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New Court Rulings Affect All Clinical, Pathology Labs

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Two Federal Court Decisions Are Bad News for Labs

EVERY PATHOLOGIST AND CLINICAL LAB ADMINISTRATOR should pay attention to two federal court decisions made recently in two different legal cases. One decision is bad news for the entire clinical lab industry. The other is bad news for lab companies that push compliance with federal anti-kickback laws.

The most important court decision came in the **American Clinical Laboratory Association's** (ACLA) lawsuit against the federal **Department of Health and Human Resources**. ACLA is challenging how the agency followed the Protecting Access to Medicare Act (PAMA) statute and learned, this week, that the federal judge had dismissed the ACLA's claims for lack of "subject matter jurisdiction." As of this date, however, the judge had not dismissed the case. *(See pages 3-5.)*

This ruling was a disappointment for the clinical laboratory industry. There is solid evidence that Medicare officials did not follow the language of the PAMA law nor the intent of Congress when it passed this law. That is why ACLA and others were hopeful that this lawsuit had the potential to convince a judge that the **Centers for Medicare and Medicaid Services** had failed to properly implement the requirements of PAMA and give the judge reason to issue directives to CMS requiring them to correct these failings.

The second important court decision was made in the whistleblower case of Chris Riedel against **Boston Heart Diagnostics Corporation**. In simple terms, the federal district court judge ruled that: 1) clinical laboratories that pay for packaging and handling of patients' specimens; and/or, 2) give discounts to patients for copayments and deductibles could be liable for filing false claims.

As you will read in THE DARK REPORT's exclusive analysis of this case on pages 6-9, several attorneys state that this ruling sets a new standard for how clinical labs and other providers comply with federal anti-kickback law. "Because these theories stem from a federal district court decision, lawyers can rely on them as persuasive authority in other federal courts nationwide," stated Justin T. Berger, an attorney representing the plaintiff in the case against Boston Heart. He is a principal at the law firm of **Cotchett, Pitre and McCarthy, LLP**. Stated differently, this ruling means labs that offer inducements for specimen processing, or that do not bill patients for the balance of their charges, may now be subject to claims of filing false claims. TDR

Court Dismisses ACLA Claims in PAMA Case

In major setback for labs, judge says court lacks jurisdiction in case against HHS on lab payment rates

CEO SUMMARY: While acknowledging that the American Clinical Laboratory Association raises important questions in its case against the federal Department of Health and Human Services, a district court judge ruled that the court cannot resolve the dispute and dismissed the ACLA's claims for lack of "subject matter jurisdiction." While not dismissing it outright, the judge effectively ended the case. A lawyer for the ACLA expected a dismissal within days. ACLA has not yet decided to appeal.

CLINICAL LABS SUFFERED a big setback last week when a U.S. District Court judge dismissed the arguments the **American Clinical Laboratory Association** (ACLA) made against the federal **Department of Health and Human Services** (HHS) in a lawsuit ACLA filed last year.

In the lawsuit filed December 11, in U.S. District Court for the District of Columbia, ACLA charged that under PAMA, HHS collected data from only a subset of the nation's clinical laboratories and then used that limited amount of data to set clinical lab payment rates for this year that were estimated to be about 10% lower than the rates it paid clinical labs in 2016.

In her decision, U.S. District Judge Amy Berman Jackson acknowledged that the ACLA's case raises important questions about how HHS implemented the Protecting Access to Medicare Act of 2014 (PAMA), but said the court cannot resolve the dispute and dismissed the ACLA's claims for lack of "subject matter jurisdiction."

Jackson did not dismiss the case, however, although she may do so in the coming days, the ACLA's lawyer told THE DARK REPORT. *(See "ACLA Lawyer Says Judge's PAMA Ruling Is Narrow," page 6.)*

The federal **Centers for Medicare and Medicaid Services** had predicted that under PAMA, it would cut what it pays laboratories by $390 million this year. However, because the methods HHS used to collect the market-rate data under PAMA were so flawed, Medicare payments to clinical laboratories decreased

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by $670 million this year, stated clinical labs in filings supporting the ACLA's case.

The federal **Office of Inspector General** reported that $670 million is about 10% of the $6.8 billion that Medicare paid under Part B for lab tests in 2016. *(See "Legal Briefs Explain Problems With PAMA Implementation," TDR, April 16, 2018.)* Over 10 years, the reductions in what CMS pays labs under PAMA will equal $4 billion, Virgil Dickson reported for *Modern Healthcare*.

Such deep cuts in payment caused some labs to close and others to cut back on the services they provide to the nation's seniors on Medicare, according to legal filings from the **American Association of Bioanalysts (AAB)**, the **Advanced Medical Technology Association**, the **College of American Pathologists**, and the **National Association for the Support of Long Term Care**. Labs serving nursing homes and rural areas were affected most severely, ACLA and other lab organizations said.

'Indefensible Assertion'

"HHS' continued assertion that collecting data from less than 1% of clinical laboratories nationwide meets the standards for a market-based system is indefensible," ACLA President Julie Khani said in a statement following the court decision. "By intentionally omitting data from more than 99% of laboratories, HHS is undermining Congress' goal of protecting beneficiaries and supporting value-based care delivery.

"This is an extremely disappointing outcome for ACLA's members and the millions of seniors they serve—including the most vulnerable Medicare beneficiaries—who rely on clinical laboratory tests for their most basic health needs," she added.

In particular, Khani took issue with the decision that the court lacked jurisdiction in the case. "The court's decision that it is powerless to require HHS to comply with the statutory requirements sets a harmful precedent that allows agencies to circumvent Congress' express directions at the expense of patient care." *(See sidebar on page 5.)*

In the first paragraph of a 13-page Memorandum Opinion, Judge Jackson explained the issues, writing that ACLA challenged a regulation that implements Section 216 of PAMA that required certain labs to report what private payers pay so that HHS could use that data to set Medicare rates.

