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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Bridging the Schism within Your Laboratory

THERE'S A SIGNIFICANT SCHISM BECOMING VISIBLE within the house of laboratory medicine. I am calling your attention to this development because this schism probably exists within your own laboratory organization.

On one side are a very large number of pathologists, lab administrators, and laboratory scientists who have yet to acknowledge that the lab testing marketplace they have known their entire career is coming to a rather swift end.

On the other side are the forward-thinkers in your lab. These are the individuals who are quick to read the tea leaves. They understand the implications of different healthcare trends on the ability of your lab to deliver high quality lab testing services in a financially-sustainable manner.

It is important for you to distinguish between these two groups and the schism that divides them, because it represents either conflict or opportunity for your lab organization. The conflict will come because those individuals who have yet to recognize and accept the fundamental changes in care delivery and how providers are to be reimbursed will firmly defend maintaining the status quo despite the best efforts of the forward thinkers in your lab.

The opportunity will be based on the success of the lab's forward thinkers, in collaboration with senior administration, to win over the group wanting to maintain the status quo. Both groups within your lab need to understand how healthcare's evolution requires your lab to evolve in parallel and introduce new lab services that deliver value to physicians, patients, and payers.

Just as this schism exists within your laboratory organization, it also exists within the various national clinical lab and pathology societies, associations, and colleges. Across their memberships—and among their officers and boards of directors—the same schism exists. This fact is reflected in the content of their newsletters, bulletins, and current event blogs (distinct from their clinical journals), where few stories are published that inform members about the real-world, down-and-dirty things happening in today's rapidly-evolving healthcare marketplace.

Here at THE DARK REPORT, we experience this same schism. We are regularly praised by readers for our candid, forthright reporting of these often-negative issues. But we also hear other readers who express their desire to have most all of the editorial content focus on more positive aspects of lab management. TDR

Could Health Insurers Be At War with Clinical Labs?

Lab industry buzz interprets payer actions as consistently against smaller regional labs

CEO SUMMARY: It may sound ridiculous to assert that the nation's largest health insurers are now "waging war" against clinical labs. However, some very smart people in the profession of laboratory medicine are expressing this opinion. To support such a conclusion, they point to payers' recent drastic price cuts and network contracting strategies. Moreover, these lab observers are concerned that, without a vigorous response by lab industry leaders, many community labs will be forced to close in coming years.

By Robert L. Michel

ARE PAYERS AT WAR WITH CLINICAL LABORATORIES? More than a few thoughtful pathologists and lab administrators are asking this question.

It is notable that changes in how payers deal with clinical lab testing are causing some smart people in the lab industry to describe these developments as "payers waging war on labs."

Of course, it is highly unlikely that the executives at different health insurers have made a conscious decision to "go to war" against clinical labs in the pursuit of cutting the cost of lab testing to their members. Yet the majority of labs are consistently worse off in the wake of payer actions to cut costs.

In conversations with some lab executives, they point out how, over the past 36 months, both government health programs and private payers have taken actions damaging to the financial sustainability of all clinical labs—whether large or small. Moreover, during this time, these damaging actions are more numerous and happening more frequently than has ever been seen previously in this country.

Their evidence to support a payers' war on clinical labs tends to involve several types of payer actions. For example, payers restrict access to patients by excluding large numbers of regional laboratories from provider networks.

Another tactic is change the design of different health insurance products so that clinical labs not holding favored network contracts with a payer will find it nearly impossible to get paid. Alternatively, the design of these health plans requires the out-of-network lab to collect a substantial

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deductible or out-of-pocket amount directly from the patient.

Probably the best instance of a payer excluding labs from its networks is **Aetna, Inc.** During 2011 and 2012, it acknowledged that it was dropping as many as 400 clinical labs from its provider networks throughout the United States.

Also, payers regularly reduce payments to clinical labs. This can be accomplished in several ways. One tactic is simply to impose deep cuts to prices for clinical lab tests.

One example of the strategy of arbitrarily reducing the prices paid for lab testing, comes from how the Medicare program handled the implementation of the 114 new molecular diagnostics CPT codes last year. Decisions by Medicare and its Medicare administrative contractors significantly reduced the prices paid to clinical labs for a substantial number of molecular CPT codes.

Another example of payer chicanery was the policy implemented by the **Blue Cross Blue Shield Association** that changed the way laboratories would be paid whenever they provided lab testing services to patients using their Blue Card benefits in other states. The policy went into effect on October 12, 2012. *(See TDR, July 16, 2012.)*

Critics within the lab industry observed that this change by the national BCBSA was in direct violation of the terms of the BCBS members' policies. Yet regional Blue Cross plans across the nation complied with the new requirement and hundreds of the nation's community laboratories found it nearly impossible to get paid for the lab tests they provided under the Blue Card program.

Have a story about a "payer war" on your lab? Tell us about it.

THE DARK REPORT is investigating the practices health insurers use to cut lab testing costs by excluding community labs, violating existing contracts to force participating labs to accept lower rates, and similar actions that may violate state and federal laws and regulations. All information will be held in strict confidence. Call our editor at 512-264-7103 or email rmichel@darkreport.com.

These points raise the question: Is there sufficient evidence to support a conclusion that a large proportion of the actions taken by private and public health insurers in recent years represent a war against clinical laboratories?

This is a serious charge to level against the collective health insurance establishment, ranging from the federal Medicare program to the largest private health insurance organizations that typically cover millions of Americans.

Yet, the fact that the charge is serious is precisely one reason why reasonable and experienced lab professionals should ask this question for themselves.

To be fair, payers may believe that rising costs—including the annual increase in the cost of clinical lab testing—are unsustainable and they need to take steps to control these costs. However, when they do, their efforts are often ham-handed and at least unsophisticated. Also, some payers tend to apply a one-size-fits-all approach, meaning that all labs large and small are affected equally.

