G2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

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Enforcement Climate for Labs Toughest Since LabScam

The current federal enforcement climate for clinical laboratories is the toughest it's been since the government cracked down on labs in the early 1990s as part of Operation LabScam, according to two attorneys participating in a legal and policy panel discussion at G2 Intelligence's Lab Institute conference, held Oct. 10-12 in Arlington, Va.

"This is a challenging time for clinical laboratories and for all health care providers," said Hope Foster, Esq., a member of the health law group at Mintz Levin (Washington, D.C.). "When the issue of health care fraud and abuse and enforcement is a topic during a presidential debate, you know that the topic has risen in significance and visibility."

Foster said she is seeing more activity regarding laboratories and lab services than she has seen in the last 20 years. Much of her work is in representing the "misunderstood" in their dealings with the federal government, she explained, noting that many of the current enforcement efforts rely on the ability of contractors to identify overpayments in what amounts to a "bounty" system.

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Hospital in N.Y. Receives Rare Order to Shut Down Lab

The laboratory at Edward John Noble Hospital in the rural upstate town of Gouverneur was in disarray at the time the New York Department of Health (DOH) issued a rare shutdown order on Sept. 28, records show.

The closure has brought inpatient operations at the facility to a virtual standstill and forced it to send its patients elsewhere. E.J. Noble is now looking to partner with another hospital in order to guarantee appropriate lab supervision.

The lab had been managed by ClearPath Diagnostics, a Syracuse, N.Y.-based pathology practice. However, DOH records say that it terminated its contract during the summer. Among the reasons it cited:

- The laboratory couldn't acquire reagents because it had not paid its supplier bills;
- Various supplies were being used past their expiration date, including fingerstick glucose controls, bovine albumin solution, lactose testing supplies, blood testing supplies, vacutainers, blood collection sets, and agar;

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Hospital in New York Receives Rare Order to Shut Down Lab, *from page 1*

- The laboratory lacked basic supervision to the point that its appointed supervisor worked as a bench technologist, forcing her to neglect her supervisory duties due to overwork;
- There is no policy in place for resolving complaints from providers for delayed tests;
- The laboratory lacks both a biosafety program and a biohazard risk assessment plan;
- The hospital did not provide basic personal safety equipment such as goggles and face shields; and
- The lab lacked documentation as to whether staff had been trained in the packing and shipping of infectious materials.

The DOH's concern peaked in September, after it received reports that a patient received a transfusion with an incorrect blood type due to samples that had been mistakenly switched, according to records.

That patient, identified in media reports as Jack Hutton, a 62-year-old lung cancer patient under hospice care, died of a stroke about two weeks after the transfusion. Department of Health spokesman Jeffrey Hammond said the death has not been directly linked to the transfusion.

Moreover, the lab flunked its own state-mandated proficiency tests—also as the result of switched samples—according to the DOH report.

In response, the DOH gave E.J. Noble a list of items that required corrections. It also asked it to limit its testing menu and to confine its blood banking activities to type O negative and transfer all patients requiring other blood types out of the hospital. However, that did not resolve the issues, according to the DOH report, leading to the shutdown order.

The DOH's concern peaked in September, after it received reports that a patient received a transfusion with an incorrect blood type due to samples that had been mistakenly switched, according to records.

Hammond said he was unaware of any other laboratory ordered closed by his department. "It's a very rare occurrence," he said.

E.J. Noble has since submitted a plan of correction to the state. However, Hammond indicated that it could take weeks, if not longer, for the state to approve the plan, reinspect the lab, and approve its reopening. "I can't give a specific timetable," he said.

The hospital has also approached other facilities in the area for them to provide operational oversight. One of them, Samaritan Health in Watertown, N.Y., 35 miles to the south, confirmed that E.J. Noble had sought help in managing its laboratory earlier this year. "They've reached out in the past regarding some issues," said hospital spokesperson Krista Kittle. She added that E.J. Noble Chief Executive Officer Charles P. Conole approached Samaritan earlier this month, seeking a firm plan of commitment.

