G2 Compliance Report

For Hospitals, Laboratories and Physician Practices

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New Jersey Lab President Charged in Referral Scheme; Physician, Two Employees Arrested

Federal agents arrested the president and part-owner of Biodiagnostic Laboratory Services (BLS; Parsippany, N.J.), a New Jersey physician, and two employees in April on charges they participated in a long-running cash-for-referral scheme.

Arrested were BLS President David Nicoll, 39, of Mountain Lakes, N.J.; his brother Scott Nicoll, 32, of Wayne, N.J., a senior BLS employee; and Craig Nordman, 34, of Whippany, N.J., the CEO of Advantech Sales LLC—an entity used by BLS to make illegal payments. They are charged with bribing doctors to refer patient blood samples to BLS and to order unnecessary tests, resulting in tens of millions of dollars in profit for the company. BLS is also charged with the conspiracy. The charges were announced by New Jersey U.S. Attorney Paul Fishman.

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OIG Issues Revised Self-Disclosure Protocol

The Department of Health and Human Services Office of Inspector General (OIG) April 17 released a revised provider self-disclosure protocol (SDP), including new guidance on calculating penalty multipliers, reporting conduct involving excluded individuals, and reporting potential violations of the anti-kickback statute.

The SDP establishes a process for providers to voluntarily identify and disclose potential cases of fraud involving federal health care programs, including "guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability under OIG's civil monetary penalty (CMP) authorities," the revised SDP said.

Tony Maida, deputy chief in the administrative and civil remedies branch of OIG's Office of Counsel, said OIG thought "it would provide more transparency to providers if we gave them specific guidance on some of the most common conduct we've received under the SDP."

OIG has resolved more than 800 disclosures in the past 15 years, according to the revised SDP.

60-Day Rule

The revised protocol also addressed a proposed 60-day overpayment rule from the Centers for Medicare and Medicaid Services (CMS),

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New Jersey Lab President Charged in Referral Scheme, *from page 1*

Frank Santangelo, 43, of Boonton, N.J., a physician with offices in Montville and Wayne, is charged in the complaint for allegedly accepting bribes to refer patients to BLS and violating his duty of fidelity to patients. Santangelo allegedly received more than $700,000 in bribe payments from BLS and sent the company more than $4.2 million in blood referrals.

"Kickbacks have no place in the health care industry," said Tom O'Donnell, special agent in charge for the Office of Inspector General of the U.S. Department of Health and Human Services. "Federal and state taxpayers, and vulnerable patients, deserve better."

Inducement for Referrals

According to the complaint, between 2006 and 2013, BLS and entities it funded paid millions of dollars to physicians to induce them to refer patient blood samples to BLS. From these referrals, BLS received at least tens of millions of dollars from private health insurance companies and Medicare.

Numerous physicians were bribed under the guise of lease, service, or consulting agreements. Under the lease and service agreements, between 2006 and 2009, physicians were frequently paid thousands of dollars a month by BLS for space in medical offices that BLS did not need or actually use and to perform routine blood drawing services that had little real dollar value.

In a text message referenced in the complaint, David Nicoll wrote to Santangelo about the status of their referral agreement, stating that BLS "really can't afford the 40-50,000 [dollars] a month if the girls aren't going to be drawing any blood," to which Santangelo responded by stating, "U no u can count on me" and "I never let u down."

According to the complaint, between 2006 and 2013, BLS and entities it funded paid millions of dollars to physicians to induce them to refer patient blood samples to BLS. From these referrals, BLS received at least tens of millions of dollars from private health insurance companies and Medicare.

When the state of New Jersey sought to address the problem of laboratories using lease agreements to bribe physicians for referrals—effectively prohibiting all leases between blood laboratories and physicians in 2010—BLS, David Nicoll, Scott Nicoll, and Nordman funded and used at least half a dozen entities to disguise bribe payments to physicians.

In one example from the complaint, a physician was paid $1,500 per month by Nordman—who identified himself as both a BLS employee and the CEO of Advantech—for spending less than two minutes each month filling out a one-page questionnaire asking how often sales representatives visited the physician's office, which insurance companies were in-network for the physician, and which out-of-network insurance companies did the physician bill. In reality, the payments were to refer patients' blood samples to BLS.

