G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

Issue 13-10 • October 2013

Inside this issue

www.G2Intelligence.com

UPCOMING CONFERENCES

Lab Institute 2013:
It's Make or Break Time:
A Path Forward For Labs
Oct. 16-18, 2013
Hyatt Regency Crystal City
Arlington, Va.
www.labinstitute.com

Lab Leaders' Summit 2013
Dec. 9, 2013
Union League Club of New York
New York City
www.lableaderssummit.com

Laboratory and Diagnostic Investment Forum
Dec. 10, 2013
Union League Club of New York
New York City
www.labinvestmentforum.com

Mayo Cleared of False Claims Charges; Case Provides Valuable Insights for Compliance Officers

A recent whistleblower case involving the Mayo Clinic provides a unique perspective on what documentation is required to meet the conditions of payment for surgical pathology claims and seems to overturn a long-held understanding concerning reporting for certain surgical pathology billing codes.

Compliance officers (COs) can gain valuable insights into the complexity of billing and documentation requirements for surgical pathology services by reviewing the court document from the Sept. 4 Eighth Circuit ruling dismissing an alleged False Claims Act (FCA) violation by the Mayo Foundation. These insights may be valuable in decisions a CO may be faced with in the future.

In the case, the Eighth Circuit Court agreed with a lower court's decision when it held that Mayo did not violate the FCA by choosing not to create separate written reports for every permanent slide it prepared and

Continued on page 2

Employee Background Checks Must Be Done Correctly Or Your Lab Could Face Accusations of Discrimination

Not hiring individuals just because they said yes to a question on your organization's employment application about whether they have ever been convicted of a crime, or because a background check indicates some kind of criminal record, could get your laboratory in trouble with the Equal Employment Opportunity Commission (EEOC).

While performing criminal background checks on prospective employees may be a reasonable component of your hiring practices, if it results in a disparate impact on the basis of race, color, religion, sex, or national origin you may be violating the Civil Rights Act of 1964. An Aug. 9 memorandum opinion issued by the U.S. District Court of Maryland implies that an employer, such as a laboratory, must make certain that its hiring policies and the use of background checks incorporate safeguards that allow additional investigation if an otherwise qualified applicant has some kind of criminal record or credit history problem. In other words, don't automatically reject an applicant who has checked that box on your application that says "Have you ever been convicted of a crime?"

Continued on page 9

Mayo Cleared of False Claims Charges, *from page 1*

reviewed in each medical case it reported (*Ketroser et al. v. Mayo Foundation et al.*, case number 12-3206). The relators, David Ketroser, Gary Latz, Robert Smith, and Jason Kennedy, argued that Medicare regulations required a written report for every permanent slide a laboratory billed to Medicare. As a result, they alleged that Mayo "habitually submitted false claims for Medicare payment of surgical pathology services not provided."

However, the relators failed to provide even one example of a claim Mayo submitted to Medicare seeking payment for surgical pathology services. According to the court document, FCA liability attaches to the actual claim for payment, not to an underlying allegedly fraudulent activity. Without at least one claim to substantiate its FCA allegation, the court was frustrated and pointed to what it called a "well established principle" that a relator alleging a systematic practice of submitting false claims, as is the case here, must provide some representative example of the alleged fraudulent conduct.

No Separate Reports

Laboratories providing surgical pathology services covered under Current Procedural Terminology (CPT) codes 88300 though 88309 are well aware that a report issued by a pathologist on any particular medical case must account for all procedures done to reach a final diagnosis, including any special stains or additional slide reviews, if the laboratory is going to bill for those services. The relators in this case interpreted Medicare regulations to mean that a separate written report must be prepared for any permanent slides prepared, reviewed, and billed. They also believed that the conditions of payment for these CPT codes required these separate reports.

The court reviewed the CPT descriptions and the Medicare regulations and found that no such requirements existed. Instead, it found that CPT codes 88300 through 88309 required "reporting" but did not explicitly require separate written reports for each slide examined for a particular surgery. As support for its ruling, the court pointed to another category of pathology services, "clinical consultation services," which requires a "written narrative report" included in the patient's medical record. The court inferred from this comparison, and another comparison for diagnostic ultrasound that also specifically requires a written report, that if a written report was required for each slide, the CPT code book would specify that requirement.

