G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Inside this issue

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Take Steps Now to Avoid Claims Denials That Will Occur After January 6, 2014

Clinical laboratories could face denial of claims under Medicare beginning in January as a result of missing or incorrect information about referring providers.

The Affordable Care Act, Section 6405, "Physicians who order items or services are required to be Medicare enrolled physicians or eligible professionals," requires physicians or other eligible professionals to be enrolled in the Medicare program to order or refer items or services for Medicare beneficiaries and must be of a provider type that is eligible to do so. Labs already have the information they need to determine their risk of claims denials due to missing or incorrect information in the ordering or referring provider's Provider Enrollment, Chain and Ownership System (PECOS) enrollment records. This also allows labs to determine if the ordering/referring provider is eligible.

Continued on page 2

Caris Still on the Hook for Majority Of Whistleblower Allegations

A whistleblower suit that alleges Caris Life Sciences submitted false claims to Medicare, paid kickbacks to referring physicians and hospitals, and retaliated against an employee for reporting the alleged false claims emerged almost intact after a motion by the defendants to dismiss the suit.

In an Oct. 23 ruling by the U.S. District Court for the Northern District of Texas, Judge Jorge A. Solis denied the majority of the motion for dismissal by defendant Caris, granting only the argument that the relators failed to plead specific facts demonstrating that payment of travel fees and honoraria to physicians attending Caris-sponsored meetings actually induced any Medicare claims to be submitted.

Caris Life Sciences Inc., Caris Diagnostics Inc., and Miraca Life Sciences Inc. (Caris) filed a motion to dismiss a whistleblower lawsuit brought by former employees of Caris based on the argument that the plaintiffs failed to state a specific claim for which relief can be granted as defined in the Federal Rule of Civil Procedure 9(b). The lawsuit was brought by Marsha Fontanive, a former sales representative, and

Continued on page 9

Take Steps Now to Avoid Claims Denials, *from page 1*

This requirement was rolled out in two distinct phases. The first phase, initiated Oct. 5, 2009, was to include edits in the claims adjudication process to detect, but not deny, problematic claims and include specific remittance advice remark codes (RARCs or remark codes) and claims adjustment reason codes (CARCs or reason codes), in the billing laboratory's remittance advice (RA). CARC codes inform the submitter of the reason the claim is denied or adjusted, while the RARC provides additional remarks that further identify what is wrong with the claim or expands on the CARC. The messages are intended to alert the billing laboratory that the identification information for the ordering/referring provider is missing, incomplete, or invalid or that the ordering/referring provider is not eligible to order or refer.

The second phase will begin Jan. 6, 2014, and will turn the edits on, at which time claims will be denied. It is through these codes currently included in their RAs for denied claims that labs can detect problematic claims and take steps to avoid those denials or communicate the problem to an ordering or referring provider in the future. The Centers for Medicare and Medicaid Services (CMS) has also provided labs with information they can use to correct their billing files before claims are submitted. This is important because once the claim is submitted and denied, the only recourse for the lab is to appeal the claim, a costly and inefficient process.

Required Information and Informational Messages

Any laboratory suppliers having the ability to query their billing computer for RARCs and CARCs and sort them according to the identification alphanumeric code designations will be able to estimate their risk, correct their files, and communicate with the offending ordering/referring provider about the problem.

The Centers for Medicare and Medicaid Services (CMS) has also provided labs with information they can use to correct their billing files before claims are submitted. This is important because once the claim is submitted and denied, the only recourse for the lab is to appeal the claim, a costly and inefficient process.

The edits will verify that the provider is enrolled in Medicare and will ensure the ordering/referring provider has a valid National Provider Identifier (NPI) and that the NPI matches the NPI listed in the PECOS record. The edits will compare the first four letters of the last name on the claim to ensure they match the first four letters of the last name as they appear in the PECOS record. It is important that the claim does not include any extraneous information in the last name field such as a middle initial, title, or other designation. The name fields on the claims should only include the requested first name and last name information.