Definition of 'Applicable Lab'

"Plaintiff [ACLA] contends that the definition of the term 'applicable laboratory' in the regulation violates PAMA and the Administrative Procedure Act (APA)," Jackson wrote. "In response, defendant [HHS] asserts that in the statute, Congress expressly precluded judicial review of issues such as these, and the court has no jurisdiction to hear the case. While the Court acknowledges that plaintiff's arguments on the merits raise important questions, it agrees with defendant that it cannot resolve this dispute, and it will dismiss this matter for lack of subject matter jurisdiction."

Earlier this year, lawyers familiar with the case said the ACLA's position was strong despite a provision in PAMA that precluded clinical labs or other aggrieved parties from challenging the law in court. *(See TDR, Jan. 2, 2018.)*

Challenge to Methods Used

Instead of challenging the rates HHS set for the 2018 Clinical Laboratory Fee Schedule, the lawsuit challenged the methods HHS used to gather the data it needed to estimate how much private health insurers paid clinical labs. In challenging those methods, the ACLA noted that HHS did not collect data from most hospital labs. Instead, it collected data from only a small number of hospitals, excluding almost all hospital labs which collect higher rates than most other labs operating in the United States, ACLA

Following Federal Judge's Ruling, Lab Industry Hopes Congress Might Act to Fix PAMA

AS IT REVIEWS ITS OPTIONS, the American Clinical Laboratory Association (ACLA) will ask Congress to reform the Protecting Access to Medicare Act of 2014, said ACLA President Julie Khani. Other options include asking the court to reconsider, filing an appeal, and asking Congress to revise PAMA.

"Congress must reform and modernize the clinical lab fee schedule to ensure that beneficiaries can continue to access the lab services and diagnostics they need," Khani said.

In a statement to THE DARK REPORT, **Quest Diagnostics Inc.** agreed with Khani, saying it supported the ACLA's efforts and called on Congress to reform and modernize the CLFS, "to ensure that all patients can continue to access the lab services they need."

David P. King, Chairman and CEO of **Laboratory Corporation of America**, acknowledged that because the court recognized the important questions ACLA raised in its lawsuit about how CMS gathered the data, Congress needed to respond.

"The court's refusal to reach the merits of these important questions makes it critical for Congress to act quickly to force CMS to comply with the law as written," King added.

Other lab organizations and lab companies also were concerned about the ruling. Mark S. Birenbaum, PhD, Administrator of AAB and the **National Independent Laboratory Association**, said both organizations were concerned that the federal judge dismissed these arguments, especially because the low payment rates established by HHS have had a significant negative financial effect on labs.

"While the lab community considers future legal options, the real work right now is persuading Congress to stop the next round of cuts to the Medicare Part B Clinical Laboratory Fee Schedule from going into effect on Jan. 1, 2019," he added.

Broken Payment System

R. Bruce Williams, MD, President of the **College of American Pathologists**, said members of CAP were "concerned over this broken payment system and the drastic Medicare cuts hitting clinical laboratories, especially those in healthcare shortage areas and rural communities, across the United States today and over the next several years." CAP will continue to call on Congress to amend PAMA, he said. "Legislation is needed to ensure reimbursements are accurate and truly reflect costs for the clinical tests provided to patients," he added.

claimed in its lawsuit, *ACLA v. Alex M. Azar, II, Secretary of HHS.*

As of press time, the judge had not dismissed the case. ACLA is meeting with its members and lawyers to assess its options and determine a course of action. One big question will be whether ACLA should appeal this decision and what arguments it could assert as part of the appeal.

Meanwhile, various lab associations and groups are lobbying members of Congress. The goal is to educate legislators to how the actions by CMS in its interpretation of the PAMA statute are reducing the access of Medicare patients to quality laboratory testing services, particularly in small communities and rural areas. However, Congress is distracted by a host of issues during this budget cycle and election year. That makes fixing PAMA a tough challenge. TDR

—Joseph Burns

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ACLA Lawyer Says Judge's PAMA Ruling Is Narrow

Several Important questions were not answered, ACLA needs to decide whether it will file an appeal

CEO SUMMARY: Many lab professionals were disappointed at the news that a federal judge dismissed the American Clinical Laboratory Association's arguments in its lawsuit against the federal Department of Health and Human Services (HHS). In an interview, the ACLA's lead lawyer on the case discussed the key issues and explained ACLA's claims about how HHS failed to follow the intent of Congress when it implemented the Protecting Access to Medicare Act. Now ACLA is considering whether it will appeal and what other legal options it may have in this case.

FOR CLINICAL LABS, IMPORTANT QUESTIONS WERE LEFT UNRESOLVED on Sept. 21, when a U.S. District Court judge dismissed the arguments the **American Clinical Laboratory Association** (ACLA) made in its case against the federal **Department of Health and Human Services** (HSS).

In a lawsuit ACLA filed last year, the ACLA made a compelling case that under the Protecting Access to Medicare Act of 2014 (PAMA), HHS set clinical laboratory rates for 2018 based on a flawed data-collection process. The process was flawed because HHS did not follow Congress' intent. Instead, it collected data on what private health insurers pay labs from only 1% of the nation's clinical laboratories, ACLA charged in its lawsuit filed Dec. 11, 2017, in U.S. District Court for the District of Columbia.

When the **Centers for Medicare and Medicaid Services** used that limited amount of payment data to set the rates for this year's Clinical Laboratory Fee Schedule, the resulting rates were 10% lower than the rates HHS paid clinical labs in 2016.

In a Memorandum Opinion issued Sept. 21, U.S. District Judge Amy Berman Jackson dismissed the ACLA's arguments in the case, saying the court lacked "subject matter jurisdiction."

In the Protecting Access to Medicare Act of 2014 (PAMA), Congress said clinical labs were precluded from challenging the rates set under the law. In her opinion, Berman cited the preclusion provision as being a significant reason for rejecting the ACLA's arguments.