Laboratories providing surgical pathology services covered under CPT codes 88300 though 88309 are well aware that a report issued by a pathologist must account for all procedures done to reach a final diagnosis, including any special stains or additional slide reviews, if the laboratory is going to bill for those services.

The court then turned to the relators' claim that it was a "standard industry practice" to generate such reports. The standard industry practice claim was based on a College of American Pathologists recommendation published in an article in the *Archives of Pathology & Laboratory Medicine* 1608 (October 2008) titled, "Reporting Guidelines for Clinical Laboratory Reports in Surgical Pathology." This does not constitute evidence that Medicare expects written reports for every permanent slide, the court said. The court pointed out that the authors were considering what must be done for each surgical case, not for each specimen in a case.

The relators desired "that the Medicare regulation and CPT Codebook be interpreted to require a separate written report for each permanent slide that is billed as a separate surgical pathology service. This fails to state an FCA claim of knowing fraud," said the court. The relators pleaded a claim of regulatory noncompliance, not a plausible claim of false or fraudulent claim submittals by Mayo.

Conclusions

Laboratory COs can learn several valuable lessons from this case, not the least of which is that we cannot rely on what we think the rules or regulations require; we must re-

search regulations and make objective analysis or interpretations of those regulations or Medicare payment rules. Documentation of what your lab has done or not done, and the reasons and basis for why a particular decision was made, are important documents and should remain part of the permanent record of policies and procedures.

Takeaway: Whistleblowers in a lawsuit against Mayo Clinic misinterpreted Medicare requirements regarding pathology billing. The case provides important lessons for compliance officers, who should always stay abreast of court rulings concerning compliance and billing. G2

Quest, LabCorp Subject of Whistleblower Suit in Virginia

Quest Diagnostics and Laboratory Corporation of America (LabCorp) find themselves once again targets of a recently unsealed whistleblower lawsuit filed by Chris Riedel, former CEO of Hunter Laboratories. The lawsuit, filed in 2007 but only recently unsealed, alleges that Quest and LabCorp violated the Virginia Fraud Against Taxpayers Act when it billed the state Medicaid program more than it should have under Virginia regulations that require labs to provide their services to Medicaid patients at the same rate billed to others.

This is not the first suit filed by Riedel against these two laboratories, the two largest laboratory companies in the United States. In 2005, Hunter and Riedel filed a similar suit under a California False Claims Act law alleging the labs violated the California law when it charged the Medi-Cal program more than it charged other purchasers of comparable services. In 2011, Quest settled for $241 million and LabCorp settled for $49.5 million.

The lawsuits allege violations of the anti-kickback statute because the labs offered deeply discounted pricing on private business in order to gain or "pull through" the referrals of Medicaid patients with higher reimbursements. This "swapping" of referrals for the benefit of both parties (i.e., Quest and LabCorp get the higher reimbursing pull-through referrals while the referring party gets deeply discounted private business that it can bill at a mark-up and make substantial profits) is often cited by the Health and Human Services Office of Inspector General as indicative that kickbacks are occurring. This arrangement puts competitors at a distinct disadvantage and forces them to either meet the discounted rates offered by Quest and LabCorp or lose referrals to the bigger labs.

The lawsuits allege violations of the anti-kickback statute because the labs offered deeply discounted pricing on private business in order to gain or "pull through" the referrals of Medicaid patients with higher reimbursements.

The lawsuit also alleges the use of false records or statements to obtain the Medicaid payments when Quest and LabCorp knowingly billed Virginia Medicaid in excess of their lowest charge to others for the same services. The suit includes explicit descriptions of the alleged scheme and provides tables that purportedly portray defendant's lowest fees compared to Virginia Medicaid fees.

Hero or Villain

In these lawsuits filed in 2007 by Hunter and Riedel, descriptions of what most knowledgeable lab insiders consider normal practice for the laboratory industry are laid out in explicit detail. Riedel may have chosen the Medicaid programs, specifically those in states where there is some kind of best price regulation, because he has a good chance to win the suits or gain settlements without going to court. In addition, the lawsuits draw attention to a practice the government and Medicare program have known about for decades but have yet to address. In any case, when the public reads news articles about these alleged fraud schemes, the end result is a negative portrayal of all labs.

