G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

September 2019

INSIDE THIS ISSUE

www.G2Intelligence.com

G2 INTELLIGENCE
Upcoming Events

Lab Reimbursement Summit 2019:
Practical Strategies for Maximizing Revenue and Minimizing Claim Denials in 2019
Save up to $200!
October 3, 2019
Courtyard by Marriott Charlotte Airport/ Billy Graham Parkway

www.LabLeadershipSummits.com

Lab Institute 2019:
Embrace Distruption, Build Revenue, and Reduce Risk of Noncompliance
Save up to $600!
November 6-7, 2019
Crystal Gateway Marriott, Arlington, VA

www.LabInstitute.com

Billing & Coding: Myriad Genetics Pays $9.1 Million to Settle Claims of Falsely Billing Medicare for Hereditary Cancer Tests

In March 2018, Myriad Genetics got a piece of mail no lab provider ever wants to see in its inbox: an OIG subpoena asking for billing records in connection with "an investigation into possible false or otherwise improper claims for payment under Medicare and Medicaid." At issue were claims for what was then Myriad's new myRisk Hereditary Cancer test over a 39-month period starting Jan. 1, 2014. And now, in its most recent Form 8-K filed with the US Securities and Exchange Commission (SEC), Myriad reveals that it has agreed to settle the claims for $9.1 million.

The Billing Controversy

Launched in September 2013, the Myriad myRisk Hereditary

Continued on page 2

Compliance Perspectives: What to Do When Respiratory Safety & Religious Rights Collide

THE SCENARIO

A lab requires all employees who work with or near materials emitting toxic vapors to wear respirators with tight-fitting facepieces. Since facial hear interferes with a tight seal, the lab adopts a no-beards policy for those employees. One employee, a practicing Sikh, refuses to obey the new policy because his religion requires men to have beards.

What would you do in this situation?

Respiratory Safety v. Religious Rights

Rule 1: OSHA: Employers must ensure that tight-fitting respirators form a complete seal with the face and not let employees use such respirators if their facial hair compromises the required seal (OSHA Respiratory Protection Standard, Section 1910.134(g)(1)).

Continued on page 2

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

BILLING AND CODING, *from page 1*

Cancer is a 25-gene panel that blends genetic test status and personal/family cancer history to identify clinically significant mutations affecting inherited risks for eight hereditary cancers launched in September 2013. The billing problems may have stemmed from Myriad's use of CPT Code 81211, which describes full sequencing analysis of BRCA genes together with CPT Code 81213, describing duplication and delection analysis of the genes.

Explanation: As reported by GenomeWeb, CMS had issued coding edits to keep labs from stacking these codes, which together amounted to approximately $2,900 in payment, and guided industry to use the substantially lower-paying CPT Code 81162 (comprehensive analysis of BRCA 1/2) instead. CPT Codes 81211 and 81213 should be used only if there's a modifier indicating that separate services have been performed on different days, advised CMS. The new CMS coding policy and attendant pay cut was bad news for a company as dependent on Medicare payments as Myriad (which reportedly gets roughly 8% of its hereditary cancer revenues from Medicare).

The Settlement

The legal case began as a whistleblower lawsuit accusing Myriad of violating the False Claims Act (FCA). As Myriad noted in the SEC Form 10-K it filed after getting the OIG subpoena 17 months ago, potential penalties under the FCA include payment of up to three times the damages sustained by the government, civil penalties ranging from $5,500 to $11,000 per false claim and exclusion from the federal health care programs.

Myriad denies any wrongdoing. And according to Myriad's new 8-K filing, after its 17-month investigation, the DOJ has decided not to intervene in the case. Even so, the firm has chosen to shell out the $9.1 million "to avoid a lengthy and distracting litigation with the relator." Myriad added that it "believe it demonstrated that the key allegations made in the complaint were false" and that said it doesn't expect to have to make any changes to its billing practices.

COMPLIANCE PERSPECTIVES, *from page 1*

Rule 2: Anti-Discrimination Laws: Employers must make reasonable adjustments in employment policies to accommodate the religious beliefs of their employees (*Title VII, Civil Rights Act of 1964*).

