G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

Issue 13-11 • November 2013

Inside this issue

www.G2Intelligence.com

Swapping Discounts With Skilled Nursing Facilities Gets Lab in False Claims Trouble

Diagnostic Laboratories and Radiology Services will pay $17.5 million to settle allegations of paying kickbacks to skilled nursing facilities (SNF) in exchange for the referral of fee-for-service Medicare and Medicaid laboratory testing.

The settlement covered both the federal and California's False Claims Acts (FCAs) alleged violations. Any laboratory doing business with SNFs should read about this case and follow its progress because of the implications for those labs.

Diagnostic Labs, formerly Kan-Di-Ki Inc., one of the largest providers of laboratory and radiology services for nursing homes in California, took advantage of different payment systems in SNFs for patients in a Part A (inpatient) or Part B (outpatient) stay. The system, known as consolidated billing (enacted as part of the Balanced Budget Act of 1997) said that SNFs should be paid under a consolidated billing

Continued on page 2

Lab Institute Addresses Key Regulatory, Reimbursement Topics for Clinical Laboratories

Attendees at G2 Intelligence's 31st annual Lab Institute (Oct. 16-18, Arlington, Va.) gleaned insight on issues vital to their survival as they navigate the rough waters of government regulations and ever-increasing scrutiny of federal and state agencies while trying to grow their business in a highly competitive marketplace.

Among the issues discussed during a session on regulatory compliance were Clinical Laboratory Improvement Amendments (CLIA) proficiency testing issues, Stark and anti-kickback developments, pricing issues, and increasing qui tam actions.

S. Craig Holden, an attorney with Ober | Kaler (Baltimore), advised labs to be mindful of the rules governing referrals of proficiency testing (PT) samples to other labs, which is a violation of CLIA. The issue became critical last year when an accidental referral of a PT sample nearly cost a prominent university laboratory its CLIA license because, according to the Centers for Medicare and Medicaid Services (CMS), it has no choice but to revoke certification if a referral occurs because regulations do not allow any flexibility.

Continued on page 9

Swapping Discounts With Skilled Nursing Facilities, *from page 1*

arrangement, essentially a bundled payment, for nearly all services including laboratory testing for Part A beneficiaries and fee-for-service for SNF patients in a Part B stay.

The Part A patients were paid a set fee by Medicare for all of the included services, which allowed the SNF to negotiate, if it could, discounted rates from other providers like labs and increase its profits on Part A beneficiaries. The discounts they received, if any, should have been shared with the government.

According to a report in the California Watch (*http://californiawatch.org/*), Diagnostic Lab provided discounts as steep as 70 percent off its regular fees, or capitation rates low as $1 per patient per day for Part A patients, as long as the SNF referred its Part B lab and radiology services to Diagnostic. The alleged scheme started in March 2005, and the case was filed in 2010 and unsealed in November 2011.

Diagnostic stated in court documents that the whistleblowers made the leap that giving discounts equals an intent to induce referrals and that there is no factual evidence that tied any specific referral to any remuneration. In a *Watch* news article, Zack Buck, a visiting assistant professor at Seton Hall Law School who teaches a class on health care fraud and abuse, said, "Diagnostic may have some right to offer discounts to their clients. The question is, where do you cross the line and it becomes an inducement to refer business? That's what's sticky."

The settlement has been reported at $19.4 million and $17.5 million. The difference is the $1.9 million paid to the attorneys of the two whistleblowers in the case. Former employees, salesmen Jon Pasqua and Jeff Hauser, said they tried to report the questionable practices to supervisors but were ignored. They will receive $3,755,500 to share as their part of the recovered money.

Practical View

These kinds of arrangements are not all that uncommon in the laboratory industry. Laboratories that do business with SNFs face complex pricing and service challenges in a marketplace where resources are already tight and profit margins are already thin, if they exist at all. Labs and nursing homes may even be part of the same system in some cases. Competition for the more profitable Part B business can lead to aggressive arrangements or contracts where the involved facilities both receive some benefit but, because the lab is receiving the higher-paying referrals directly, it becomes the entity at fault under the anti-kickback statute and FCA.