One potential solution is a direct-bill law for all laboratory services requiring that only the lab that performed the test can bill for it for any payer, private or government. Such a bill would have the effect of leveling the playing field for all labs and lower the risk of these kinds of alleged schemes.

Takeaway: Labs must pay attention to the outcomes of lawsuits alleging illegal discounting and any government pronouncements resulting from them and should be prepared to adjust business models, especially if operating in a state with best price regulations.

Whistleblower Protected From Retaliation Even if Not an Employee

An individual does not need to be an employee of a company to file an anti-retaliation claim under the False Claims Act (FCA), according to a Florida judge.

Before May 2009, only individuals employed by a company had the right to file claims for retaliation under the FCA anti-retaliation provisions if they were fired or suffered other consequences from exposing fraudulent activities by a company. However, that changed with the passage of the Fraud Enforcement and Recovery Act (FERA). A recent settlement involving a Florida hospital and clinics and two doctors brought the retaliation issue to light.

The two entities sought dismissal of the retaliation claim based on the fact that Koch was not their employee. The judge ruled that because of a change in the FCA's anti-retaliation language as a result of FERA, which became law in 2009, the suit was valid.

The case resulted in the defendants paying the United States $3.5 million to settle allegations of fraudulently billing the Medicare, Medicaid, and TRICARE programs for radiation oncology services that were not eligible for payment.

In this case, *United States ex rel. Koch v. Gulf Region Radiation Oncology Centers Inc., et al.*, the relator, Richard Koch, filed an anti-retaliation suit against his employer and the two other entities involved in the suit, neither of which actually employed him.

Background

Koch was hired in 2008 as an administrator/manager by West Florida Medical Center Clinic. Several mergers with West Florida Medical Center Clinic and Sacred Heart Health System eventually resulted in Koch becoming an employee of Gulf Region Radiation Oncology (GRRO). In January 2010 Koch was fired by GRRO after raising concerns about the organization defrauding government health care programs. Koch subsequently filed an anti-retaliation suit against GRRO and included the predecessor companies West Center Clinic and Sacred Heart Health System, even though they maintained a separate legal status.

The two entities sought dismissal of the retaliation claim based on the fact that Koch was not their employee. The judge ruled that because of a change in the FCA's anti-retaliation language as a result of FERA, which became law in 2009, the suit was valid. FERA expanded the anti-retaliation to reach nonemployers by removing the word employer from the FCA's retaliation provisions.

What does this mean for a laboratory? Potentially, if a hospital system sells its outreach laboratory business to another laboratory, it may still be held liable under FCA anti-retaliation provisions for acts committed by the new company under certain circumstances. This change in the retaliation section of FERA will help employees who are "blackballed" or otherwise prevented from gaining employment in a particular marketplace because they filed a whistleblower lawsuit.

Takeaway: The anti-retaliation provisions of the False Claims Act can result in problems for a laboratory even after it is sold to another company. Labs should be aware that individuals who are no longer employees can still file anti-retaliation claims.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Robert Mazer, Esq., is a principal with the law firm of Ober|Kaler in Baltimore.

The Two Faces of Government Advice: Reliance on Agency Counsel May Not Always Be Reasonable

Clinical laboratories and pathologists frequently struggle with issues related to Medicare payment and compliance. It's no wonder. One court stated recently, "Picture a law written by James Joyce and edited by E. E. Cummings. Such is the Medicare statute, which has been described as 'among the most completely impenetrable texts within human experience.'"[1] The same might be said about related regulations and interpretations issued by the Centers for Medicare and Medicaid Services (CMS), and legal and regulatory authorities addressing licensure and certification.

In many cases, the issue of concern relates to whether a particular type of payment claim is permissible. There may be questions, for example, whether a service provided under particular arrangements can be billed or about the proper code to be included on the claim. In that event, the laboratory or pathologist may have a so-called "duty of inquiry" before submitting claims to Medicare or other federal payer. The False Claims Act (FCA) states that a person who acts in "reckless disregard" of the truth may be determined to have knowingly submitted a false claim.[2] Therefore, if incorrect claims are submitted, the failure to make a reasonable and prudent inquiry to determine whether such claims were permissible could result in liability under that statute.[3]

Compliance advice is available from various sources. The conventional wisdom, however, is that the safest course is to contact the relevant administrative agency or government contractor and then to carefully document the advice that it provides. This approach is encouraged frequently by government agencies. CMS offers that "CMS' local contractor medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices."[4] Similarly, CMS's Clinical Laboratory Improvement Amendments of 1988 (CLIA) Web site states, "If you have any questions regarding CLIA, contact the appropriate State Agency."