Both rules serve important purposes: Rule 1 protects employees' safety; Rule 2 protects their religious freedom. But sometimes the rules conflict.

Resolving the Respirator v. Religion Dilemma

In fact, the dilemma has an escape hatch. But you can't crawl through it unless you understand a few things about the law.

The key: Accommodation doesn't mean doing anything and everything the employee wants. You need only make accommodations that are

LCA

Glenn S. Demby, Executive Editor

Barbara Manning Grimm, Managing Editor

Brian Sharples, Layout & Design

Andrea Stowe, Account Executive

Michael Sherman, Director of Marketing

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to $150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact G2 Intelligence's corporate licensing department at andrea@plainlanguagemedia.com or by phone at 888-729-2315. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement.

Lab Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

"reasonable" and don't cause you "undue hardship."

Unfortunately, there are no bright line definitions. The question of whether a particular accommodation is "reasonable" or "undue hardship" is left for courts, arbitrators and tribunals to sort out case by case. The good news is that you can use previous court cases to figure out what to do if you get requests for religious accommodations from your own employees.

Respirator v. Religion: The Chevron Case

That scenario we posed above isn't hypothetical. It's based on an actual case. And while it happened at a manufacturing plant (operated by Chevron) and involved machinists, the same principles apply to labs.

Upon getting the memo announcing the no-beard policy, the machinist, who had been with Chevron for several years, notified his supervisor that he couldn't comply because of his religion.

Chevron temporarily suspended him without pay while it looked for jobs he could do without using a respirator. But it took over six weeks to find him a position. And the new job—janitor—was less challenging and paid 17% less. After initially taking the job, the machinist had second thoughts and sued Chevron for not letting him continue working as a machinist.

Question: Did Chevron do enough to accommodate the machinist?

Answer: Yes, the federal court said. Since Chevron couldn't and wouldn't force him to shave, there were only 2 ways it could let him keep working as a machinist:

- Assign him duties involving exposure to toxic gases knowing his respirator didn't fit properly; or
- Assign him only duties not involving exposure to toxic gases.

Option 1 would force the company to risk not only the machinist's safety but liability under OSHA (Cal-OSHA in this case).

Option 2 would force the company to revamp its entire assignment system and expose co-workers to more assignments involving exposure to toxic gases to pick up the slack.

Both options would impose undue hardship on Chevron, the court concluded, and dismissed the claim [*Bhatia v. Chevron USA Inc.*, 734 F2d 1383, U.S.C.A. 9th Cir., 1984].

WHAT TO DO

So, let's go back to the scenario. What would you do if an employee refused to obey a no-beards policy on religious grounds?

Step 1: Ensure No Beards Policy Is Really Necessary for Safety

The first thing to do is conduct a personal protective equipment (PPE) hazard assessment and consider whether you really need a no-beards

Continued on page 4

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

COMPLIANCE PERSPECTIVES, *from page 3*

policy to ensure safety. Remember that facial hair is only a problem if you're using tight-fitting respirators. So, consider whether you can safely allow employees to use a respirator that doesn't require a face seal and thus can be used by employees with beards, e.g., positive pressure hood and helmet type respirators and respirators and respirators that can be used with a continuous-flow, supplied-air respirator.

Step 2: Look for Ways to Exempt Employee from Policy

Firing an employee *on the spot* for refusing to obey a no beards policy is a failure to accommodate that will make you liable for religious discrimination. To its credit, Chevron didn't do this. Instead, it looked for accommodations that would allow the machinist to keep his job *and* his beard. And if you ever confront the situation, you'll be expected to do the same thing. Questions to ask:

- Can you let the employee keep his job and assign him only duties that don't involve exposure to hazards requiring him to use the tight-fitting respirator?

If the answer is NO:

- Can you assign the employee to a similar job not involving the use of respirators with the minimum loss of salary and benefits?