➤ Control of Healthcare Costs

It is true that health insurers need to control costs in every aspect of care delivery—whether it's the cost of primary or specialist care, hospitalizations, or ancillary services. So it's a bit unfair to paint insurers with a broad brush and suggest that they are waging war against clinical labs.

On the other hand, there is an equally serious reason why every pathologist, lab scientist, administrator, and lab manager should take up this question and give it serious consideration. If it is true that payers have decided to go to war against clinical labs, then at risk is nothing less than

If Payers Are Waging War against Clinical Labs, Then Who Are Their Allies and Collaborators?

WHENEVER A NATION GOES TO WAR, it wants allies. Assume, for a moment, that payers in the United States today are waging war against clinical laboratories. In such a case, who are their allies?

The evidence suggests that publicly-traded laboratory companies are natural allies for private health insurance companies. It could be argued that, since the mid-1980s, the economic interests of public lab companies have had more in common with the nation's largest health insurers than with their smaller regional and community-based lab peers.

The advent of closed-panel gatekeeper model HMOs during the 1990s brought private health insurers and public lab companies into close collaboration. HMOs exchanged exclusive network access to patients for deeply-discounted capitated payment rates in deals where the public lab companies were also at partial or full risk for utilization.

When closed-panel HMOs faded in the late 1990s, the cozy relationships between public lab companies and the nation's larger health insurers continued. Their evolution followed a pattern of the lab companies offering deeply-discounted prices. In exchange, payers granted the lab companies exclusive or near-exclusive access to the payers' provider networks. Plus, labs got the payers to exert pressure on physicians to keep their lab test referrals in-network. Both of these aspects of network management favored the contracted national labs over community labs.

Public Labs, Payers Are Cozy

During the past 15 years, these cozy relationships between public lab companies and health insurers matured into more sophisticated contract relationships. On the outside were regional independent labs and the lab outreach programs of community hospitals. With each passing year, these labs lost access to large groups of patients in their communities. They were also getting paid less for the lab testing they provided.

For some state Medicaid programs, a variant of this scenario is in play. Where states adopted a managed care model for Medicaid patients, Medicaid officials found the public lab companies were natural allies. They often exchanged exclusive access to Medicaid patients for deeply-discounted prices from large lab companies. Typically, this strategy excludes community labs in those states from providing lab testing services to Medicare patients.

Medicare's View Of Prices

Because of Medicare's different economic model, federal officials view public laboratory companies much differently than private payers do. As demonstrated by events in recent years, Medicare officials—aware that the national labs do not offer Medicare the same deeply-discounted lab test prices they give to private insurers—have taken steps to reduce prices paid to all laboratories.

There is irony in this situation. Public lab companies use the fee-for-service prices from Medicare Part B to subsidize the often money-losing prices they give to private payers. Medicare officials—along with some in Congress—have noticed this trend and seem determined to lower Part B lab test prices sharply.

If this is a war against labs on the part of Medicare officials, these actions hurt all labs. But they are particularly devastating to the finances of regional and community labs (which do not have the economies of scale that the national labs enjoy).

The point of these observations is to illustrate how public lab firms have served as allies to private health insurers, some state Medicaid programs, and Medicare Advantage plans. From that perspective, public lab companies are enablers of the conceptual payers' war against clinical labs happening today.

the clinical viability and financial sustainability of community-based medical lab testing services.

Contributing To Patient Care

It is a fact that the overwhelming majority of individuals who are trained in laboratory medicine and hold scientific and technical degrees and certifications entered the profession to contribute to patient care. Moreover, the rich diversity of local labs and community hospital laboratory outreach programs are the reason why, every day, physicians and their patients can get speedy and accurate lab test results no matter where they live and work in the United States.

Yet today—for purely financial reasons—government health programs and private health insurers may be, in effect, taking steps that will destroy the diversity of community labs and regional lab organizations that have provided top-quality lab testing services in markets large and small throughout the United States. Moreover, the smaller communities typically are underserved by the two national lab companies, each of which operates regional hub laboratories in about 30 cities.

Another relevant fact recognized by the pathologists, Ph.D.s, and clinical laboratory scientists who work in small labs located in small towns and in rural areas is that their communities are often hundreds of miles away from one of the national labs' hub testing facilities.

Gaps in Covered Geography

Insurance executives overlook the fact that, while it is easy for them to do a money-saving lab test deal with a national lab, those national labs have gaps in their geographical coverage that only the smaller, regional, family-owned, and specialty labs can fill. Similarly, someone needs to do clinical lab testing in nursing homes and long-term care facilities, an essential sector of the lab test market that was abandoned by the public labs two decades ago because they considered nursing home business to be unprofitable.

These are some reasons why the healthcare system cannot afford the loss of these community-based clinical lab testing providers. Such a loss would be particularly devastating when the number of retirees on Medicare is rising and tens of millions of Americans suffer from one or more chronic diseases.

In this assessment of how the actions of payers are seriously eroding the financial stability of so many smaller laboratories, THE DARK REPORT is pointing out the same primary issues of concern that lab administrators and pathologists discuss privately when they attend conferences and converse among themselves.

Need For A Unified Voice

The contradiction is that professionals throughout laboratory medicine recognize these threats, yet their lab societies and associations have not found a way to speak with a unified voice and bring together all the diverse interests to work effectively to change this situation.

For its part, THE DARK REPORT is interested in hearing from clients and regular readers who would like to contribute, in an *ad hoc* way, to providing the information needed to tell the story about the harm certain payer contract strategies and actions are having on the quality and survivability of the nation's smaller clinical labs, hospital labs, and specialty labs. Anyone with such information to share can contact the offices of THE DARK REPORT in complete confidence.