Tips for Labs

Laboratories doing business with nursing homes should have contracts in place that spell out the specifics of the arrangements between the parties. If there are provisions that include discounts for the Part A beneficiaries, make certain that the contract clearly states that the discounts are not dependent on the referral of Part B services.

Besides the contract, the laboratory should be able to show that the discount offered on the Part A business is commercially feasible and would be profitable even without any Part B referrals.

Also, the regulations governing this relationship do not require the SNF to defer the Part B billing to the lab providing services. It could contract in an "under arrangements" manner for the services and bill them directly to Medicare. The lab could discount its services equally for both sets of business and reduce its risk since there is no "swapping" of discounts. Other things to consider when doing business with SNFs are that these kinds of clients tend to have high service needs for

services that are, for the most part, not reimbursed and they have high turnover of employees requiring repeated training to maintain compliance with the billing needs of the laboratory.

Takeaway: It is likely that, because of this case, laboratories doing business with nursing homes may face increased scrutiny and whistleblower suits and should examine their arrangements with their SNF clients to ensure compliance with anti-kickback statute provisions.

Vendor's Failure to Complete Quality Reporting Forms Costs Home Health Agency a 2 Percent Decrease in Payment

CMK Home Health Agency Inc. of Illinois will receive a 2 percent reduction in its 2012 market basket payment because a Centers for Medicare and Medicaid Services (CMS)-approved survey vendor did not timely submit quality reporting survey data required by the Deficit Reduction Act (DRA) of 2005.

A Provider Reimbursement Review Board (PRRB) decision issued Aug. 22 concluded that it is the home health agency (HHA) provider's responsibility to monitor its chosen vendor to ensure data is submitted timely without problems. The board said it has no flexibility to waive the penalty regardless of circumstances because there is no statutory or regulatory allowance for relief.

Background

Between 2005 and November 2009, quality-reporting requirements under the DRA have expanded to include additional quality measures and certain forms, and survey tools have been created by CMS to replace older Outcome and Assessment Set forms, referred to as OASIS. In 2009, providers were required to begin reporting quality measures surrounding patient experiences with home health services and through a new survey tool referred to as Consumer Assessment of Healthcare Providers and Systems (CAHPS).

After an extensive period of CMS training vendors to administer the surveys, HHAs would contract with these CMS-approved vendors for the actual reporting of the data.

On Sept. 16, 2011, the Medicare Administrative Contractor (MAC) for CMK informed the HHA that it would receive the reduction in reimbursements because it had not complied with data reporting requirements. It had not submitted the CAHPS data in a timely manner. CMK requested a redetermination and was denied. CMK appealed, leading to the PRRB decision.

Should Providers Be Punished for a Government-Approved Vendor's Error?

CMK argued that it should not be punished because it had complied with the regulations in choosing, designating, and authorizing a CMS-approved vendor to submit the data and that it had submitted the necessary patient records and other data to the vendor in a timely fashion so that it could meet reporting requirements on behalf of CMK. The vendor failed to meet its obligation.

CMK also provided an open letter from the vendor in which "the vendor acknowledged that it was solely at fault for the Provider not meeting the quality data submission requirements that were linked to the CY 2012 annual payment update for the home health prospective payment system."

Ultimately, the PRRB noted that the home health CAHPS guidelines and protocols manual required CMS to ensure compliance with privacy rules but not to ensure vendor performance on its contracts with individual providers. In the written de-

cision, the MAC representative argued that CMK is seeking relief from the wrong party—it should seek relief instead from the contracted vendor that did not meet its contractual obligations.

The PRRB said it does not have authority to grant equitable relief to the HHA. The good news is that the 2 percent reduction applies only during 2012. CMK has an opportunity to correct the problem for the next reporting period.

Takeaway: Regardless of the issue, whether it is a reduction in payment or an allegation of fraud and abuse, the laboratory or provider is ultimately responsible to ensure compliance with laws, rules, and regulations by its contracted vendors or agents.