If the answer is NO:

Step 3: Don't Compromise Safety for Religion

When push comes to shove and no less restrictive accommodations are available, protecting workplace safety takes precedence over religious rights. In other words, you don't have to violate respiratory protection or other OSHA laws to accommodate an employee's religious preference. Or, to state it in legal terms, violating laws designed to ensure employees' safety is an undue hardship, not a reasonable accommodation.

But remember that push only comes to shove when you determine that no reasonable alternatives that will protect respiratory safety are available.

G2 INTELLIGENCE LAB LEADERSHIP SUMMITS

Lab Reimbursement Summit 2019:

Practical Strategies for Maximizing Revenue and Minimizing Claim Denials in 2019

Courtyard by Marriott Charlotte Airport/Billy Graham Parkway

October 3, 2019

Register Now at www.lableadershipsummits.com

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Explaining the Legal News: Why ACLA Court Win Boosts Chances of PAMA Pricing Relief

By now, you've no doubt heard the news that the American Clinical Laboratory Association (ACLA) "won" its lawsuit against CMS over PAMA lab pricing. Only it's not as simple as that. The favorable US Court of Appeals for the District of Columbia Circuit ruling in late July is anything but final victory in the legal war against PAMA. Paradoxically, though, it may lead to final victory on other fronts. Here's a rundown of what's going on so you know what's happening and can explain it to your lab execs.

What the Lab Industry Is So Ticked Off About

The idea of the PAMA statute is to base Part B lab test prices on market rates. Industry opposition and the ACLA lawsuit isn't about the concept of market pricing—on the contrary, it was a concept the industry embraced—but with how CMS took the good idea and distorted it beyond recognition in its implementation, specifically its decision to exempt virtually all hospital labs from the data-reporting requirements. As a result, the pricing data CMS collected was skewed and didn't accurately represent the private market the way Congress intended when it passed the legislation.

Litigation is a strategy of last resort. For years, industry tried to negotiate a solution and expand data-reporting to hospital labs but CMS stuck to its guns and the controversial new PAMA Clinical Laboratory Fee Schedule rates took effect in 2018. Frustrated by the lack of progress on the regulatory front, the industry led by the ACLA, escalated things by taking CMS to court. The essence of ACLA's legal claim is that CMS abused its power by rewriting rather than implementing PAMA.

CMS Wins Round One

In September 2018, it looked like the litigation strategy would fail when U.S. District Judge Amy Berman Jackson dismissed the lawsuit. While acknowledging that ACLA's "arguments on the merits raise important questions," she reasoned that the court didn't have jurisdiction over, i.e., legal authority to rule on, how a federal agency like CMS engaged in PAMA rate-setting.

ACLA Wins Round Two

Despite the setback, the ACLA decided to maintain the pressure by filing an appeal. We're not challenging the rate-setting itself, the ACLA argued, but the *implementation* of the rate setting. The agency's "egregious violation of the statutory requirements should not be shielded from judicial review," noted the ACLA appeal. And it worked. The Court of Appeals agreed that there's a difference between the federal agency's establishing test payment amounts and establishing the process for collecting pricing data. The former isn't subject to judicial review but the latter is. Result: The ACLA could proceed with its suit.

Continued on page 6

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

EXPLAINING THE LEGAL NEWS, *from page 5*

What It All Means

Although it's *a* victory, the Court of Appeals ruling isn't *final* victory. It just means that ACLA can take its case to court and raise those "important questions" the lower court avoided answering. Victory on the merits may take years, if it happens at all.

But that's not the point—at least not the whole point. All along, the industry strategy in opposing the CMS PAMA pricing scheme has been to engage the agency on multiple fronts—in court, in Congress and in behind the scenes negotiations. Success on the litigation front increases the industry's credibility in Congress and leverage in negotiations. In fact, those efforts were already starting to bear fruit before the new Court of Appeal ruling came down, including:

- CMS' agreement to include certain hospital outreach labs in data-reporting for 2019 (see, *Lab Compliance Advisor, (LCA)*, Jan. 21, 2019); and
- The introduction of a new Congressional bill to delay the reporting of lab payment data required by PAMA by one year.