Various recorded conversations are also detailed in the complaint, including one in which Nordman urges another physician to order more tests, stating, "That's where it really is. I mean, if we get 10 bloods for $1,000, as opposed to 10 bloods for $4,000 or five bloods for $4,000, obviously there's more. We get paid a percentage, obviously."

In a second conversation, Scott Nicoll tells this same physician, "I would like to be able to get you, you know, around 1,500 [dollars] a month if I can, but I need—we

would either need more tests or more patients or something along those lines . . . you're doing about $1,000 a bag per patient . . . if we could, we could somehow get that up in the two's, then I'm looking at making 4,000, and I have no problem paying you know 1,500 [dollars] for it."

Profit of $200 Million From Conspiracy

Over the course of the charged conspiracy, BLS has made more than $200 million from the testing of blood specimens and related services. David Nicoll received more than $33 million in distributions from BLS during that same period, during which he also spent millions on personal items: more than $5 million on high-end and collectible automobiles, including approximately $580,000 for a Yenko Nova and approximately for $365,000 for a Yenko Chevelle, approximately $300,000 for a Ferrari, and approximately $291,000 for a Corvette; more than $700,000 to purchase a Manhattan apartment for a female companion; $600,000 on private jet charters; $392,000 on tickets to sporting events; $216,000 at electronics stores; and $154,000 at a gentleman's club and restaurant.

"It is alleged in today's complaint that the president and other employees of BLS bribed physicians to refer patients to their lab and order unnecessary lab tests, reaping millions of dollars, all in the name of greed," stated Shantelle Kitchen, acting special agent in charge, IRS-Criminal Investigation, Newark Field Office. "Medical tests should only be run when medically necessary, not so someone can buy exotic cars and charter private jets. This type of health care fraud will not be tolerated and IRS-Criminal Investigation, along with our law enforcement partners, will vigorously investigate these crimes to bring the perpetrators to justice."

David Nicoll, Scott Nicoll, and Nordman are charged with one count of conspiring to violate the anti-kickback statute and the Federal Travel Act. Santangelo is charged in two counts—with substantive violations of the anti-kickback statute and the Federal Travel Act, for allegedly using the interstate mail in aid of commercial bribery. If convicted, the defendants face a maximum potential penalty of five years in prison on each of the counts with which they are charged. Each count also carries a maximum $250,000 fine, or twice the gross gain or loss from the offense.

BLS is also charged with the conspiracy and faces a maximum potential penalty of five years of probation and a $500,000 fine, or twice the gross gain or loss.

Labs to Get Refunds From New York State Health Department

More than 200 independent and hospital clinical laboratories, including members of the American Association of Bioanalysts (AAB), will benefit from the recent successful conclusion of a lawsuit by AAB and other laboratories against the New York State Department of Health (NYSDOH).

The lawsuit charged that the department's clinical lab evaluation program overcharged clinical labs for inspection and reference fees to subsidize activities that had no relation to the regulation of clinical labs.

In a statement on the refunds, Mark S. Birenbaum, Ph.D., AAB's administrator, said, "AAB is glad that we were able to lay the groundwork and assist our members and other labs in New York to recover the fees that continued to be wrongfully charged to them. We have successfully fought this battle for our members since 1984 in three separate lawsuits."

Under the recent settlement, NYSDOH will refund a total of $18 million. It covers fees paid from 2007-2008 through 2010-2011. In addition, 23 AAB labs that were part of a previous lawsuit (1998-2006) are also entitled to recover a portion of their fees for 2006-2007.

This complaint followed a 1999 AAB lawsuit that resulted in a $5 million refund in 2011 to 35 AAB member laboratories. When NYSDOH accounting and billing practices remained unchanged, AAB and individual labs took new action in 2009 to recover the excess fees that continued to be collected each year. The lawsuit was extended through the 2010-2011 fiscal year, until it was just settled, shortly before the setting of a trial date.

AAB's general counsel Jeffrey J. Sherrin of O'Connell & Aronowitz (Albany, N.Y.) handled all three lawsuits against NYSDOH. "Even in difficult fiscal times, the state recognized the need to make the laboratories whole and found the monies to do so, he said. "Hopefully, this brings an end to the need for these lawsuits." G2

Texas Hospital Fined Over Lab Deficiencies

A central Texas hospital has been fined $10,000 as a result of deficiencies in lab testing procedures.