Appeals of Recovery Auditors' Decisions Drive Increase In Part A First-Level Claims Appeals

Recovery audit contractor (RAC)-related first-level appeals or redeterminations accounted for 39 percent of all appealed first-level Part A claims in 2012, but 80 percent of all redeterminations were for Part B claims, according to an October 2013 Office of Inspector General (OIG) report.

Overall, contractors processed 2.9 million redeterminations involving 3.7 million claims in 2012, a 33 percent increase over 2008. Another notable item in the report, "The First Level of the Medicare Appeals Process, 2008-2012: Volume, Outcomes, and Timeliness (OEI-01-12-00150)," is that the number of claims processed increased by only 3 percent while the number of redetermination requests increased by 33 percent. This could be attributed to an overall increase in claims denials and audits by the Centers for Medicare and Medicaid Services (CMS) contractors like RACs, Zone Program Integrity Contractors, and the Comprehensive Error Rate Testing program. CMS maintains the Medicare Appeals System, which is supposed to support the first four levels of the appeals system but does not currently track redeterminations.

Favorable Redeterminations and Time Frames

It is important to note that appellate favorable decisions in redeterminations decreased in Part A claims from 50 percent in 2008 to 24 percent in 2012, while Part B favorable decisions maintained about a 50 percent rate with the exception of durable medical equipment redeterminations, which changed from 51 percent to 38 percent during the same period.

The OIG said contractors were able to meet required time frames for completing redeterminations but did not meet required time frames for transferring files to the second level of appeals. The report indicated that this was a result of the increased unfavorable redetermination decisions.

It is important for compliance officers to pay attention to these reports because of the increased scrutiny of claims submitted by providers and the increased activities of Medicare subcontractor audit programs. Understanding the appeals process helps compliance officers make better decisions about what to appeal and how long the process will take from start to finish. This report indicates that carefully structured appeals and redetermination requests have a pretty good rate of success and provide important information the laboratory can use to avoid claims denials in the future.

Takeaway: Claims denials and the resulting appeals are on the increase, and providers who understand the appeals process will likely have a higher success rate than those who do not.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Clinical Laboratories Face Expanded Exposure To False Claims and Overpayment Demands

Timothy Blanchard, Esq., and Margaret Manning, Esq., are partners with the law firm of Blanchard Manning (Orcas, Wash.).

Recently, amendments to the Medicare statute, evolving False Claims Act (FCA) jurisprudence, and subtle changes in Medicare regulatory requirements and interpretations have expanded the potential for exposure of clinical laboratories and other providers to false claims and allegations and overpayment demands.

These changes alone warrant greater attention to regulatory compliance, but there is also a worrying trend in enforcement—compliance issues that regulators have historically addressed through provider "corrective action plans" or "plans of correction" are increasingly being used as bases for the position that the claims for the services provided while the compliance issue was pending are not payable by the Medicare program and constitute overpayments that must be refunded or, worse still, treated as false claims, with attendant draconian penalties.

By now most providers are aware of the mandatory "voluntary" refund requirement adopted in the Affordable Care Act, which increases the burden on providers to find, quantify, and refund Medicare overpayments (see 42 U.S.C. §§1320a-7k(d) and 1320a-7a(a)(10)).

Proper identification of overpayments requires recognizing when a lapse of compliance with regulatory requirements triggers an overpayment and when a deficiency, while requiring corrective action, does not render otherwise proper claims improperly paid.

Since at least 2001, providers have relied upon the series of cases, beginning with the decision in *U.S. ex rel. Mikes v. Straus*, 247 F.3d 687 (2nd Cir. 2001), that recognized the distinction between "conditions of participation" (COPs) and "conditions of payment" within the context of the FCA. The developing FCA case law in question—discussed further below—has blurred or outright rejected the well-established distinction between conditions of participation and conditions of payment, with the result that services furnished during any regulatory compliance misstep is a candidate for a false claims lawsuit predicate.