Takeaway: After years of frustration, it appears that the balance may be tipping and that industry is winning the battle with CMS over PAMA pricing. Chances are that real relief will come in the form of new legislation or, more realistically, revised regulations long before the court battle is renewed.

Lab Management: Billing Company Contract Liability Risks & How to Avoid Them

Like many labs, you may outsource your billing and coding to an outside medical billing company. While this might be cost-effective, be aware that it can put your lab at risk for liability under federal and state kickback laws to the extent the billing company charges fees based on a percentage of claims for which it bills and codes.

The Dangers of Percentage Compensation Arrangements

The federal anti-kickback statute (AKS) makes it illegal to offer or pay any remuneration to induce referrals of lab tests or other services reimbursed by Medicare, Medicaid and other federal health care programs (which we'll refer to collectively as "Medicare"). Percentage compensation arrangements raise a red flag under the AKS because they're based on the volume and value of business generated rather than the fair market value of the services provided.

While this principle makes sense for direct arrangements between labs and physicians and other referral sources, it doesn't seem to pertain to an arrangement between labs and third party billing companies who don't generate any referrals. However, the AKS defines "referrals" broadly as

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

including arrangements not just directly referring but also "recommending and arranging for" services reimbursed by Medicare. The OIG interprets this language as including the provision of marketing services. And it may stretch things even more by interpreting billing and coding as marketing.

OIG Advisory Opinion 2011-17

Even though arrangements paying volume-based percentage fees to third party management companies for billing and marketing services are common in the lab industry, the OIG has historically taken a dim view of them. For example, in Advisory Opinion 2011-17, the OIG weighed in on a proposed arrangement under which physicians would pay 60% of their gross collections from allergy testing and immunotherapy services to a third party company for a fully array of laboratory management services, including billing and coding.

The parties contended that the fee was equal to fair market value but the OIG wasn't impressed. The AKS was implicated under the "recommending and arranging for" services language, the OIG noted, reasoning that the management company's provision of print materials to the physicians in their offices and use of management company personnel to review patient files and flag those who may be suitable for allergy testing constituted marketing.

The OIG also found that the arrangement didn't qualify for the personal services and management contracts safe harbor (which we'll discuss below) because aggregate fees were based on the volume and value of business generated between the parties and not set in advance. Even though an arrangement that doesn't qualify for safe harbor treatment can still be legal, the Finally, the OIG concluded that there weren't adequate safeguards in place to allay the AKS concerns. Elements of the arrangement that the OIG cited as being problematic:

- The percentage fee wasn't tied to the actual services the lab services management company provided; and
- The use of management company to review physicians' charts and identify potential allergy testing patients created the risk of overutilization.

How to Manage the AKS Liability Risks

If possible, try to structure your arrangements to meet all seven criteria of the regulatory safe harbor for personal services and management contracts. Focus on three key criteria, including ensuring that the contract:

- Sets the amount of total aggregate compensation in advance, rather than being based on a rate yielding a total amount that can't be determined at the outset of the deal;
- Bases total compensation on fair market value; and
- Doesn't determine compensation in a way that takes into account the volume or value of Medicare referrals or business generated by the parties.

Continued on page 8

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

LAB MANAGEMENT, *from page 7*

The other four criteria the arrangement must meet for the safe harbor to apply:

- It must be contained in a written agreement signed by both parties;
- The agreement must have a term of at least one year;
- The agreement must set out the exact services required to be performed; and
- The arrangement must serve a commercially reasonable business purpose.

Takeaway: You probably already realize how percentage compensation arrangements raise AKS liability risks when your lab contracts with third party marketing companies. What you may not realize is that these same risks may arise when the third party you contract with provides billing and coding services. While you might think you're making a purely administrative arrangement, the OIG may interpret the contract as a marketing deal and subject it to AKS scrutiny, especially when the billing company's fees are pegged to the volume or value of claims billed and coded.

OIG Monthly Work Plan Review: August 2019

Of the 12 new items in the OIG's Work Plan this month, six indirectly impact lab providers and services.