There may be questions, for example, whether a service provided under particular arrangements can be billed or about the proper code to be included on the claim. In that event, the laboratory or pathologist may have a so-called "duty of inquiry" before submitting claims to Medicare or other federal payer.

Advisory Opinion Process

But not all responses to requests for government advice provide the same protection. A request for a legally binding advisory opinion can be submitted to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) regarding application of the federal anti-kickback statute and most other Medicare-related statutory provisions that can lead to criminal penalties, civil monetary penalties, or federal exclusion. However, the OIG requires that the requesting party provide extensive information regarding the arrangement and to certify that related payments

1. *Catholic Health Initiatives-Iowa, Corp. v. Sebelius*, 841 F. Supp.2d 270, 271 (D. D.C. 2012) (citations omitted).
2. *31 U.S.C. § 3729(b)(1)(A).*
3. *See U.S. ex. rel., Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 530 (6th Cir. 2012).
4. *Medicare Learning Network, Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians* (March 2012).

reflect fair market value. Additionally, the 60-day statutory deadline for issuance of an advisory opinion is routinely extended by the OIG, and a response typically takes more than one year.

As part of a similar process, CMS may be requested to provide a binding advisory opinion regarding application of the physician self-referral prohibition (commonly referred to as the Stark law). This is frequently not a feasible alternative, however; CMS's determination that an existing arrangement violates the Stark law could result in an obligation to return all payments received for services resulting from impermissible referrals.

Informal Requests for Advice

Informal advice may be sought from government representatives on many other issues. Federal agencies and Medicare contractors will frequently respond to letters or e-mails or provide telephone advice. However, this advice will not necessarily be correct. For that reason, the OIG's compliance guidance for clinical laboratories suggests that it may not always be reasonable to rely on it. The OIG states:

> [W]here a clinical laboratory . . . requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a Federal health care program, the clinical laboratory should document and retain a record of the request and any written or oral response. . . . The laboratory should memorialize its determination *as to whether reliance on any such advice is reasonable*.[5]

A laboratory that receives and then relies on such informal advice may have little recourse if it turns out to be incorrect and, as a result, it is later determined that the lab received Medicare payments to which it was not entitled or that it violated laboratory certification requirements. Based on the Supreme Court's decision in *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*,[6] in which a Medicare fiscal intermediary was permitted to recover Medicare payments that it had advised a home health agency could be properly claimed, HHS administrative law judges (ALJs) have generally rejected arguments based on a Medicare contractor's or administrative agency's erroneous advice. In one such recent decision, the ALJ stated that "those who deal with the government are expected to know the law and may not rely on the conduct of government agents contrary to law."[7]

***"[W]here a clinical laboratory . . . requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a Federal health care program, the clinical laboratory should document and retain a record of the request and any written or oral response. . . . The laboratory should memorialize its determination* as to whether reliance on any such advice is reasonable."**
—HHS Office of Inspector General

Other ALJs have stated that "a provider's reliance on statements from either the fiscal intermediary or a state employee—even one who . . . could unquestionably be characterized as a 'responsible government agent'—is simply unreasonable"[8] or that

5. Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45085 (Aug. 24, 1998) (emphasis added).
6. 467 U.S. 51 (1984).
7. *Rodriguez v. CMS,* DAB No. CR2869, at 5 (July 24, 2013).
8. *Caretenders Visiting Servs. of Columbus, LLC v. CMS,* DAB No. CR2311, at 8 (Jan. 19, 2011).

"[e]rroneous oral advice is inadequate, as a matter of law, to estop the government from enforcing federal law."[9]

Similarly, in *Wade Pediatrics v. CMS*,[10] the Departmental Appeals Board (DAB) stated that a laboratory charged with referral of proficiency testing (PT) samples to another laboratory could not have reasonably relied on oral statements from a CMS investigator to believe that such referrals were permissible. According to the DAB, CMS regulations clearly prohibited a laboratory from sending PT samples to another laboratory for analysis, and the laboratory's director was responsible for assuring its compliance with applicable regulations.