During phase one, ending Jan. 5, 2014, if the claim does not pass the edits, it will not be denied but it will include the reason code CO-16, meaning the claim lacks information that is needed for adjudication and will include one or both of the following remark codes on the RA:

- N264: *Missing/incomplete/invalid ordering provider name*
- N265: *Missing/incomplete/invalid ordering provider primary identifier*

During phase one, RAs may also include the code N544: *Alert: Although this was paid, you have billed with a referring/ordering provider that does not match our system record. Unless corrected, this will not be paid in the future.*

Also look for remark codes N574 and N575, which indicate that the ordering/referring provider is not eligible to order/refer lab services.

Correcting Your Computer Files

CMS has published a list of NPIs and the correct spelling of all physician last and first names, last updated Nov. 6. With this information at hand, the laboratory can identify physicians and providers with records that do not match their billing files

and correct their records, in many cases without contacting the physician office. It may be possible for the laboratory's information technology (IT) department to automate the comparison of the files which are provided in Adobe Acrobat (PDF) format and as a comma-separated values or CSV file that can be converted to an Excel or other format that is easier to use for IT purposes.

These files can be found at *www.cms.gov/Medicare/* in the Provider Enrollment and Certification section under the Medicare provider-supplier enrollment link.

The beneficiary cannot be held liable and the use of advance beneficiary notices is not allowed in this case because the denial is not due to medical necessity.

The one case where the laboratory cannot correct the problem itself is when the provider is not eligible to order laboratory services. Only physicians and certain types of nonphysician practitioners are eligible to order or refer items or services for Medicare beneficiaries. For Medicare purposes, the following list identifies who can order/refer:

- Physicians (doctor of medicine or osteopathy, doctor of dental medicine, doctor of dental surgery, doctor of podiatric medicine, doctor of optometry—optometrists may only order and refer DMEPOS products and services and laboratory and X-ray services payable under Medicare Part B);
- Physician assistants;
- Clinical nurse specialists;
- Nurse practitioners;
- Clinical psychologists;
- Interns, residents, and fellows;
- Certified nurse midwives; and
- Clinical social workers.

Chiropractors are not eligible to order/refer items or laboratory services and there may be limits on the types of services that may be ordered by physicians like dentists, podiatrists, and optometrists. Lab tests ordered/referred by physicians in these categories may be denied also. If the laboratory gets denials for ordering/referring ineligible providers, the laboratory can contact the ordering provider and inform them of the problem and take steps to avoid submitting the incorrect claims. The laboratory may choose to not perform the tests ordered/referred by a noneligible provider and thereby avoid the cost of performing the testing for which they will not get paid. The beneficiary cannot be held liable and the use of advance beneficiary notices is not allowed in this case because the denial is not due to medical necessity. All of the above information is contained in the *MLN Matters* article SE1305, which can also be found on the CMS Web site.

Takeaway: Laboratories can obtain the information they need from CMS to estimate their risk of denials based on the upcoming ordering/referring denial edits and can take steps to avoid denials and costly appeals of claims by correcting their billing computer NPI and physician identification files. G2

J&J Receives Strict Corporate Integrity Agreement As Part of $2.2 Billion Settlement

In the third-largest settlement the government has reached with a pharmaceutical company, Johnson & Johnson (J&J) and two of its subsidiaries have agreed to pay $2.2 billion in fines and penalties and to comply with terms of a 101-page corporate integrity agreement (CIA).

The CIA includes certifications by its management employees that they will comply with the terms of the agreement. In addition to the $2.2 billion fine, the settlement includes an executive financial recoupment program that provides for forfeiture of annual incentive compensation for certain covered executives in the event of misconduct discovered by J&J and J&J Pharmaceutical Affiliates.

The five-year CIA will cause J&J to make significant changes in its operation, provide greater transparency, and submit detailed reports to the government about its compliance program and business operations to the Health and Human Services Office of Inspector General.

As part of the CIA, J&J must change its executive compensation program to permit the company to recoup bonuses and other long-term incentives even after executives leave the company if the executives or any of their subordinates engage in significant misconduct.

In a Nov. 4 announcement, the U.S. Department of Justice revealed the settlement with J&J and two of its subsidiaries, Janssen Pharmaceutical Inc. and Scios Inc., that resolved several allegations including misbranding drugs, promoting off-label use of certain drugs, and paying kickbacks to physicians and pharmaceutical distributors. The settlement covered both federal and state alleged Medicare and Medicaid false claims violations.