Medicare Payments of Positive Airway Pressure (PAP) Devices for Obstructive Sleep Apnea (OSA) Without Prior Sleep Study

Issue: OIG analysis of the 2017 Comprehensive Error Rate Testing (CERT) program for positive airway pressure (PAP) device payments revealed overpayments of up to $566 million potentially attributable to improper claims for PAP devices used to treat OSA for beneficiaries who didn't have a positive diagnosis of OSA based on an appropriate sleep study.

OIG Action: OIG will examine Medicare payments to durable medical equipment providers for PAP devices used to treat OSA to determine whether an appropriate sleep study was conducted in accordance with "reasonably necessary" coverage criteria.

Review of Medicare Diagnosis-Related Group (DRG) Window Policy

Issue: Lab and other outpatient services directly related to inpatient admission are considered part of the inpatient payment and thus not separately payable by Medicare. The DRG window policy defines when CMS deems outpatient services to be an extension of inpatient admissions, including services that are: (1) provided within the 3 days immediately before an inpatient admission to an acute-care hospital; (2) diagnostic services or admission-related nondiagnostic services; and (3) provided

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

by the admitting hospital or by an entity wholly owned or operated by the admitting hospital.

OIG Action: OIG will determine the number of admission-related outpatient services that weren't covered by the DRG window policy in 2018, including services provided before the start of the DRG window and services provided at hospitals sharing a common owner, and figure out how much Medicare and beneficiaries would have saved if the DRG window policy had been updated to include more days and other hospital ownership structures. The agency will also interview CMS staff to identify other payment models that CMS could use to pay for outpatient services related to inpatient admissions.

Opioids in Medicaid: Review of Extreme Use and Overprescribing in the Appalachian Region

Issue: While opioid abuse and overdose deaths are a national crisis, the problem is particularly acute in the Appalachian region. In 2017, the opioid overdose death rate was 72% higher in Appalachian counties than non-Appalachian counties. This is of particular concern for Medicaid beneficiaries, who are more likely to have chronic conditions and comorbidities that require pain relief, especially beneficiaries who qualify through a disability.

OIG Action: OIG will identify beneficiaries who received excessive amounts of opioids through Medicaid, beneficiaries who appear to be doctor- or pharmacy-shopping, and prescribers associated with these beneficiaries.

Medicare Market Shares for Diabetic Testing Strips (DTS) from April to June 2019

Issue: Section 1847(b)(10)(B) of the Social Security Act (the Act) requires OIG to study and report on the Medicare market share of DTS before each round of the Medicare competitive bidding program. CMS uses these data briefs to ensure that bidding suppliers meet the 50-percent rule (section 1847(b)(10)(A) of the Act). Section 50414 of the Bipartisan Budget Act of 2018 amended section 1847(b)(10)(A) by requiring that, for bids to furnish DTS on or after Jan. 1, 2019, CMS must use both mail order and non-mail order data when assessing compliance with the 50-percent rule. Previously, OIG reported only mail order data in its data briefs used for CMS's assessment of compliance with the 50-percent rule.

OIG Action: For this series, the first data brief will determine the Medicare market share of mail order DTS from April through June 2019. The second data brief will determine the Medicare market share of non-mail order DTS for the same 3-month period. This will be the fifth series of OIG data briefs describing the Medicare market share of DTS that OIG has produced since 2010 and the second series that will include both mail order and non-mail order DTS data.

Continued on page 10

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

OIG MONTHLY WORK PLAN REVIEW, *from page 9*

Medicare Part B Services to Medicare Beneficiaries Residing in Nursing Homes During Non-Part A Stays

Issue: Medicare pays physicians, non-physician practitioners, and other providers for services rendered to Medicare beneficiaries, including those residing in nursing homes (NHs). Most of these Part B services aren't subject to consolidated billing; accordingly, each provider submits a claim to Medicare. Since the 1990s, OIG has identified problems with Part B payments for services provided to NH residents. An opportunity for fraudulent, excessive, or unnecessary Part B billing exists because NHs may not be aware of the services that the providers bill directly to Medicare, and because NHs provide access to many beneficiaries and their records.