Impact on Penalties

In certain instances, however, reliance on incorrect government advice may prevent imposition of penalties, if, based on that advice, the laboratory reasonably believed that it was complying with relevant laws and regulations. This is because imposition of penalties—whether civil, criminal, or administrative—frequently requires an intent to violate a law or regulation or recklessness or deliberate indifference as to whether the practice or payment claim was compliant. In a memorandum issued in 1998, then Deputy Attorney General Eric H. Holder Jr. instructed government attorneys to consider the following before alleging an FCA violation:

In certain instances, however, reliance on incorrect government advice may prevent imposition of penalties, if, based on that advice, the laboratory reasonably believed that it was complying with relevant laws and regulations. This is because imposition of penalties—whether civil, criminal, or administrative—frequently requires an intent to violate a law or regulation or recklessness or deliberate indifference as to whether the practice or payment claim was compliant.

> ***Guidance by the Program Agency or its Agents.*** Did the provider directly contact either the program agency (e.g., the Health Care Financing Administration) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?[11]

The corollary to this principle is that proof that an entity engaged in conduct after being advised by a government agency that it was impermissible may result in a determination that there was an intent to violate the relevant legal or regulatory requirement or at least substantial indifference as to whether the conduct was permissible.

Application of Principles

Application of these principles can be demonstrated using a simple example in which a laboratory asks a Medicare contractor if a particular type of payment claim is permissible. If the contractor states incorrectly that an unlawful type of claim is permissible and the laboratory then submits claims reflecting this advice, it could

9. *Sherrod v. CMS,* DAB No. CR2463, at 6 (Nov. 8, 2011).
   Whether and under what circumstances a federal agency may be estopped from asserting a position as a result of a private party's reliance on its prior statements is not perfectly clear. A federal appellate court indicated recently that estoppel may be appropriate in the case of an agency's "affirmative misconduct," i.e., improper conduct which goes beyond "mere negligence." *Bartlett v. Dep't. of Agric.*, 716 F.3d 464, 475-76 (8th Cir. 2013).
10. DAB No. 2153, at 21-24 (2008), *petition for review denied*, 567 F.3d 1202 (10th Cir. 2009).
11. Memorandum for All United States Attorneys, et al., from Eric H. Holder Jr., Deputy Attorney General, re: Guidance on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998).

later be required to return related overpayments. But the laboratory should have a strong basis for asserting that it did not knowingly or willfully violate the law—or that it did not act with deliberate ignorance or reckless disregard for whether the claims were proper—and therefore penalties should not be assessed. By contrast, following a Medicare contractor's incorrect advice that certain claims were impermissible could result in loss of revenue to which the laboratory was entitled.

The consequences of disregarding the contractor's advice depends on the circumstances. If the contractor said correctly that a particular type of claim was impermissible, a laboratory that nevertheless filed such claims could face substantial penalties (as well as overpayment liability). In the absence of a reasonable, good-faith belief that the contractor's advice was incorrect, the laboratory may be shown to have knowingly and willfully violated the law or acted in reckless disregard as to whether its payment claims were permissible.

Failed Attempts to Obtain Government Advice

What if the contractor or agency ignores the request for advice, declines to respond, or sends a reply that does not address the issue about which advice was requested? Although there may be no clear case law addressing this scenario, a recent decision indicates that a laboratory's failed attempt to obtain government advice could potentially serve as a defense against imposition of penalties. In *U.S. ex rel. Williams v. Renal Care Group, Inc.*,[12] the federal government filed an FCA action against a dialysis provider and related entities for submission of Medicare claims using a payment method that the government asserted was unavailable. The lower court found that in submitting these claims, the defendants acted with "reckless disregard" of applicable Medicare statutes and regulations. The appellate court disagreed based on the specific facts and circumstances presented, finding, among other things, that the dialysis provider had requested advice from its own legal counsel, its counsel had requested clarification from CMS—to which it did not receive a response, its counsel had documentation of a conversation with an individual from CMS that supported her client's billing, and CMS and the OIG had knowledge of its billing arrangements.