Time is running out for many clinical labs. The list of lab closures and bankruptcies is growing. That is why it is time to get out the hidden details of these strategies and actions by payers. These facts should be used to educate the public, the media, and elected officials about why the clinical labs they rely on in their own communities are on a path to extinction. TDR

BRLI-Horizon BCBS Lawsuit Is Window to Payer Actions

Lab company says it is owed $20 million because health insurer violated its agreement

CEO SUMMARY: Do "actions speak louder than words?" In New Jersey, one lab company sued a major health insurer for "breach of contract and fraud." Court documents include claims describing how one health insurer became ever more sophisticated in how it played one public lab company against another in order to drive down its lab testing costs. This court case may be representative of how other payers have adopted aggressive policies designed to reduce what they pay for lab tests.

ACTIONS FROM HEALTH INSURERS often give the impression that they are willing to "wage war against clinical labs" in some form or fashion. A court case in New Jersey provides support for this opinion.

The case is *BioReference Laboratories, Inc. v. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey*. It was filed on December 18, 2013, in the Superior Court of New Jersey.

Seldom do pathologists and lab administrators see the details of the contracts negotiated between the nation's largest lab companies and major health insurers. Thus, this case represents a window into this world.

Moreover, the charges described by **BioReference Laboratories, Inc.** (BRLI) in its suit against **Horizon Healthcare Services, Inc.**, offer useful insights into how some payers are becoming more assertive at denying claims—even those submitted by a contracted network laboratory provider—using methods that some attorneys might argue border on questionable business behavior.

In other words, lab leaders who take the time to read BRLI's complaint will gain a better understanding about the tactics of obfuscation and non-cooperation that they may be encountering with some payers in their own regions.

Why BRLI Sued This Payer

In its legal filing, BRLI describes its claims against Horizon:

> *This action for breach of contract and fraud arises from Horizon's refusal to pay BioReference for laboratory testing that BioReference performed for thousands of Horizon's members. Although Horizon is required to pay BioReference for these tests pursuant to a provider agreement between the parties, Horizon has evaded its payment obligations by fraudulently misrepresenting to BioReference that a substantial number of its members were excluded from the contract. As a result of Horizon's willful misconduct, BioReference has suffered damages well in excess of $20 million.*

The court papers show that this payer gained substantial price discounts on lab

tests from BioReference Laboratories. The lawsuit states that:

BioReference has been performing laboratory testing for Horizon's members for more than twenty years pursuant to a series of written provider agreements. In the most recent version of the agreement—a 2007 amendment to the parties' 2003 provider agreement (the "2007 Amendment")—the parties negotiated a limited carve-out of Horizon's payment obligations for a particular class of Horizon members subscribing to certain enumerated "Managed Care" products offered by Horizon.

Specifically, the parties agreed that services rendered by BioReference to "Managed Care members (including HMO, POS, Direct Access, NJ Plus, and Medicare Advantage products)" would not be reimbursed by Horizon, and that BioReference would not bill Horizon's members for such services, "provided that, Horizon provides [BioReference] a means for identification of the Managed Care members and works with [BioReference] on the administration of this provision."

THE DARK REPORT interprets this statement, in the context of the full lawsuit, as a market response to events that occurred in 2007 involving major health insurers and the national lab companies. In that year, **Laboratory Corporation of America** landed a sole-source, 10-year national contract with **UnitedHealthcare**. As part of that decision, UnitedHealth excluded **Quest Diagnostics Incorporated** as a national network provider.

➤'Tit For Tat' By Lab Firms

In response to this development, Quest Diagnostics won an exclusive national contract with **Aetna, Inc.**, by March 1, 2007, that excluded LabCorp. In the same month, LabCorp beat out Quest to win the Horizon contract in New Jersey.

Given these events, it is clear why BioReference would agree, in the 2007 (non-exclusive) contract amendment, to provide "free lab tests" to Horizon's managed care patients. Essentially, the free testing for this segment of Horizon's business represented the ultimate deep discount so that Horizon would choose to continue to allow BRLI to serve patients in Horizon's other health insurance products.

BioReference's lawsuit described what happened next:

...in the period immediately following the adoption of the 2007 Amendment, Horizon began fraudulently to miscategorize a substantial and growing number of its members as "Managed Care" members. Under the 2007 Amendment carve-out, Horizon's miscategorizations had the direct result of denying payment to BioReference for hundreds of thousands of lab tests that BioReference performed.

➤Payment To BRLI Stops

This action by Horizon resulted in non-payment for BRLI's claims, described in the lawsuit as follows:

Horizon improperly denominated at least two of its largest new PPO products as Managed Care products in order to circumvent its payment obligations to BioReference under the Amended Contract. By so doing, Horizon was able to sweep a substantial percentage of BioReference's laboratory testing for Horizon members into the Managed Care Exclusion, and thereby obtain the tests for nothing.

The suit describes these products as PPO and HMO services provided to the New Jersey State Health Benefits Program, (NJSHB) by Horizon under the name "NJ Direct." In the request for proposal, NJSHB defined the PPO insurance plan as follows, quoted from the BRLI suit:

With respect to the request for a PPO plan proposal, the NJ RFP stated: "The Plan must have the normal components of a PPO; namely in-network discounted providers and an out-of-network indemnity approach where services from any

provider are reimbursed according to a reasonable and customary approach."

From 2008, BRLI said that "Horizon fraudulently misrepresented to BioReference that NJ DIRECT was a Managed Care product and therefore subject to the Managed Care Exclusion." This meant Horizon was not paying BioReference Laboratories for those lab test claims.

Was New Jersey Defrauded?

One interesting claim raised in this case by BioReference is that Horizon may have defrauded the State of New Jersey. BRLI said in the court filing that:

The impact of Horizon's fraud may extend well beyond BioReference. Upon information and belief, NJ DIRECT is self-funded by SHBP (and/or the State of New Jersey), meaning that SHBP pays Horizon to administer the plan, but bears the ultimate financial risk and expense of actual medical services provided to its members. Unless Horizon is refunding or crediting to SHBP any refunds Horizon receives from BioReference pursuant to the Managed Care Exclusion, Horizon would be enjoying an improper windfall at the expense of both BioReference and SHBP.

