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INSIDE THIS ISSUE

ACLA Court Win May Tip the Battle Over PAMA Pricing

Take that, CMS! The American Clinical Laboratory Association (ACLA) *can* sue to get the agency's PAMA lab pricing scheme struck down after all. So ruled the US Court of Appeals for the District of Columbia Circuit in late July, roughly 10 months after the lower court ruled that the ACLA couldn't take its claims to court.

PAMAgeddon

The focal point of the ACLA and lab industry's opposition isn't with the idea of basing Part B lab test prices on market rates but rather CMS' implementation of the concept, specifically its exemption of virtually all hospital labs from the data-reporting requirements. As a result, the pricing data collected was skewed and didn't accurately represent the private market the way Congress intended when it passed the legislation.

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

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Data Breaches Leave Labs and Patients Exposed

Two recent data breaches at major labs may have compromised the personal health information of approximately 19.6 million patients. No wonder the industry and privacy experts are revisiting best practices for preventing future incidents.

At Quest

The larger of the two breaches involves Quest Diagnostics, one of the biggest blood testing companies in the US. In late May, Quest was notified by billing and collections vendor American Medical Collection Agency (AMCA) that a hacker had access to its system and Quest customer information for nearly eight months, between

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effect in 2018. Frustrated by the lack of progress on the regulatory front, the industry led by the ACLA, escalated the dispute by taking CMS to court. The essence of ACLA's legal claim is that CMS abused its power by rewriting rather than implementing PAMA.

In September 2018, it looked like the litigation strategy would turn out to be a dead end 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 on PAMA rate-setting.

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.

What It 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.

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Business Trends: More Hospitals Looking to Outsource Their Lab Testing

Looking for new business opportunities? A new survey shows a substantial jump in the number of hospitals looking to outsource lab services. creating potential opportunity for labs. Although no hospitals plan to outsource their entire lab functions, the July survey by global investment bank and financial services company UBS finds that 23% of hospitals in the United States are interested in outsourcing more lab services, up from just 4% in April.

The Outsourcers

UBS surveyed 75 hospital CEOs and CFOs, with oversight for 655 hospitals throughout the country. Respondents were geographically dispersed:

- Midwest: 33%
- South: 33%
- Northeast: 18%
- West: 16%

The majority of respondents, 88%, were responsible for non-profit hospitals. The hospitals they oversee tend to be larger: 41% oversee hospitals with 300 or more beds, and 39% oversee hospitals with 100 to 300 beds.

The hospitals are in various areas:

- Rural: 28%
- Urban: 23%
- Suburban: 22%
- Small town: 11%
- Multiple: 16%

Size Doesn't Matter

Interestingly, the survey finds that smaller hospitals are equally likely to use third-party outsourcing as large hospitals:

- Hospitals with more than 300 beds: 24%
- Hospitals with less than 300 beds: 23%

Location May Matter

Hospitals in the South and Midwest appear most interested in increasing lab outsourcing:

- South: 28%
- Midwest: 27%
- West: 17%
- Northeast: 9%

Opportunity for Labs

Perhaps most surprisingly, hospitals are looking beyond the usual suspects

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Business Trends: More Hospitals Looking to Outsource Their Lab Testing, *from page 3*

when it comes to outsourcing. When asked which third-party lab they are considering using for outsourcing, the survey finds:

- LabCorp: 42%
- Quest Diagnostics: 33%
- Other: 17%

This is especially noteworthy, because in April, respondents were split 50-50 between LabCorp and Quest; "other" wasn't even on the radar.

Additional Considerations

The survey does not ask whether recent data breaches involving LabCorp and Quest caused some respondents to choose "other." Given the timing of the survey in relation to news of the breaches, however, there may be a connection.

Survey findings suggest that reimbursement pressure from Protecting Access to Medicare Act (PAMA) cuts may be a factor with regard to lab outreach strategy, which the survey also asked about. But it does not look at PAMA as it relates to lab outsourcing. Here again, though, there may be a connection.