In many cases it will be appropriate to seek advice from a Medicare contractor or administrative agency regarding compliance with legal and regulatory requirements. However, as the OIG indicated, any such advice should be carefully evaluated before it is relied upon.

According to the court, based on these and other factors, "the defendants were not in reckless disregard of the truth or falsity of their claims"; they had consistently sought clarification on the issue, followed industry practice in attempting to interpret ambiguous regulations, and were forthright with government officials regarding the arrangements.[13]

Conclusion

In many cases it will be appropriate to seek advice from a Medicare contractor or administrative agency regarding compliance with legal and regulatory requirements. However, as the OIG indicated, any such advice should be carefully evaluated before it is relied upon.

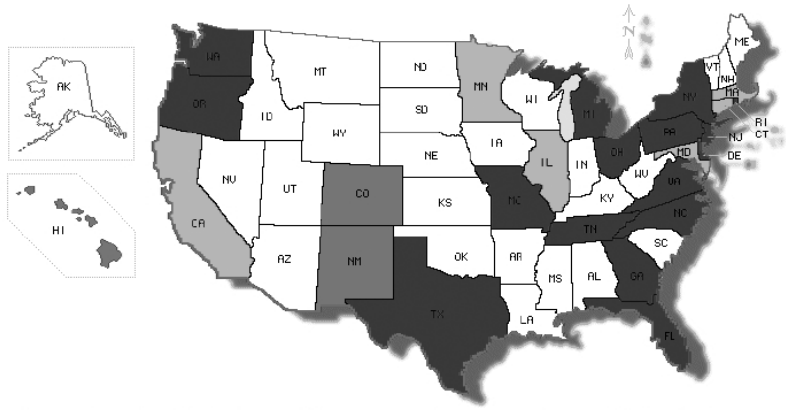
Robert Mazer, Esq., can be reached at 410-347-7359, remazer@ober.com.

12. 696 F.3d 518 (6th Cir. 2012).
13. 696 F.3d at 531.

Employee Background Checks Must Be Done Correctly, *from page 1*

The Maryland case was filed by the EEOC and is based on the theory that there is a disparate impact criminal background and credit history checks have on African American and male applicants. The defendant, Freeman, is a company that provides integrated services for expositions, conventions, corporate events, meetings, and exhibit programs. The EEOC claimed that Freeman implemented a hiring policy that appears neutral but resulted in a discriminatory effect. Ultimately, the EEOC lost the case primarily because the defendant had detailed policies that allowed for consideration of any findings on criminal background records and had clearly stated criteria for credit checks, and because the EEOC could not provide reliable and timely evidence that Freeman's hiring practices actually resulted in a disparate impact against any class of applicants. It is important to note that this case started with a single complaint by an applicant filed on Jan. 17, 2008.

Ban the Box:
Major U.S. Cities and Counties Adopt Fair Hiring Policies to Remove Unfair Barriers to Employment of People with Criminal Records



States where localities have banned the box
States with statewide ban the box
States with statewide ban the box and individual localities that have banned the box

Source: National Employment Law Project: Resource Guide, Updated April 2013 at www.nelp.org

Freeman did everything it was required to do including providing a reason for performing the background checks, limiting the checks to only those jobs where the checks were relevant to the job, and giving applicants an opportunity to explain any findings. It even went so far as to include the following statement on its application where the box asking about criminal convictions was located: "A conviction does not automatically mean you will not be offered a job. What you were convicted of, the circumstances surrounding the conviction and how long ago the conviction occurred are important considerations in determining your eligibility. Give all the facts, so that a fair decision can be made." Applicants were also required to sign an authorization for Freeman to conduct the background screens, which were done after a job offer was made but before the applicant began work.

According to a recent National Employment Law Project report, an estimated 65 million people, one in four adults, have a criminal record that may show up on a criminal background check. This criminal record creates challenges for applicants in their efforts to get a job, even when the item is old or unrelated to the job being sought.

Many cities and states around the country have implemented policies to remove the box on an employer's application form that asks about a criminal record, hence the term "ban the box." In all, 50 municipalities and some states have implemented some kind of policy to promote fair hiring policies and eliminate barriers to employment of people with criminal records. Some of the more prominent cities include Chicago; Jacksonville, Fla.; Philadelphia; San Francisco; Memphis, Tenn.; and Baltimore.

