G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Health Plan Security Breach Results in $1.2 Million Fine

Affinity Health Plan Inc. (AHP) has agreed to pay the federal government $1.2 million to settle allegations it violated the Health Insurance Portability and Accountability Act (HIPAA) by failing to erase protected health information from photocopiers it returned to equipment leasing agents.

AHP filed a breach report with the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) in 2010 indicating that unsecured electronic protected health information (ePHI) for an estimated 344,579 patients was released because it had not erased the hard drives of leased photocopiers before it returned them. In the resulting settlement agreement, AHP agreed to pay $1,215,780 and to pay its own costs associated with the breach and meeting the requirements of the settlement agreement. The Health Information Technology for Economic and Clinical Health, or HITECH, Act, requires covered entities to notify HHS of any breach of any unsecured protected health information.

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Texas Laboratory Has Certificate Revoked For Proficiency Testing Violations

The Health and Human Services Departmental Appeals Board recently upheld the revocation of a clinic laboratory's Clinical Laboratory Improvement Amendments certificate after it was found in violation of several proficiency testing (PT) requirements. The laboratory admitted to all of the material facts in the case but appealed the Centers for Medicare and Medicaid Services (CMS) decision to revoke its certificate, pleading that the sanction imposed was too harsh based on the circumstances surrounding the violation.

Planned Parenthood Choice of Abilene, Texas, a clinical lab certified under CLIA, admitted that prior to submitting its first-quarter 2011 PT report, the lab employee charged with performing the tests called a second lab and compared results. The violation was discovered during an Oct. 6, 2011, certification survey. The surveyor found that the lab did not meet two separate conditions of participation that govern the enrollment and testing of proficiency samples and the requirement that govern a laboratory director's requirements for labs performing moderate-complexity testing. As a result, CMS revoked the lab's CLIA certificate and cancelled the laboratory's approval to receive Medicare payments.

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Health Plan Security Breach Results in $1.2 Million Fine, *from page 1*

According to OCR, AHP's breach notification explained that it was informed by a representative of *CBS Evening News* that, as part of an investigatory report, CBS had purchased a photocopier previously leased by Affinity. CBS informed Affinity that the copier that Affinity had used contained confidential medical information on the hard drive. OCR's investigation indicated that Affinity impermissibly disclosed the protected health information of these affected individuals when it returned multiple photocopiers to leasing agents without erasing the data contained on the copier hard drives.

Not only had AHP not erased the drives but, according to the investigation conducted by OCR, AHP failed to incorporate the photocopier hard drives in its security risk analysis. AHP also failed to implement polices and procedures covering the return of leased photocopiers to the leasing company.

One condition of the settlement agreement and its corrective action plan (CAP) requires AHP to employ its best efforts to retrieve all hard drives that were contained on photocopiers previously leased by the plan that remain in the possession of the leasing agent. AHP must document its efforts and explain any failure to retrieve a hard drive.

Consider the implications of this if your laboratory had to meet such a requirement. Generally, copiers are placed in convenient areas throughout a laboratory, are used for faxing and printing documents as well as copying. Just trying to figure out which machine might contain ePHI and how many patients might be involved would be a real challenge.

One condition of the settlement agreement and its corrective action plan (CAP) requires AHP to employ its best efforts to retrieve all hard drives that were contained on photocopiers previously leased by the plan that remain in the possession of the leasing agent.

The settlement agreement and the incorporated CAP and the press release are available on the OCR Web site and should be reviewed by any security officer, privacy officer, and compliance officer who has HIPAA oversight responsibility. These documents contain important information and links to other training and guidance material that will help assess risk and vulnerabilities in your laboratory.

The terms of the CAP appear pretty onerous and include very short time frames to accomplish them. For instance, AHP has five days from the effective date of the settlement agreement to use its best efforts to retrieve the photocopier hard drives and secure the ePHI contained on them, or explain why it failed to retrieve any drives. It must provide OCR with documentation describing its best efforts and why it failed to retrieve any drives if that is the case. AHP must provide written certification to OCR that it has met this requirement.