The Centers for Medicare and Medicaid Services (CMS)—which created the distinction between conditions of participation and conditions of payment and maintained it for decades—has taken a policy turn to expand the scope and impact of conditions of payment to include regulatory requirements that long were considered conditions of participation by revising the general certification included in provider enrollment applications and directly amending longstanding regulations. The result of these changes is to disqualify payments and generate overpayment liability based on regulatory lapses that would previously have been corrected without denying payment for services that were provided. Obviously, it is important to comply with COPs; failure to comply with COPs can result in termination of provider agreements, exclusion from government health care programs, and the imposition of onerous corrective action plans and integrity agreements.

Proper identification of overpayments requires recognizing when a lapse of compliance with regulatory requirements triggers an overpayment and when a deficiency, while requiring corrective action, does not render otherwise proper claims improperly paid. Decisions in the *Mikes* line of cases recognize that false claims liability could not properly be premised on certification of compliance with rules that established conditions for participation in the Medicare program rather than preconditions for receiving reimbursement. In *Mikes*, the allegations were that failure to adhere to certain professional society guidelines in furnishing services was a failure to provide services of quality meeting recognized standards of health care. The *Mikes* court concluded that however it interpreted the professional society guidelines, the quality standard was a condition of participation, not a condition of receiving Medicare payment.

Conditions of Participation

COPs are health and safety standards that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. A provider's satisfaction of these fundamental requirements is determined by CMS regional offices based on the state survey agency recommendations.

In the case of clinical laboratory services, these COP conditions are found in 42 C.F.R. Part 493 and include the Clinical Laboratory Improvement Amendments (CLIA) certification and applicable state licensure. These rules, also referred to as "conditions for coverage," establish the procedures for monitoring compliance with these participation requirements, corrective action procedures, and a range of potential sanctions, including revocation of CLIA licensure and termination of Medicare billing privileges.

Enrollment Certification

The current CMS 855B provider enrollment application, which is required for laboratories and other noninstitutional provider types, includes the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. **I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions** (including, but not limited to, the Federal antikickback statute and the Stark law), **and on the supplier's compliance with all applicable conditions of participation** in Medicare (*emphasis added*).

In addition to COPs promulgated as regulations, the Medicare statute itself includes several general COPs, including an obligation to provide services economically, only when medically necessary, of a quality that meets professionally recognized standards, and only when supported by evidence of medical necessity and quality as required by a quality improvement organization. Providers can be excluded from program participation if they are found to be unable or unwilling to comply with these fundamental requirements.

When a provider is found to have deficiencies in its compliance with the COPs, the provider is given the opportunity to correct the deficiencies (through a corrective action plan or plan of correction before further action is taken to terminate the provider's participation in government programs), unless the deficiencies are found to present "immediate jeopardy" to health and safety. Notwithstanding the certification in the CMS 855 Forms, according to CMS Program Integrity Manual §3.1A, unless and until a provider's participation is terminated, deficiencies in compliance with COPs are not to be considered a basis for denial of payment for the services provided. This ap-

proach recognizes that even a well-managed provider may, from time to time, fail to maintain perfect compliance with the participation requirements. The provider enrollment certification should be interpreted in the context of these specific Medicare program instructions.

Since these rules allow a provider to continue providing services as long as a provider retains its provider agreement (colloquially, "remains a currently certified Medicare provider") and has not been decertified or otherwise terminated from participation, lapses in compliance with COPs that are subject to correction would not influence the government's decision to pay claims submitted by the provider that otherwise satisfy applicable conditions of payment.

Conditions of Payment

By contrast, conditions of payment are requirements governing whether payment is to be made for particular items and services claims by a provider. These statutory and regulatory provisions specify that Medicare payment shall not be made unless the condition is satisfied. These provisions include specific exclusions from coverage, documentation requirements, and the Stark self-referral prohibition. For clinical laboratory services, conditions of payment include 42 C.F.R. §§410.32(a) and (d) and 405.515, and that the services be reasonable and necessary, as reflected in applicable national coverage determinations and applicable local coverage determinations. Certain other statutory and regulatory requirements, including some COP provisions, may become conditions of payment based on required provider certifications or terms of provider agreements. Some regulatory requirements, such a medical necessity, are both COPs and conditions of payment. In other words, failure to satisfy the requirement subjects a provider not only to denied payments but potential termination of its provider agreement of billing privileges.