Best Practices

To avoid a potential human resources nightmare, labs should take some steps to ensure their hiring practices do not result in a complaint to the EEOC, or if one occurs, be certain they can defend their hiring practices. First, don't reject applicants simply because they check that box on your application or because they have some

kind of criminal record in their past. Second, have detailed polices and procedures related to background checks that have been vetted by legal counsel familiar with both federal and state labor and discrimination law. Third, limit background checks either by length of time since the criminal act occurred or by relevancy to the job for which the person is applying. For instance, only perform credit history checks on applicants applying for jobs with money or financial responsibilities.

Fourth, give an applicant an opportunity to explain the circumstances surrounding a criminal conviction and document the discussion clearly in the employee record. Fifth, don't let the fear of a possible EEOC complaint deter you from doing these kinds of employee screens and background checks. There are liabilities of equal significance if you hire someone with a criminal background and they commit the same or a similar act while in your employ.

Takeaway: Criminal background checks and credit screenings are important tools to ensure a workforce that does not create problems for your laboratory, but you must do them with appropriate sensitivity to avoid complaints of discrimination. G2

Federal Trade Commission Files Privacy Complaint Against LabMD Over Unsecure Consumer Info

Protecting the personal information of consumers is a top priority for the Federal Trade Commission (FTC), and Atlanta-based medical testing laboratory LabMD failed on two separate occasions to adequately secure and protect that information, according to a complaint filed by the commission on Aug. 29.

The file found on the P2P network, a spreadsheet, contained names, Social Security numbers, dates of birth, health insurance information, and treatment codes for over 9,000 consumers.

LabMD files containing sensitive consumer information were found on a peer-to-peer (P2P) file-sharing network and, in a separate incident, in the hands of identity thieves. All total, the complaint alleges that LabMD exposed the sensitive personal information of approximately 10,000 individuals between the two incidents.

LabMD conducts tests on consumer samples collected by physicians and sent to the laboratory. It performs tests on consumers from all over the United States. The FTC complaint alleges that "LabMD failed to take reasonable and appropriate measures to prevent unauthorized disclosure of sensitive consumer data—including health information."

The file found on the P2P network, a spreadsheet, contained names, Social Security numbers, dates of birth, health insurance information, and treatment codes for over 9,000 consumers. The complaint alleges that the Sacramento, Calif., police department found LabMD documents in the hands of identity thieves in a 2012 case. These files included the same information as the others with the addition of bank account information for some of the individuals. Some of the Social Security numbers have been used by more than one person with different names, a sure sign of identity theft.

"The Commission issues an administrative complaint when it has 'reason to believe' that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest," said the FTC. "The issuance of the administrative complaint marks the beginning of a proceeding in which the allegations will be tried in a formal hearing before an administrative law judge."

The complaint includes a proposed order against LabMD that would require it to implement a comprehensive security program, something the company should have already done under the Health Insurance Portability and Accountability Act (HIPAA), and have that program evaluated every two years for the next 20 years. The order will

require LabMD to notify all of the consumers involved in the two incidents and any others whose information LabMD has reason to believe may have been compromised.

LabMD denies that it has engaged in conduct that violates Section 5 of the FTC Act in a September 17 response to the FTC complaint and asserts that the agency does not have the statutory authority to regulate the acts or practices alleged in the complaint. In its response, LabMD requests that the Administrative Law Judge deny the commission's requested relief and dismiss the compliant in its entirety with prejudice.

Takeaway: Allegations by the Federal Trade Commission that a laboratory exposed consumer info underscores the need for all health care providers to ensure they are meeting HIPAA privacy and security requirements. G2

Court Rules That Millennium Lab Lawsuit Against Competitor Can Continue

In what is considered by some a win for Millennium Laboratories (ML, San Diego), a middle district court in Florida denied motions for summary judgment by both the plaintiff and the defendant and allowed a case against a competitor to continue.

The case has been going on since Oct. 21, 2011, when ML filed the suit accusing Universal Oral Fluid Laboratories (Greensburg, Pa.) of engaging in unfair trade practices and anti-competitive marketing practices and a variety of other competitive related violations of laws in several states, including Florida, Texas, and Kentucky.

