers in your area. Communicate directly with their medical directors if you notice something amiss in a policy or coverage determination, be that an oversight, a misstatement, or an improper or incomplete interpretation. Payers make mistakes, and the mistakes won't get corrected unless someone brings them to the medical director's attention.
- Encourage your state pathology professional organization to form an active payer-relations committee if one isn't already in place, and make time to participate on that committee. State societies have proven their value time and again over the years in heading off or reforming ill-conceived local payer medical coverage policies, and the need for aggressive, grassroots action, including in the member education arena, will increase in the next five years.

Additional tips for audit-proofing your medical reports and defending the medical necessity of your work can be found at (1) Padget, D. "How to Audit-Proof Your Medical Reports: Tips for Pathologists," *G-2 Compliance Report*, V:9, October 2003, and (2) Padget, D. "Tips for Minimizing Pathology & Lab Charge Denials," *G-2 Compliance Report*, VII:7, August 2005. (Despite the age of the two articles, the principles and suggestions are still valid today, but you must ignore any CPT code changes that have since occurred.) Also consult the American Pathology Foundation's *Pathology Service Coding Handbook*.

Dennis L. Padget, MBA, CPA, FHFMA, can be reached at DennisPadget@embarqmail.com; *502-693-5462.*

Qui Tam Complaint Alleges Duplicate Testing, *from page 1*

samples were collected or samples were split in order to have enough specimen to conduct both sets of tests.

Defendants in the case are Quest Diagnostics Inc., Quest Diagnostics Clinical Laboratories Inc., Quest Diagnostics Inc. of Nevada, Quest Diagnostics Nichols Institute, Laboratory Corporation of America Holdings, and Laboratory Corporation of America.

Allegations

The whistleblower alleges that defendants have knowingly submitted, and continue to submit, false claims for the unnecessary duplicate tests ordered by different doctors instead of taking a more reasonable approach such as performing the tests once and sending copies to each of the ordering physicians. The complaint gives specific details of examples and includes documentation of these specific events attached to the complaint as exhibits.

Martinez says she complained about the practice and questioned other phlebotomists about it but was told to ask her supervisor. When she asked her supervisor, Martinez alleges that she was told to "listen more and back up everybody."

Martinez took it on herself to try to confirm her suspicions about the practice and to confirm that duplicate claims were actually being filed by asking other employees. She was told by other phlebotomists who work at other Quest patient service centers that it was done at their facilities also.

The billing was confirmed for Martinez by an employee in the billing department who told her that each of the tests had unique accession numbers and was billed separately. LabCorp was brought into the suit because one of the phlebotomists who used to work there told Martinez that LabCorp had the same policy and was doing the same thing that Quest was doing.

The counts and potential damages listed in the complaint include:

The whistleblower alleges that defendants have knowingly submitted, and continue to submit, false claims for the unnecessary duplicate tests ordered by different doctors instead of taking a more reasonable approach such as performing the tests once and sending copies to each of the ordering physicians.

- Defendants have knowingly presented or caused to be presented false claims under federal FCA laws and are subject to treble damages and penalties under the FCA;
- Defendants knowingly made false statements, created false records, and omitted material facts in order to get claims paid that otherwise would not have been eligible for payment;
- Defendants did not remit overpayments even though they were aware that the claims were in violation of Medicare billing rules and the FCA; and
- The complaint repeats each of the above counts except that they are in violation of California's False Claims Act and requests the penalties prescribed under that law.

The plaintiff is also seeking attorneys' fees and court costs.

How Whistleblower Cases Work

A whistleblower case is filed under seal to allow government prosecutors an opportunity to evaluate the lawsuit to determine if the case involves matters the government is already investigating or whether it is in the best interest of the government to intervene in the case. Often, the government may choose to reveal the suit to the defendant to allow an opportunity for a response and to cooperate with the government investigation. The law allows 60 days for this process, but there

are provisions for seeking extensions of that time frame if more time is needed to properly evaluate the case and to seek documents to facilitate that decision.