Important Questions Raised

But in the opinion, Berman also acknowledged that the court was not addressing the important questions ACLA raised about how HHS implemented PAMA. For insight into those questions, THE DARK REPORT interviewed Mark D. Polston, the ACLA's lead lawyer on the case and a partner with the firm **King & Spalding** in Washington, D.C.

The unanswered questions include:

- How the HHS misinterpreted the data-reporting requirements in the PAMA statute;

In ACLA's Lawsuit Against HHS, NILA Attorney Finds Recent Federal Court Decision 'Disturbing'

ANOTHER ATTORNEY WHO FOLLOWED THE ACLA'S CASE CLOSELY also offered an opinion on the court's decision to dismiss the clinical lab industry's arguments. That attorney is Jeffrey J. Sherrin, President of the firm of **O'Connell & Aronowitz**, in Albany, N.Y. Sherrin often represents the interests of the **National Independent Laboratory Association** (NILA).

"The decision of the federal District Court is disturbing in its reach and implications," stated Sherrin. "While the court recognized that limitations on the jurisdiction of a federal court to review administrative actions must be narrowly construed, the court goes on to extend the prohibition against judicial review of the establishment of rates well beyond the reach that Congress imposed in the PAMA statute." PAMA is the Protecting Access to Medicare Act of 2014.

"The court essentially held that since all aspects of the regulations are part and parcel of the process of establishing rates, the prohibition against judicial challenges effectively extends to any challenge to any aspect of HHS' implementing regulations," commented Sherrin. "Thus, no challenge whatsoever may be brought to anything HHS did or does in implementing the PAMA statute.

"Aside from overextending the reach of the bar to judicial review, the logical extension of the decision is that anything HHS does in implementing, or defeating, the statute and Congressional intent would be beyond challenge," he argued. "If HHS purposely falsified data, or completely ignored a statutory definition or direction, that action would be immune from challenge by logical extension of the court's decision.

"Now, what if HHS decided to just rely upon one or two labs' rates in setting the new PAMA rates?" he asked. "Then this decision would likely preclude a challenge to that blatant disregard of Congress' directions.

"The result is that the court is giving HHS free reign over how to set PAMA rates, regardless of any specific instructions to Congress," he added. "We know this because the challenge by ACLA and the associations that filed 'friend of court' briefs in this case contended that HHS did just that: It ignored a statutory definition of 'applicable laboratory' and defeated the Congressional overriding purpose of setting new rates based upon the full market, holding that the court did not even have jurisdiction to review those questions."

- How HHS collected data from only 1% of the nation's labs; and,
- How HHS excluded a large number of labs by requiring only labs that have a National Provider Identifier (NPI) number to report data to HHS.

Reporting Requirements

The requirement that labs with an NPI must report resulted in excluding all but a few hospital labs, thus causing HHS to fail to collect payment rate data from those labs that private health insurers pay the most, Polston said. By excluding labs that get paid the most, the resulting rates were skewed much lower than they would have been otherwise, ACLA argued in its lawsuit.

"At the beginning of the opinion, Judge Jackson says that the case does in fact raise important issues, which is an acknowledgment that the fundamental merits of what we're arguing here are significant," Polston explained. "And one of those issues is that the secretary misinterpreted the data reporting provisions of the statute.

"It's clear that the court recognized the primary issue, which is whether the agency appropriately interpreted the definition of 'applicable lab,'" he said. PAMA uses the term "applicable lab" to define which clinical laboratories need to report data to HHS.

'Underpay for Lab Tests'

"The HHS interpreted the term 'applicable lab' in a certain way, knowing that it would grossly underpay for diagnostic lab tests," Polston said.

"That's why the agency identified the term 'applicable lab' in the way that it did," he argued. "But, the HHS doesn't have the authority to do that when Congress told it very explicitly how it defined the term 'applicable lab.' That's the important merits question here and that's the question that we ultimately wanted the court to address on the merits."

Lab administrators and pathologists following the implementation of the PAMA statute know that one way HHS excluded labs from reporting payment data was to require that only a lab with an NPI needed to report.

"We think that, with both the provisions of the preclusion part of the statute and the question about the merits of our arguments, there is a question of what is an 'applicable lab,'" Polston explained. "On this issue, the language of the statute is abundantly clear. By that I mean the text of the wording of the statute is clear, and so is the context in which the statute is passed.

Relevant Legislative History

"In our pleadings, we pointed to some legislative history, of course," he added. "Regardless of that, we believe that the statute is clear that the secretary's insertion of the requirement that labs needed to bill under their own NPI numbers in the provisions of its regulation does not follow the clear language of the statute regarding what is an applicable lab.

"But in another section of PAMA, Congress gave a very direct requirement to the agency when it laid out a specific directive to engage in notice and comment rulemaking in order to require applicable laboratories to report their commercial rate data, and to set up the mechanisms for which to do that," Polston explained. "That provision is not precluded from judicial review. So, the issue ACLA was asking to be reviewed is not the establishment of rates, but instead the issue is how the reporting of data was done.

"We recognize that there is a connection between the rules that the secretary set forth as to who reports data, and ultimately what those rates are going to be," he continued. "But that doesn't mean they are necessarily inexplicably intertwined together," he argued. "And that's where we were most disappointed.

Notice/Comment Required

"We think Congress required rulemaking for a specific reason," Polston explained. "That was so that the affected parties—meaning the clinical laboratories that had to report—could comment on those rules. In every situation in which Congress directs agencies to engage in notice and comment rulemaking, Congress typically does so because it wants to have that notice and comment rulemaking subject to administrative and judicial review.

"The fact that Congress directed the agency to engage in notice and comment rulemaking creates the presumption that Congress wanted the agency's decisions on those comments and rulemaking to be subject to administrative and judicial review."