Compliance with this corrective action is based on the review and acceptance of the documentation and written certification. Another requirement is that AHP must conduct a security risk analysis that incorporates all electronic equipment and systems controlled, owned, or leased by AHP within 30 days of the effective date. This requirement includes developing a plan to correct vulnerabilities found in the risk analysis and, if necessary, revise current policies and procedures accordingly.

AHP must submit these documents to OCR for review and then will have an additional 30 calendar days to respond to OCR comments and recommended changes. When that process is completed, AHP has 30 more days to implement the plan and train employees. The CAP requires AHP to retain the related documentation for six years. These requirements are pretty onerous, but if AHP doesn't meet them or take appropriate action to seek extensions when needed, HHS may impose civil monetary penalties on AHP.

Takeaway: Security risk assessments must include any electronic device that has its own hard drive or internal storage and such devices must be properly disposed of (including documentation of disposal).

Congress Would Limit Stark In-Office Ancillary Services Exception

Narrowing the included services covered under the in-office ancillary services (IOAS) exception in the Physician Self-Referral Act (Stark law) would save Medicare millions and better reflect the intent of Congress, according to Rep. Jackie Speier (D-Calif.), who recently introduced a bill to close the loophole.

The IOAS exception allows a physician to circumvent the general Stark prohibition against referring patients to an entity in which he has a financial relationship as long as the services meet certain Stark law requirements. The Promoting Integrity in Medicare Act of 2013 (H.R. 2914), also known as PIMA, was introduced in the House by Reps. Speier, Ways and Means Health Subcommittee Ranking Member Jim McDermott (D-Wash.), and Dina Titus (D-Nev.). It would narrow the IOAS exception to prohibit the self-referral of certain complex services, including anatomic pathology services.

The specific services that would be eliminated from the exception are advanced imaging, anatomic pathology, radiation therapy, and physical therapy. These are services that are not typically performed at the time of the patient's initial office visit.

"Three recent Government Accountability Office (GAO) reports have examined the self-referral problem, including one released today on radiation oncology services," said Speier in introducing the bill. "All three reports have found a significant and inappropriate increase in referrals when a physician switches to self-referral, costing Medicare millions. A fourth report on self-referral in physical therapy services is expected later this year."

The bill would create a category of services called nonancillary services, which are defined as "a service that the Secretary has determined is not usually provided and completed during an office visit to a physician's office in which the service is determined to be necessary." The bill then lists the above services and provides more detail and definition for each. In the listing of the anatomic pathology service, the bill says that anatomic pathology includes the technical or professional component of surgical pathology, cytology, hematology, blood banking, pathology consultations, and clinical laboratory interpretations.

All three reports have found a significant and inappropriate increase in referrals when a physician switches to self-referral, costing Medicare millions.

The legislation would also increase civil monetary penalties for violations and require enhanced screening of claims by requiring the Health and Human Services Office of Inspector General to conduct a review specifically to determine compliance with billing of nonancillary services.

The bill is supported by trade associations and providers who perform these services in settings outside of the physician office, including the pathology and the clinical laboratory industry. According to the Web site *govtrack.us*, the bill has been referred to committee and has little chance of getting enacted. The introduction of the bill serves to demonstrate a growing concern in the government that self-referral is costing government programs millions of dollars through overutilization and abuse and has been shown to cause harm to patients.

Don't be surprised if there is an uptick in whistleblower cases based on self-referrals. Laboratory compliance officers should carefully examine relationships with physician offices where they are performing one component of one of the services listed in this bill and a physician is referring the other.

Takeaway: When a laboratory is involved with a referring physician and is also providing one component of an anatomic or billable clinical lab interpretation service, it should recognize the compliance risks and carefully monitor the relationship. G2

Government Report Concerning Self-Referral May Impact Labs Differently Than Expected

While physicians find the Government Accountability Office (GAO) study concerning the impact of self-referral of anatomic pathology services on the Medicare program flawed, inaccurate, and offensive, laboratory and pathology groups generally applaud the study, saying it proves what they have been saying for a long time.