State and federal officials say that at least a dozen deficiencies in lab procedures at Lakeway Regional Medical Center resulted in several patients undergoing unnecessary procedures and emergency room patients having to wait up to five hours for test results. The hospital, which is near Austin, has been open for only about a year.

A report made by the inspectors with the Texas Department of State Health Services at the request of the Centers for Medicare and Medicaid Services (CMS) found deficiencies at the 100-bed, $210 million hospital. The report also said the emergency room and nursing were affected by similar problems, according to a story in the *Austin American-Statesman*. The emergency room reportedly did not have policies and procedures in place regarding the treatment of stroke and heart attack patients.

The hospital voluntarily closed the blood bank and the microbiology lab at CMS's request. It also has replaced some personnel, brought in an experienced lab director, and outsourced work to other facilities in Austin.

According to reports, hospital CEO David Kreye said a review of cases found procedures were done "exactly right," just not properly documented.

Twelve of the 13 deficiencies found had to do with the lab, and four of them remain under review. Kreye said the problems have been corrected and that most of the infractions had to do with lack of documentation. However, a spokesman for CMS disagreed.

"The hospital was given several opportunities during the course of the on-site inspection to provide information that would demonstrate compliance with Medicare requirements," Bob Moos told the *American-Statesman* in an e-mail. "Further, the on-site inspection is not simply a review of policies and procedures, but an evaluation of how those policies and procedures are implemented to prevent adverse outcomes. The findings demonstrate the hospital's failure at the time to provide care in accordance with our requirements." G2

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

New HIPAA Regulations Mean New Obligations for Clinical Laboratories

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The HIPAA-HITECH regulations, "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules" (final rule), were published in the *Federal Register* on Jan. 25, 2013 (78 Fed. Reg. 5566.) The final rule not only implements many of the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act but also the Genetic Information Nondiscrimination Act. It also makes other changes under the general authority of the Department of Health and Human Services (HHS). Clinical Laboratories have six months, until Sept. 23, 2013, to come into compliance. An additional 12 months, until Sept. 23, 2014, may be available for certain qualifying business associate agreements. However, the enforcement rule changes are effective on March 26, 2013. The key issues as they apply to clinical laboratories are summarized below.

Business Associates

Downstream Contractors: If a clinical laboratory contracts with a billing company, the billing company is a business associate. Nothing new there; the billing company needs protected health information (PHI) from the clinical laboratory to provide its services. If the billing company contracts with a shredding company to dispose of its records (i.e., the clinical laboratory's PHI) the shredding company becomes a subcontractor under the Health Insurance Portability and Accountability Act (HIPAA). The final rule makes it clear, however, that each entity (clinical laboratory, billing company, and shredding company) is directly responsible for its own compliance with the business associate requirements of the HIPAA security rule and the HIPAA privacy rule, even if the parties fail to enter into written business associate agreements. Under the final rule, the clinical laboratory would still be required to enter into a business associate agreement with the billing company. The billing company, in turn, must obtain written "satisfactory assurances," now clearly in the form of another business associate agreement, from the shredding company.

Privacy Rule Obligations: The final rule provides that a business associate is responsible for (1) limiting uses and disclosures of PHI to what is provided in the business associate agreement or the privacy rule, (2) disclosing PHI to HHS for an investigation of the business associate's HIPAA compliance, (3) if disclosure of PHI is otherwise appropriate under the privacy rule, disclosing PHI in electronic form if it is requested and is stored electronically (as discussed below), (4) making reasonable efforts to comply with the minimum necessary requirements of the privacy rule, and (5) entering into a business associate agreement with a subcontractor.

Transition Provisions: The final rule grandfathers business associate agreements for up to one year beyond the compliance date, up to Sept. 23, 2014. The business associate agreement must have been in existence prior to Jan. 25, 2013, complied with HIPAA, and not be renewed or modified during the grandfather period. An automatic renewal does not constitute a renewal or modification for purposes of the availability of the grandfather period.