Will There Be an Appeal?

After outlining the specific questions that went unaddressed, Polson then turned to the options that ACLA has as it considers whether to appeal the decision or not.

"Right now, a number of options are under consideration but nothing has been

CMS Used Private Payer Lab Payment Data from Just 0.7% of the Nation's Clinical Labs

IN JANUARY, LAWYERS for clinical laboratories were confident that the legal questions the American Clinical Laboratory Association raised in its lawsuit against Alex M. Azar, the Secretary of the federal Department of Health and Human Services (HHS), had merit.

In a complaint filed Dec. 11, ACLA charged that the agency failed to comply with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA). After failing to comply with those requirements, it set the 2018 Clinical Laboratory Fee Schedule (CLFS) much lower than it would have otherwise, ACLA explained. *(See "ACLA Suit Challenges HHS' Data-Collection Efforts," TDR, Jan. 2, 2018.)*

Filed in the U.S. District Court for the District of Columbia, the lawsuit charged that HHS disregarded the requirement in PAMA that all applicable laboratories report relevant market-rate data. The issue of how HHS and the federal Centers for Medicare and Medicaid Services defined the term "all applicable laboratories" was the critical issue in the lawsuit, the lawyers said.

Under PAMA, CMS was instructed to analyze what commercial health insurers paid clinical labs and to use that private-payer data to set market-based rates for this year. But when setting the 2018 CLFS prices that went into effect Jan. 1, ACLA used a highly flawed data reporting process by preventing more than 99.3% of clinical laboratories in the United States from reporting market-rate data on the prices health insurers paid for lab tests, the lawsuit said.

The small number of labs reporting payment data was the central issue in the lawsuit because, as ACLA charged, Medicare paid more than 261,500 entities for laboratory services in 2015, but collected payment data from only 1,942 laboratories in 2016 under the PAMA final rule. That is just 0.7% of the total number of labs serving Medicare beneficiaries.

decided yet," he said. "One issue under consideration is whether to continue to pursue this case in an expedited fashion."

Regardless of the steps ACLA takes, Polston acknowledged that labs continue to struggle with low payment rates. "We recognize that this is an urgent matter," he said. "That's why, when we filed our complaint in December, we actually worked with the Department of Justice that represents HHS in this matter, to expedite the briefing in the case.

"Also, we asked the court to take the case under consideration and to rule in an expedited fashion," he added. "All of that was done in response to the various issues related to the fact that this case has some urgency, given that there is harm being done.

"By that I mean the harm that potentially befalls Medicare beneficiaries who cannot get access to some of these services that they were getting before the rates went into effect in January," he said. "There also is harm to clinical laboratories that can no longer provide services at these low rates and that may have to go out of business. This leaves more medicare beneficiaries trying to find access to these lab services in different places.

"In our complaint, we were very detailed about what that harm is, and that's why we asked the court to move quickly," concluded Polston. TDR

—Joseph Burns

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Judge Rules 'Pull-Through' Is Illegal Inducement

In court case, judge also finds waiving copays and paying shipping fees lead to false claims

CEO SUMMARY: In a ruling issued Sept. 12, a U.S. District Court judge decided that two common clinical laboratory business practices are illegal inducements that can lead to charges of filing false claims. The practices occur when labs pay physicians to package and mail patients' specimens and when labs waive copays and deductibles for patients. Essentially, the judge's decision in this federal case makes such practices illegal. That means this ruling is now required reading for clinical laboratories and their legal counsel.

CLINICAL LABORATORIES THAT PAY for packaging and handling of patients' specimens and give discounts to patients for copayments and deductibles could be liable for filing false claims under a recent court ruling by a federal judge.

The ruling was made last month in the case of *United States of America ex rel. Chris Riedel vs. Boston Heart Diagnostics Corporation*. It could have far-reaching effects on those clinical labs that pay physicians to mail specimens, as well as those labs that forgive all or part of patients' copayments and deductibles, according to Justin T. Berger, an attorney representing the plaintiff in the case against **Boston Heart Diagnostics**.

Federal Whistleblower Case

In the case against Boston Heart Diagnostics of Framingham, Mass., the plaintiffs are Chris Riedel, CEO of **Hunter Heart Inc.**, a clinical lab in Los Gatos, Calif., and the **U.S. Department of Justice**. Riedel and the DOJ are seeking money damages and civil penalties in the case that was filed originally in 2012 in U.S. District Court for the District of Columbia. Riedel and his lawyers have amended the complaint twice since then, filing the most recent version in October 2017.

When asked for comment on this ruling, a spokeswoman for Boston Heart provided the following statement: "Boston Heart is focused on helping healthcare providers and patients characterize disease, individualize treatments, and engage patients in their own heart health, in compliance with applicable laws and regulations. As Boston Heart fully cooperates with ongoing investigations, our policy is to not comment on pending litigation."

In an interview with THE DARK REPORT, Berger, a principal in the law firm of **Cotchett, Pitre & McCarthy, LLP**, of Burlingame, Calif., discussed the ruling, which was issued Sept. 12 by U.S. District Judge Reggie B. Walton. "Walton decided to grant and deny in part Boston Heart's request to dismiss Riedel's amended complaint," noted Berger. "In the ruling, Walton thus decided that two legal theo-

ries in the case would go forward to trial. Those two theories relate to payment from labs to physicians for packaging and handling of patients' specimens and waiving patient copays and deductibles."

By essentially making such practices illegal, Walton's ruling is now required reading for clinical laboratories and their legal counsel, Berger advised.

"In addition to these two issues," Berger explained, "the judge ruled on labs' use of speakers bureaus as a way to pay physicians who order large numbers of tests and on the use of large panels of tests that can lead to medically unnecessary testing. Both issues have potential liability for labs." *(See sidebar on page 12.)*

"There are several significant legal theories from this case that will proceed as the trial goes into the discovery phase," he added. "Because these theories stem from a federal district court decision, lawyers can rely on them as persuasive authority in other federal courts nationwide, meaning they are now part of case law." Although the case has not yet proceeded to trial, Berger will request that it does so in the next 12 months, he said.