The study, titled "Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer," provided data and statistics that some say show beyond any doubt that physicians who perform anatomic pathology services in their offices on their own patients order a significantly higher number of these services than providers who do not have labs in their offices.

On the other hand, the American Urological Association in a statement said the study is flawed. "The GAO's assertion that urologists and other specialists are utilizing ancillary services for financial gain is both fundamentally wrong and offensive," it says.

Many laboratory experts expect prohibiting self-referral in this area will automatically cause an increase in their volumes for these tests. That may be true for some labs, but not necessarily all labs.

According to the report, self-referred anatomic pathology services increased at a faster rate than non-self-referred services from 2004 to 2010. During this period, the number of self-referred anatomic pathology services grew from 1.06 million to about 2.26 million services, more than double. During the same period, non-self-referred services grew about 38 percent, from about 5.64 million to about 7.77 million services. Three provider specialties account for about 90 percent of 2010 referrals: dermatology, gastroenterology, and urology. Referrals for anatomic pathology services by these three specialties increased substantially the year after they set up their in-office labs, according to the study.

According to the report, self-referred anatomic pathology services increased at a faster rate than non-self-referred services from 2004 to 2010.

Many hospital and independent laboratories provide the technical components (TC) for these same physicians at a discount. The physician then provides the professional component (PC) and bills Medicare and other third-party payers directly for that service. While there is an anti-markup provision for Medicare beneficiaries for the TC, those restrictions may not always apply to other payers. In this arrangement, both the laboratory and the physician seem to benefit, but there are compliance risks.

If there are pathologists in the laboratory, or the laboratory specializes in pathology work, they would rather see both components referred to their laboratory. Some of these arrangements can result in the laboratory providing too much information with the TC work, essentially providing the physician with everything needed to report the professional component without having to perform any real work. If this is done in exchange for referrals of other government work, the Stark and anti-kickback statutes are implicated and both parties could find themselves the subject of government scrutiny.

Takeaway: If the GAO study helps bring about a prohibition of physician self-referrals for anatomic pathology services, it is likely that not all laboratories will benefit.

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

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Revised Coverage Process May Be Step Backward for Labs

The laboratory community, which fought to get standardized national coverage decisions (NCDs) almost a decade ago so it would not have to deal with local coverage decisions (LCDs) that differed by Medicare jurisdiction, may see its efforts thwarted.

The Centers for Medicare and Medicaid Services (CMS) in a recent *Federal Register* notice describes a new expedited process for the removal of an NCD it considers no longer valid, which would result in local contractors instituting LCDs if they believe a coverage decision still needs to be in place. Even if the local contractor does not immediately issue an LCD, payments could be in jeopardy in post-payment reviews if physicians revert to ordering tests for the wrong reasons or do not supply appropriate diagnosis codes when they order.

The effective date of the notice is Aug. 7, 2013. If CMS contractors begin taking advantage of these new policies soon, labs could find themselves making software changes to accommodate the removal of existing NCDs and the potential creation or revision of corresponding LCDs. One motivating factor for CMS to expedite the removal of NCDs is that the cost of maintaining NCDs is high, partly because of the quarterly requirement to update them, make the corresponding changes to editing software, and distribute those changes to all contractors. CMS also submits an annual report to Congress that tracks the agency's performance with respect to certain key steps in the process (the report is also posted on the CMS Web site).

The notice lays out the details of the new expedited administrative process for the periodic review of NCDs that have not been reviewed for 10 years to determine if there is a continued need for a national policy.

CMS is also facing a massive project with respect to converting NCDs that include ICD-9 diagnosis codes to the new ICD-10 codes. Virtually all laboratory NCDs, many of which include hundreds of diagnosis codes, will have to be converted to the new coding system by October 2014.