THE DARK REPORT contacted the executive offices of Horizon Healthcare Services for comments on this case. As of press time, no spokesperson had responded to this request.

Draw Your Own Conclusions

Readers can draw their own conclusions from the excerpts of the court case provided here. As well, the complete court filings can be accessed at the courthouse and its website.

At a minimum, the extracts of the claims made by BRLI in its court documents presented here certainly indicate that the actions of this health insurer—if true—are a demonstration of how payers can play one public lab company against another to cut their lab testing costs. TDR

How a Health Insurer Played One Lab Against Another

HEALTH INSURERS HAVE BECOME increasingly sophisticated in playing one public lab company against another as a way to continually reduce their costs for lab tests.

In the legal case filed by BioReference Laboratories against Horizon Healthcare Services of New Jersey, just such a contract strategy was used by Horizon to extract additional price concessions from BioReference, court records show.

In the lawsuit, BioReference described the sequence of events that gave Horizon an opportunity to use one lab company's lower pricing as a negotiating lever against BioReference. The lawsuit said:

In late 2006, Horizon attempted to designate LabCorp as its exclusive provider of laboratory services under all of Horizon's insurance products. LabCorp had previously served as the exclusive provider of laboratory services for Horizon's Managed Care products. With respect to non-Managed Care programs, such as PPOs and indemnity plans, LabCorp had competed with BioReference and Quest, among other laboratories, in providing services to Horizon's members.

Upon information and belief, in exchange for substantial economic inducements from LabCorp, Horizon agreed in late 2006 to terminate its existing provider agreements with BioReference and Quest, essentially anointing LabCorp as Horizon's sole full-service in-network laboratory for all of its members under all of its products.

By letter dated December 28, 2006, Horizon notified BioReference that it was terminating the 2003 Contract without cause, effective March 31, 2007.

Following negotiations between representatives of BioReference and Horizon... Horizon agreed in February 2007 to rescind its previous termination letter, contingent upon BioReference accepting new contractual conditions and payment rates.

PAMA's New Rules Affect Lab Test Pricing, Coverage

➤Association representing nation's smaller labs outlines its biggest concerns about the new law

➤➤CEO SUMMARY: For several reasons, the "Protecting Access to Medicare Act" (PAMA) has the potential to be the most disruptive federal legislation directed at the clinical lab industry since the enactment of CLIA 1988. Following passage of the law, some lab industry groups have taken different stances toward the positive and negative elements of PAMA. The following interview is one of a series designed to help lab administrators understand different viewpoints about PAMA.

SINCE THE PASSAGE, IN APRIL, OF THE "Protecting Access to Medicare Act" (PAMA), various lab industry associations have expressed different opinions about whether the law will turn out to be good or bad for different segments of the clinical laboratory industry.

THE DARK REPORT is presenting these different opinions about PAMA to provide pathologists and lab executives with insights into the lobbying strategies and legislative maneuvering that took place before the bill's passage and subsequent signing by President Obama in early April. *(See TDR, April 7, 2014.)*

➤Representing NILA

The National Independent Laboratory Association (NILA), in St. Louis, Missouri, is represented by the **District Policy Group** in Washington, D.C. According to Julie Scott Allen, Senior Vice President, and Erin Will Morton, Senior Policy and Advocacy Advisory, of the District Policy Group, NILA worked closely with policymakers and their staff leading up to the passage of the legislation, but ultimately did not support the final package.

Because NILA's members are independent regional and community clinical labs, they are concerned about how CMS will implement the sections of PAMA that call for the federal agency to gather market data from laboratories and then use that market data to set new prices for the Medicare Part B Clinical Laboratory Fee Schedule. (CLFS). They are also concerned about the law's oversight requirements.

"The Office of the Inspector General and the Government Accountability Office will conduct oversight and issue reports about CMS' implementation of the new law only after it has gone into effect, which might be too late for some labs," observed Morton. "NILA's members have questions about the OIG and GAO reports that will follow the first year and each year after PAMA payment rates go into effect in 2017."

"Will the GAO have the time needed to assess all the relevant issues and implications in its first report, due by 2018?" asked Allen. "That will be only one year

Negotiations Led Congress to Favor Large Labs Over Smaller Clinical Labs in the PAMA Law

CONGRESS SUCCEEDED IN REWRITING how clinical laboratories are paid under Medicare in the absence of any formal studies, committee hearings, or input from the full laboratory community when it passed the Protecting Access to Medicare Act (PAMA), said Julie Scott Allen and Erin Will Morton of the District Policy Group.

"The Part B Clinical Laboratory Fee Schedule (CLFS) has been a long-standing concern for Congress," Morton explained. "Policymakers have wanted to find a way to reform the CLFS."

"In the past when Congress wanted to cut lab fees, the CLFS was subject to across-the-board cuts or the institution of new copay requirements was considered," added Allen. "In recent years, Congress expressed interest in considering other approaches to manage lab costs outside of direct across-the-board cuts. When CMS came out with a final regulation to adjust CLFS rates based on their own assessment of 'technological changes' in the lab industry, Congressional staff decided it was time to act and do something themselves."

"I don't think the congressional committee staff cared whether CMS was going to make cuts the right way or not," said Allen. "I think the congressional staff simply wanted to be able to take credit for doing so while using the labs to help offset the spending required to fix the sustainable growth rate." SGR is a formula Congress uses to control federal health spending by linking physician payment to a growth target."

"We hoped that Congress would find a way to reform the CLFS that was agreeable to the community and regional laboratories and to members of Congress," stated Morton. "But that's not what happened with the new law."