Enforcement Rule

Investigation and Resolution of Violations: The final rule provides that HHS will investigate a possible HIPAA violation if a preliminary review of the facts indicates the possibility of *willful neglect* as to HIPAA compliance. However, absent indications of willful neglect, HHS may seek compliance through informal, voluntary action in appropriate cases.

Violations Due to Reasonable Cause: The HITECH Act includes four tiers of penalties focused on state of mind. The final rule clarified the definition of second-tier violations due to reasonable cause not amounting to willful neglect. The second tier likely covers many common violations by otherwise generally compliant covered entities and business associates, such as those that occur due to human error, despite workforce training and appropriate policies and procedures. Reasonable cause applies to HIPAA violations in which the entity exercised ordinary business care and prudence to comply with the provision that was violated or in which the entity knew of the violation but lacked the "conscious intent or reckless indifference" associated with a violation due to willful neglect.

If a business associate is an agent of the clinical laboratory under federal common law, the clinical laboratory can be liable for civil monetary penalties imposed on the downstream contractor for a HIPAA violation, so long as the violation arose within the scope of the agency.

Upstream Vicarious Liability: If a business associate is an *agent* of the clinical laboratory under federal common law, the clinical laboratory can be liable for civil monetary penalties (CMPs) imposed on the downstream contractor for a HIPAA violation, so long as the violation arose within the scope of the agency. The same is true for a business associate and a subcontractor. HHS's description of federal common law of agency is that it is based on the right or authority of the clinical laboratory to control the business associate's conduct in the course of performing the service, even if that right was not actually exercised with respect to the violation for which the CMP is imposed.

Marketing

The final rule requires a HIPAA authorization for treatment communications and for communications that are otherwise permitted under the definition of *health care operations*, *if* the clinical laboratory or other covered entity (or a business associate) receives financial remuneration from the third party whose product or service is subject to the communication. *Financial remuneration* is direct or indirect payment to the covered entity or business associate from, or on behalf of, the third party whose product is the subject of the communication. Certain exceptions exist for prescription refill reminders or communications about a currently prescribed drug. *Direct remuneration* means the payment is paid directly to the covered entity or business associate and *indirect remuneration* means that the remuneration was channeled through a third party. *Financial remuneration* for marketing purposes does not include in-kind or other nonfinancial subsidies.

Sale of PHI

Direct or indirect remuneration received by a covered entity or business associate in exchange for the disclosure of PHI represents a "sale" of PHI, and a HIPAA authorization must be obtained from each individual. Exceptions exist for, among other things, public health activities, research, treatment, and other purposes designated by HHS. Disclosure includes granting access directly or through licenses or lease agreements. Remuneration for sales of PHI includes in-kind value. The final rule

allows cost-based fees for the costs of preparing and transmitting the data, including direct and indirect costs so long as there is no profit factor.

Research

The final rule permits covered entities to combine conditional and unconditional authorizations for research if they differentiate between the two activities and allow for an opt-in of unconditional research activities. Future research studies may now be part of a properly executed authorization that includes all the required core elements. Previously, covered entities could not combine or condition authorizations for purposes other than research that involves treatment, while a separate authorization was needed for future research or to create or build a central research database or repository. This change brings HIPAA in line with common rule requirements related to biospecimens and databases.

Disclosures About a Decedent

The final rule permits disclosure of information about a decedent, previously restricted to a personal representative, to be made to family members and others who were involved in the care or payment for care of the decedent prior to death, unless inconsistent with any prior expressed preference by the decedent that is known to the covered entity.

Notice of Privacy Practices

The final rule requires that a covered entity include uses and disclosures of PHI in its notice of privacy practices. The notice can list categories that require authorization, such as marketing and sale of PHI. The notice must include a statement that other uses and disclosure not described in the notice will be made only with authorization from the individual. In addition, the notice must include the new right to restrict certain disclosures of PHI to a health plan where the individual pays out of pocket in full for the health care item or service. Finally, the notice must include a statement regarding a breach of unsecured PHI, although an entity-specific statement is not required.

The final rule amends the privacy rule to allow individuals to request electronic copies of their PHI that is maintained in an electronic health record or other electronic designated record set, such as clinical, billing, or other records used to make decisions about the individual.

