Volume XXIV, Number 16 Monday, November 20, 2017

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

Is the Worm Turning in Favor of Hospital Labs?

SINCE THE MID-1990S, HOSPITAL OUTREACH LABORATORY PROGRAMS have lost market share steadily to the nation's biggest public lab companies. In these two decades, public lab companies traded deeply-discounted lab test prices to health insurers in exchange for exclusive network provider status.

Then, about eight years ago, having captured many managed-care contracts across the nation, big lab companies adopted another effective strategy. The big labs began to educate insurers about the higher prices for outreach lab tests that insurers were paying to hospitals. Seeking to cut costs, several large payers began to exclude significant numbers of hospital laboratory outreach programs from their provider networks.

Today, however, the worm may be ready to turn in favor of hospital labs. Several market forces portend a more favorable environment for hospital labs to regain a larger share of lab test referrals from office-based physicians. One market force is the transition to value-based provider payment. A second is the drive to integrated clinical care. The third, surprisingly, may turn out to be the secondary effect of the deep price cuts coming to the Medicare Part B lab test prices.

The first two market forces are intertwined. Medicare and private payers are moving to value-based reimbursement as they seek to reward providers who deliver integrated clinical care that keeps patients healthy and out of hospitals.

From this trend, hospital labs stand to benefit. Because they are part of integrated delivery networks, hospital labs are positioned to support integrated clinical care and precision medicine. By contrast, independent labs seek to maximize profits under fee-for-service payment by funneling a large volume of specimens into regional testing centers to achieve the lowest average cost per test. Therefore, independent lab companies generally struggle to deliver value under value-based payment.

What will the large national labs do if Medicare's lower Part B fees in 2018 cut so deeply into profits that these lab companies need to seek higher prices from insurers to reimburse them for high-volume routine testing? If insurers do not grant the necessary price concessions to the big labs, would that reopen the door for hospital outreach labs to offer insurers value by further supporting integrated clinical care and keeping patients out of hospitals? TDR

Paths of Hospital Labs, Independent Labs Diverge

This new development in the lab test market has profound implications for all types of labs

CEO SUMMARY: With each passing year, the primary role of hospital and health system labs evolves in a different direction than that of independent lab companies. This trend is a response to the creation of integrated delivery networks paid on value and how they are scored on their ability to keep patients out of hospitals while delivering improved patient outcomes. Hospital labs must adapt their testing services and lab operations to meet these needs in the inpatient, outpatient, and outreach sectors.

BY ROBERT L. MICHEL

OVER THE PAST 24 MONTHS, the paths of many hospital and health system laboratories have begun to diverge from that of independent lab companies.

The reasons for this divergence are complex and have less to do with how private health insurers are reducing reimbursement for lab tests and are more related to the way the healthcare system is changing.

This development is significant because it means hospital labs will evolve to serve different marketplace needs than those served by independent clinical lab companies. It will also change the relationships that hospital laboratories have had with independent lab companies in several ways.

At least four distinct drivers are propelling this divergence. They are:

- Need for hospitals and health systems participating in ACOs and integrated delivery networks to have a full longitudinal record of every patient's lab test data—whether the tests were performed in inpatient, outpatient, or outreach settings.
- Need for the patient's longitudinal lab test data to have the same test methodologies and reference ranges.
- Changes in the reasons why office-based physicians may prefer to use the lab testing services of their local hospital or health system laboratory versus independent lab companies.
- Changes to the way hospitals contract for anatomic pathology testing services that traditionally have been provided to hospitals by private pathology group practices on contract.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Hospitals and health systems operating as part of accountable care organizations—or contracting with health insurers—must have a complete record of each patient's lab test data to support the ACOs' and health insurers' need to monitor their patients' care over time, as well as to demonstrate that the hospitals and health systems are delivering care that supports the ACOs' and health insurers' efforts to improve patient outcomes and control costs.

Supporting ACO's Needs

Hospital- and health system-based pathologists and lab administrators have learned the value of a complete record of a patient's lab test results. Not only is it important to have patients' complete test result histories that use the same test methodology and reference ranges, but it is clinically valuable to have the results of all lab tests done for each patient in inpatient, outpatient, and outreach settings. This understanding gives hospitals and health systems what could be called a home-field advantage versus independent clinical lab companies.