"As Congress debated the SGR, the National Independent Laboratory Association (NILA) made a proposal that would have represented labs' interests and served to improve lab payments under the Medicare program," explained Allen. "Despite interest in that proposal, and in the face of opposition by those representing the national labs, the congressional focus shifted back to making fee schedule reductions. When that happened, it put the community and regional labs at greatest risk because the CLFS cuts that are now coming through this law may affect all labs that provide Medicare services—but larger labs will be more likely to survive deep cuts while smaller labs may not.

"The real question now is how competitive the market for lab services will be in the coming years and that will depend on how CMS writes the language to implement PAMA," noted Allen. "Another question that labs are asking is whether the cuts under PAMA, which could be as deep as 75% off current Medicare reimbursement rates, are better or worse than what CMS was proposing to cut before PAMA."

"Previously, CMS was going to make a number of price adjustments to the CLFS, and we were unclear about how deep those cuts would be," she continued. ""But now we're very clear on how far CMS can go because the law allows for cuts of 10% per year for three years and then 15% per year for three more years, totaling up to 75%.

"Under CMS' plan, community labs might have faced a quick death versus the slow death that they may see under PAMA. Which is better for a community lab?" she asked. "I say both are the wrong approach, and both are bad for community labs.

"During the negotiations on direct 'market' adjustments to rates, NILA wanted a payment adjuster for community labs that recognized their increased cost of providing services to beneficiaries whose access to tests would otherwise be threatened if they no longer could provide services," added Allen. "Congress instituted payment adjusters for other healthcare providers that recognized the increased costs of service in rural geographic areas or the need to recognize the effect of payment changes when a business' volume of services is significantly less than that of larger competitors. This type of adjuster was not supported by those representing the national laboratory providers."

after new CLFS payment rates are established and we might not know the full impact this law will have by then."

"A report from OIG also is very concerning to NILA because OIG is specifically tasked with review of the top 25 tests by expenditures," noted Morton. "We are not sure if those tests will be ranked by overall dollar value or by volume. That question is very important as we do not want CMS to consider a list of the top 25 codes by volume as a target for their review of the fee schedule."

Top 25 CLFS Lab Tests

"The OIG analysis outlined in the new law looks to be too similar to the way the OIG conducted its evaluation in its damaging and significantly misleading June 2013 report," stated Allen. "In that report, the OIG concluded that CMS could save $940 million per year simply by setting lab test rates for the 25 top CLFS tests closer to those paid by state Medicaid programs and a few Federal Employee Health Benefits plans.

"That 2013 OIG report created a perception in Congress that something should be done to make major cuts to Medicare lab test rates," she continued. "Our fear is that this is what Congress wants to do again. There is no date for the release of the first OIG report under the law. The law just says OIG should do an annual analysis."

Another issue is the requirement in PAMA that CMS gather payment data and use that payment data to establish prices for the CLFS without considering other factors. The law specifies that, beginning in 2016, reporting labs must submit the volume and price paid for each assay by each payer.

NILA members are concerned about the market data component of PAMA. "Gathering that level of detail will make it difficult for GAO to get much useful information after only a few months of assessment," she said. "The GAO might say it doesn't have enough data to evaluate the effects of the law. GAO has to report no later than October 1, 2018."

The law calls for potential new cuts to Medicare lab test fees when new prices take effect in 2017. PAMA restricts CMS from cutting the price of a specific test by no more than 10% per year for 2017, 2018, and 2019, followed by cuts not to exceed 15% per year for 2020, 2021, and 2022.

It is the magnitude of those multi-year cuts to CLFS lab test prices that concern NILA's community and regional lab members as well as others in the clinical laboratory industry. Thus, the comments by Allen and Morton about how CMS, GAO, and OIG fulfill their responsibilities under PAMA reflect the concerns of the clinical laboratory testing industry.

"There is some hope that, because PAMA calls for CMS to establish an advisory committee of lab industry representatives, this committee could serve as a place for the lab community to raise issues about pricing and coverage—not only for new lab tests but for those on the existing fee schedule," observed Allen. "There was consensus in the lab industry that an advisory committee was needed in an effort to bring transparency to the CMS process. NILA would argue that if the committee is set up properly, it should be used to help CMS set appropriate rates for all tests, not just new test rates."

Advisory Committee To CMS

"CMS has an opportunity to create a robust advisory committee to help ensure the right expertise is brought to any new CMS process relating to lab testing," noted Morton. "However, the problem is that CMS ultimately doesn't have to do anything that the advisory committee recommends, and it is currently set up only to help review new tests. Therefore, labs may still not have a mechanism to get the answers they want from CMS." TDR

—Joseph Burns

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Calloway Labs Settles With Feds, West Virginia

Pain management lab will pay $4.675 million to resolve charges of Medicare and Medicaid fraud

CEO SUMMARY: West Virginia is the second state in recent years to settle claims of Medicare and Medicaid fraud filed against Calloway Laboratories of Woburn, Massachusetts. Last month, the pain management lab company agreed to pay $4.675 million to resolve that case, while not admitting liability. During the period that Calloway was alleged to have submitted fraudulent claims in West Virginia, it was operating under a federal corporate integrity agreement signed with the OIG.

LAB COMPANIES OFFERING PAIN MANAGEMENT SERVICES continue to attract the attention of federal and state healthcare prosecutors. Last month, **Calloway Laboratories, Inc.**, of Woburn, Massachusetts, agreed to pay $4.675 million to settle fraud charges related to falsely billing the Medicare and Medicaid programs in West Virginia.

Booth Goodwin, the U.S. Attorney for the Southern District of West Virginia, stated that, from March 2009 through April 2013, Calloway billed Medicare and West Virginia Medicaid using codes for pathology services and for urine drug testing. The charges are similar to those Massachusetts Attorney General Martha Coakley brought against Calloway in 2010.