In addition to possibly collaborating with Samaritan, E.J. Noble has also approached Canton-Potsdam Hospital in Potsdam, N.Y., 35 miles to the northeast, as a potential collaborator, according to media reports. Conole did not return repeated phone calls seeking comment.

Clinical Lab Services Under the OIG's Microscope in 2013

In its recently released work plan for fiscal year 2013 (which began this Oct. 1), the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services says it will continue to scrutinize billing practices and payment rates for Medicare Part B clinical laboratory services.

The plan, posed at *www.oig.hhs.gov*, cites works in progress in three lab areas:

- **Billing characteristics and questionable billing in 2010**: This study will look into the growth in lab spending due to the increased volume of services ordered. In 2008, Medicare paid about $7 billion for lab services, a 92 percent increase from 1998.
- **Reasonableness of Medicare lab payment rates versus other payers**: The OIG will determine how the methods for setting Medicare payment rates for 20 lab tests, representing the most frequently ordered and most costly in terms of total dollars paid, vary from the rates of state Medicaid and the Federal Employee Health Benefits program.
- **Frequency screening for glycated hemoglobin A1C tests and appropriate payment**: Preliminary OIG work in two contractors showed variations in the frequency-screening procedures. Medicare does not consider it reasonable and necessary to perform the test more often than once every three months in a controlled diabetic patient unless documentation of medical necessity supports more frequent testing.

OIG to Release Updated Guidance On Exclusion Authority, Demske Says

The Department of Health and Human Services Office of Inspector General (OIG) will release an updated guidance on its exclusion authority within the next few months, Gregory Demske, chief counsel to the inspector general, said during a conference Oct. 1.

Demske, who became chief counsel in April, replacing Lewis Morris, also said the OIG would release an update of its voluntary provider self-disclosure protocol shortly.

"The new [exclusion] guidance will include best practices for organizations to follow, and will also explain how the OIG resolves cases where an entity hires or contracts with an excluded person," Demske said at the 2012 Fraud and Compliance Forum, jointly sponsored by the American Health Lawyers Association and the Health Care Compliance Association.

Demske said the OIG last visited the topic of exclusions in a September 1999 Special Advisory Bulletin, and he said an update was in order.

The OIG solicited comments and recommendations for the updated self-disclosure protocol in a June 18 *Federal Register* notice. The protocol has been revised several times since its original publication in 1998.

In August, the OIG received comments from industry stakeholders saying the OIG should suspend an obligation to report and return overpayments within 60 days for Medicare providers who voluntarily enter into the provider self-disclosure protocol.

OIG Anti-Fraud Efforts

In addition to discussing some of the OIG's upcoming efforts, Demske focused on the agency's broader mission, which he defined as encompassing enrollment, payment, compliance, oversight, and remediation issues.

With regard to enrollment, Demske said the Patient Protection and Affordable Care Act (ACA) has given the OIG "more tools to be a stronger gatekeeper for the Medicare system from the outset," helping to prevent fraudulent payments from being made in the first place.

For example, Demske said the ACA authorizes the OIG to exclude or penalize anyone who lies on their Medicare application.

Demske said two other ACA provisions that will help detect and prevent fraud are the:

- Authority to suspend payments when there is a credible allegation of fraud; and
- 60-day repayment rule, which requires providers to identify and return an improper payment within 60 days (failure to do so can lead to False Claims Act liability).

Demske also said the OIG was continuing its efforts to evaluate hospitals on a broad range of compliance issues. To date, the OIG has issued 42 draft or final reports to hospitals, Demske said, and there are 45 reviews in progress.

The hospital compliance initiative is "looking at a range of claims that we consider to be high-risk, including short-stay claims," Demske said.

The OIG notice on the provider self-referral protocol is at *https://www.federalregister.gov/articles/2012/06/18/2012-14585/solicitation-of-information-and-recommendations-for-revising-oigs-provider-self-disclosure-protocol.*

Noridian to Handle Medicare Workload for Jurisdiction E

Noridian Administrative Services (Fargo, N.D.) has been awarded the contract to handle Medicare Part A and Part B fee-for-service claims in Jurisdiction E, previously called Jurisdiction 1 and serviced by Palmetto GBA (Columbia, S.C.). The "cost plus award fee" contract has an estimated value of $345.2 million and a maximum duration of five years.