"This global settlement resolves multiple investigations involving the antipsychotic drugs Risperdal and Invega—as well as the heart drug Natrecor and other Johnson & Johnson products," said Attorney General Eric Holder in announcing the settlement. "The settlement also addresses allegations of conduct that recklessly put at risk the health of some of the most vulnerable members of our society—including young children, the elderly, and the disabled."

As part of the CIA, J&J must change its executive compensation program to permit the company to recoup bonuses and other long-term incentives even after executives leave the company if the executives or any of their subordinates engage in significant misconduct. The agreement also requires the above-mentioned certification by company executives, including senior executives and certain members of J&J's independent board of directors. The company must also report payments it makes to physicians for research, educational speaker events and other work promoting the use of its products, and the payment of grants to physicians and pharmaceutical companies that promote their drugs for off-label use.

The investigation involved agencies of the federal government as well as several state agencies and involved both civil and criminal actions and plea agreements. The whistleblower suit will result in payments to relators in Pennsylvania, Massachusetts, and California totaling approximately $167 million.

Holding Individuals Accountable

This case may be an indication of a more aggressive approach to settlement agreements whereby individuals, company officers, and potentially board members are held accountable for their actions or for not controlling the actions of their subordinates. It takes the very aggressive approach of making a company change compensation agreements for executives to deter individuals from trying to profit off of misconduct by the requirement of the financial recoupment program as part of the CIA. Also, the head of each business unit must sign an annual certification of compliance with not only the settlement agreement but also with company policy and procedure related to its compliance program.

Takeaway: The government is increasing its efforts to hold individuals such as company executives and upper-level managers accountable for their participation in schemes and frauds involving false claims and kickback violations as a means to deter such activity.

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COMPLIANCE PERSPECTIVES

Direct Patient Access to Laboratory Test Results: Keeping the Doctor in the Picture

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On Sept. 19, 2013, the Department of Health and Human Services (HHS) announced its postponement of the Sept. 23, 2013, deadline under the Health Insurance Portability and Accountability Act (HIPAA) omnibus rule for most clinical laboratories to revise their notices of privacy practices (NPPs), resulting in a temporary reprieve from HHS enforcement for clinical laboratories that have not yet revised their NPPs. HHS's enforcement delay extends to all CLIA and CLIA-exempt clinical laboratories (i.e., licensed in the states of New York or Washington), except clinical laboratories presently required by state law to provide individuals with access to their laboratory test reports, and clinical laboratories that operate as part of a larger legal entity, such as a hospital (and do not use laboratory-specific NPPs).

HHS delayed enforcement to allow time for HHS to finalize its amendments (proposed Sept. 14, 2011) to the HIPAA privacy rule and CLIA regulations to permit individuals to receive their laboratory results directly from CLIA and CLIA-exempt laboratories (the "proposed rule") and to allow affected laboratories to avoid the burden and expense of multiple revisions to their NPPs within a short period of time—once to meet the deadline and yet again to incorporate the changes of the impending CLIA/HIPAA amendment.

Although HHS indicated in its Sept. 19 announcement that the rule would be finalized "within a short period of time," sources from the Centers for Medicare and Medicaid Services (CMS) indicated as recently as Oct. 30, 2013:

> *[D]ue to the recent Federal Government shutdown, publication of the Patient's Access to Test Reports rule has been delayed. At this time the expected publication date has not been determined.*

As affected laboratories watch and wait for the final CLIA/HIPAA rule regarding access to laboratory results, and for HHS's announcement that the enforcement delay will end, laboratories should continue to identify and make ready both the changes to their NPPs necessitated by the omnibus rule and their other protocols for responding to patient requests for laboratory results so that they can be prepared once the rule is finalized and issued by HHS.