THE DARK REPORT is first to identify this divergence and attempt to describe it in ways that help hospital lab administrators, pathologists, and executives at independent clinical laboratory companies meet the changing needs of the marketplace. As this divergence becomes more obvious, fundamental changes will reshape the goals, motives, and lab test service mix of hospitals compared with those of independent lab companies in five significant ways.

Changes For IVD Firms

First, IVD manufacturers will need to develop analyzers, automation, and testing systems customized to the new needs of hospital labs, compared to those of independent lab companies.

Second, companies that sell software and laboratory information systems to labs will need to customize their products to the new requirements of hospital and health system laboratories. These products will have functions distinct from those products the IT companies sell to independent lab companies.

Third, reference and esoteric lab companies that serve hospitals and health systems will need to do more than simply be a source of send-out testing. The success of these labs will depend on how well they collaborate with hospital labs to improve patient outcomes and reduce costs.

Fourth, as hospital labs build new clinical relationships with office-based physicians in their communities, their efforts could tip the competitive balance in favor of hospital and health system labs over commercial lab companies.

Fifth, providers of anatomic pathology services—be they the local private group practice, a large regional pathology practice, or a pathology lab company—will undergo a reordering as administrators of hospitals and health systems renegotiate the mix of surgical pathology services to match their institution's clinical and financial needs. In some cases, pathologists may become employees of the hospital or health system.

Healthcare's Transformation

The divergence of hospital laboratories from other types of clinical laboratories is rooted in the evolution of the changes remaking the health system. Some of the principles transforming healthcare are:

- Having physicians provide care to achieve early diagnosis, manage patients with chronic diseases, and reduce hospitalizations.
- Having integrated healthcare systems eliminate silos so that they can provide seamless care for patients from cradle to grave.
- Adopting personalized (or precision) medicine initiatives.
- Using data to help managed care organizations adopt population health

(Continued on page 6.)

As Clinical Laboratory Industry Evolves, Different Lab Test Sectors to Gain Market Share

COMPARED WITH THE SITUATION THREE DECADES AGO, the clinical laboratory industry today has more variety in the types of lab organizations that provide diagnostic testing services to the nation's hospitals, nursing homes, physicians, and other providers.

At the start of the 1990s, there were essentially three categories of labs. They were hospital labs, independent lab companies, and anatomic pathology labs. Only a handful of reference and esoteric testing labs existed. Specialty lab testing companies were few in number. Physician office laboratories (POLs) were plentiful, but had limited test menus.

At that time, few hospital labs did outreach lab testing for office-based physicians. A large number of private regional lab companies and about 10 publicly-traded lab firms dominated the independent lab sector. All of the test menus of the independent labs were similar. The basic differentiators were the size of the region served and the volume of tests performed.

Major Market Differences

That is not the case today. The major differences from 30 years ago include:

- Many hospitals and health systems have viable lab outreach businesses.
- The two multi-billion-dollar public lab companies have a national duopoly that serves office-based physicians while a small number of private independent lab companies barely survive serving small towns and nursing homes.
- There is a robust sector of large reference and esoteric testing lab companies serving hospitals and health systems primarily.
- Investors are funding a fast-growing sector of specialty lab companies that offer a limited menu of proprietary or patented lab tests.
- An aging workforce and consolidation among hospitals and health systems are forcing smaller pathology groups to sell, merge with others, or simply go out of business.
- Physician office labs offer expanded test menus due to more waived tests and the automation and miniaturization of laboratory analyzers.

Rise Of Specialty Labs

Over the past decade, the clinical laboratory industry has experienced one other important trend: a sharp rise in the number of specialty lab companies. Typically, these lab companies offer a specific menu of tests directed at certain medical specialties.

The largest number of specialty lab companies are in cardiology and cardiovascular testing; toxicology, pain management, and pharmacogenomics testing; and molecular diagnostics and genetic testing.

Thirty years ago, hospital labs served the inpatient and outpatient sectors while independent lab companies held an overwhelming share of the office-based physicians in the outreach sector. Today, hospital labs with outreach programs, the two large national lab companies, and the numerous specialty lab companies compete intensely for the test referrals coming from office-based physicians, making competition for lab test referrals from office-based physicians the most intense it has been since the early 1990s.