Jurisdiction E covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. It includes more than 3.5 million Medicare fee-for-service beneficiaries and serves approximately 500 Medicare hospitals and 86,500 physicians. This jurisdiction comprises approximately 8.9 percent of the national Medicare A and B fee-for-service claims volume.

With the newly awarded contract, Noridian has a lock on Medicare A and B business on the West Coast and in key states along the Rocky Mountains. Since 2011, the company has handled this combined workload for 10 states consolidated in Jurisdiction F: Alaska, Washington, Oregon, Idaho, Montana, Wyoming, Utah, Arizona, North Dakota, and South Dakota.

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COMPLIANCE PERSPECTIVES

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Labs Beware: Business and Legal Challenge Presented By Out-of-Network Billing

Managing out-of-network status is one of the many challenges facing health care providers, including independent laboratories. Out-of-network status can present even greater complications for laboratories than for most other types of providers because the patient's treating physician, rather than the patient, typically chooses the laboratory that performs the testing ordered for the patient. Even though the patient did not make a conscious decision to utilize a particular laboratory, the patient may experience financial consequences if the laboratory is not in-network.

In such situations, the patient often does not understand why money is owed to the out-of-network laboratory and may become upset with the laboratory and the treating physician upon learning the reason for the charges. Laboratories understandably wonder what steps they can take to avoid this situation while limiting legal and business risks.

Even though government enforcement activity in this area is rare, this issue takes on new importance in light of the increasingly aggressive steps being taken by private insurers to ensure that members use in-network providers and to limit the amounts paid to out-of-network providers. Private insurers want to discourage the use of out-of-network laboratories because the negotiated rates paid to in-network laboratories often are lower than the amounts paid to out-of-network laboratories.

To incentivize patients to stay in-network, private insurers impose financial consequences on patients who use out-of-network laboratories, and such insurers expect those laboratories to collect copayments, coinsurance, deductibles, and other amounts owed by patients for their services.

Actions being taken by private insurers to protect their networks include but are not limited to (1) threatening to revoke the in-network status of physicians who order from out-of-network laboratories, (2) disregarding the assignment of payment by patients to out-of-network laboratories and then paying patients directly, and (3) capping out-of-network benefits payable to patients.

Another timely example is a new Blue Cross and Blue Shield (BCBS) Association policy that changes how regional BCBS plans reimburse for laboratory testing performed for patients who access services outside their home state or region.[1] Before implementation of this policy, a laboratory could contract with and bill the local BCBS plan in its region for services rendered to patients covered by other BCBS plans.[2] The local BCBS plan would then determine reimbursement at the in-network rate.[3]

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[1] *New BlueCard Policies Affect Lab Test Claims,* The Dark Report, Jul. 16, 2012, at 3.
[2] *Id. at 5.*
[3] *Id.*

Under the new policy, a laboratory must bill the BCBS plan where the specimen was drawn, and that plan will reimburse the laboratory at the out-of-network rate unless the laboratory is in-network with that plan.[4] The BCBS Association's change in policy undoubtedly will result in many patients being billed for out-of-network services for the first time.

In addition, some private insurers have recently initiated litigation against out-of-network providers based in part on allegations regarding unconscionable out-of-network charges and the routine waiver of amounts owed by patients. For example, in February 2012, Aetna Life Insurance Co. filed a lawsuit in California state court against several ambulatory surgery centers (ASCs) claiming in part that the ASCs induced Aetna's members to utilize their services by waiving coinsurance, deductibles, and other amounts owed (cost-sharing amounts).[5]

Laboratories should carefully consider legal risks when formulating an out-of-network billing strategy.