The Hutcheson decision can be read to create an untenable situation for providers because it essentially finds that the existence of a kickback anywhere in the chain of relationships upstream from the provision of items or services to a Medicare patient makes claims for those items or services not payable by Medicare—regardless of whether the billing provider knew, or should have known, about the kickback.

At least for now, one U.S. Court of Appeals has rejected the distinction and the *Mikes* rationale. *U.S. ex rel. Hutcheson v. Blackstone*, which can perhaps be viewed as a case of bad facts making bad law, appears to ignore the structure and internal logic of the Medicare statute in favor of a simplistic rule that is inconsistent with the statutory COP and condition of payment scheme created by Congress and implemented by CMS. The *Hutcheson* court rejected the district court decision, which had followed *Mikes* and concluded that a condition of payment could not be hidden in the enrollment form certification but rather must be expressly stated in applicable statutes and regulations. In *Hutcheson*, the relator alleged that Blackstone paid kickbacks to doctors across the country so they would use its products in certain spinal surgeries. In other words, the case did not involve temporary lapses of perfect compliance with all regulatory requirements.

Is Compliance With the Anti-Kickback Statute a Condition of Payment?

It is true that the 855B certification expressly refers to compliance with the anti-kickback statute (AKS). It is also true that effective March 23, 2010, under 42 U.S.C. §1320a-7b(g), "a claim that includes items or services resulting from a violation of [AKS] constitutes a false or fraudulent claim for purposes [of the False Claims Act]." Does that mean that the AKS is a condition of payment or just a statutorily designated false claim predicate?

The *Hutcheson* decision can be read to create an untenable situation for providers because it essentially finds that the existence of a kickback anywhere in the chain of relationships upstream from the provision of items or services to a Medicare patient makes claims for those items or services not payable by Medicare—regardless of whether the billing provider knew, or should have known, about the kickback. This holding, if followed by other courts, may make it impossible for any provider to avoid potentially ruinous overpayment and FCA liability because it is impossible to determine whether every indirect upstream relationship was free of a violation of the AKS.

Faced with potential liability based on this line of reasoning, providers should do what they can to demonstrate that they behaved reasonably under the circumstances to avoid entering into arrangements that include improper arrangements somewhere upstream. This will require a broader focus on due diligence in transactions and may warrant stronger representations and warranties up the line.

In *Hutcheson*, the allegations were not that the provider violated the anti-kickback statute, but that its supplier paid kickbacks to physicians who performed services at the provider's facility, using the supplier's products. The *Hutcheson* court concluded that if the government had known about the kickbacks upstream from the provider it would not have paid the provider's claims. Although that case was not about overpayments to the provider, if its rationale is correct, the provider has received overpayments because Medicare would not have paid had it known about the alleged kickbacks. This conclusion is questionable, but opens an expansive range of potential exposure for providers.

Consider the following scenario: A provider reviewing the latest *G2 Compliance Advisor* discovers, years after its claims were filed and paid, that its supplier or ordering doctor has been convicted of violating the anti-kickback statute, and that the items or services that the provider long ago billed were the subject of a kickback somewhere upstream from the provider. Based on the *Hutcheson* rationale, the provider would have become aware that it had received Medicare overpayments for those services and have an obligation to report and repay them to avoid FCA liability.

Faced with potential liability based on this line of reasoning, providers should do what they can to demonstrate that they behaved reasonably under the circumstances to avoid entering into arrangements that include improper arrangements somewhere upstream. This will require a broader focus on due diligence in transactions and may warrant stronger representations and warranties up the line.