Competition For Specimens

Despite the substantial reduction in the number of independent lab companies offering standard test menus, the still-growing number of specialty testing lab companies has filled that vacuum. These specialty lab companies fight furiously to win the lab test referrals of those specialist physicians who can refer the largest number of patient specimens for their proprietary tests.

(Continued from page 4.)

management and personalized medicine strategies.

- Requiring hospitals, physicians, and other providers to report patient outcomes data.
- Encouraging patients to be more financially responsible for the cost of care by selecting hospitals, physicians, and other providers based on outcomes and prices.

Hospitals and health systems that are early adopters recognize that their labs will be required to provide all patient testing so that physicians and other providers will have the information they need to deliver appropriate and timely care whenever and wherever a patient enters the healthcare system. What's more, accountable care organizations and patient-centered medical homes that send their patients to these hospitals and health systems also will want continuity in lab test data and each patient's cumulative lab test result history in their EHRs.

Support For Integrated Care

As hospitals and health systems consolidate and deliver more personalized medicine, their labs will need to support these models of clinical care. To achieve full integration of care delivery, healthcare organizations need to connect all clinical service lines and the associated support services within their institutions seamlessly.

This clinical service integration was one motivation for **NYU Langone Health** of New York City to enter into an outreach laboratory joint venture with **Sonic Healthcare USA** last summer.

"[This lab joint venture is] significant because outreach is an important component of our physicians' diagnostic process," stated Mark Pollard, Vice President of Hospital Operations at NYU Langone in an interview with THE DARK REPORT. *(See TDR, Sept. 18, 2017.)*

NYU Langone recognized how a partner could help it standardize lab processes throughout the health system, including test results, testing methods, and reference ranges.

"With more than 2,000 physicians in the NYU Langone ambulatory healthcare network, the opportunity to standardize test results is significant," Pollard explained. "Not only is standardization important for physicians and patients, but it is also important so that we can mine our own clinical data.

Population Health Measures

"That lab data will give us a much better understanding of population health measures," he said. "Standardized, uniform lab test data will allow us to develop more predictive models for treatment and clinical interventions across our entire patient population. By partnering with a single laboratory provider we hope to enhance our ability to get at that outreach lab test data."

The example of NYU Langone Health demonstrates why the integration of all service lines will have a favorable effect on hospital and health system laboratories because it puts them in the favored position to continue as the primary providers of lab testing services throughout their parent organizations.

The natural advantages of hospital and health system labs are obvious: faster turnaround time for reporting results; a complete cumulative patient lab test record that includes inpatient, outpatient, and outreach test results; and local clinical pathologists and PhDs who know the patients and the physicians.

Home-field Advantage?

In tomorrow's healthcare system, the winners will be those integrated delivery networks that achieve effective integration of clinical care while practicing precision medicine that keeps patients healthy and out of hospitals and lowers the cost of care. These goals play to the strengths of hospital and health system labs that start with a home-field advantage.

Integrated Clinical Lab Data Record: Will This Give Advantage to Hospital Labs Moving Forward?

IN THE FEE-FOR-SERVICE WORLD OF SILOED HEALTHCARE, it was not essential for providers to have access to a full and complete medical record of patients, including lab test data produced from inpatient, outpatient, and outreach settings. That is no longer true.

In the era of fee-for-service medicine, clinical care was provided in silos. In the coming era of value-based reimbursement, the goal is to provide seamless clinical care, typically provided in integrated delivery networks.

In the FFS world of siloed healthcare, it was not essential for providers to have access to each patient's full medical record, including a complete record of that patient's lab test data from inpatient, outpatient, and outreach settings. But as health systems seek to deliver value-based care, all providers need each patients' complete record of lab test results if they are to deliver timely and appropriate care that does not duplicate earlier testing.

"It quickly becomes obvious to these [health system] administrators that longitudinal data on patient care must be available if they are to succeed in any integrated model of care delivery, such as ACOs or patient-centered medical homes," said Linda Flynn, Founder and CEO of **L.S. Flynn & Associates**, of Florence, Ky. *(See TDR, Sept. 9, 2013.)*

Real-time Lab Data Access

"For example, clinical care cannot be managed efficiently if a hospital or primary care clinic can't get the lab test data it needs at the point of care," she added. "Similarly, if the lab test data is not in a readable format in the physician's electronic health record (EHR) system or hospital's EHR, that also interrupts timely and accurate care.