Pull-Through Decision

"One very important development in this case so far is the issue of what happens when labs write off copays and deductibles," commented Berger. "The judge's decision relating to writing off copays and deductibles is the first to address head-on the issue of what labs call pull-through." Pull-through is a practice labs use when they want physicians to send all of their specimens to them, rather than using multiple labs.

"This is the first decision that directly ties pull-through to false claims and kickbacks, because this judge said that it gives rise to false claims and to kickbacks," he emphasized.

"Here's what I mean regarding how this case addresses the practice of pull-through, which is something we've seen more and more over the past 10 years," he explained. "When labs write off or give big discounts to patients covered by private insurers who otherwise would need to pay copayments and deductibles in full under the requirements of their health plans [and in compliance with the laws of many states], the labs are seeking to 'pull-through' the doctors' other business, including the Medicare and Medicaid business of those doctors.

Labs Writing Off Co-Pays

"A lab that does this knows that—in order to keep its ordering physicians happy and the patients of those ordering physicians happy—the lab can write off copays and deductibles as an inducement to get the physicians to send all their lab test business to that lab," stated Berger. "Labs will do this regardless of whether the lab is the best around or has the best levels of service among its competitors.

"Essentially, this federal judge is saying that—by allowing this theory to proceed—it is considered to be a fraud on taxpayers," Berger said. "That issue has come up in other cases, but only tangentially, such in the **Blue Wave Healthcare Consultants** whistleblower case in South Carolina. *(See "In HDL Case, Judge Imposes Damages, Penalties of $114 Million," TDR, May 29, 2018.)*

Violations of Federal Law?

"But in the Blue Wave case, pull-through was not a focus of the government's case by any means," he added. "The Boston Heart case is different and so is likely to prompt a lot of discussion about what labs should do regarding how to be compliant when collecting copays and deductibles. Labs will need to discuss this case with their lawyers on how to ensure that they're not violating federal law in light of this decision.

"The way for labs to protect themselves from such court claims is not to write off copays or deductibles and not

to give discounts to patients who owe copayments and deductibles," advised Berger. "Instead, labs should go through all contracts to make sure no physicians are waiving copays or deductibles.

Issue of Importance to Labs

"That was the first issue of importance to labs in Judge Walton's ruling," he continued. "The second issue of importance to labs is that it reconfirms that labs should not pay physicians for packaging and handling patients' specimens to send those specimens to the labs.

"Again, the Blue Wave case addressed this issue too, and everyone took note of that decision in South Carolina," stated Berger. "Since then, most labs have shied away from the practice of paying packaging and handling fees or labs have morphed that practice into something else.

"But all labs should know now that this decision in the Boston Heart case says that paying packaging and handling fees is out of bounds," warned Berger. "It is a form of kickback. Also, this decision highlighted the fact that just putting a thin veil over the practice by making the payment, not directly to the physician, but to an office staff member or to a family member, is no better. In fact, in many ways, putting such a veil on the practice is worse because it's evidence that the lab is trying to hide the practice.

Kickback Violation

"That's what's alleged in this case, and the federal court found that it's a kickback violation," he said. "Now that the judge has issued his ruling, labs paying physicians to mail specimens and labs forgiving all or part of patients' copayments and deductibles are the two theories that will proceed in this case. TDR

—Joseph Burns

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Boston Heart Case Issues May Lead to Legal Jeopardy

IN ADDITION TO ISSUES related to paying for shipping and handling of patients' specimens and to writing off patients' copayments and deductibles, clinical labs need to be aware of the legal jeopardy related to paying for speakers bureaus and large panels of tests, said Justin T. Berger, an attorney with Cotchett, Pitre & McCarthy.

In the federal case against Boston Heart Diagnostics, the court found that paying speakers bureau fees to physicians who order a high number of tests could be a kickback violation, Berger said.

"But the court also found that the complaint against Boston Heart didn't sufficiently allege that the Boston lab knew that the practice of paying for speakers was illegal," he explained. "For that reason, the court is not allowing that claim to go forward based on the current allegations in the amended complaint. But, the court confirmed that the type of practice involving paying physicians as speakers can be a kickback.

"There are many labs that have some form of speakers bureau or who pay physicians to speak at conferences and other meetings," he advised. "So labs will want to review this decision on the speakers bureau issue.

"The other issue that deserves attention relates to medically unnecessary tests that are part of big panels of tests," Berger warned. "With big panels, all of the tests in the panel may not necessarily be medically necessary for every patient. To order these large panels of tests, labs encourage physicians to just check one box and not look at each patient's needs. That raises the question of medical necessity.

"For these reasons, labs should review this case closely and discuss implications of this ruling with their in-house or external legal counsel," he said.

Compliance Update

Peeking at Whistleblower Claims: How Labs Induce Physicians

Once-sealed qui tam lawsuit now is public, describes different schemes to reward referring docs

In recent decades, probably no sector of the U.S. healthcare system has seen the level of fraud and abuse that seems to pervade the clinical laboratory industry. The common perception is that illegal inducements between lab companies and referring physicians are rampant and federal prosecutors have failed to bring enough violators to justice to effectively discourage these activities.

What is challenging for federal prosecutors charged with enforcing the federal Anti-kickback Statute, and the Stark Law on physician self-referral, is the myriad of creative ways lab companies invent to induce and reward physicians for their lab test referrals.

This is equally challenging for the independent labs and hospital lab outreach programs that compete against those labs willing to interpret federal compliance requirements aggressively.