Right to Request a Restriction of Uses and Disclosures

The final rule creates a new right to restrict certain disclosures of PHI to a health plan under which the health care item or service is paid out of pocket in full. Clinical laboratories must operationalize this key change in the privacy rule. Clinical laboratories still can submit restricted information for required Medicare and Medicaid audits under the privacy rule's *required by law* requirement.

Access to Protected Health Information

Individuals: The final rule amends the privacy rule to allow individuals to request electronic copies of their PHI that is maintained in an electronic health record or other electronic designated record set, such as clinical, billing, or other records used to make decisions about the individual. A clinical laboratory must provide an electronic, "machine readable copy," which means digital information stored in a standard format enabling the PHI to be processed and analyzed by a computer. HHS provides flexibility as to the exact format, acknowledging that systems may vary, but requires the clinical laboratory to accommodate individuals' requests for specific formats, if possible.

Third Parties: Under the final rule, a clinical laboratory must comply with an individual's request to transmit PHI directly to another individual when such request is in writing, is signed by the individual, and clearly identifies the designated person and where to send the copy of the PHI. If a clinical laboratory already requires that access requests be written, either the same request or a separate written request can be used to access the individual's PHI.

Fees: Under the final rule, covered entities can charge reasonable cost-based fees for preparing and transmitting PHI, including labor costs for copying PHI; supply costs for both paper and electronic copies, including CDs or USB flash drives; and postage for shipping portable media. Fees related to maintaining systems, infrastructure, and storage are not considered reasonable, cost-based fees.

Timeliness: The final rule removes the 60-day time frame for retrieval of records held off site, leaving covered entities with 30 days to provide access to records to individuals in all circumstance, with a one-time 30-day extension. Clinical laboratories should check state law related to more stringent timeliness requirements and modify current policies and procedures.

Breach Notification Rule

Definition of Breach: The final rule modifies the definition of *breach* under the breach notification rule by adding language to clarify that an impermissible use or disclosure of protected health information is presumed to be a breach unless the responsible entity can demonstrate that there is a low probability that the protected health information has been compromised.

Harm Standard: The final rule modifies the harm standard to require the use of a more objective risk assessment. The new standard requires that the covered entity conduct a risk assessment of at least the following factors: (1) the nature and extent of the PHI involved, including the types of identifiers and the likelihood of reidentification, (2) the unauthorized person who used the PHI or to whom the disclosure was made, (3) whether the PHI was actually acquired or viewed, and (4) the extent to which the risk to the PHI has been mitigated.

The final rule modifies the definition of* breach *under the breach notification rule by adding language to clarify that an impermissible use or disclosure of protected health information is presumed to be a breach unless the responsible entity can demonstrate that there is a low probability that the protected health information has been compromised.

Notification to Individuals: The final rule clarifies certain aspects of notice. Most significantly, it states that notice has not been given if a written notice is returned as undeliverable. Clinical laboratories responding to a breach with more than 10 notifications returned as undeliverable may take some reasonable time to search for correct, current addresses for the affected individuals but must provide substitute notice "as soon as reasonably possible" and within the original 60-day time frame for notifications.

Notifications to the Media: The final rule clarifies several points regarding media notifications, including that media outlets are not obligated to publicize each and every breach notice they receive (and a failure to publicize does not render the notice provided insufficient) and that covered entities must deliver a press release directly to the media outlet being notified. Posting a general press release on a Web site, for instance, is insufficient.

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OIG Issues Revised Self-Disclosure Protocol, *from page 1*

contending that "the SDP may mitigate potential exposure" to the proposed rule's overpayment requirements.

The CMS proposed rule, released in February 2012, would require physicians to return an overpayment and "to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment," all within 60 days of first identifying the overpayment.

However, the proposed rule would suspend the 60-day obligation to return overpayments if OIG confirmed the receipt of a provider's timely submission under the SDP.

In return for a suspension of the 60-day obligation, "OIG expects disclosing parties to disclose with a good faith willingness to resolve all liability within the CMPL's [Civil Monetary Penalties Law] six year statute of limitations as described in section 1128A(c)(1) of the [Social Security] Act," the revised SDP said.

The proposed rule would suspend the 60-day obligation to return overpayments if OIG confirmed the receipt of a provider's timely submission under the SDP.

OIG said it would provide additional guidance regarding the SDP and the 60-day rule after CMS releases a final rule.