"One hospital client is currently organizing its ACO and this is a significant problem," Flynn added. "The ACO administrators recognize that physicians cannot easily work with lab test data produced by several different lab companies because of the different test methodologies, different names for the same tests, and different reference ranges."

"By not paying attention to what their labs do, hospitals have allowed specimens from hospital patients—whether inpatients, outpatients, or outreach patients—to go to other labs," she said. "Now, as they participate in ACOs, hospital administrators are recognizing that this situation needs to be changed."

Uniform Lab Test Record

In fact, the need for a uniform longitudinal patient record with the same test methodologies was one important goal in an outreach laboratory joint venture announced last August between **NYU Langone Health of New York City** and **Sonic Healthcare USA**.

"One interesting element in this lab partnership is that NYU wanted more standardization in how lab testing was handled throughout the health system," stated Noel Maring, Vice President of Hospital Affiliations for Sonic. "For example, NYU has had six or more laboratory companies serving their different operations. That meant NYU's physicians—in the inpatient, outpatient, and outreach settings—were forced to deal with the different testing methods and different reference ranges of these six lab providers. The laboratory joint venture will solve that problem in ways that make physicians more productive and improve patient care." *(See TDR, Sept. 18, 2017.)*

These are the clinical and market forces that will cause the paths of hospital and health system labs to diverge from the paths of independent lab companies. This divergence will go as fast as the shift from fee-for-service payment to value-based reimbursement occurs, thus causing a major realignment in the lab marketplace. **TDR**

Contact Robert L. Michel at 512-264-7103.

Lab Market Update

Surprisingly Low Price Paid for Miraca's AP Lab Is a Warning

Buyer's low-ball offer is market signal to pathology groups, other labs looking to sell

EVEN INTO THE MID 1980s, coal miners used canaries as an early-detection system for the presence of carbon monoxide and other toxic gases. In this way, canaries served as a sentinel species to save miners' lives.

Clinical laboratories and pathology groups don't have a sentinel species to warn them about trouble ahead, but they do have a sentinel event: the recent sale of **Miraca Life Sciences** for $175.6 million, including $40 million in debt the buyer is acquiring.

On Sept. 22, **Avista Capital Partners** purchased Miraca Life Sciences from **Miraca Holdings**, a Japanese company. The surprisingly low price is almost $500 million less than Miraca paid just six years ago! This is a signal that the market is reducing the price it is willing to pay for anatomic pathology groups and clinical lab companies. Pathologists and lab owners looking to sell their AP practices or labs may find prices are sharply lower today compared to even a few months ago.

The reason: the multi-year sharp declines in the reimbursement for clinical and anatomic pathology testing services, compounded by the prospect of much-steeper-than-expected cuts to the final 2018 Medicare Part B Clinical Laboratory Fee Schedule as published by Medicare officials last Friday.

Today, Miraca Life Sciences is one of the nation's largest independent anatomic pathology laboratories. MLS serves 3,000 physicians and 5,500 patients each day.

Some lab professionals expected that the lab would be worth a much higher price, given that Miraca Holdings purchased MLS for $725 million just six years earlier. In October 2011, Miraca Holdings Inc., Japan's largest clinical diagnostics and laboratory testing company, agreed to pay **Caris Life Sciences** $725 million, including the repayment of the existing debt. *(See DarkDaily.com, Oct. 12, 2011.)*

A 'Major Chop Job'

"When you consider that Miraca sold MLS for $175.6 million after paying $725 million to buy the company in 2011, that's a major chop job to that investment," stated Joseph Plandowski, co-founder of **In-Office Pathology**, a consulting firm in Lake Forest, Ill., that works with physicians to develop their own in-house pathology, toxicology, and immunology clinical labs.

"In just six years, the market value of Miraca Life Sciences fell by almost one-half billion dollars," observed Plandowski. "One big reason why the price for MLS is so much lower today is that CMS has aggressively cut what it pays for lab testing services," explained Plandowski. "The other factor is that competition among pathologists and independent labs is tough and getting tougher." TDR

—Joseph Burns

Contact Joe Plandowski at 847-840-3077 or iopathology@gmail.com.