Lawsuit Provides a Roadmap

However, now there is a document that is a good roadmap to understanding some of the methods a lab company can use to induce physicians. As The Dark Report researched the background behind the recent ruling by the judge in the whistleblower case filed by Chris Riedel against **Boston Heart Diagnostics Corporation** *(see pages 6-9)*, one of the documents it reviewed is the second amended complaint in this case that was filed in October 2017 and is unsealed.

The lawsuit filed by the plaintiff, Riedel, provides great detail and documentation of specific ways that he alleges Boston Heart Diagnostics violated federal healthcare laws. This document opens a useful window on methods that some labs use to induce physicians for their lab test referrals.

When asked to comment on this lawsuit, a spokesperson for Boston Heart Diagnostics provided this statement: "Boston Heart is focused on helping healthcare providers and patients characterize disease, individualize treatments, and engage patients in their own heart health, in compliance with applicable laws and regulations. As Boston Heart fully cooperates with ongoing investigations, our policy is to not comment on pending litigation."

In the lawsuit, Riedel describes how he was a Director on Boston Heart's Board of Directors "from 2007 until majority control of the company was acquired by **Bain Capital Venture Fund** in late 2010. Mr. Riedel resigned from the Board around the fourth quarter of 2010. Prior to his resignation, Mr. Riedel had advised Boston Heart against engaging in the practices described in the complaint on several occasions."

Thus, Riedel has first-hand knowledge of the business decisions made at Boston Heart during this time. Bain Capital sold its interest to **Eurofins Scientific SE** in February, 2015. Eurofins continues to own

and operate Boston Heart Diagnostics today.

In the first section of the lawsuit, the plaintiff described "at least four forms of illegal kickbacks to doctors and clinics [utilized by Boston Heart] in order to induce those doctors and clinics to refer Medicare business to them, and to bill Medicare for redundant and unnecessary testing."

Four Types of Inducements

Here are short descriptions of the four forms of "illegal kickbacks," as described in the court document:

2. *First, Defendant promised to doctors that it will waive co-payments or patient deductible payments from the doctors' privately-insured patients. In exchange for this benefit, the doctors send all of their lipid-related business, including Medicare business, to Defendant. As such, the waiver of deductibles and co-payments constitutes illegal remuneration, designed by Defendant to induce the referral of Medicare business to Defendant.*
3. *Knowing co-pay waiver schemes were under scrutiny and illegal, Defendant tweaked its fraud in 2016 to charge patients a "special fee" named a "Know It Now Price." This is the amount which will be charged to patients in lieu of a standard calculation of their co-pay or deductible. For 75% of the tests on the fee schedule, the charge is $2.00 or less. For 95% of the tests, the charge is $7.00 or less. This is a fraction of the co-payment requirement (usually in excess of $100) based on Boston Heart's charges to insurance companies. Boston Heart's sales representatives tell physicians these are not co-payments and the prices are substantially below Boston Heart's costs.*
4. *Second, Defendant pays doctors kickbacks in the form of inflated "packaging" fees for drawing blood specimens and packaging them for shipping to the lab. The fees paid by Defendant far exceed fair market value and constitute illegal remuneration designed to induce the referral of Medicare business to Defendant.*
5. *A year after both a fraud alert issued by the Health and Human Services Office of the Inspector General ("OIG"), and after the Department of Justice intervened in a false claims act lawsuit against three of its competitors, and with knowledge its payments were illegal, Boston Heart took steps to conceal the direct payments from Boston Heart to physicians in two ways. First, Defendant began paying the fees to physicians' staff or family members. Second, Defendant began making the payments through intermediary companies. A Boston Heart sales representative, Heidi Ann Mooney, described the change to a physician: "[The Department of] Justice said we can't pay you directly, so we pay [a third party], they take some of the money and they pay you. It is all about perception."*
6. *Third, some of the physicians that refer patients to Boston Heart are also shareholders of Boston Heart. The shareholder physicians engage in strictly prohibited self-referrals without disclosing their financial stake in Boston Heart to their patients. This is a violation of the Stark Law and of Federal prohibitions on self-referrals and anti-kickback laws. Every bill to Medicare for tests performed on a self-referred patient is a False Claim.*
7. *Fourth, Boston Heart paid outrageous consulting fees to referring physicians. For example, in 2012 and 2013, the Company paid over $200,000 to Jeff Young NP, and Dharmesh Patel MD, who were among the top referral sources to the Company. The physicians were paid under the group name Heart Attack and Stroke Prevention Alliance (HASPA, preventevents.com), located at 210 Liberty St., Jackson*

TN 38301. The consulting fees were paid primarily for these physicians to solicit physician clients for Boston Heart by speaking at seminars where they explained to physicians how much money they could make by receiving packaging fees and splitting specimens between multiple labs, and how Boston Heart's large panels would have no impact on their patients. Detailed financial projections, based on the number of specimens submitted daily, and splitting specimens between 2 or 3 labs, were presented in handouts and slides.

Description of 'Overbilling'

Many lab professionals wondered how some labs get paid much more money for certain lab tests. The court documents describe one way that the defendant lab company bills the Medicare program, as follows:

11. *Boston Heart also overbills Medicare by performing and charging for medically unnecessary tests. Boston Heart bills Medicare for the individual components of its lipid panel test, rather than using the lipid panel CPT code for billing. Boston Heart added four additional tests to its pre-packaged lipid panel test beyond the industry standard, bloating a common panel with additional tests to inflate its bills to Medicare. Because Boston Heart's lipid panel is not a standard lipid panel, and because Boston Heart bills for the individual components, it charges Medicare over $100 per panel test, rather than the $18.97 allowed for a lipid panel test.*
12. *The bloated panel also includes redundant and duplicative testing. Boston Heart's panel includes both an Apo B test, and an LDL-P test. These tests measure the same thing: total LDL particles. There is no medical benefit to conducting both tests on a single patient because the tests provide the same medical information, and the course of treatment would not be affected by conducting both tests.*

The judge's ruling that is described on pages 10-12 deals with the plaintiff's claim that the practice of a lab waiving patient deductibles and co-pays violates federal law and the judge will allow that claim to be heard as the case moves to trial.