Laboratory professionals nevertheless continue to express apprehension about the changes proposed by HHS more than two years ago. This article will discuss two commonly expressed concerns, the first procedural—the challenge of patient authentication, and the second substantive—the potential for greater professional liability resulting from releasing directly to patients highly complex or highly sensitive test results (such as human immunodeficiency virus (HIV), abnormal pathology, and genetic testing) without the benefit of the treating provider's interpretation and guidance. This article will suggest that one way to lessen these concerns is for laboratories to keep the ordering physician in the picture. Specifically, laboratories should note that the proposed rule does not require laboratories to provide a patient with *immediate* access to laboratory reports. Rather, once the proposed rule takes effect,

the HIPAA rules give the laboratory *30 days* to provide access in response to a patient request (with one additional 30-day extension available), leaving the laboratory time and opportunity to address either or both of these concerns with the patient's physician.

Background

Patients' direct access to laboratory test results is governed by two federal laws: (1) the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which regulates all clinical laboratory testing performed on human specimens for diagnosis, prevention, or treatment of disease or impairment; and (2) the HIPAA privacy rule, which exempts CLIA laboratories from providing laboratory test results directly to patients unless states allow it. Under CLIA, a laboratory may disclose patient test results only to (1) a referring laboratory, (2) an individual responsible for using the test results in the treatment context, or (3) an "authorized person." States may define an "authorized person" as either a health care provider or a patient, or both.

According to HHS in its September 2011 comments to the proposed rule, 23 states have no laws addressing who may receive a laboratory test report directly from a laboratory (which means that laboratories may not directly release test results to patients), 13 states explicitly prohibit laboratories from releasing reports directly to patients, seven states and the District of Columbia allow direct reporting of test results by laboratories to patients, and seven other states allow the laboratory to provide test reports to the patient but only with the requesting provider's prior approval.[1]

The Proposed Rule

In the proposed rule published Sept. 14, 2011, CMS, the Centers for Disease Control and Prevention, and the Office for Civil Rights jointly proposed a rule requiring clinical laboratories covered under CLIA and HIPAA to report test results directly to patients upon request (most laboratories must comply with both laws). The proposed rule was prompted by a concern that current CLIA and HIPAA regulations prevent patients from taking a more active role in their personal health care decisions.

In essence, the proposed rule proposes to preempt states' direct patient access laws as well as regulations that restrict patients' direct access to laboratory results and to establish a national standard for such patient access. If finalized as proposed, it will preempt state laws and regulations to the extent that the state laws and regulations are in conflict with HIPAA because they prohibit clinical laboratories from directly providing test results to patients. Specifically, the proposed rule would directly affect clinical laboratories in the 36 states with laws that currently either prohibit or are silent regarding direct reporting of laboratory results to patients. Further, it also would preempt state laws that allow direct reporting only with provider approval. Once the proposed rule is finalized, laboratories would be required under the HIPAA privacy rule to provide these test results to patients in the form or format requested (i.e., paper or electronic) if they are readily producible in that manner. According to HHS, laboratories "that have electronic reporting capabilities are expected to provide the individual with a machine readable or other electronic copy of the individual's protected health information. (The individual always retains the right to request and receive a paper copy, if desired.)"

The Challenge of Patient Authentication

However, before a laboratory may disclose test results in response to a request for direct access, the proposed rule requires that the laboratory must first verify that the person requesting access to test results is the same individual who provided the specimen for testing. A laboratory is permitted to provide an individual with access

1. For impact by state, see, Proposed Rule, CLIA Program and HIPAA Privacy Program; Patients' Access to Test Reports; 76 Fed. Reg. at 76717, Table 3, Impact of Proposed Rule Changes on Laboratories, at *http://www.gpo.gov/fdsys/pkg/FR-2011-09-14/pdf/2011-23525.pdf.*

to only those completed test reports that, *using the laboratory's authentication processes*, can be identified as belonging to that patient. HHS outlined its version of the process necessary for a laboratory to respond to a patient request for records, as follows:

> *Processing a request for a test report, either manually or electronically, would require completion of the following steps: (1) Receipt of the request from the patient; (2) authentication of the identification of the patient; (3) retrieval of test reports; (4) verification of how and where the patient wants the test report to be delivered and provision of the report by mail, fax, e-mail or other electronic means; and (5) documentation of test report issuance.*

Although the HIPAA privacy rule likewise requires covered entities to "verify the identity and authority of a person requesting protected health information (PHI) . . . if the identity or authority of the person is not already known to the provider,"[2] neither HIPAA regulations nor the applicable HHS guidance provide any implementation specifications for "authentication of the identification of the patient" other than that it must be done using the laboratory's "authentication processes." As a result, laboratories must review their protocols to ensure that they have in place reasonable and workable "authentication processes."