According to Aetna, because the ASCs did not intend to collect the patients' cost-sharing amounts—which are part of the aggregate charges billed to Aetna—the ASCs inflated their charges on claims submitted to Aetna and thus violated California's insurance fraud statute,[6] its prohibition on unfair competition,[7] and other California laws.[8] Aetna also contended that the ASCs' out-of-network billing practices amounted to tortious interference with Aetna's member and provider contracts.[9] United Healthcare Services Inc. filed a similar complaint in the same court a few months later.[10]

Given these activities, laboratories should carefully consider legal risks when formulating an out-of-network billing strategy. Discounting or waiving cost-sharing amounts owed by private-pay patients could implicate certain state laws. While a small number of states have enacted specific prohibitions against a provider's waiver of all or part of cost-sharing amounts owed by patients, most states have not expressly addressed the issue. A few highlights of relevant state laws are discussed below.[11]

Insurance Fraud

As demonstrated by the cases filed by Aetna and United, waiving all or part of cost-sharing amounts could give rise to claims under state insurance fraud statutes. Virtually all states have an insurance fraud statute, and, generally, these laws prohibit the presentation of a false or fraudulent claim for payment under an insurance policy. Some state insurance fraud statutes allow only the Attorney General's Office or another state agency to enforce the law, while others permit private parties (which could include private insurers, competitors, or others) to bring suit.

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[4] *Id.*

[5] *Complaint, Aetna Life Insurance Company v. Bay Area Surgical Management, LLC, et al.* (Cal. Super. Ct. of Santa Clara County, filed Feb. 2, 2012, No. 112CV217943).

[6] Cal. Penal Code § 550(a)(6). California's insurance fraud statute prohibits the knowing submission of any false or fraudulent claim for payment of a health care benefit.

[7] Cal. Bus. & Prof. Code § 17200 et seq. Under this law, "unfair competition" includes any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising.

[8] Complaint, *Aetna Life Insurance Company v. Bay Area Surgical Management, LLC, et al.* (Cal. Super. Ct. of Santa Clara County, filed Feb. 2, 2012, No. 112CV217943, at 15-16).

[9] *Id.* at 24-25.

[10] Complaint, *United Healthcare Services, Inc. v. Bay Area Surgical Management, LLC, et al.* (Cal. Super. Ct. of Santa Clara County, filed Jun. 18, 2012, No. 112CV226686).

[11] This article does not address all possible state laws implicated by waiving all or part of cost-sharing amounts owed by patients, or all theories that could be alleged under the laws highlighted. In addition, potential implications under federal law are beyond the scope of this discussion.

Regardless, the theory in such cases is typically that because a laboratory routinely waived cost-sharing amounts and never intended to collect the full charge for services provided, the laboratory filed false or fraudulent claims because the charges stated on the claims do not represent the actual charges for the services.

For example, if a laboratory's charge for a service is $100, and it routinely waives the patient's out-of-network coinsurance obligation of 20 percent (or $20), the enforcing party could argue that the laboratory's charge for the service is actually $80 because the laboratory never intended to collect the full $100 charge.

To mitigate risk, a laboratory should consider disclosing its out-of-network billing practices to private insurers. If the laboratory makes such a disclosure, the enforcing party may have difficulty demonstrating that the laboratory intended to commit fraud.

Florida is one state that specifically addresses waiver of amounts owed by patients. Florida's insurance fraud statute prohibits any service provider, other than a hospital, from billing amounts as the provider's usual and customary charge if the provider has agreed with the insured or intends to waive deductibles or copayments, or if the provider does not intend to collect the total amount of the usual and customary charge.[12] In determining whether a violation has occurred, the statute allows consideration of evidence of whether the service provider has made a good-faith attempt to collect the deductible or copayment.[13]

To mitigate risk, a laboratory should consider disclosing its out-of-network billing practices to private insurers. If the laboratory makes such a disclosure, the enforcing party may have difficulty demonstrating that the laboratory intended to commit fraud.

Patient Inducement

A laboratory's waiver of all or part of cost-sharing amounts could also give rise to claims of patient inducement. Unlike the federal government—which prohibits giving something of value (including the waiver of copayments, coinsurance, or deductibles) to induce a Medicaid or Medicare beneficiary to use a particular provider[14]—most states do not have a specific ban on such conduct. However, some states do have an anti-kickback statute that could be read broadly to extend to patient inducement.