Labs IN COURT

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

Federal Court Dismisses Whistleblowers' 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 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.].

Drug Abuse Treatment Owner Guilty of $57 Million Drug Test Pass-Through Billing Conspiracy

Case: The owner of a northern Florida substance abuse treatment center pleaded guilty for his role in a $57 million pass-through lab testing billing and money laundering scheme. The way it worked: The treatment center owner cut a deal with a lab owner to send patient urine samples to the lab for urine drug testing in exchange for a 40% share of the insurance reimbursements. The lab owner did his part by arranging with managers of two rural hospitals to bill private insurers to secure the highest possible rates for the tests.

Significance: Making the scheme even more egregious is that the same treatment center owner also brokered parallel urine drug testing deals between the rural hospitals and other substance abuse facilities, pocketing 30% of reimbursements as his commission. In addition to forfeiting $10.2 million in ill-gotten gains, he's looking at a high fine and time behind bars when sentencing is handed down.

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Labs in Court, *from page 5*

Massachusetts Practice Busted for Taking Free POCT Cups from Millennium

Case: A northern Massachusetts medical practice and Detroit pain clinic became the latest downstream providers to pay the OIG a five-figure fine to settle kickback claims in the form of accepting free point of care test cups from now defunct Millennium Laboratories. The settlement amounts: $87,650 and $44,900, respectively, are consistent with the range of what other providers have paid since autumn 2017 when the feds began targeting the physicians on the receiving end of the Millennium scandal.

Significance: Millennium used the freebies to pay physicians for referrals of custom profile panels and other tests to carry out what the feds claim is the largest ever kickback scandal involving lab services. (For more on the physician crackdown, see *Lab Compliance Advisor, (LCA)*, June 18, 2018).

Millennium Free POCT Cup Physicians Settlement Scorecard (as of Aug. 1, 2019)

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
July 12, 2019	Anesthesia Services, P.C. d/b/a University Pain Clinic (UPC)	$44,900	NO
June 14, 2019	HKD Treatment Options, P.C.	$87,650	NO
Dec. 21, 2018	Tulsa Pain Consultants, Inc.	$98,942	YES
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

Lab Uses Billing Info of Another Lab to Get Around Payment Restrictions

Case: In 2015, Kentucky Medicaid and private payors began having doubts about the legitimacy of urine drug test claims submitted by CAL Laboratory Services and restricted payments to the toxicology lab. Undeterred, the owner of CAL arranged with his counterpart at Tristate Medical Laboratories to have tests referred to and performed by CAL billed to health insurance programs using Tristate's billing information to make it look like Tristate performed the tests. In exchange, he paid Tristate's owner 40% of the $1.3 million in fraudulent reimbursements received on the tests.

Significance: Four principals of CAL and Tristate pleaded guilty to their role in the conspiracy. Two of the defendants died after being convicted; the other two are awaiting sentencing. In addition to fines and possible prison, the owner of Tristate is likely to get a 10-year Medicare and Medicaid exclusion.

Kickbacks: OIG Withdrawal of Old Safe Harbor Proposals Clears Way for Meaningful Reform

Like the rest of the health care industry, labs need more not fewer new and modern Anti-Kickback Statute (AKS) safe harbors. So, the OIG's decision to cancel new safe harbors in incubation seems like bad news. In fact, it can be interpreted as just the opposite, i.e., as an indication that real kickback relief is on the way. Here's the dope.

Proposed Safe Harbors Being Withdrawn

On Aug. 1, the OIG announced that it was withdrawing two proposed rules to create new or expand existing AKS safe harbors:

A 1994 proposed rule that would have codified in regulations OIG's authority to levy civil monetary penalties (CMPs) when a hospital knowingly makes incentive payments to a physician as an inducement for reducing services to Medicare or Medicaid beneficiaries; and

A 2002 proposed rule that would have expanded an existing safe harbor at 42 CFR 1001.952(k) to include waivers of cost sharing amounts for Part A and B services for holders of Medicare SELECT policies, a type of Medicare supplement (Medigap) plan.