Although many laboratories presently are able to offer patients the option to obtain requested laboratory records through an electronic "portal" that can be programmed to limit access to a unique patient identifier, there are also many laboratories that have not yet adopted such technologies. Moreover, there are many *patients* who have yet to adapt to such systems. As a result, laboratories will need to have a "low-tech" protocol to authenticate patients who opt to make in-person requests. This protocol could be relatively straightforward—the laboratory can simply require that when an individual presents himself or herself at the laboratory, the person must present some type of picture identification, such as a driver's license, whereupon the laboratory should also document its "authentication" of the patient.

Likely more complicated are requests made by telephone or mail or fax. Absent HHS specifications or recommendations, it is uncertain whether for telephonic, faxed, or mailed patient requests, laboratories have any obligation to develop and adopt new systems requiring unique "passwords" or other identifiers or whether they are permitted to rely on less precise or secure identifiers, such as caller ID or handwriting comparisons. In some cases, such as where the majority of testing is performed for patients within a particular community or region, it may be reasonable for the laboratory's authentication processes to require patients to come to the laboratory with appropriate photo identification.

One option is to enlist the help of the patient's referring physician (and staff). Because laboratories have 30 days to respond to the request for records, laboratories might offer patients the choice of picking up the records directly from the laboratory (which may require in-person authentication) or to obtain the records through the treating physician (who may be more convenient or have more efficient means of verifying the patient's identity or authority to receive the results).

Professional Liability Concerns

Despite its laudable aim of enabling patients to take a more active role in their personal health care decisions, the proposed rule nevertheless causes concern for some laboratory professionals due to the increased risks of professional liability resulting from patients receiving directly, without the benefit of the treating provider's concurrent interpretation and guidance, highly complicated or highly sensitive test results. Concerns with releasing laboratory test results directly to patients include worries about patients' inability to understand complex laboratory testing results, which are often expressed in ranges; results that

2. *See* 45 C.F.R. 164.514(h)(1).

must be interpreted in the context of other medical conditions and treatments; test results that may indicate different issues for comorbid conditions; test results that have varying significance for different age groups; and added risks to patients (and potential liability to laboratories and doctors) from "unfiltered" test results in connection with difficult diagnoses or highly sensitive illnesses such as HIV, abnormal pathology, and genetic testing.[3]

However, it is important for laboratory professionals to keep in mind that even though the proposed rule removes CLIA as an obstacle to providing test results to patients immediately, the proposed rule nevertheless gives laboratories the discretion to delay providing more sensitive results for 30 days. Nor does the proposed rule limit a laboratory's communicating with the treating or ordering provider about any of the patient's test results prior to releasing the reports to the patient in order to alleviate any of the above concerns.

Another safeguard that laboratories may choose to adopt is to develop and send a cover letter to patients to accompany some or all test results, especially results that involve highly sensitive or complicated information. Such a protocol could be adopted for certain categories of testing, including sexually transmitted diseases (STDs), drug and substance use, HIV, hepatitis, genetics, prenatal care, and cancer. The cover letter should make clear that the results are being provided at the patient's express request, that they are copies of results that previously have been communicated directly to the patient's physician, and that the patient should consult the physician about any questions about the results. By way of example only, the New York State Department of Health has recommended the following language be included in a prominent position on direct-to-consumer laboratory test reports:

> *[This] report should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health care practitioner.*

Of course, it is important for the laboratory director to be involved in establishing and approval of any protocols of this nature, as well as in approval of the patient cover letter.

What Should Laboratories Do to Prepare for the CLIA/HIPAA Final Rule?

Watch for Publication of Final Rule and HHS's Announcement: Laboratories should watch for the publication of the final CLIA/HIPAA rule regarding access to laboratory results, as well as for HHS's announcement of the end of the NPP enforcement delay for laboratories.