Furthermore, providers should continue to monitor available information regarding entities with which they have had relationships because frequently fraud and abuse allegations come to light only years down the road. As soon as issues about an entity from a past relationship come to light, providers should evaluate whether they have an obligation based on the new information to consider whether they may have received any improper Medicare payments as a result of prior behavior of an entity somewhere upstream. A provider should document its analysis regarding these matters to demonstrate the functioning of its compliance program and seek qualified legal advice when necessary.

Takeaway: Although there seems to be little that individual providers can do to stem these challenging trends, providers should take steps to improve their ability to defend themselves against significant evolving threats involving conditions of participation and conditions of payment.

Timothy Blachard, Esq., can be reached at tim@blanchardmanning.com, *360-376-2292. Margaret Manning, Esq., can be reached at* peg@blanchardmanning.com, *360-376-4465.*

Lab Institute Addresses Key Regulatory, *from page 1*

In response to the incident, the laboratory community lobbied Congress to change the CLIA regulations to allow CMS some flexibility in sanctions imposed. The result is the Taking Essential Steps for Testing Act of 2012, which permits, but no longer requires, revocation of a CLIA certificate for PT sample referrals in certain cases and allows for intermediate sanction in place of the two-year CLIA licensure prohibition imposed on a lab owner or operator.

Holden also addressed what he sees as a likely change to the Stark regulations concerning the in-office ancillary services exception that allows physicians to refer diagnostic tests, including radiology and anatomic pathology tests, to a testing facility in their own office. Lawmakers introduced the Promoting Integrity in Medicare Act of 2013 (H.R. 2914) after a Government Accountability Office report showed that physicians who changed to a self-referral model in which they received a financial benefit significantly increased the number of referrals for those same services as they did before they received any financial benefit.

The legislation would amend the in-office ancillary services exception to exclude anatomic pathology services, defined to include the professional and technical components of surgical pathology; cytopathology; certain hematology, blood banking, and pathology consultation; and clinical laboratory interpretation services paid under the Medicare Physician Fee Schedule. If the law passes, laboratories that are providing some or all of the technical components for these tests would have to unwind those relationships but may see an increased volume of referrals for these tests and services.

Also under Stark and the anti-kickback statute, CMS has proposed to extend the exception and safe harbor for donated electronic health records (EHRs) until December 2016. This proposal would exclude laboratories, among others, as permitted donors of EHRs. This is considered good news for laboratories because of the expense involved with the donation of EHR software under these exceptions as they currently exist.

The legislation would amend the in-office ancillary services exception to exclude anatomic pathology services, defined to include the professional and technical components of surgical pathology, cytopathology, certain hematology, blood banking, pathology consultation, and clinical laboratory interpretation services paid under the Medicare Physician Fee Schedule.

Holden also announced some changes that may be forthcoming concerning in-office phlebotomists (IOPs). Labs are permitted to place a phlebotomist in the office of a physician who refers tests to the lab as long as the phlebotomist does not perform any services that would normally be provided by office personnel. The phlebomist can perform blood collection and processing only. An unresolved issue with IOPs is whether the lab can legally pay rent for the space occupied by the phlebotomist. Holden believes that clarification on that issue will be provided soon but labs would still have to adhere to any state laws governing IOPs.

Pricing Issues

Holden reviewed a variety of pricing and discounting issues for laboratories and offered this advice for laboratories: Never tie discounts on laboratory services billed to the physician office, defined as client pricing, to the referral of Medicare or Medicaid tests; ensure that client bill pricing is profitable on a stand-alone basis if no other referrals are received from the client; don't discount below the cost to provide the services; and be aware of pricing patterns across all clients so that similar clients receive comparable pricing. Certain state laws may prohibit discounting lab testing or may require that the

state Medicaid program receive the lowest price offered to any similar client or third-party payer, noted Holden, who advised labs to be aware of the laws in their states.

Holden also noted that the expansion of the False Claims Act (FCA) under the Fraud and Enforcement and Recovery Act of 2009 and the Accountable Care Act creates a new FCA exposure for labs. He also pointed out that mandatory compliance programs will precipitate an increase in self-reporting problems and that smaller, less sophisticated laboratories will be disproportionately impacted.