The first OIG provider SDP was published in 1998, and OIG has issued three open letters since then offering additional guidance. OIG released a notice in June 2012 calling on the public to provide recommendations for a revised protocol. Maida said there was strong support from commenters in favor of incorporating OIG's original SDP and the three open letters into one document.

Additional Guidance

The revised SDP also provided guidance on how OIG calculates penalties for providers disclosing potential violations, noting that "we believe that individuals or entities that use the SDP and cooperate with OIG during the SDP process deserve to pay a lower multiplier on single damages than would normally be required in resolving a Government-initiated investigation."

Although OIG said the multiplier it uses may vary on a case-by-case basis, it said a common practice is to require a minimum multiplier of 1.5 times the single damages. OIG's Maida said OIG has never articulated the 1.5 multiplier before. "We do think providers should pay some type of multiplier, but we also want to incentivize them to enter the SDP," Maida said.

Laurence J. Freedman, an attorney with Patton Boggs LLP, Washington, D.C., says that specifying the 1.5 multiplier is an indication from OIG that "providers do want some clear expectation of what their involvement with the SDP will entail."

In addition, OIG will require a minimum settlement of $50,000 to resolve any anti-kickback-related disclosures using the SDP and a minimum settlement of $10,000 for any other disclosures using the SDP.

Overall, Freedman said the revised SDP offers more explicit guidance that reflects current practices. "It reiterates a commitment to having an efficient process, and reflects OIG's more detailed thinking on how the process should work," Freedman said.

However, Freedman said the revised SDP still gives no indication of a Department of Justice endorsement of the SDP. OIG refers all disclosures of criminal conduct to DOJ, and while OIG will advocate to DOJ on behalf of the disclosing providers, DOJ is not bound by the SDP, Freedman said.

Excluded Individuals

The revised SDP also included specific guidance on how to disclose information about any conduct involving employees who are discovered to be excluded from participating in federal health care programs.

Providers must include:

- The identity of the excluded individual;
- The excluded individual's job description;
- The excluded individual's dates of employment;
- Descriptions of any background checks performed on the employee before or during his or her employment;
- Descriptions of the employee screening process;
- A description of how the provider discovered the employee was an excluded individual; and
- A description of any corrective actions that were taken to ensure no excluded individuals are hired in the future.

Freedman said the new guidance "shows an emphasis on entities finding excluded individuals within their organizations and reporting them. It highlights provider expectation."

Potential Anti-Kickback Violations

Additionally, OIG's revised SDP provided guidance on information that may prove helpful in resolving disclosures related to potential violations of the anti-kickback statute "and, if applicable, the Stark Law."

The revised SDP included several examples of helpful information for providers to disclose, such as:

- How fair market value was determined;
- Why required payments from referral sources were not made or collected in a timely manner; and
- Whether payments were made for services that were never done or documented.

"OIG will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the AKS and, if applicable, the Stark Law," the revised SDP said.

Bio-Reference Denies Allegations Of Wrongful Termination, Anti-Kickback Violations

Bio-Reference Laboratories (Elmwood Park, N.J.) has denounced and denied a complaint filed against the company in Superior Court of New Jersey by a former employee claiming she was wrongfully terminated.

Valerie Greco filed a complaint against the company April 3 alleging the company wrongfully terminated her after she reported unlawful billing practices to her supervisors. According to the complaint, Bio-Reference in December 2010 assigned Greco as an in-office phlebotomist at Fair Haven Internal Medicine, which is part of Integrated Medicine Alliance in Fair Haven, N.J. The principal physician of the practice is Jan Glowacki, M.D.

Within the first week of Greco's assignment, she telephoned Colleen Sykes, a Bio-Reference sales representative, and James Mitra, phlebotomy supervisor, to tell

them that she was not performing blood draws (venipunctures) on patients at the office because Fair Haven's own assistants were doing that and she was just processing the paperwork on a computer that Bio-Reference provided to the Fair Haven practice, according to the complaint. Greco told Sykes that this arrangement was not proper and not what she expected and asked to be relocated.

According to the lawsuit, in early January 2011, Greco observed that Fair Haven and Bio-Reference were engaged in the following billing practices she considered to be illegal: The medical practice impermissibly billed both Medicare and non-Medicare patients, who visited the office solely for blood draws, as an "office visit." It also charged a separate venipuncture fee of $15. Bio-Reference charged a venipuncture fee as well, even though it did not perform them (commonly called "double billing").