Investigators from the **Office of Inspector General** (OIG) of the federal **Department of Health and Human Services** and the **West Virginia Medicaid Fraud Control Unit** charged that healthcare providers did not deem pathology services to be necessary, did not order such services, and that Calloway did not provide pathology services.

Instead, Calloway performed a type of medical review on every urine drug screen, Goodwin said. Although neither Medicare nor West Virginia Medicaid cover such reviews, the programs paid the claims because Calloway submitted them under the code for covered pathology services, he added.

Similar Case In 2010

In a similar case brought in July 2010, Coakley charged that Calloway falsely billed **MassHealth**, the state's Medicaid program, for urine screening services that were not ordered by a doctor or authorized by prescribers for a medically necessary purpose. Coakley also charged that Calloway engaged in a kickback scheme to obtain urine drug screening business illegally and have MassHealth pay for the drug screens. *(See TDR, August 23, 2010.)*

In 2012, Calloway paid $20 million to the Commonwealth of Massachusetts and $7.7 million to the federal government to resolve allegations of kickbacks involving the state Medicaid program and the federal Medicare program. Four defendants

pleaded guilty to criminal charges and were excluded from participating in any Medicaid or Medicare program, stated Coakley at the time of the settlement.

Since March, 2012, Calloway has operated under both a three-year compliance and monitoring program involving an independent compliance reviewer and annual site and record audits with Massachusetts and a five-year corporate integrity agreement with the Office of Inspector General.

No Admission Of Liability

Calloway spokesman David Ball said payment of $4.675 million by Calloway would "resolve the matter without an admission of liability" and that the agreement Goodwin announced on May 21 concludes an inquiry "into a legacy issue dating from 2009 and involved a disagreement about services ordered and performed, but not covered." For some of that time, the company operated under previous management.

"By resolving this matter, Calloway eliminates the financial uncertainty associated with litigation and is now well positioned to focus on advancing its commitment to provide state-of-the-art clinical toxicology laboratory services to patients and providers nationwide," Ball said.

Calloway laboratories came under new ownership at the end of 2012. That is when **Ampersand Capital Partners**, a private equity firm in Wellesley, Massachusetts, acquired Calloway and named Gail Marcus, the former CEO of **Caris Diagnostics** (now **Miraca Life Sciences**) as President and CEO. *(See TDR, October 8, 2012.)*

A Target For Private Payers?

The rapid growth in pain management testing, provided by a host of newly-formed lab companies, makes this sector of lab testing a ripe target for cost-cutting by private payers. Some payers have dropped hints that more restrictive coverage guidelines and reduced prices will soon be forthcoming. TDR

Do Govt. Prosecutors Have Pain Management Labs in Their Sights?

NO SINGLE SECTOR OF LABORATORY TESTING has grown faster or been as controversial as that of pain management since it emerged about 15 years ago.

During this same time, compliance with federal and state laws has been an issue within the pain management sector. Compliance may be an issue because many lab owners in the pain management sector lack experience working in traditional clinical laboratories. Thus, they did not gain hands-on experience with the complicated issues associated with clinical laboratory compliance with Medicare and Medicaid laws and regulations.

Probably the first company to focus almost exclusively on this sector was **AmeriTox, Inc.**, of Midland, Texas. Its business and marketing practices were questioned in 2007. That's when a *qui tam* lawsuit alleging Medicare and Medicaid fraud was filed by a former AmeriTox sales representative. In 2010, without admitting guilt, AmeriTox agreed to pay $16.3 million to settle the case.

During these same years, pain management lab companies and their questionable business practices caught the attention of Martha Coakley, Attorney General for the state of Massachusetts. Between 2008 and 2012, Coakley pursued cases against five labs (including Calloway Labs) and signed settlements with each of them. *(See TDR, October 17, 2011.)*

In addition to the $27.7 million settlement with Calloway labs that was described earlier in this story, Coakley entered into settlements with the **Willow Street Medical Laboratory, LLC** (2007–$8.15 million settlement); **Boston Clinical Laboratories, Inc.** (2009–$600,000) **System Coordinated Services, Inc.** dba **Life Laboratories** (2010–$450,000); and **Diagnostic Laboratory Medicine, Inc.**, (2011-$153,770.)

'Game Changer' Mass Spec for Microbiology at UNC

Academic center microbiology lab reports multiple benefits from use of MALDI-TOF system

CEO SUMMARY: Microbiologists at the University of North Carolina are using MALDI-TOF mass spectrometry to slash the time to answer and significantly cut lab costs. Their goals are to improve patient outcomes and reduce average length of stay. In a one-year study presented last month, UNC microbiologists reported that consumable costs for many microbiology tests were reduced by 92% and that, based on the performance of this new instrument system, the ROI may be as short as 24 to 36 months.

MASS SPECTROMETRY IS THE HOT NEW TECHNOLOGY in clinical laboratory testing. At one academic center, the microbiology laboratory has used mass spec to cut the cost of reagents by 92% while measurably improving patient outcomes.

This innovative work was done at the **University of North Carolina School of Medicine** and **UNC Health Care** in Chapel Hill. The gains came after the microbiology lab began to use MALDI-TOF (matrix-assisted laser desorption/ionization–time of flight) analysis for some lab testing.

"I don't like to use the word 'revolutionize,' but this MALDI-TOF technology has revolutionized our lab," declared Peter Gilligan, Ph.D. "We can diagnose infection more efficiently and treat patients much quicker, both of which help decrease healthcare costs."

Gilligan is the Director of Clinical Microbiology-Immunology Laboratories and Phlebotomy Services at the University of North Carolina Hospitals and a Professor of Pathology and Laboratory Medicine. Early in the fall of 2012, he and his colleagues began to use MALDI-TOF in the microbiology laboratory.