At the core of this case are certain agreements Universal entered into with physician customers under which the physicians submit specimens to Universal for testing. Universal then bills third-party payers, including Medicare and Medicaid, and splits profits it makes on the tests with the physician consumers, which on the face appear to implicate the anti-kickback and physician self-referral (Stark) laws. These laws do not provide for a private cause of action, except perhaps under the qui tam provisions of the False Claims Act, so the ML suit takes the approach that these arrangements may be illegal and create fair trade and anti-competitive advantages for Universal in the marketplace.

As a result of this decision by the Florida court, the lawsuit will continue and eventually go back to court.

Takeaway: Millennium Laboratories will be allowed to pursue its unfair trade lawsuit against Universal Oral Fluid Laboratories. G2

G2 Compliance Corner

Our hospital is taking a conservative view/interpretation of a coding service's comment, insisting on receiving "narratives only" diagnosis information from physicians submitting orders for our outreach program. Our systems cannot handle narrative diagnosis information. What are the requirements for physicians submitting diagnosis information for laboratory services?

There is a requirement that physicians include diagnosis information to support the medical necessity of all tests they order. That information may be in the form of a narrative or an ICD-9 code. There is no regulatory requirement that a physician submit narrative information only on its requests for laboratory services. They may submit either a narrative or an ICD-9 code. If the diagnosis information is incomplete or the ICD-9 code submitted is not specific enough, the lab must call the physician's office for the correct information and document the call.

Labs must maintain documentation of the source for all of the diagnosis information they include on their claims (See *CMS Internet Only Manuals*, Chapter 16, Section 120.1 Negotiated Rulemaking Implementation).

News-At-A-Glance

KANSAS HOSPITAL REACHES FALSE CLAIMS SETTLEMENT: Hutchinson Regional Medical Center Inc. paid $853,651 on Sept. 17 to the United States to settle alleged false claims for hyperbaric oxygen wound therapy services that were either not medically necessary or lacked adequate documentation to demonstrate medical necessity. This amount was in addition to previous refunds by the hospital that totaled over $1.7 million. The government imposed a corporate integrity agreement (CIA) on the hospital that requires the appointment of a compliance officer and compliance committee, creation of a board of directors compliance committee, creation of a code of a conduct for the hospital, and written policies and procedures within 90 days of the effective date of the CIA. Other obligations include training, audits, background checks, and the creation of a disclosure program to foster reporting of compliance problems and get compliance questions answered, anonymously if the employee desires. The policies related to the disclosure program must include nonretaliation language for those reporting potential problems, fraud, or abuse. In addition, Hutchinson must hire an independent review organization and submit quarterly and annual reports to the Office of Inspector General.

FRAUDSTERS COME IN ALL GENDERS AND AGE GROUPS: In a one-count indictment, 62-year-old Mary Monica Wilson-Lefler of Sewickley, Pa., was accused of violations of the False Claims Act. Wilson-Lefler, described as a salesperson, offered a business arrangement to two Pittsburgh durable medical equipment (DME) companies involving special air mattresses known as powered pressure reducing mattresses or PPRAMS. These devices are designed to reduce serious skin ulcers in bedridden patients. Wilson-Lefler would visit long-term-care facilities to find patients and then, according to the indictment, she would handle all of the paperwork necessary to allow the DME companies to submit the claims for the mattresses. In some cases, Wilson-Lefler fabricated skin conditions and is accused of forging documents, including physician orders. None of the 83 patients for whom claims were submitted had any serious skin conditions, and they did not need the mattresses at all, according to the indictment. The scheme netted nearly $200,000 for the DME companies and the same amount for Wilson-Lefler. Wilson-Lefler faces a maximum sentence of 10 years in prison and a $250,000 fine.

INSPECTOR GENERAL COMPLETES UPDATES TO SANCTION LIST: Beginning with the September updates to the List of Excluded Individuals and Entities, the list will include National Provider Identification (NPI) numbers and fields for waiver and waiver states. The NPI is the most important addition for compliance officers and others conducting sanction screening in your laboratory. While not all providers have NPIs, many do, and the NPI is a much easier to obtain data point than a date of birth or Social Security number in the case where verification of a positive hit is needed. If your lab uses the downloadable file to update your sanction lists, your software may need to be updated to accommodate these additions. Also, policies and procedures may need to be changed to account for using the additional information.

 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