Fla. Lab Sells to Labcorp, But Keeps Nursing Homes

Vista Clinical Diagnostics sells retail business. But will keeping nursing homes be genius or folly?

CEO SUMMARY: Vista Clinical Diagnostics of Clermont, Fla., is betting big on the nursing home sector just when many labs serving nursing homes are worried about steep Medicare cuts coming Jan. 1. After selling its physician office referral testing, 35 patient service centers, and a mobile testing service to LabCorp, Vista will retain its nursing home business in Florida and several other states. It will continue to serve approximately 150 skilled nursing homes and more than 200 assisted living facilities.

CONCERNED ABOUT LOWER FEES coming from Medicare starting Jan. 1, **Vista Clinical Diagnostics** sold its retail lab testing business to **Laboratory Corporation of America**. The surprise twist in this transaction is that Vista will retain its nursing home business, according to reporting in *The Orlando Sentinel*.

Several aspects of this transaction confirm the popular wisdom that the coming Medicare lab test price cuts will undermine the financial stability of smaller independent labs, particularly those serving nursing homes.

Many lab executives and Wall Street analysts expect to see a wave of community lab company failures, bankruptcies, and sales to the national lab companies starting in 2018. Vista's sale of its retail lab testing operations is a real-world example of how the deep cuts to Medicare lab test prices already are pushing the owners of small labs to sell.

LabCorp did not buy the nursing home business of Vista, however, and Vista told a newspaper reporter that it would continue to serve its nursing home clients in Florida, Virginia, and the Carolinas. Its decision is contrary to the popular wisdom that small labs serving nursing homes face a bleak financial future starting next year when deep Medicare cuts take effect.

Few Facts Are Known

The limited information about what business lines Vista sold and what it kept—or what Vista assets LabCorp wanted to buy and what it didn't—make it difficult to determine the original goals both the buyer and the seller had for this sales transaction.

For example, did Vista want to sell both its retail lab testing business and its nursing home operations? If so, was LabCorp unwilling to pay enough for the nursing home business? Did this cause Vista to withhold these assets from the final sale because it wanted to sell the retail business now, when it would be worth more than after the Medicare lab test price cuts take effect Jan. 1?

Or, was Vista unwilling to sell its entire lab testing business to LabCorp

because it believed LabCorp intended to stop serving those nursing homes after it acquired Vista's lab assets? In this scenario, Vista's owners may have wanted to do the right thing for their clients and were willing to continue serving them, despite the Medicare price cuts.

There is also the possibility that Vista's owners believe they can continue serving nursing homes, despite the negative financial effects of the Medicare fee cuts. That strategy may include their belief that, when other small lab companies struggle financially, Vista can pick up their nursing home clients and the resulting larger size can help Vista stay financially solvent, if not profitable.

Terms Not Disclosed

LabCorp did not announce the deal and terms were not disclosed. Yet, the *Sentinel* noted that LabCorp acquired the retail portion of Vista's business, meaning its 35 patient service centers (PSCs) throughout the state, its mobile testing operation, and its physician-referral business. The transition to LabCorp began in the last week of October and is expected to continue for several months, the *Sentinel* added.

In the article by *Sentinel* health reporter Naseem Miller, the newspaper reported that LabCorp will hire about 40 of Vista's 180 employees. Miller wrote that, "Vista is also keeping some of its employees, as it plans to maintain the laboratory portion of the business and focus on servicing nursing homes."

Based in Clermont, Fla., Vista was founded in a garage in 2004. Despite a desire to remain an independent lab, the owner, Davian Santana, found it difficult to win managed care contracts from health insurers. He also faces the prospect of steep cuts in Medicare payments beginning Jan. 1. Facing those two problems, Vista CEO Davian Santana decided to sell, Miller wrote.

"It's been difficult, but this was the best from every aspect, including for our employees," Santana said in the *Sentinel* article.

Like other clinical laboratories, Vista knows that the cuts proposed under the 2018 Part B Clinical Lab Fee Schedule will affect all sectors of the lab business. According to experts who have analyzed the proposed fee schedule, the nursing home sector will be hit particularly hard.