Here is what the lawsuit said about the defendant's practice of waiving charges to patients:

43. *The deductible waivers are no different. Again, in the case of the Complete One panel, the deductible payment, if charged, could be the entire $614.29, depending upon the patient's insurance plan and medical care. Boston Heart sales representatives encourage physicians to order additional tests with the Complete One pane [on the test request form]. Attached as Exhibit 3 is an Explanation of Benefits ("EOB") for a panel of Boston Heart tests showing the total charges to be over $4,000. Despite the EOB showing the services were not covered, the patient was never charged for the tests.*
44. *Accordingly, the waiver of a deductible payment is a significant benefit that a physician can provide to his or her patients. Knowing this, Defendant promises physicians that it will waive deductibles, so long as the physicians send all of their lipid-related business—especially the highly profitable Medicare business—to the Defendant's laboratory. Boston Heart waives the remaining fee, writing off hundreds or thousands of dollars of charges for some patients.*

Clinical lab managers and pathologists seldom get to see a detailed description of the business practices used by labs accused of violating federal laws. This knowledge could help competing labs explain to physicians why certain of these practices could expose the physicians themselves to federal enforcement actions. TDR

Legal Update

Defunct, Oft-Troubled Calloway Labs Hit with $1.4M Federal Judgement

Whistleblower case results in civil judgement, has common elements with ongoing Boston Heart case

How often is a defunct lab company in the news? That was the odd development last week when it was announced that a U.S. District Court had entered a $1.4 million civil judgement against **Calloway Laboratories, Inc.**, a toxicology lab company formerly based in Woburn, Mass., for business practices during the period May 2014 through November 2014.

An interesting fact gives this development additional significance. After facing state and federal charges prior to 2012 that resulted in jail sentences, fines, and penalties, Calloway Labs was acquired by a private equity company that year and an experienced lab industry executive became its CEO. So this civil settlement involves claims that Calloway violated federal law under its new owners and new executive leadership.

False Claim Allegations

In a press release, the U.S. Attorney's Office for the Eastern District of Kentucky said that the $1,374,058 judgement was "part of a settlement agreement resolving False Claims Act allegations that, during the period May 2014 to November 2014, Calloway submitted false claims for payment for urine drug testing referred by physicians to whom Calloway provided free testing supplies. As part of the settlement agreement, Calloway acknowledged that it provided free testing supplies to physicians for the purpose of inducing or rewarding referrals of urine drug testing to Calloway. Calloway then submitted claims to Medicare and TRICARE seeking payment for the testing referred by these physicians."

The judgement is the result of a whistleblower lawsuit filed by a former Calloway employee. The whistleblower will be awarded a portion of whatever the federal government collects from the civil judgement.

This would be the second major government enforcement action against Calloway during the last four years that it was in business. The first came in 2010, when then-Attorney General of Massachusetts, Martha Coakley, filed 42 indictments against Calloway labs, two of its officers, and two employees of a sober house.

Coakley, in a press release, said the defendants "engaged in a pervasive kickback scheme involving two straw companies which funneled kickbacks to sober houses, as well as paid middlemen and a medical office to illegally obtain urine drug screening business paid by **MassHealth**, the Commonwealth's Medicaid program."

Those charges resulted in Calloway Labs agreeing to pay $20 million to settle criminal charges (without admitting guilt) in March, 2012. Later that year, in October, ex-Calloway executives Arthur Levitan and Patrick Cavanaugh pled guilty and were sentenced to four years of probation. Kelli

Ann Cavanaugh pled guilty in Jan. 2013 and received a similar sentence.

Ampersand Capital Partners entered the picture at this time. It acquired Calloway Laboratories before the end of 2012 and installed Gail Marcus as President and Chief Executive Officer. At that time, Calloway Labs still had about 250 to 300 employees.

Lab Company Closed in 2015

Less than 33 months later, Ampersand and Marcus made the decision to close Calloway Laboratories, effective October 16, 2015. This is also the same period identified in the Department of Justice press release as when Calloway Laboratories was "submitting false claims to federal healthcare programs... by providing physicians with free testing supplies in violation of the federal Anti-Kickback Statute and the Stark Law."

This raises the interesting question about the level of oversight and due diligence exercised by Ampersand, the new owner of Calloway Laboratories during that time, and its executive team. For example, the CEO, Marcus, had two decades of experience at such major health insurers as **Cigna** and **UnitedHealthcare**, followed by two years as CEO of **Caris Diagnostics** in Irving, Texas. It would be expected that such experienced ownership and management would recognize which of their lab's business practices might be non-compliant with federal healthcare laws.

Oversight and Due Diligence

That same question about oversight and due diligence by executives with years of experience managing lab companies is an element in another whistleblower case involving a clinical laboratory company.

This *qui tam* case is unfolding in the U.S. District Court for the District of Columbia. It is *United States of America ex rel. Chris Riedel versus Boston Heart Diagnostics Incorporated*. The original lawsuit was filed under seal in 2012, but the second amended complaint is public. The claims that the plaintiff asserted against the defendant contained detailed descriptions of Boston Heart's business practices that are alledged to be violations of federal healthcare laws.

The recent important ruling by the judge in this case is the subject of the story on pages 6-9. Attorneys tell THE DARK REPORT that this ruling sets a new bar for lab compliance, as it relates to specific ways that labs induce physicians in exchange for lab test referrals.

What connects this story to the Calloway Laboratory compliance issues is that Boston Heart also had owners, a board, and executives who were experienced professionals and who would be expected to be familiar with proper due diligence and how to comply with federal healthcare laws. Boston Heart provided a statement about this whistleblower case which is shown on page 10.