Physician Inducement

All laboratories accepting specimens from New York must hold a license issued by the New York State Department of Health (NYS DOH) and should therefore take notice of a New York state regulation establishing that a laboratory's routine waiver of copayments, coinsurance, or deductibles for services performed for patients of a referring "health services purveyor"[15] is deemed consideration given for the referral of specimens and is therefore prohibited.[16]

In addition, the New York regulation prohibits the waiver of fees owed by health maintenance organization (HMO) patients to an out-of-network laboratory where such waiver results in consideration being received by the referring health services purveyor.[17] The regulation does, however, permit a clinical laboratory to waive copayments, coinsurance, deductibles, or fees if the patient cannot afford to pay, or if the cost of collection is greater than the amount owed.[18]

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[12] Fla. Stat. Ann. § 817.234(7)(a).
[13] *Id.*
[14] 42 U.S.C. 1320a-7a(a)(5).
[15] A health services purveyor includes any entity that provides health-related services. N.Y. Comp. Codes R. & Regs. tit. 10, § 34-2.2.
[16] N.Y. Comp. Codes R. & Regs. tit. 10, § 34-2.12.
[17] *Id.*
[18] *Id.*

In a 2010 advisory letter to licensed laboratories, the NYS DOH noted a "troubling increase in the number of complaints alleging laboratories are offering inducements" and reminded laboratories that the routine waiver of copayments, deductibles, or coinsurance amounts that would otherwise be out-of-pocket expenses for patients and their families is prohibited.[19] The letter noted, however, that "laboratories must engage in balance billing to the extent costs of collection do not exceed the amount to be collected, the patient is not medically indigent, and the patient is not a member of an HMO."[20]

The NYS DOH expects laboratories to train their sales representatives on these requirements, to document this training, and to monitor communications between sales representatives and new accounts.[21] Licensed laboratories should take steps to ensure compliance with this regulation because the NYS DOH does engage in enforcement activities, particularly when it receives competitor complaints.

Recommendations

The state laws discussed above represent only a few examples of statutes that laboratories should take into account when formulating an out-of-network billing strategy. If a laboratory waives all or part of cost-sharing amounts owed by patients who are financially needy or medically indigent, or offers discounts to patients for prompt payment, it should document and closely follow those policies, implement eligibility standards that are consistent with industry standards, and keep eligibility documentation and proof of attempts to collect on file. Any laboratory that decides to waive all or part of cost-sharing amounts owed by other out-of-network patients should consider applicable legal and business risks and implement compliance safeguards, such as disclosure to private insurers.

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[19] Letter from the Betty Kusel, director, regulatory affairs program, the New York State Department of Health to Regulated Laboratories (May 11, 2010).

[20] *Id.*

[21] *Id.*

Enforcement Climate for Labs Toughest Since LabScam, *from page 1*

In addition, the number of whistleblower lawsuits continues to escalate dramatically with such lawsuits representing more than 90 percent of all False Claims Act settlements. "The government is not necessarily driving the agenda for enforcement," she said. "The whistleblower bar is a key determinant of what's happening with regard to bringing false claims act cases against laboratories and the mandatory investigations that stem from such complaints."

Peter Kazon, Esq., senior counsel with Alston & Bird (Washington, D.C.), agreed that the emphasis on fraud and abuse recoveries isn't going away. "From the lab standpoint, what you see is a far more competitive marketplace, which makes the pressure to do deals that are on the edge or maybe in the grey area that much stronger."

Kazon added that recovery audit contractors (RACs), zone program integrity contract auditors, and other government auditors "aren't necessarily looking for fraud, they're looking for recordkeeping mistakes," which underscores the importance of labs having a solid compliance program and comprehensive document retention policy.

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The RAC program has expanded since its implementation and is becoming more sophisticated as auditors use analytics to track payments. Recently, the Centers for Medicare and Medicaid Services (CMS) began conducting a pilot project in seven states in which RAC contractors will conduct prepayment reviews. RACs are required to post on their Web sites information about what areas they are reviewing, explained Foster, who said labs and pathologists should find out who their RAC contractors are and check their Web sites on a regular basis.

"You should understand how the procedures work, what they are examining, and take a look at your own systems to see how you are dealing with the issues they are examining," she said. "There's a lot you can do affirmatively to deal with RAC audits."