OIG Action: OIG will determine whether Part B payments to Medicare beneficiaries in NHs are appropriate and whether NHs have effective compliance programs and adequate controls over the care provided to their residents.

Use of Telehealth to Provide Behavioral Health Services in Medicaid Managed Care

Issue: While all 50 States and the District of Columbia currently provide some Medicaid coverage of telehealth, there's limited information about how States use telehealth to provide behavioral health services to Medicaid managed care enrollees.

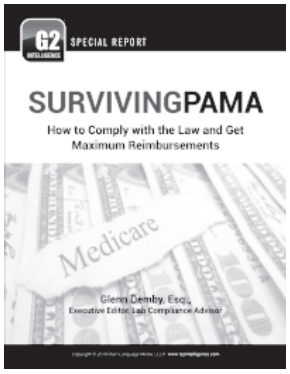
OIG Action: OIG will analyze how selected States and managed care organizations (MCOs) use telehealth to provide behavioral healthcare. It will also review selected States' monitoring and oversight of MCOs' behavioral health services provided via telehealth and identify States' and MCOs' practices on how to maximize the benefits and minimize the risks of providing behavioral healthcare via telehealth.

SURVIVING PAMA

How to Comply with the Law and Get Maximum Reimbursements

What Your Lab Can Do to Survive and Thrive Under PAMA

- Analyzes the market-based pricing concept
- Explains the PAMA pricing data reporting system
- Covers the new payment and coding rules
- Breaks down the controversy over CMS implementation of PAMA
- Highlights the impacts of PAMA and sets out specific strategies



To place an order call 888-729-2315 or visit https://www.g2intelligence.com/surviving-pama/

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

LabCorp Must Go to Trial to Defend against Deceptive Trade Practices Charges

Case: Fourteen patients sued LabCorp for allegedly overcharging them for lab tests. In March 2018, a North Carolina federal court tossed their class action ruling that the patients didn't have a valid legal claim for unfair and deceptive trade practices. Undaunted, the patients tried again with a slightly new theory: LabCorp violated the consumer protection laws not in the way it billed the tests but because of the excessive prices it charged. LabCorp once more asked for dismissal but the court refused, saying the new claim was legally valid and that the patients could take it to trial.

Significance: Surviving a motion to dismiss just means the patients will get the chance to prove their claims in court. And that won't be easy. To constitute an unfair or deceptive trade practice, a business practice must be "egregious or aggravating." The patients will have the "considerable burden" of showing that LabCorp's prices were so excessive and its billing practices so coercive as to reach that level.

Federal Court Dismisses Urine Drug Test False Billing Claim

Case: Whistleblowers accused a national lab company of falsely billing Medicare and Medicaid for high complexity quantitative urine drug tests under CPT code G0431 at up to $476 per test. According to the complaint, the lab falsely marketed the capabilities of its UDT machines knowing they were capable only of basic qualitative testing, billed at $20 per test. The lab denied the charges and asked the California federal court to toss the case without a trial. And that's just what it did.

Significance: The court didn't determine that the whistleblowers' claims were invalid, only that they weren't specific enough. How did the lab market the machines and why was this fraudulent? How many false claims did the lab submit and how much did the government overpay as a result. So, the court gave the whistleblowers permission to revise their complaint and try again [*United States v. Carolina Liquid Chemistries, Corp.*].

Lab Fails in Bid to Get Medicare Payment Suspension Set Aside

Case: In 2017, CMS suspended 100% of Medicare payments to True Health Diagnostics (THD) based on what it called "credible allegations of fraud." Two years later, while the suspension was still in place (although it had been reduced to 35%), CMS imposed a second suspension on the basis of "credible" fraud allegations. THD denied any wrongdoing and asked the Texas federal court to issue a temporary restraining order barring CMS from enforcing the suspensions until the underlying fraud allegations

Be a part of the conversation this year! G2 INTELLIGENCE PRESENTS THE 37TH ANNUAL Lab Institute 2019

Continued on page 12

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

LABS IN COURT, *From Page 11*

were resolved. But the court refused saying it had no jurisdiction, i.e., legal authority to adjudicate a Medicare appeal at this stage.