Boston Heart's Directors

In the court documents, Riedel says he served on Boston Heart's board as a director from 2007 until fourth quarter 2010. The lawsuit identifies other board members at this time as Susan Herzberg, President and CEO; Peter Parker, Chairman; Alice Limkaking, Chief Business Officer; Frank Yunes, Secretary and General Counsel; and Jeff Crison. Of this group, Herzberg had the most relevant and applicable experience with how labs comply with federal healthcare laws, having previously worked at **Oxford Health Plans**, **Quest Diagnostics**, and **Abbott Laboratories**.

Given the similarities of non-compliance in the court allegations against Calloway Laboratories and Boston Heart Diagnostics, the unanswered question is how experienced investors and lab executives failed to keep their companies compliant with federal healthcare laws. TDR

Pathology Errors a Factor in 3 Deaths at VA Hospital

➤33,000 cases handled by the Chief of Pathology since 2005 are under review by other pathologists

➤➤CEO SUMMARY: Outside pathologists are reviewing the pathology reports of almost 20,000 patients of an Arkansas Veterans Administration hospital following termination of a Chief of Pathology who was believed to have handled cases while impaired. Currently, the review identified 256 cases where the pathology report missed the diagnoses and the potential for severe consequences existed. Serious consequences have been confirmed in 11 patients and three of these patients are now dead.

THERE IS A NEW CASE OF PATHOLOGY ERRORS that caused patient harm, this time at a Veterans Administration Hospital in Arkansas. News reports say that misdiagnosis is believed to be a factor in the deaths of at least three patients.

A review is underway at **Veterans Health Care System of the Ozarks** in Fayetteville, Ark., after officials determined that an impaired pathologist's work led to three deaths. The Veterans Health Care System of the Ozarks serves veterans in 23 counties in Northwest Arkansas, Southwest Missouri, and Eastern Oklahoma.

➤Chief of Pathology Involved

Pathologist Robert Morris Levy, MD, identified himself to *FBSM/KXNW News* as the pathologist. Prior to his termination last April, he had been Chief of Pathology at the Veterans Health Care System of the Ozarks. *FBSM/KXNW* reported that Levy "denied he was impaired on duty."

In the *NWA Democrat-Gazette*, J.T. Wampler reported that three deaths resulted from incorrect pathology reports and that a review was underway.

In his news story, Wampler quoted Veterans Health Care System Interim Director Kevin Parks, who said, "The review has found 256 cases in which the pathology report missed the diagnosis with possibly severe consequences. These range from extended, avoidable hospitalization to lasting disability or death."

In most of the 256 cases, VA officials did not know if the misdiagnosis had any serious consequences. However, serious consequences were confirmed in 11 of those cases, and three of those patients died, Wampler reported. Misdiagnosis is believed to be a factor in at least one death, and the other two cases were being reviewed, he added.

VA officials are reviewing every one of more than 33,000 cases the pathologist has been involved with since he was hired in 2005 and those cases are prioritized by risk, Wampler reported.

Another news outlet said that these 33,000 cases involve 19,794 veterans. They or their family members have been notified by mail about this situation and the fact that the cases are being reviewed.

The review of these cases is expected to be completed by year-end, in part because the **University of Arkansas for Medical Sciences** has sent nine pathologists to work at the Fayetteville veterans system site fulltime, Wampler wrote. "The system will bring in more pathologists from outside the state, but that will have to wait until the beginning of the new federal fiscal year on Oct. 1," he added.

A final report will be made public in January, said Wampler. Meanwhile, VA officials who are reviewing the 33,806 case reports have so far gone through fewer than half (14,980) of them, he reported. "Of those reviewed, 9,979 have no errors, 863 appeared to have errors with no lasting consequences to the patients involved and those cases will get a further review, and 3,882 reviews are complete but a final report is not finished," he wrote. The VA will send letters to patients and families when final results are available.

Was Pathologist 'Impaired?'

In June, VA officials announced that the review began after administrators discovered that pathologist Levy at the **Fayetteville Veterans Administration Hospital** tested samples while impaired. The pathologist confirmed that he had worked while impaired with alcohol in 2016, but said he did not work while impaired after that, Wampler wrote. The Veterans Affairs Office of Inspector General is investigating the retention of the pathologist after his first reported impairment, officials said.

Levy was suspended in March 2016 for being impaired, but returned to work in October 2016 after counseling. In October 2017, the pathologist was no longer involved in clinical work after the hospital discovered a second instance of working while impaired, Wampler reported. After a personnel department review, the pathologist was fired in April of this year, he added.

The *Minneapolis Star-Tribune* reported that, "Levy was licensed to work in California, Florida, and Mississippi (VA doctors do not need to be licensed in the state in which they practice). Online searches reveal active licenses in California and Florida, although Levy has said he does not intend to return to pathology.

U.S. Attorney Is Investigating

During a news conference this summer organized by the Arkansas VA health system, Parks said the nature of the now-terminated pathologist's impairment would not be publicly disclosed because it is a personnel matter.

The *Arkansas Democrat-Gazette* reported that U.S. Attorney Duane Kees of the Western District of Arkansas was present at the press conference and did confirm his office was investigating these developments. Kees did not speculate as to what charges, if any, might be under consideration.

These developments happened within months of the news that pathology errors caused patient harm at **Wake Forest Baptist University Medical Center** in Wake Forest, N.C. In that case, an inspection by officials from the **Centers for Medicare and Medicaid Services** (CMS) resulted in a decision to pull the hospital's accreditation. The hospital's plan of corrective action was accepted by CMS and the hospital's Medicare billing privileges were restored. *(See TDR, April 16, 2018.)*

Double Warning to Pathology

These examples of serious pathology errors associated with patient harm should be a double warning to the pathology profession. The patients and the American public are raising their expectations about the quality of healthcare they receive. They also have the expectation that the pathology profession is using quality-management methods to continually reduce the number of errors in how pathology specimens are handled and diagnosed. **TDR**

—Joseph Burns