One common area for review is whether labs have the proper orders for the service that is being provided, added Kazon. "That is a particularly frustrating area for laboratories because now that you don't need a physician signature this really depends a lot on the records that physicians are keeping. This means that your requisition forms have to be clear so you can show auditors where something has been ordered. You also need to work with your physicians to make sure they are maintaining appropriate documentation."

Some of the auditor visits arise from complaints that have been filed by competitors, physicians, employees, or former employees, said Foster. "To the extent that laboratories are aware of concerns that have been raised, they should look at what's being complained about and determine if there is any validity to it, and if there is, do something about it. I'm dealing with a case right now where the auditor showed up with a letter, and we were told that this arose from a complaint about inappropriate billing. I urge you to take complaints seriously."

Proficiency Testing Referral

Legislation giving CMS leeway in enforcing sanctions on clinical laboratories for violating proficiency testing referral rules recently passed the House and is expected to pass the Senate. Both Foster and Kazon say they believe the legislation will help minimize cases in which labs are severely punished for what may be an inadvertent mistake. Currently, CMS takes a strict interpretation that the Clinical Laboratory Improvement Amendments (CLIA) require the agency to revoke a lab's certificate for one year and bar its owner and operator from running another lab

for two years for intentional PT referral. The pending legislation would allow CMS to substitute intermediate sanctions for the two-year prohibition and would make the one-year certificate revocation for the lab optional rather than mandatory.

"My interpretation of the statute is that if you cheat it's intentional but if it's an error, it's not," said Foster. "I understand CMS's interpretation, but I don't agree with it."

Kazon added that in many of the instances where a PT test is referred to another lab, it's due to an automated system designed to elicit a confirmatory test. "Everybody will be happy to see these cases go away," he said. "The law won't solve all of the problems. It still gives CMS a lot of discretion, but it does take away CMS's view that they have no choice. To its credit, CMS is supportive of the change."

Discounting

The issue of providing price discounts remains a sensitive issue that labs must deal with carefully, both attorneys said. Providers must be aware of both federal and state laws, which can vary widely. "I am asked this question often, and I always say we need to figure out the market you're in, we need to figure out who you want to provide the discount to, we need to look at the size of the discount, and we need to consider how you're marketing those discounts," said Foster. "It's a complex analysis."

On the federal level, there is a law that prohibits labs from charging Medicare "substantially in excess" of their usual charges, but that term has never been defined despite several attempts by the Health and Human Services Office of Inspector General. "As a result, this law is somewhat obscure," said Foster. "There is no requirement under Medicare law that Medicare must be charged a laboratory's lowest price."

Both Foster and Kazon advise that labs conduct a thorough analysis of applicable federal and state laws before discounting any services.

Loss of One CLIA Certificate Ricochets to Three Other Labs

A recent ruling on revocation of certification under the Clinical Laboratory Improvement Amendments (CLIA) illustrates the need to consider the collateral consequences, particularly on labs with the same owner or operator, in determining whether to challenge the sanctions, notes attorney Robert E. Mazer with Ober/Kaler in Baltimore.

Mazer summarized the stakes involved in an e-mail to G2 Intelligence. "In a Department Appeals Board (DAB) proceeding, a lab that received a notice of CLIA sanctions did not file an administrative appeal; instead it sent a letter to the Centers for Medicare and Medicaid Services (CMS) asking it to reconsider and to permit the lab to perform waived testing at least. After the appeal period expired, CMS revoked the lab's CLIA certificate.

"Approximately a week later, CMS revoked the CLIA certificates of three other labs owned by the same individual who owned the lab that had had its CLIA certificate revoked. The original lab then attempted to challenge the revocation, but, according to the DAB, it was too late to do so."

How the Case Unfolded

In September 2010 a recertifcation survey was conducted at Kids Med (Delta Medical Branch) in Elsa, Texas, and based on the findings, CMS notified its owner-director, Dr. William A. Aviles, that the facility was not in substantial compliance with several

CLIA conditions of participation. Accordingly, effective March 14, 2011, CMS would suspend the lab's CLIA certificate and cancel its approval to receive Medicare payments. The lab had 60 days to request an administrative hearing; otherwise, CMS would revoke the certificate.