Compliance Timeline: Laboratories should be mindful of the timing requirements. Once finalized, HIPAA-covered laboratories would be required to comply with the final rule by no later than 180 days after effective date (effective date is 60 days after publication in the *Federal Register*). Thus, laboratories will have a total of *240 days* (approximately eight months) to comply from the date the final rule is published.

Prepare Changes to Notice of Privacy Practices: Laboratories should identify and make ready the changes to the NPPs necessitated by the HIPAA omnibus rule in order to promptly update NPPs once HHS issues the final rule on access to laboratory results.

Authentication Process: As discussed above, each laboratory should review and update its authentication processes.

Professional Liability: Laboratories should consider preparing a "cover letter" to patients regarding sensitive information (e.g., HIV information, genetic testing, STDs, cancer screening), provide informational and general materials about the test or disease or condition being tested, and establish and implement a policy for handling "alert values."

Training: Laboratories should start preparing and scheduling training sessions for staff members so they will be prepared to handle patient requests for test results.

If you have additional questions or would like assistance on any compliance issues stated above, please contact David Gee, Esq., at DavidGee@dwt.com, *206-757-8059; Adam Greene, Esq., at* AdamGreene@dwt.com, *202-973-4213; or Kristen Blanchette, Esq.,* at KristenBlanchette@dwt.com, *213-633-6875.*

3. *See, Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy*, the National Academy for State Health Policy (January 2010), page 10.

Caris Still on the Hook for Majority of Whistleblower Allegations, *from page 1*

Lindsey Vitez, who had worked in the billing department. There have been several recent cases that have used this rule as an argument to get false claims lawsuits dismissed, if not entirely, at least partially.

The ruling allows the False Claims Act (FCA) case to go forward, exposing Caris to a variety of allegations and potentially significant fines and punishments if it loses in the end. The case is important to those laboratories and life science companies that perform similar testing and use similar marketing strategies and techniques, such as those used by pharmaceutical companies, to increase referrals for their products. It is also important to laboratories performing and billing for laboratory-developed and genetic tests that are considered somewhat controversial by some experts concerning their efficacy and use in diagnosing or treating patients. In today's laboratory marketplace, these laboratories include many small, specialty laboratories that perform genetic and molecular-based tests.

One of the dangers of a case like this is the exposure to public scrutiny concerning the way these laboratories bill for and market their tests and how well established and documented is the claimed clinical use for these tests. Other whistleblowers that follow the case may note similar activities by their employers and may believe they can make a similar case against their employing lab.

The Allegations

In the amended complaint filed on April 16, the relators (plaintiffs) alleged distinct FCA violations involving billing for the test known as "Target Now," FCA allegations involving the anti-kickback statutes (AKS), and violations of the FCA whistleblower provisions. Target Now is a test offered by Caris's oncology department to identify optimal cancer treatments.

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Regarding the billing allegations, the relators claim that Caris billed for technical component services that did not qualify, services that were not reasonable and necessary, unbundling, double billing, overbilling certain pathology and cytogenetics services, and billing for undocumented services.

The specific requirements of this kind of billing are often unique and involve rules that can be different than the rules applicable to many common laboratory tests. This can lead employees to believe that something improper is going on when, in fact, there is nothing untoward going on at all. However, in this case, according to the complaint filed, the relators apparently have provided a fairly substantial amount of records and documentation to lead Solis to allow the case to proceed.

One particular allegation was that Caris billed for hematology tests that were compromised because the samples were exposed to excessive heat during transport to the laboratory. According to the complaint, Caris knew the samples were compromised but performed and reported the tests anyway and then billed Medicare for them.

In another allegation, the relators assert that Caris filed false claims because it billed for Target Now tests on first-line surgical specimens even though it had no documentation or evidence to support the efficacy or benefit to patients. Other allegations include that Caris employees changed the date of service on some claims and added diagnosis codes taken from Medicare coverage policies to avoid denials.

According to the ruling, Solis denied Caris's argument that the plaintiffs had not provided sufficient detail to support that claims were submitted and allowed the case to go forward. The claims of wrongdoing as described in the complaint are in great enough detail and provide names and dates of actions purportedly witnessed directly by the relators that Solis repeatedly denied Caris's arguments that the claims did not contain sufficient particularity and should be dismissed.