The notice lays out the details of the new expedited administrative process for the periodic review of NCDs that have not been reviewed for 10 years to determine if there is a continued need for a national policy. Many laboratory NCDs could fall within this time frame depending on the date that CMS uses to determine when they were last reviewed. Previously, it could take from nine to 12 months to remove an NCD because they had to go through a formal reconsideration process. Under the new expedited process, the time frame will be shortened considerably and the result will be immediate upon publication of the final determination. At this point, a local contractor would make coverage determinations.

CMS to Provide Rationale

Under the new process, CMS will periodically publish a list of NCDs proposed for removal along with the rationale for the proposed removal. The public will have 30 calendar days to comment on the entire list of NCDs. The commenters are asked

to include their rationale to support their comments. After consideration of all comments, CMS will decide to remove the NCD, retain the NCD, or start a formal reconsideration of the NCD. No specific time frame is provided for when they must complete this part of the process. When the decisions are finalized, CMS will publish final determinations and provide brief rationale for each determination. The final determinations will be effective immediately upon posting to the CMS Web site. Criteria for removal of older NCDs include:

- Local contractor determinations about coverage better serve the program and its beneficiaries;
- Technology is obsolete;
- In the case of noncoverage because a service was considered experimental, the service may no longer be considered experimental;
- Newer polices supersede the older coverage policy;
- The national policy no longer meets current definition of a national policy; and
- The benefit category is no longer consistent with a category in the Social Security Act.

One potential impact of this new process is that an item or service that has enjoyed coverage under an existing NCD may no longer be covered when the local contractor is making coverage determinations. Further, an item or service may be covered in one jurisdiction but not in another. Providers, manufacturers, and independent labs may find themselves with the same problems and issues that existed prior to the creation of national coverage policies a decade ago.

One thing not specifically addressed in the notice is what guidelines providers and suppliers should follow to make medical necessity determinations after an NCD is removed. Generally, NCDs are put into place as a remedy for improper utilization of a test or service. The NCD forces a behavior change until the problem ceases to exist. It is not far-fetched to assume that in a post-payment review an auditor could find a test to be not reasonable and necessary if it did not meet the requirements of a removed NCD.

One potential impact of this new process is that an item or service that has enjoyed coverage under an existing NCD may no longer be covered when the local contractor is making coverage determinations.

Also, in the absence of an NCD or LCD, a laboratory could not legally issue an Advance Beneficiary Notice and could find itself liable for denials based on subjective medical necessity determinations made by government auditors or error testers with no way to seek payment from the beneficiary.

The idea that medical necessity determinations can be based on retired coverage decisions is not new. In a Nov. 20, 2012, *Part B News* published by Noridian Administrative Services, now Noridian Healthcare Solutions, the contractor explains that providers remain responsible for correct performance, coding, billing, and medical necessity whether or not an LCD is in place. In the same article, it warns that "post-pay review will continue not only as before, but also with the addition of Recovery Audit Contractors (RACs). Payment for a service does not mean the service was medically necessary and/or correctly billed. The service may therefore be subject to recoupment even several years later." Without the ability to present an ordering physician with an active NCD or LCD, a laboratory may find it difficult to get physicians to comply with a request for a diagnosis that supports the tests they order.

The 2013 notice supersedes the previous 2003 *Federal Register* notice and any subsequent guidance documents issued in the intervening period. It is meant to provide clarity and define how the agency will provide transparency for the NCD process. In addition to the expedited process for removing unnecessary NCDs, the notice also covers procedures for requesting a new NCD or a redetermination of an existing NCD, how the public can participate in the NCD process, issues concerning informal contacts prior to requesting an NCD, what constitutes complete formal requests for new NCDs or for seeking reconsideration of an existing NCD, external requests for NCDs, CMS-generated internal reviews of NCDs, and time frames for all of these processes. The stated motivation for taking on this project, according CMS, is that clinical science and technology are evolving and items and services that were once considered state-of-the-art or cutting-edge may be replaced by more beneficial technologies or clinical paradigms.