Holden's presentation should help raise awareness of where laboratory compliance officers and administrators should focus their compliance resources in the coming 12 to 24 months.

Takeaway: Laws and regulations that affect laboratories are constantly evolving, so it is critical that compliance officers ensure they stay abreast of these changes by attending programs like Lab Institute.

District Court's Judgment May Exceed Community Hospital's Annual Revenue

An Oct. 3 judgment against Tuomey Health Care Systems (Sumter, S.C.) of $237 million for alleged violations of the physician self-referral laws, commonly referred to as the Stark laws, may exceed the hospital's annual revenues—estimated at $200 million in 2011.

The Tuomey case has been ongoing since a whistleblower complaint was filed in 2005 by an orthopedic surgeon, Michael Drakeford, M.D., who Tuomey tried to hire as a part-time physician. The complaint alleged that Tuomey entered into compensation arrangements with physicians that exceeded fair market value, were not commercially reasonable, and took into account the value and volume of referrals to Tuomey.

The complicated case revolved around the hospital attempting to prevent local physicians from performing surgeries and other procedures at competing surgical centers by entering into the suspect arrangements with referring physicians. Tuomey had previously lost two jury trial cases on the same complaint and at one time faced a lower fine of $39 million, but that was before the Department of Justice filed a motion with the U.S. District Court of South Carolina requesting the additional fines and penalties based on FCA calculations that take into account treble damages and a $5,500 to $11,000 per claim penalty.

The complicated case revolved around the hospital attempting to prevent local physicians from performing surgeries and other procedures at competing surgical centers by entering into the suspect arrangements with referring physicians.

According to various documents, including court documents, Tuomey had received the advice of counsel and had received a favorable opinion from a compensation expert concerning the compensation package offered to the physician and its relationship to fair market value.

Tuomey raised a number of arguments before the court, all of which were denied, and Tuomey was ordered to pay the penalties. Tuomey has already stated that it will once again appeal the decision to the U.S. Court of Appeals for the Fourth Circuit. Many observers believe that a post-judgment settlement may be in the works given the size of the fine and Tuomey's possible inability to pay it.

Lessons for Laboratories

While Tuomey is not specifically a laboratory case, it nonetheless has lessons that labs can learn from studying its details, the most prominent of which is Tuomey's reliance on experts to no avail and its unwillingness to accept responsibility for its actions.

If a laboratory finds itself the subject of a whistleblower complaint or FCA action, it should make certain that all decisions concerning its actions from that time forward include the advice and counsel of objective, third-party legal experts and, if possible, limit the involvement of executive-level company officers who may have been party to the offending activity.

Takeaway: The government seems to be willing to aggressively prosecute Stark and other violations of laws and regulations under the FCA laws, which result in larger penalties and fines in addition to the actual damages incurred by the Medicare program.

FDA Details Oversight of Medical Applications On Smart Phones and Tablets

A new Food and Drug Administration (FDA) final guidance for manufacturers and developers of medical applications used on mobile platforms specifies that the agency will focus its oversight authority on the functionality of the software applications as opposed to the devices themselves.

The FDA will exercise enforcement discretion when it comes to mobile medical applications and focus on those applications that pose a greater risk to patients if they don't work as intended. FDA cites as an example, "The interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform."

While the guidance document is interesting to read, it is applicable only to those companies or individuals that actually develop these applications and would likely result in specific labeling and marketing activities. However, if a hospital or health system intends to create a mobile application customized for its own patients or providers, it should read the final guidance.

Takeaway: Mobile medical applications are becoming more integrated in the treatment and education of patients, and government oversight is inevitable. Compliance officers should be aware of any government regulations in this area and make determinations if there is any applicability to their laboratories.

G2 Compliance Corner

What date of service should be used for the interpretation of a diagnostic test (professional component or PC) when the PC is performed on a different day than the technical component?