AKS Violations

The claims involving allegations of AKS violations are based on two activities. The first is the waiver of technical component (TC) bills to hospitals that did not qualify for any exception under Medicare billing rules that would permit Caris to bill directly to Medicare. In this case, Caris was supposed to bill the hospital for the TC. However, in meetings with sales representatives, Caris purportedly feared that hospitals who were billed for the TCs would stop referring Target Now tests to Caris. Caris allegedly held these bills while it tried to qualify the hospitals, unsuccessfully, so it could file the claims directly to Medicare. Meanwhile, Caris continued to bill for the professional components of these tests.

The second AKS allegation concerned alleged illegal kickbacks to physicians who attended Caris meetings disguised as travel expenses and honoraria. Ultimately, Solis granted a dismissal for this particular allegation, the only one granted.

Retaliation Against Whistleblower

Vitez claimed she was retaliated against, and subsequently resigned as a result of the retaliation, for bringing the alleged improper coding and billing practices to light. She claimed that after she refused to alter reports and conceal errors she was removed from her position of identifying underbilling and internal coding errors and suffered various forms of retaliation that she reported directly and anonymously to her superiors. Caris asserted that the claim should be dismissed because it did not know that Vitez was involved in protected conduct but, once again, Solis refused to grant the dismissal.

With the number of whistleblower cases on the rise and the size of some of the rewards relators have received, laboratories have to be careful to take steps to prevent employees from becoming whistleblowers.

The Potential Danger to Encourage Other Whistleblowers

While the details of the allegations in this complaint are specific to this case, many of the issues related to the allegations are similar in many respects to perfectly legal activities surrounding the billing and marketing practices of laboratories engaged in the same kind of testing. These can easily be misconstrued by an employee who is not familiar with the rules and regulations involved and may result in whistleblower lawsuits.

With the number of whistleblower cases on the rise and the size of some of the rewards relators have received, laboratories have to be careful to take steps to prevent employees from becoming whistleblowers. Some things that can be done include making sure lines of communication are open, all allegations are taken seriously and properly investigated, employees who report potential problems are treated with respect and informed of the outcome of any investigation or review, and that supervisors are properly trained in what they can and cannot do to a person who may be a whistleblower and is still employed by the laboratory.

Takeaway: Publicly disclosed court cases and rulings can easily be misconstrued by employees and make them suspicious of a laboratory's billing and marketing practices. Laboratories should have active whistleblower prevention policies and practices. G2

Toxicology Company Files Suit Against Competitor

US Health Group Inc. (USHG) is seeking a temporary restraining order and temporary injunction against Physicians Choice Laboratory Services (PCLS) and some of its employees, alleging that they "attempted to steal, usurp, redirect, and hijack the plaintiff's toxicology business, their money, hundreds of urine samples, customer lists, and trade secrets," according to documents filed in a Dallas District Court.

PCLS and USHG once worked together in an arrangement where a third lab, a client of USHG, US Toxicology (UST), performed toxicology screening tests and then referred testing to PCLS for confirmation testing when necessary. The arrangement was severed in August 2013 by PCLS but the lab made it clear, according to the court petition, that it would continue to honor its contractual and fiduciary duties under the original agreement. However, some of PCLS's employees had a different idea and, according to the court documents, are alleged to have committed a variety of forms of interference, defamation, and deception on a daily basis.

The petition alleges, among other things, the defendant's employees fabricated various stories about the plaintiff in an effort to sabotage its business operations. PCLS allegedly told USHG clients that USHG was bankrupt, going out of business, and under investigation by law enforcement. The complaint alleges that PCLS destroyed USHG referral scripts, interfered with urine sample collections, stole USHG's marketing material and replaced it with their own, replaced contact information for USHG with its own information, and made false statements about USHG. Later additions to the petition include complaints against True Fit Medical LLC and US Specialty Labs Inc.

The temporary restraining order and a temporary injunction have been granted to USHG and UST, but they are also seeking a jury trial to recover $1 million in lost business, attorneys' fees, legal fees, and pre- and post-judgment interest.