Any individual or entity can request an NCD or seek a change to an existing NCD. A laboratory may want to request one, or an update to an existing NCD, because it wants to establish coverage or it wants to limit or expand coverage. While CMS encourages laboratories and other providers to communicate via conference call or a meeting with staff in the Coverage and Analysis Group within the Center for Clinical Standards and Quality at CMS before submission of a formal request, it is not required. A requester may want to have this prerequest meeting to make certain it has all of the necessary supporting documentation for its request. Among the criteria for a new laboratory NCD is a full and complete description of the test to include the target Medicare population and the relevance and usefulness of the test within the targeted population. The requester must also provide scientific evidence like peer-reviewed literature or clinical trial study results in support of the request. If the requester has submitted an application to the Food and Drug Administration for a 510(k) clearance, certain sections of the application may be copied and used to support the request.

One way to address this is retain the existing edits in your billing system so you can accurately monitor the volume of orders that would not have met the previous criteria for payment.

Develop Procedures

Laboratory compliance officers and managers and directors of billing for a laboratory can prepare for the challenges presented by these changes by developing specific procedures to respond to posted notices of NCDs proposed for removal. Assign an individual to be responsible to monitor both CMS and the local contractors you do business with and make sure that person participates in any CMS listservs where this information is posted. Develop policies to address what the laboratory will do in the case of the removal of an NCD and there is no existing LCD when there is no longer published medical necessity guidance. One way to address this is retain the existing edits in your billing system so you can accurately monitor the volume of orders that would not have met the previous criteria for payment. Each laboratory will have to make a determination about what it will do with that information, and that determination should include input from appropriate legal counsel.

Takeaway: Post-payment determinations of medical necessity are subjective, and the guidance provided by a previously active NCD or LCD can be used to deny claims and seek recoupment in a post-payment audit or review.

Texas Laboratory Has Certificate Revoked, *from page 1*

According to CLIA regulations, a laboratory must treat and analyze PT samples in the same manner as patient samples and it may not engage in interlaboratory communications pertaining to PT results until after the due date for reporting results to the PT program. By its own admission, a laboratory employee did contact another laboratory because she was unsure of her results because she was testing proficiency samples for the first time during her one-year tenure at the laboratory. During her interview, she stated that she had contacted the San Angelo, Texas, Planned Parenthood lab to compare results before she submitted her result to the PT program. She also said that both labs arrived at the same result independently.

The surveyor interviewed employees of the San Angelo laboratory who she contacted and confirmed that conversations occurred between the two labs about PT results. However, San Angelo personnel thought the results were not discussed until after they had been submitted.

In the appeal, Planned Parenthood admitted to the call but stated that it was an innocent error by someone unaware of the prohibition regarding calling other sites. The second violation concerned the fact that the laboratory director did not sign the required statements attesting that the PT samples were tested in the same manner as patient specimens. The employee even carefully documented the improper call in the testing record: "Called Nanci about unsure results. Nanci said to call [San Angelo] location and compare results. After speaking with Heather Keeling, all of our results are the same. Submitted the results online."

During her interview, she stated that she had contacted the San Angelo, Texas, Planned Parenthood lab to compare results before she submitted her result to the PT program.

To further implicate improper activities may have occurred, the decision document includes a footnote concerning CMS's observation of "an obvious and unexplained change on the lab's answer sheet. The answer for sample Rh04 has been changed from positive to negative." The note further states that the San Angelo lab also reported a negative on the same sample which, according to the note, implies that the testing employee changed her result to match the San Angelo lab's result.

The judge accepted Planned Parenthood's denial of any wrongdoing but it was not considered a material fact by the judge. The lab tried to invoke the recent change in CLIA law to allow CMS discretion in revoking a CLIA certificate based on violations of PT provisions, but the judge pointed out that the law allows discretion but does not require that CMS not revoke a certificate. The judge also pointed out the violations occurred well before the CLIA change occurred, and it cannot be applied retroactively.