"We have benefited in multiple ways from using MALDI-TOF in our microbiology and immunology laboratories," stated Gilligan. "We can now identify a pathogen in about an hour, thus saving about one to two days versus the time it takes to identify such pathogens using conventional molecular methods.

"This methodology also allowed the microbiology lab to identify organisms that would previously have been disregarded," he continued. "One such organism causes breast abscesses and another is associated with eye infections.

Equally Accurate

"This mass spec technology is more efficient and cheaper than conventional lab tests," observed Gilligan. "It is equally accurate when identifying bacterial and fungal infections in patient samples."

The team at UNC conducted a one-year study to assess the performance of its MALDI-TOF analyzer. The study showed

that using mass spec to identify bacterial and fungal infections in patients led to a 92% reduction in the cost of reagents needed to run clinical microbiology tests. For cash-strapped clinical labs, this is a significant benefit.

After subtracting the cost of the mass spec analyzer, the cost savings from mass spec come from not using reagents, Gilligan explained.

In conventional testing, clinical microbiologists use reagents to determine which pathogens are present in a patient's sample. Reagents require different amounts of time to identify the pathogen and that time can range from about 24 to 48 hours. In such a setting, the researchers estimated that the costs of identifying 21,930 organisms in a year would have been $84,491.

More Pathogens Were Found

Using MADI-TOF mass spec, Gilligan's lab identified pathogens that lab technologists would not have previously considered to be the cause of infection. One was *Corynebacterium kroppenstedtii*, believed to cause breast abscesses.

"This is a big deal and an important way for the lab to add value," noted Gilligan. "Doctors would see patients with chronic infections and no one knew what caused these infections. Now we know and we can treat patients much more effectively than before.

"When we dug through the literature, we found several organisms that we didn't know about before. One was associated with breast abscesses and another one was associated with eye infections," he said. "Before we would just dismiss them as being a contaminant or not being significant. This technology makes us rethink the assumptions we made previously in clinical microbiology."

Perhaps the most significant result from the study is the potential that clinical labs will adopt MALDI-TOF MS widely and the use of reagents and reagent rentals will decline sharply. If that happens, then labs may be more inclined to buy equipment outright rather than sign long-term pay-as-you-go reagent rental agreements. If that happens, labs will need to prove the return on investment for such capital expenditures to hospital finance departments.

Presenting The Findings

Gilligan and Clinical Microbiology Fellow Anthony Tran, DrPH, presented the findings from their study at the 2014 general meeting of the **American Society for Microbiology**. The meeting took place in Boston on May 18.

For the study, Gilligan and Tran analyzed the costs of identifying microorganisms from 21,930 samples from patients at UNC Hospitals over the course of one year (April 1, 2013, to March 31, 2014). The specimens consisted of enteric pathogens, *enterococci*, gram negative non-glucose fermenters, *staphylococci*, *streptococci*, and yeast.

Using MALDI-TOF mass spec, Gilligan and Tran produced results in about an hour, depending on the organism. The cost of materials for testing the nearly 22,000 organisms was $6,469, a savings that represented 92% of the cost of traditional testing methods.

Staff Time Savings Added

Additional savings of $118,620 (or 82% of the total with conventional testing) came from cutting the time clinical laboratory scientists would need to prepare and process the samples using reagents, Gilligan and Tran said. The staff of UNC's Clinical Microbiology Laboratories conducted the study. The labs are part of the McLendon Clinical Laboratories at UNC Hospitals in Chapel Hill.

"We estimate that, because of the reduced cost of reagents and time saved for lab technologists, the upfront cost of the MALDI-TOF instrument will be offset in less than three years from purchase," Tran said.

New Technology Has Microbiologists Rethinking Assumptions About ROI

SPENDING $250,000 for one analyzer was the largest expenditure ever for the microbiology department at the University of North Carolina School of Medicine and UNC Health Care, said Peter Gilligan, Ph.D., the director of Clinical Microbiology-Immunology Laboratories and Phlebotomy Services at the University of North Carolina Hospitals.

In 2012, UNC Hospitals spent $250,000 to buy a MALDI-TOF mass spectrometry analyzer from **bioMérieux**, a company in North Durham that has previously worked with UNC Health Care. Gilligan called the investment a "game changer."

Big Capital Expenditure

"That amount is a big number for hospitals and for our microbiology lab. It's the most money we've ever spent on a piece of equipment. No question about it," he emphasized. "But it's a sophisticated piece of equipment that has made us rethink the way we do things in the lab and our attitudes toward equipment. Maybe the expense of this equipment will be offset by downstream benefits for patients, such as more rapid and accurate diagnosis and better targeting of antimicrobial therapy."

Another benefit is that the MALDI-TOF MS system increases lab efficiency significantly. "I can't stress enough that the savings are really in efficiency," stated Gilligan. "Our lab's workload increases continually, yet we're not hiring new technologists. So somehow we had to become more efficient and smarter. This technology allows us to do that.

"I predict that every hospital with more than 300 beds will want to have this technology in their laboratory," he said. "It's a game changer that uses new diagnostic technology to identify microorganisms in an inexpensive way that is consistently accurate.

"Besides increased speed and accuracy, what's significant about MALDI-TOF is that diagnostics and microbiology companies have made money by selling reagents and disposables for conventional analyzers," observed Gilligan. "There's a substantial profit to be made from disposables.

"Now with MALDI-TOF, labs have a system that doesn't use disposables," he noted. "Each test uses a toothpick-sized sample and a little bit of chemical that costs pennies to identify microorganisms.

"For our MALDI-TOF system, consumable costs are basically just the slides and the chemical," stated Gilligan. "But where it once cost our lab $4 to $5 in disposables to identify an organism, now it costs 50¢ or less!

"If a lab can run 5,500 isolates per year on this machine and the machine runs for five years, then savings will be significant over the life of the instrument," he said. "Running 5,500 isolates annually for five years would total 27,500 isolates at $4 to $5 per isolate. That would total $110,000 to $137,500 in reagents and other disposables. Running 27,500 isolates at 50¢ each would total $13,750.