Black Eye for the Laboratory Industry

This kind of public infighting and unprofessional activity can do harm to all laboratories, particularly those involved in drug testing, in the eyes of the public and government regulators who oversee the laboratory industry.

Takeaway: A laboratory should be able to control the actions of its employees, but in a case like this where unprofessional and unscrupulous activity allegedly is involved and encouraged by the company, a legal recourse may be the only avenue available to resolve the issues.

Compliance Corner

My laboratory is confused about the application of the modifiers 59 and 91 for laboratory services. Can you briefly explain how each should be used?

Both modifiers are used to report a repeat test or Current Procedural Terminology code performed on the same date of service when the repeat test is medically necessary. The modifier 91 is to be used when the same exact test is performed more than once on the same day. For instance, a blood glucose is performed in the morning, and the result is abnormal. The patient is treated and later in the day, a second glucose is performed to determine if the treatment was effective.

The 59 modifier is used when the repeat test is either a different test, a different specimen, or is taken from a different site. This modifier can be used to bypass correct coding initiative (CCI) pairs and medically unlikely edits (MUE) units of service that exceed the allowed amount. The 59 modifier must be used judiciously and documentation must be maintained to support the medically necessary reason for bypassing the CCI and MUE edits.

News-At-A-Glance

MEDICARE COVERAGE OF INCARCERATED BENEFICIARIES: A new fact sheet designed to educate providers and suppliers on Medicare's policy generally not to pay for medical items or services furnished to incarcerated beneficiaries became available in October on the Centers for Medicare and Medicaid Services Web site in the Medicare Learning Network section. The fact sheet is only concerned with billing under Medicare fee-for-service policies and covers the following information: policy background, the definition of individuals who are in custody (or incarcerated) under a penal statute or rule, how to determine whether a beneficiary is in custody under a penal statute or rule, Medicare claims processing for items and services for incarcerated beneficiaries, exception to Medicare policy, and Informational Unsolicited Response (IUR). The IUR process is designed to mitigate a vulnerability in the Medicare system when a beneficiary has been incarcerated but Social Security Administration (SSA) and Medicare records have not yet been updated. In this period, claims may be paid erroneously. The IUR process is initiated when SSA files are updated and overpayments are discovered. The process recoups the overpayments.

LABCORP SUED FOR ALLEGEDLY MISREADING A PAP SMEAR: A family member of a cervical cancer victim, Sharon Woodrum, is suing Laboratory Corporation of America (LabCorp) and the physician who treated her because of an allegedly misread Pap smear test that resulted in her cancer going undetected for over a year. According to an article in the *West Virginia Record*, Dorothy Craig was a patient of Dr. Rick L. Houndersheldt on Dec. 21, 2009, when she visited his office because she was experiencing vaginal bleeding. Apparently, Craig had a history of cervical cancer but that information was not included with the requisition for the Pap smear, which was referred to LabCorp. The report for the test gave a diagnosis of "negative for intraepithelial lesion and malignancy." Almost a year and a half later, Craig was still complaining of vaginal bleeding and was referred by Houndersheldt to a gynecologist. She was diagnosed with advanced cervical cancer and referred to Edwards Comprehensive Cancer Center in Huntington, W.Va., for treatment but her treatment options were limited by that time. Woodrum claims LabCorp was negligent and misread the Pap test and that Houndersheldt should have known of Craig's history of cervical cancer and reported that information to LabCorp when he submitted the slide for interpretation. She is suing for compensatory and punitive damages with pre- and post-judgment interest.

BROOKLYN WOMAN SENTENCED TO PRISON FOR ROLE IN FRAUD SCHEME: Irina Shelikhova, 50, of Brooklyn, was sentenced in the Eastern District of New York for her role in a Medicare fraud scheme, according to the Department of Justice. After living as a fugitive in Ukraine for nearly two years, Shelikhova was arrested at the John F. Kennedy International Airport on June 15, 2012. She is ordered to forfeit $36.2 million and to pay restitution of $51 million; is excluded from Medicare, Medicaid, and all federal health programs; and faces deportation from the United States upon her release. Shelikhova pleaded guilty on Dec. 18, 2012, to one count of conspiracy to commit money laundering and is one of 13 individuals convicted in this case.

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