What are the lessons to be learned? After reviewing this case, it is obvious that this laboratory committed a series of violations, partly because it was not attentive to its CLIA requirements and was not very well managed. As a final irony, by the time this was resolved, the laboratory no longer performed the testing for which it was sanctioned. Laboratory directors and executives are responsible for everything that goes on in their laboratories. It is imperative that these responsible persons take compliance with regulations and laws as seriously as they take other leadership responsibilities. If not, as in this case, the mistakes of one poorly trained and supervised employee can determine the future or nonfuture of a laboratory.

Takeaway: The quality and effectiveness of employee training must be monitored and audited to ensure the critical messages required for their area of responsibility are effectively communicated.

Bostwick Labs Reaches Settlement Over Allegations Of Illegal Payments to Physicians

Bostwick Laboratories has agreed to pay $503,668 to resolve civil fraud allegations that its sales representatives made illegal payments to physicians to induce them to enroll patients in a clinical study using the lab's services, the Justice Department announced Aug. 20 (*United States ex rel. Gluck v. Bostwick Labs, Inc.*, E.D.N.Y., No. 09-cv-4136).

The settlement between the government and Bostwick of Uniondale, N.Y., stemmed from a qui tam, or whistleblower, action filed in 2009 by urologist Robert Gluck in the U.S. District Court for the Eastern District of New York.

The study, "Determination of the Accuracy of PCA3Plus Urine Assay for the Detection of Prostate Cancer," obligated physicians to send both the PCA3Plus urine assay for the PCA3Plus study and prostate biopsy samples for each patient to Bostwick, the government said.

Approximately $100,000 of the settlement amount will go to Gluck as the relator's share, plus some $67,000 in attorneys' fees. Gluck was among the physicians approached by Bostwick about participating in the study, the government said.

The illegal payments to enroll patients in the study served to induce certain physicians to use Bostwick's laboratory testing services, some of which were not medically necessary under the circumstances, the government said. In settling, Bostwick made no admission of liability.

The study, "Determination of the Accuracy of PCA3Plus Urine Assay for the Detection of Prostate Cancer," obligated physicians to send both the PCA3Plus urine assay for the PCA3Plus study and prostate biopsy samples for each patient to Bostwick, the government said. The biopsy samples otherwise could have been sent to any number of laboratories, according to the allegations.

Bostwick, which sponsored the study, "in effect paid those physicians to steer their prostate biopsy analysis business to its laboratories," the government charged.

The lab then submitted claims to Medicare and the TRICARE military health plan seeking reimbursement for both the prostate biopsy test analysis and the PCA3Plus urine assay analysis for each patient enrolled in the study, even though the prostate biopsy was the "gold standard" for prostate cancer detection and the PCA3Plus urine assay was not medically necessary in such situations, the government said.

The settlement was announced by U.S. Attorney Loretta E. Lynch and Special Agent in Charge Tom O'Donnell of the New York Office of Inspector General for the Department of Health and Human Services.

"Decisions involving medical treatment and testing go to the heart of the doctor-patient relationship, and must be based on the needs of each patient and possibility of the advancement of science," Lynch said in a statement. "They cannot and should not be based on illegal payments from laboratories. Our office is committed to stopping such inducements, and returning patient care to the forefront of the doctors' decisions."

"In order to ensure the best possible treatment for our nation's Medicare population, it is important that the relationship between labs and physicians be free of any illegal inducements, and we will continue to investigate such allegations," added O'Donnell.

Takeaway: Labs cannot pay physicians to get them to enroll patients in a clinical study using the lab's services. Such payments are considered illegal inducements.

—Kimberly Scott

Florida Hospital Pays $26 Million in a Suit Filed by Auditing Firm

A whistleblower lawsuit filed by the president of a consulting firm hired by Shands HealthCare resulted in the $26 million settlement of alleged False Claims Act (FCA) violations, according to an announcement by the Department of Justice (DOJ).