"The important clinical benefit is that our lab now identifies an organism in minutes instead of days," he added. "This information helps physicians shorten the length of stay for hospitalized patients. It is our lab's contribution to cutting healthcare costs.

Game-Changing Technology

"While that effect on the healthcare system is important, this technology is a game changer in microbiology for two reasons," explained Gilligan. "First, mass spec helps us increase productivity because the lab does work with the same number of people. That's important because our financial department wants us to be as efficient and cost effective as possible.

"Second, the aging population will increase microbiology workload even as retirement shrinks the number of microbiologists in the workforce," he continued. "As we need to hire more microbiologists, they may not be available. This technology gives us a bit more breathing room."

In an interview with THE DARK REPORT, Gilligan outlined the potential return on investment from using MALDI-TOF MS analysis. "This relatively new technology that is not only superior to what we used previously, but once you pay for the equipment, it is a lot less expensive," he said. "The cost of a mass spec analyzer is about $250,000. For most labs, it will probably take about two years to recoup that cost in the savings from not using reagents.

Useful Life Of Lab Analyzers

"Most labs estimate that the useful life of an analyzer is about five years," Gilligan added. "Thus, after the first two years, your lab will have about three years of instrument use when the cost will be extremely low and that analyzer will generate tremendous cost savings during those three years."

MALDI-TOF MS analyzes proteins and identifies pathogens by comparing the proteins it finds in patient samples to known microorganisms stored in a database. Within the past five years, the technology has been used in clinical microbiology labs and Gilligan's lab was one of the first in the country and the first in North Carolina to do so.

Gilligan, Tran, and other researchers plan to publish their results. Doing so will require them to add in the costs of validating the instrument, a cost that was not included in the analysis so far.

"There was a cost to get to the point of using this equipment, and we need to prove that the machine will do what the manufacturer says it will do under controlled conditions in the lab," Gilligan explained. "For the validation, we used known isolates and tested them with this system. That gave us some idea about the accuracy of the equipment."

Once the costs of validation are added, the next step is to measure the effect of MALDI-TOF MS on patient outcomes. Melissa B. Miller, Ph.D., Director, Clinical Molecular Microbiology Laboratory, is working on that analysis.

"Melissa Miller and her collaborators are looking at specific patient outcomes as they related to coagulase-negative staphylococci to determine whether they are a contaminant in the blood culture or the cause of bloodstream infection," Gilligan said. "Now that we're using MALDI-TOF MS, we have better tools to identify the organism that's causing the infection and these tools do the analysis more quickly.

"Given that MALDI-TOF MS identifies pathogens within hours instead of days, hospitals can use more targeted medications and use fewer broad-spectrum antibiotics," commented Gilligan. "Targeted medications may allow hospitalized patients to leave the hospital sooner."

A study published last year involving the use of MALDI-TOF MS showed that the **Methodist Hospital** in Houston cut more than 2.6 days from the length of stay for patients with gram-negative infections. That represented substantial savings and improved patient outcomes. *(See TDR, May 6, 2013.)*

Cutting Length of Stay

"With this analyzer we may be able to stop broad-spectrum antibiotics sooner or let patients go home sooner," he added. "Those are significant outcomes. Our MALDI-TOF was a big capital commitment, which told us that the hospital had faith we could ultimately save money and most importantly improve patient care.

"We have a multi-hospital system and one strategy we are considering is to use this equipment to serve other hospitals," explained Gilligan. "Currently all the institutions are implementing a common information system. Once that is in place, our lab can use this analyzer to identify pathogens in patients in other hospitals in the system and quickly report those results." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Inpatient utilization has declined in Boston, Indianapolis, and Newark. That's the finding of a new report issued May 27 by **Kaufman Hall**, a consulting firm based in Skokie, Illinois. The data was collected by **Tufts Medical Center** in Boston; **Barnabas Health** in West Orange, New Jersey; and **Community Health Network** in Indianapolis. For the 2010-2012 period, inpatient utilization dropped among most age groups and service lines in these three metropolitan areas. Kaufman Hall said "the studies show a broad-based transition underway from an inpatient-focused to an outpatient-focused healthcare system."

MORE ON: *Inpatient*

For nine counties in Eastern Massachusetts, overall inpatient utilization declined 5% (and 10% for patients 65 and older). Newark's inpatient ultilization decline was 4.3% (and 10.2% for the 65-74 year old cohort). The nine-county area around Indianapolis saw a 2.5% drop in inpatient utilization (and just a 0.4% decline for patients 65 and older). Kenneth Kaufman, Chair of Kaufman Hall, noted that, "These findings are further evidence that markets around the country are reaching an inflection point in the shift from inpatient to outpatient orientation."

SPENDING GROWTH IN HEALTHCARE IT

Most pathologists and lab managers know that one of the hottest growth sectors in healthcare is information technology (IT), but few people know exactly how much is spent each year on these IT systems. A recently-released report by **Transparency Market Research** of Albany, New York, estimates that global spending on healthcare IT was $35.1 billion in 2013. In the report, titled "Healthcare Information System Market, " the research firm also predicts that, by 2019, such spending worldwide will reach $53.2 billion annually. That is a compound average growth rate of 7.1% between 2013 and 2019.

TRANSITIONS

• Donald Steen, 67, of Dallas, Texas, died of complications from leukemia on May 13. A CPA, Steen was the Chairman and CEO of **AmeriPath, Inc.** from 2004 until 2007, at the time when AmeriPath was acquired by **Quest Diagnostics Incorporated**. He held executive positions at **Welsh, Carson, Anderson & Stowe**, **United Surgical Partners International Inc.**, **Columbia/HCA Healthcare Corporation,** and **Medical Care America, Inc.**

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 30, 2014.