In a March 14, 2011, letter to CMS, Aviles acknowledged serious mistakes but asked to be allowed to at least continue providing waived tests. The agency turned him down on April 19 and again warned of automatic revocation on May 10 if he did not appeal. No hearing request was filed by the deadline, so the lab's certificate was revoked.

About a week later, CMS notified three other labs in the area served by Kids Med—Mid-Valley Pediatrics, Donna Medical Clinic, and Mercedes Children's Clinic—that Kids Med's certificate loss also meant their CLIA certification was revoked.

On Aug. 31, 2011, Kids Med filed with the DAB a request for hearing, arguing that Aviles's March 14 letter was a timely and complete appeal. As an alternative, there was good cause, the lab said, to allow it to file beyond the 60-day deadline. The next day, the three other labs filed nearly identical responses.

In further skirmishing, Kids Med maintained that the problems leading to the revocation were isolated and the fault of a single, new employee who was since reassigned. It also noted that because its certificate loss affected a total of four facilities, the impact on the community is disproportionately harmful.

In January 2012, Administrative Law Judge (ALJ) Richard J. Smith granted a CMS motion to dismiss the case on grounds that the March 14, 2011, letter was not a hearing request and that by failing to exercise its appeal rights in a timely manner the lab failed to show good cause why its letter should be amended to meet appeal requirements or why the hearing request deadline should be extended. On Aug. 14, 2012, the DAB upheld the ALJ's decision.

OIG Roundtable Focuses on Next-Generation CIAs

The Department of Health and Human Services Office of Inspector General in August hosted a roundtable meeting with various health care providers to solicit feedback regarding their compliance "best practices" and efforts to implement their respective corporate integrity agreements (CIAs).

A summary of the meeting released Oct. 9 revealed concerns that providers have regarding implementation of the CIAs, as well as suggestions for the OIG on how to improve the CIA process.

The roundtable addressed four main topics:

- Defining "covered persons" and "relevant covered persons";
- Understanding the role of the compliance officer and the role of the board of directors;
- Understanding claims review requirements; and
- Understanding arrangement review requirements.

The roundtable summary is available at *https://oig.hhs.gov/compliance/compliance-guidance/docs/Focus_on_Compliance.pdf.*

News-At-A-Glance

DIAGNOSTIC TESTING KICKBACKS: A New Jersey physician pleaded guilty in federal court in Newark, N.J., Oct. 10 to taking kickbacks in exchange for referring patients to a diagnostic testing facility (*United States v. Cardoso*). Lucio Cardoso, who has an internal medicine practice in Newark, is the seventh person to admit to violating the federal anti-kickback statute by soliciting and receiving illegal payments for patient referrals to Orange Community MRI LLC in Orange, N.J. From March 2010 through December 2011, Orange Community MRI paid Cardoso at previously negotiated rates for each MRI and CT scan he referred to the facility, according to the government. Cardoso received $75 for each Medicare or Medicaid patient he referred for an MRI, $50 for each CT scan referral, and $25 for each ultrasound referral, federal prosecutors said. The anti-kickback charge carries a maximum penalty of five years in prison and a maximum $250,000 fine, or twice the gain or loss caused by the offense. Sentencing is scheduled for Jan. 30.

JAIL TIME FOR HEALTH CARE FRAUD: A western Pennsylvania man was sentenced in federal court in Pittsburgh to 37 months in prison and ordered to pay restitution of $550,077 to a Blue Cross plan he defrauded, federal prosecutors said (*United States v. Guzik*). Randall Frederick Guzik was sentenced Oct. 1 in U.S. District Court for the Western District of Pennsylvania following his guilty plea in May to one count of health care fraud. Federal prosecutors said Guzik bilked Highmark Blue Cross and Blue Shield, which serves western Pennsylvania, of more than $500,000 through fraudulent billings for X-rays between January 2007 and May 2011. Guzik billed for conventional joint X-rays for people insured by Highmark, according to the indictment, which claimed the billings were false in that no conventional joint X-rays were provided, the dates of the services were fabricated, the billed services were not provided in the locations represented on the billings, and the health care providers listed on the billings did not perform the services.

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