What's Really Going On_

According to the notices, OIG is withdrawing the proposed rules to comply with an executive order instructing government agencies to identify regulations that can be repealed, replaced or modified. But the real intent of the move may be to clear the decks for bigger and better things. The 1994 and 2002 proposed rules were wallowing in obscurity and were probably never going to be finalized. In fact, the OIG indicates that, to its knowledge, the public never relied on nor was even aware that the rules existed. And with more meaningful relief in the pipeline, it makes sense that the OIG said that it's getting rid of those old proposals now to "avoid confusion."

By contrast, the CMS initiative to amend the AKS safe harbors and exceptions to the beneficiary inducement CMP provisions for coordinated care has garnered significant attention. After collecting public feedback, CMS sent a proposal to the White House Office of Management and Budget. Once OMB clears the proposal, it will become public which will probably be some time this fall.

OIG News: Myriad Genetics Pays $9.1 Million to Settle Hereditary Cancer Test False Billing Claims

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 in 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 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.

New Laws: Congress Tables Bill to Make Whole-Genome Sequencing Available to Medicaid Kids

In early August, Representatives Scott Peters (D-CA) and John Shimkus (R-IL) introduced in the US House of Representatives a bill to provide "certain undiagnosed children under the Medicaid program" access to whole-genome sequencing. Here's a briefing.

The Context

By cost-effectively using DNA to detect thousands of conditions that traditional diagnostics may fail to pinpoint, including neurologic, metabolic and other inherited diseases, whole-genome sequencing can be instrumental in saving lives and ensuring that children receive appropriate treatment as fast as possible. "By quickly pinpointing the cause of rare genetic diseases, doctors can prevent unneeded tests or surgeries, shorten hospital stays and reduce medical costs," said Stephen Kingsmore, president and CEO of Rady Children's Institute for Genomic Medicine in San Diego.

The Bill

The so called "Ending the Diagnostic Odyssey Act" amends the Social Security Act to give states the option of providing whole genome clinical services to children in their Medicaid programs with the federal government funding up to 75% of the costs. Eligible recipients include individuals under age 21 (although states can reduce the age threshold to 18, 19 or 20) who are otherwise eligible for Medicaid. Individuals would also be eligible up to age of 26 if they meet certain criteria. "It's hard enough for parents and families to face an unknown medical future for a young child and they should have access to every available diagnostic tool," bill co-sponsor Peters said in a statement.

The Prospects of Passage

Being a bi-partisan measure gives the bill a better chance of passing the House. Currently, there's no companion bill in the Senate but the sponsors are hopeful that there soon will be. "Our hope," says Peters, "is that this legislation opens the door to find answers to medical mysteries so that all children and families who need it can have access to this life-changing genomic medicine."

FDA Watch: FDA Greenlights Assays Using New Test Model for Lyme Disease Diagnosis

Lyme disease is on the increase. And so is the number of products cleared for detecting it. In fact, products for detecting tickborne diseases have been reaching the U.S. market at a dramatically stepped up pace in the past two years. In 2018, the Food and Drug Administration (FDA) approved two different donor screening tests to detect Babesia, a tickborne parasite responsible for the babesiosis infection. Meanwhile, researchers at Columbia University developed the first multiplex array for diagnosis of Lyme disease and other tickborne diseases. The most recent development is the FDA's expansion of clearance for four previously cleared tests to cover new indications to aid in the diagnosis of Lyme disease. Here's why these approvals are significant and different from anything the agency has cleared before.

The Lyme Disease Challenge

Lyme disease is caused by the bacteria Borrelia burgdorferi which is transmitted to humans through the bite of infected ticks. Typical symptoms include fever, headache, fatigue, and skin rash called erythema migrans. If left untreated, infection can spread to the joints, heart, and nervous system.