In this case, government prosecutors have requested five six-month extensions of the date they must decide to intervene in the case while they conduct their discovery to help make the intervention decision. Judge Kimberly J. Mueller accommodated the first four requests because the supporting statements made by Assistant U.S. Attorney Catherine J. Swann showed enough progress to reasonably expect that more discovery was necessary and appropriate.

However, in her comments when approving the fourth extension, Mueller warned prosecutors that the next request must include, "a detailed explanation with dates and specific timelines, which will be subject to this court's scrutiny. The explanation should detail what prejudice will result if the seal is lifted, and why the United States needs to evaluate defendants' respective positions before it can decide whether to intervene." In her order denying the extension and unsealing the case, Mueller said the government did not meet her criteria.

What the Government Has Done Behind the Sealed Case

During the extensions, the government has been gathering documents and conducting audits on samples of claims from the Medicare and Medicaid files. It has involved a Zone Program Integrity Contractor and the Medicare Administrative Contractor in these audits and used their expertise to evaluate samples of claims to try to substantiate the allegations. The government has also used the claims audits to develop a settlement model and it has revealed the suit to the defendants, as was allowed by the court, in an effort to begin negotiating an informal settlement agreement.

Conclusion

The case can go either of two ways. The defendants can settle with the government, admitting no liability and be done with it, or they can choose to take the case to court. Considering the potential magnitude of these allegations, the defendants may choose to fight it out in court if they have a reasonable expectation of winning.

There are circumstances where the described billing practice may be justified if billed correctly using appropriate modifiers, but these exceptions are limited. There is also the possibility that the relator has not been thorough in her limited investigation and she may be wrong about what she believes. We will not know for sure until the case settles or goes to court, but it is certainly a case that must be watched by the laboratory compliance community.

Takeaway: Labs must be cautious about performing duplicate testing on patient specimens when ordered by different physicians. G2

More Trouble for Embattled Virginia Laboratory

Cigna Corp. is suing Health Diagnostic Laboratory Inc. (HDL) of Richmond, Va., for $84 million, alleging that the laboratory operated a scheme to circumvent safeguards against unreasonable and excessive charges by forgiving copays, coinsurance, and deductibles.

In a lawsuit filed on Oct. 15, Connecticut General Life Insurance Co. and Cigna Health and Life Insurance Co. say HDL unlawfully obtained at least $84 million under the scheme.

HDL is currently under investigation by the federal government for allegedly paying kickbacks to physicians in the form of specimen collection payments to garner referrals, among other issues. HDL's CEO, Tonya Mallory has resigned, reportedly

to help her brother open a new business. Both the *Wall Street Journal* and *Forbes* have published stories alleging other misconduct by the lab.

Forgiving Patient Responsibility Charges

Cigna is a managed care company and one of its responsibilities is to control health care costs. It accomplishes this by making the members of its plans responsible for paying part of the cost of their health care though copays and coinsurance. It also provides incentives to its members if they use in-network providers by charging lower copays than they would allow for an out-of-network provider. These in-network providers generally charge Cigna a lower rate. In its lawsuit, Cigna alleges that HDL, an out-of-network provider, undermines these penalties and incentives by promising Cigna members that they will not be charged any out-of-pocket costs.

The lawsuit cites several court cases and a government fraud alert intended to demonstrate that the HDL fee-forgiving business model is illegal and runs contrary to the whole notion of managed care.

The lawsuit also alleges other unlawful conduct:

- HDL encourages health care providers to order unnecessary tests through the use of large panels of tests regardless of whether all of the tests are necessary and then explains that patients will not complain because HDL will never bill them for the patient responsibility;
- HDL has paid providers in exchange for referrals; and
- By paying fees to providers, HDL has caused them to violate their agreements with Cigna which require them to refer to in-network providers only.

In addition to the $84 million, Cigna also is seeking:

- A declaration that the products and services provided by HDL under its fee-forgiving program do not constitute covered services;
- Return of all monies paid to HDL by Cigna;
- Monetary damages;
- Exemplary and punitive damages;
- Pre- and post-judgment interest; and
- Reasonable and necessary attorneys' fees and court costs.