Between 2003 and 2008, six hospitals in the Shands HealthCare network knowingly submitted inpatient claims to Medicare, Medicaid, and TRICARE for certain services and procedures that Shands knew were correctly billable only as outpatient services or procedures, the government alleged. The consultant, Terry Myers of the health care consulting firm YPRO Corp., was contracted by Shands during 2006 and 2007 to conduct audits of its billing processes. The suit included allegations under the Florida False Claims Act as well. The whistleblower will receive some portion of these settlements, but the amount is not yet determined.

Shands says that it took immediate steps to correct the vulnerabilities in its billing processes uncovered in Myers's firm's audit and outlines those steps in Blouin's statement.

According to Shands, the whistleblower was hired by Shands as an independent consultant to conduct a routine audit of its billing practices. The auditor found inconsistencies in Shands's billing processes for some patients, indicating that Shands may have billed some short overnight stays as inpatient admissions rather than less expensive outpatient or observation services. The patients received all of the services that were included in the claims, and the failure to provide high-quality care was not in question, according to Melissa Blouin, director of news and publications, UF&Shands, the University of Florida Academic Health Center. Blouin says that Shands officials fully cooperated with the state and federal investigation and negotiated the settlement agreement announced today to avoid long and costly litigation. Shands does not admit any wrongdoing and has not admitted to any liability.

"Shands regularly and proactively conducts audits of its billing practices. It makes constant improvements to remain current with the complicated, evolving health care regulatory environment, which is subject to continued change in policy and guidelines," said Blouin.

Shands says that it took immediate steps to correct the vulnerabilities in its billing processes uncovered in Myers's firm's audit and outlines those steps in Blouin's statement. They included improvements to case management protocols and utilization review processes, the use of improved software, implementation of new policies and procedures, supplemental employee training, and the engagement of expert physician advisers to help assess coding.

Shands does not say in its statement whether or not it has a compliance program in place, and the DOJ announcement does not mention that as a factor in its settlement. At this time, the DOJ announcement does not say that Shands was put under a corporate integrity agreement as part of its settlement agreement, which could mean there are mitigating circumstances.

The DOJ, as it often does, used the announcement of the settlement to tout the success of its anti-fraud efforts, including the Health Care Fraud Prevention and Enforcement Action Team initiative, commonly referred to as HEAT, and the coor-

dination of efforts between different federal and state investigators. The details of the investigation and insight into the entire episode are not readily available and were not reviewed by G2 Intelligence, so it is not possible to accurately determine what part the whistleblower played in the investigation and resulting FCA case. There are many questions this case raises.

Make sure there is a follow-up exit conference to discuss, in great detail, the variances and compliance issues reported in any report issued by the consultant.

In the press release, Timothy M. Goldfarb, CEO of Shands HealthCare in Gainesville said, "We hold ourselves accountable for the highest standards of care and service. The case in question does not involve the failure to provide high-quality patient care, but rather inconsistent billing processes. We proactively initiated an independent audit that identified some opportunities to improve billing processes at Shands. We took immediate steps to make improvements."

The DOJ announcement said that of the $26 million settlement, $25,170,400 will go to Medicare and other federal health care payers. The settlement also resolved allegations under the Florida False Claims Act; the state of Florida will receive $829,600. Myers's portion of these recoveries has yet to be determined.

Avoiding Future Problems

One lesson that can be gleaned from this case relates to the process a health care entity uses when contracting with consultants or other independent professionals when they will be working on compliance-sensitive projects. Make sure your contract requires the full disclosure of any compliance issues the consultant encounters while working for your laboratory, whether or not they are directly related to the services they are performing on your behalf. Make sure there is a follow-up exit conference to discuss, in great detail, the variances and compliance issues reported in any report issued by the consultant. Make it a requirement that the audit report recommend steps your laboratory should take to correct any problems discovered during an audit and then make sure all of the recommendations are followed up or document the reason a particular recommendation was not followed. Have the consultant return after an appropriate time to assess your efforts at following up on his or her findings.