Greco reported these practices to Mitra and Sykes, who allegedly told her to "keep her mouth shut and keep billing for the venipuncture charge on behalf of Bio-Reference." At the end of January 2011, Greco said she confronted Glowacki about the billing practices and accused him of committing Medicare fraud. According to the complaint, "Dr. Glowacki remained silent during this conversation, did not deny anything, and angrily walked away."

In April 2011, Mitra telephone Greco and told her not to return to Fair Haven because Glowacki no longer wanted her on the account. At the end of April Greco was notified that she would be terminated and could file for unemployment benefits. A subsequent offer of employment allegedly was blocked because of her allegations regarding the billing practices of Bio-Reference and Fair Haven.

The lawsuit filed by Greco alleges wrongful discharge and seeks compensation for lost wages, benefits, and other remuneration, as well as punitive damages and attorneys' fees.

Bio-Reference Disputes Charges

In a statement issued April 12, Bio-Reference said it "strongly denounced and denied" the allegations and said that it would vigorously defend this case to vindicate itself against the "frivolous allegations."

According to the statement, the company has completed a preliminary review of the allegations and has determined that the complaint is baseless, frivolous, and totally without merit. The complaint describes a series of events that are unsupported by facts and seeks compensation for nonexistent damages, says Bio-Reference.

In a statement issued April 12, Bio-Reference said it "strongly denounced and denied" the allegations and said that it would vigorously defend this case to vindicate itself against the "frivolous allegations."

"The company's preliminary review of all electronic requisitions (the method used in this office) submitted by the account during the time when the plaintiff was assigned to that office to be a phlebotomist reveals no apparent Medicare or other billing issues," says the statement. "The company believes it has found no evidence that any Medicare patients, drawn by the physician's staff, were billed by the company to Medicare for venipuncture fees.

"The company also believes, based on its preliminary review, that the totality of blood draws involving the plaintiff are miniscule in number and the amount of anticipated reimbursement from those phlebotomy services billed to Medicare from the account over the period the plaintiff worked as the location was less than $250. In addition, the company believes the billing practices relating to this account are consistent and compliant with Medicare and Medicaid regulations." G2

News-At-A-Glance

IMPROPER TEST UNBUNDLING: A Texas physician and her spouse have paid $430,000 to settle allegations they submitted false claims to Tricare, Medicare, and Medicaid for certain laboratory tests, according to U.S. Attorney for the Western District of Texas Robert Pitman. The settlement resolved allegations that Dr. Bola Elemuren, a family practitioner doing business as the Family Medical Clinic in Harker Heights, and her husband and office manager, John Ogunmuyiwa, knowingly overcharged Tricare for automated gynecology-related laboratory tests from 2003 to 2008. The test is a single procedure that must be billed under an inclusive billing code at a predetermined rate, Pitman said in a statement. The defendants "unbundled" and inflated their charges by separately billing the test under multiple current procedural terminology codes at a higher total cost to Tricare, prosecutors asserted. The unbundled claims made it appear as if the clinic performed more than one test and therefore was entitled to more than one payment from the government. The case was settled out of court following an investigation by the Department of Defense Criminal Investigative Service, Pitman said. He said the settlement agreement was not an admission of liability by Elemuren, Ogunmuyiwa, or Family Medicine Clinic.

RAC APPEALS USUALLY SUCCESSFUL: When hospitals have chosen to appeal Recovery Audit Contractor (RAC) Medicare claims denials, almost three-quarters (72 percent) of denials have been overturned as of the fourth quarter of 2012, according to the latest American Hospital Association (AHA) RACTrac survey. Michael Ward, AHA's senior associate director for policy, says that the appeals overturned percentage is consistent with previous RACTrac surveys. "The numbers tell us that hospitals that choose to appeal have a pretty good success rate," Ward said. The survey, which includes cumulative hospital RAC information from January 2010 through the end of 2012, found that hospitals have appealed roughly 40 percent of the 292,000 RAC denials issued over that time frame. The overturned RAC denials have a total value of $105 million, AHA said in the survey, released March 8.

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