The Centers for Medicare and Medicaid Services has not provided any guidance or a specific policy that addresses this, according to the Jurisdiction 6 Part B Medicare Administrative Contractor (MAC), National Government Services (NGS). In an item published on its Web site, NGS states the following: "There is no policy from the Centers for Medicare and Medicaid Services (CMS) that requires billing to be one way or the other. As a result, we will process claims for diagnostic testing procedures with a date of service that is reflective of the day in which either the professional component (i.e., interpretation) or the technical component of the diagnostic testing procedures was performed."

Laboratories should check with the MAC in their own jurisdiction to see if the contractor has published a policy on this topic. If there is no policy, laboratories should pick the date of service that best fits their processes until CMS issues a policy that provides specific information. At the same time, laboratories should not interpret this to address global billing issues. Global billing is a separate issue and must be addressed separately.

News-At-A-Glance

DON'T EXPECT TO GET A LEVEL-THREE APPEAL RESOLVED ANY TIME SOON: Most appeals that reach the third level in the appeals process may be delayed up to 28 months according to a notice posted by the Health and Human Services Office of Medical Hearings and Appeals (OMHA) on its Web site due to the overwhelming number of receipts and the existing workload within the agency. Appeals submitted after July 15 will be entered into the agency's case processing system and then held until they can be accommodated on an administrative law judge's (ALJ) docket for adjudication. An average 191 days are required for the appeal to be adjudicated by the ALJ. OMHA says that even though they are processing a record number of cases, they are receiving more than they can handle. This is likely due to the activities of Centers for Medicare and Medicaid Services auditing subcontractors and the resulting number of denials and demands for refunds. The number of appeals will correspondingly increase. Laboratories that have active appeals submitted after July 15 or are considering appeals now should take this delay into account and try to overturn denials in the redetermination and reconsideration part of the appeals process.

PATIENT FILES WHISTLEBLOWER SUIT COSTING A DEVICE MANUFACTURER $30 MILLION: A manufacturer of heart pacemakers continued to sell devices it knew were defective; hid the defects from patients, doctors, and the Food and Drug Administration; and misled physicians about the problems. Boston Scientific Corp. and its subsidiaries, Guidant LLC, Guidant Sales LLC, and Cardiac Pacemakers Inc. (Guidant), paid $30 million to settle allegations that it sold the defective devices from 2002 through 2005 that were implanted into patients, thereby risking their lives if the defective device failed. The devices, cardiac pacemakers, had a defect that could cause them to short-circuit when activated by an irregular heartbeat and render them ineffective. According to the government complaint, Guidant corrected the problem but rather than recall the defective devices it continued to sell them until its stock was depleted. The whistleblower, James Allen, a patient who received one of the defective devices, will get a $2.25 million share of the settlement.

VIRGINIA WHISTLEBLOWER SUIT AGAINST QUEST DIAGNOSTICS ENTERS NEW PHASE: In a motion to dismiss the whistleblower suit filed against it in Virginia, Quest Diagnostics argued that there is no statutory or regulatory provision requiring it to charge Medicaid its lowest fees and therefore the relator has failed to state a claim in sufficient detail. Quest says the Virginia Fraud Against Taxpayers Act (VFATA) and applicable regulations require laboratories to charge Medicaid the same price it charges the public. Quest says that is the list price it charges cash-paying customers. In a previous case a consulting company won a similar case under federal and New York false claims acts. In *United States ex rel. Associates Against Outlier Fraud v. Huron Consulting Group, Inc.*, the court ruled that the relator, "could not assert that Huron caused the submission of false charges because there was no rule, regulation or standard governing how hospitals should set their charges and how those charges must be related to hospital costs." Quest also argued that the relator's claim is based on conduct before Jan. 1, 2003, which is before the effective date of VFATA, which is not retroactive. The trial is scheduled for early 2014.

 G2 Compliance Advisor (ISSN 2330-5053) is published by G2 Intelligence, 24 Railroad Street, Keene, NH 03431-3744 USA. Tel: 800-531-1026 or +1-603-357-8101. Fax: +1-603-357-8111. Web site: www.G2Intelligence.com.

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