Takeaway: Independent consultants can add real value to your compliance program by providing an outsider's perspective, but they can also pose risks to your laboratory if it does not account for all of the things found in any report the consultant issues.

G2 Compliance Corner

Our laboratory continues to be unclear on what the rules are for performing and billing complete blood counts (CBCs) when the physician orders "CBC." Can you help?

Medicare considers an order for a CBC to mean an order for the test described by Current Procedural Code (CPT) 85027, which does not include a differential. If a physician wants a differential, the order must include a specific request for it like "CBC with differential." In that case the laboratory would perform and bill the test described by CPT code 85025. Another question that often arises concerning these tests relates to manual differentials (85007). Basically, you should only bill this test if the physician specifically orders it. The order might look like this, "CBC and manual differential." Performing a manual differential as a result of an instrument flag or a laboratory policy is not a billable test. Medicare considers this a quality control measure necessary to complete an order for a CBC with differential.

This month we are introducing a new feature in G2 Compliance Advisor *in which we answer compliance-related questions from our readers. Do you have a question? Please send to Christopher Young at cpyoung@cox.net.*

News-At-A-Glance

MARYLAND HOSPITAL FAILS TO REFUND OVERPAYMENTS: After learning of Medicare overpayments for cardiac perfusion studies, senior financial managers at Maryland General Hospital did not refund the money until whistleblower litigation forced them to repay. The hospital paid $750,000 to resolve the overbilling allegations and to resolve the delayed return of the overpayments discovered in February and August of 2007. The whistleblower, Kenneth Creeger, worked in the finance department at Maryland General from 2001 to 2009. He will receive $119,728 as a result of the settlement. Since the alleged improper activities, Maryland General, an acute-care hospital that is part of the University of Maryland Medical Systems Corp., said in a statement that it has implemented an extensive compliance program.

GAO RECOMMENDS CMS STANDARDIZE CONTRACTOR AUDIT REQUIREMENTS: The administrative burden and costs associated with providers responding to the various Centers for Medicare and Medicaid Services (CMS) contractors could be reduced if CMS minimizes the differences in postpayment reviews between contractors, concludes a new report. The report, "Medicare Program Integrity: Increasing Consistency of Contractor Requirements May Improve Administrative Efficiency" (GAO-13-522), describes four contractors that conduct post-payment audits or reviews and delineates the existing similarities and differences between them. It also recommends changes CMS could make to accomplish the standardization. CMS concurred with the report's recommendations and agreed to take steps to reduce differences in post-payment review requirements. The four types of contractors covered by the report are Medicare Administrative Contractors, which process and pay claims; Zone Program Integrity Contractors, which investigate potential fraud; Recovery Auditors, which identify potential fraud on a post-payment basis; and Comprehensive Error Rate Testing contractors, which determine the national Medicare fee-for-service improper payment rate. Representatives of three provider associations interviewed for the report said some of the differences in the contractors' post-payment claims review requirements can impede effectiveness and efficiency of the claims reviews by complicating providers' responses to additional documentation requests or their understanding of claims review decisions.

THE CASE THAT KEEPS GIVING: Yet another conspirator has pleaded guilty to his role in the Biodiagnostic Laboratory Services LLC (BLS) bribery and fraud scheme that resulted in more than $100 million in payments to the New Jersey lab. Len Rubenstein, 42, of Holmdel, N.J., pleaded guilty in a Newark federal court to conspiring to violate the anti-kickback statute and the Travel Act by laundering money and making cash payments of thousands of dollars to doctors on behalf of BLS. Rubenstein faces a maximum potential penalty of five years in prison and a $250,000 fine on the bribery conspiracy charge and 20 years in prison and a $500,000 fine on the money laundering charge, or twice the gross gain or loss from the offense. He has also agreed to forfeit $250,000. Sentencing is scheduled for Nov. 12, 2013. The investigation has so far recovered more than $3 million through forfeiture alone.

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