Significance: Federal courts generally do have jurisdiction to rule on claims "arising under" U.S. laws like the Medicare Act. But that jurisdiction kicks in only after the federal government agency in this case, HHS via CMS renders a final decision. That wasn't the case in this situation because THD hadn't "exhausted its administrative remedies," i.e., gone through the CMS process for contesting suspensions due to overpayments [*True Health Diagnostics, LLC v. Azar*].

Lab Fires Sales Rep Due to Performance, Not Age

Case: A lab sales rep claimed she was fired due to age discrimination. Her evidence: A remark allegedly made by her manager: "Sometimes people feel that this job is better suited for younger people." The lab claimed she was fired for performance problems. Lab's evidence: Customer complaints, negative performance reviews and placement into and failure to meet the goals of a performance improvement plan. Ruling: The sales rep didn't have enough evidence to make out a prima facie case of discrimination.

Significance: "Stray remarks alone do not give rise to the inference of discrimination," explained the Arkansas federal court. And the evidence clearly showed that she wasn't meeting the lab's reasonable performance expectations [*Taylor v. Abbott Labs., Inc.*].

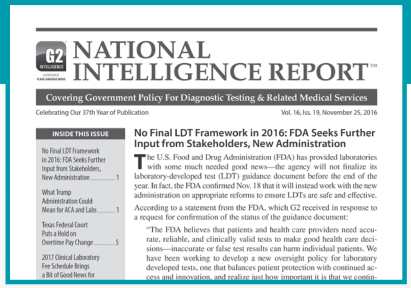
G2 INTELLIGENCE

Special Offer for *Lab Compliance Advisor* Readers

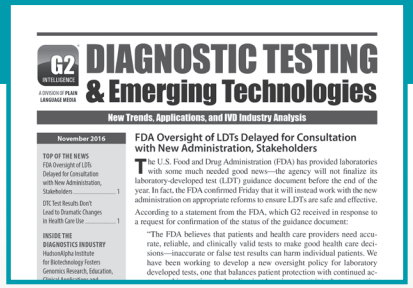
Test Drive G2 Intelligence Memberships for Just **$155 for 3 Months**


Your Independent Source for Business & Financial News
LABORATORY INDUSTRY REPORT™
HIGHLIGHTS
2017 Clinical Laboratory Fee Schedule: The 3 Changes Affecting Your Reimbursement

Laboratory Industry Report
The place the lab industry turns for business intelligence and exclusive insight into what's happening to key companies, as well as the Wall Street view on the lab industry, the latest analysis of mergers, buyouts, consolidations and alliances.


NATIONAL INTELLIGENCE REPORT™
Covering Government Policy For Diagnostic Testing & Related Medical Services
No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration

National Intelligence Report
From Stark and Anti-Kickback to Medicare and congressional lobbying efforts, NIR keeps you updated and richly informs your business planning and risk assessment.


DIAGNOSTIC TESTING & Emerging Technologies
New Trends, Applications, and IVD Industry Analysis
FDA Oversight of LDTs Delayed for Consultation with New Administration, Stakeholders

Diagnostic Testing & Emerging Technologies
News, insider analysis, statistics and forecasts on the important innovations, new products, manufacturers, markets and end-user applications vital to the growth of your lab.

To subscribe or renew *Lab Compliance Advisor*, call 888-729-2315

Online: www.G2Intelligence.com **Email:** customerservice@plainlanguagemedia.com

Mail to: Plain Language Media, PO Box 509, New London, CT, 06320 **Fax:** 855-649-1623

Multi-User/Multi-Location Pricing? Please contact Andrea Langsam by email at: Andrea@PlainLanguageMedia.com or by phone at 888-729-2315.

© 2019 Plain Language Media LLLP, 888-729-2315. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com