What Does This Mean for Other Labs

For years there has been a debate concerning the legality of out-of-network labs providing services as if they were in-network providers and not charging copays and coinsurance to patients. These arguments generally concern how this practice may be viewed from the Medicare perspective of anti-kickback laws. This case sheds a whole new light on that business model. If a laboratory is operating such a program, it should thoroughly review this case to determine if its practices violate state-based insurance fraud and business fraud laws and regulations.

Takeaway: This case may be the first of many civil cases by private insurance companies involving laboratories that operate fee-forgiveness programs or inducements to patients.

Compliance Corner

Can a laboratory discount patient prices in circumstances other than financial hardship?

This is a timely question because of the recent efforts by the government to make health care pricing transparent by publishing prices different providers charge for the same service. As patients become more involved in their own health care, the subject of patient discounting is likely to come up more in the future than in the past. When a laboratory considers discounting patient pricing for any reason, it must keep in mind the circumstances surrounding the request. In any case, the laboratory should never discount its patient pricing to the point where it would not be willing to accept that price for all of its patient. Further, the laboratory should never discount its prices in exchange for referrals.

News-At-A-Glance

HEALTH PLAN TO PAY $500 MILLION FOR ROLE IN HEPATITIS C OUTBREAK: Health Plan of Nevada and Sierra Health Services, both part of the UnitedHealth group, will pay $500 million in punitive damages for their role in a 2007 hepatitis C outbreak. Depak Desai, M.D., a doctor with the health maintenance organization, infected two patients with hepatitis C by not sterilizing equipment and reusing anesthetic vials. The award is the largest verdict this year so far and comes on the heels of an award of $24 million in compensatory damages paid to the two patients, who were contaminated during a colonoscopy procedure performed by Desai. The trial involving the two patients is the first of what could be many related to a 2007 hepatitis outbreak that required Nevada officials to notify 50,000 patients that they may have contracted the disease as a result of Desai's mistakes. "The number announced today has no grounding whatsoever in reality," said Tyler Mason, a UnitedHealth spokesman, in an e-mailed statement. "It represents fantasy damages, not punitive damages." Attorneys for Brunson and Meyer originally asked for $2.5 billion, which they allege is 15 percent of UnitedHealth's profits over a 10-year period. The insurer will appeal the jury's findings in the case.

OPEN PAYMENTS DATA AVAILABLE DECEMBER 31: Ready or not, the Centers for Medicare and Medicaid Services (CMS) is giving providers until Oct. 31 to correct errors in their open payments database before publication on Dec. 31. Laboratories were not required to provide data for the database, but the information contained there may prove useful to laboratories in gaining information about existing and potential clients. The CMS Web site at *www.CMS.gov/openpayments* includes a variety of tools to search and view the data and allows for a download of the data sets. According to a statement on the Web site, the publication of the data is required by the Social Security Act. It provides information about the financial relationships that doctors and hospitals have with device manufacturers concerning payments made to doctors for such things as research activities, gifts, speaker fees, meals, or travel. The site includes access to a factsheet and instructions on how to find information or search the database.

YONKERS CARDIOLOGIST SENTENCED TO THREE YEARS IN PRISON: In another case of physician misconduct, Rohan Wijetilka, 65, of Manhattan, N.Y., was convicted of health care fraud and sentenced to three years in prison, in addition to paying $2 million in forfeitures and restitution. Wijetilka not only committed fraud against government payers, he also committed fraud against other insurance providers. Wijetilka maintained a cardiology practice where he saw patients and performed diagnostic tests. He continued his illegal activities even after receiving written notice from the New York Department of Health's State Board for Professional Medical Conduct that he was under investigation. The board served Wijetilka with formal charges of professional misconduct, including alleged fraudulent billing. In addition to the charges of fraudulent billing mentioned above, he is also accused of filing false reports and failing to maintain adequate medical records. In order to attract new patients to his clinic, Wijetilka would prescribe controlled substances such as oxycodone to patients in exchange for them undergoing unnecessary diagnostic tests and other procedures.

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Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Christopher Young, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher

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