In 2017, the last year for which the Centers for Disease Control and Prevention (CDC) has published data, a total of 42,743 confirmed and probable cases of Lyme disease were reported to the agency, an increase of 17% from 2016.

The Newly Cleared Tests

Laboratory diagnosis of Lyme disease has traditionally used a two-tier process for detecting the presence of antibodies against Borrelia burgdorferi in a patient's blood. Antibodies are proteins present in the blood when the body is responding to a specific infection. Testing follows a two-tier approach in which a pair of enzyme immunoassays (EIA) are performed followed by a separate protein test called a Western blot to confirm a clinical diagnosis of Lyme disease.

While the FDA has cleared laboratory tests for detecting Lyme disease before, the four clearances announced on July 29, 2019, break new ground because they are the first the agency has approved that follow a different model relying only on EIA technology-based tests which can be run concurrently or sequentially. The products which were approved via the FDA 510(k) pathway were all developed by Branchburg, NJ-based Zeus Scientific, including:

- The ZEUS ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System;
- The ZEUS ELISA Borrelia burgdorferi IgG/IgM Test System;
- The ZEUS ELISA Borrelia burgdorferi IgM Test System; and
- The ZEUS ELISA Borrelia burgdorferi IgG Test System

Data Breaches Leave Labs and Patients Exposed, *from page 1*

Aug. 1, 2018 and March 30, 2019. Information of about 11.9 million patients might have been compromised, including credit card numbers, bank account details, medical data and Social Security numbers. Lab results were not compromised because Quest didn't share that information with AMCA. Upon learning of the breach, Quest stopped sending collection requests to AMCA, sent notifications to health plans and enlisted the help of security experts to mitigate the damage.

At LabCorp

A few days after notifying Quest of the above breach, AMCA informed another one of its mega-lab clients, LabCorp, of a breach potentially affecting 7.7 million patients. As in the Quest situation, personal and financial information was compromised but not lab test results. However, *The Washington Post* reports that during the LabCorp breach "the hacker was able to access names, birthdays, addresses, phone numbers, dates of service, account balances and other information." According to *The Wall Street Journal*, LabCorp responded by notifying approximately 200,000 of its customers that their credit card information may have been compromised. In announcing this action, LabCorp CEO **David P. King** also pointed out that the breach wasn't the direct result of anything the company had done and that the company "believed the impact to LabCorp customers would be minimal."

> *"During the LabCorp breach "the hacker was able to access names, birthdays, addresses, phone numbers, dates of service, account balances and other information."*
>
> *The Washington Post*

Legal Ramifications and Other Fallout

Coincidentally or not, King announced his retirement as LabCorp CEO on the same day he addressed the breach.

Reportedly, credit card details for approximately 200,000 patients from AMCA have been found for sale on the dark web.

A class-action lawsuit has been filed by more than 1,000 LabCorp customers, alleging that it failed to protect the confidential information of millions of patients and that "wrongful disclosure has harmed the plaintiffs and the classes believed to include millions of individuals." Quest has also been hit with a class-action lawsuit.

Retrieval-Masters Creditors Bureau, the parent company of AMCA, filed for Chapter 11 bankruptcy protection. In its petition it cited a "cascade of events."

Best Practices

The Quest and LabCorp breaches and resulting legal action are a striking reminder of the importance of preventing data breaches and responding properly when prevention fails.

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Data Breaches Leave Labs and Patients Exposed, *from page 11*

Best practices:

- Inform patients that you share their PHI with third parties and explain the resulting risks;
- Ensure that all contracts with billing and collections firms require immediate disclosure of data breaches;
- Include contract language requiring billing and collections firms to take appropriate measures to address breaches involving your lab's data;
- Establish internal policies regarding data breaches that address patient notification, outreach to health plans, assistance from security experts, and media outreach; and
- Have a contingency plan in place for billing and collections services in case the current vendor become unavailable—or consider using two vendors if your volume warrants it so that a backup is immediately available.