Vista Keeps Nursing Homes

Therefore, by retaining the nursing home business, Vista is making a major bet that it can survive. But it faces an uphill fight. When the **Centers for Medicare and Medicaid Services** announced the 2018 Clinical Laboratory Fee Schedule, experts estimated that lab payments from Medicare would be slashed by 20% to 38%, depending on the test involved. Small independent community labs serving rural areas and labs serving nursing homes would be affected severely, the experts predicted. *(See TDR, Oct. 9, 2017.)*

According to Vista's website, the lab company serves more than 150 skilled nursing homes and more than 200 assisted living facilities throughout Florida and has more than 200 couriers. Recently, Vista expanded to collect specimens from nursing homes in North Carolina and Virginia.

Vista's core lab is in Clermont. It also has labs in Lake City, Fla., and Danville, Va. The laboratories offer coagulation, chemistry, hematology, immunochemistry, microbiology, molecular testing, serology, and urinalysis.

Why Sell Now?

Other public facts about Vista can be interpreted as evidence that the decision to sell its retail lab operations at this time is based, in some part, on the financial erosion that its owners projected will happen from the Medicare Part B fee cuts in 2018. Another factor may be that private payers are expected to follow by also lowering what they pay for lab tests.

On May 31, 2015, for example, the *Sentinel* published a story about Vista with the headline, "Independent Lab Stays Course in Niche, Resists Sale." An optimistic Santana stated, "There is an emerging market where employers are beginning to take a very special interest in their employees' health. We want to help them with that and in saving costs. We've already bought a pharmacy."

The *Sentinel* also reported that Vista had "contracts with 170 nursing homes and assisted-living facilities. Some 200 mobile phlebotomists draw samples in those facilities." At the time, Vista had five employees dedicated to custom service where, for $39, they would drive to a patient's home or office and draw blood, rather than have the patient visit a PSC.

Expensive Lab Services

Maintaining such services is costly for any lab. Keeping 200 mobile couriers in the field, offering same-day lab results on "98.6% of test menu results," and charging self-pay patients no more than Medicare Part B prices are features few labs can afford to offer. Many independent lab companies find that reimbursement for lab tests is generally inadequate to cover the full costs of such services.

Could the reality be that, in a competitive clinical laboratory marketplace, Vista found itself excluded from the provider networks of important health insurance plans? And, at the same time, the lab company found itself not only being paid less—if at all—as an out-of-network laboratory, but facing more and tougher audits from private payers and the Medicare program?

Whatever the answer to these questions, the biggest question about Vista's decision to sell its retail operations and keep its nursing home business is, will this business strategy turn out to be genius or folly for Vista's owners? TDR

—Joseph Burns

Vista Posted Rapid Growth During Its First Nine Years

In 2012, Vista Clinical Diagnostics was the subject of a story published in *Clinical Lab Products*. Vista's CEO, Davian Santana, discussed the lab company's growth and service philosophy.

In its first nine years, the lab company had experienced an average annual growth rate of 60%, Santana explained. In the article, he attributed the lab's success to two business strategies.

First, Santana disclosed that Vista began offering same-day results in 2004, with "98.6% of their test menu results delivered the same day."

The second strategy that fueled the multi-year growth rate is the lab's policy of charging self-pay patients the same rates that Medicare would pay.

As a trained medical technologist, Santana noted that, after earlier working for **Beckman Coulter** to install and validate medical equipment in Florida, he saw how clinical laboratories worked across the state, CLP reported. From that experience, he noticed a lack of personalized care, high prices, and long wait times for patients to have their blood drawn and to get their results.

"The patient was not being put first," Santana told CLP. "Likewise, neither were the physicians or the facilities who depended on those labs to deliver timely and accurate results. What's good for our patient is what works for us."

In the same CLP article published Aug. 10, 2012, the writer, Jim Huth, quoted Pat Owen, Vista Clinical's Chief Operating Officer. "Our retention rate is extremely high, and we earn that honor every day."

For Owen, other labs were treating clinical lab work almost as if it were a commodity. "We took something that was a commodity, and brought back humanity to it," she told CLP. "This comes from the top and trickles all the way down."

Tougher Times Ahead as Labs React to Fee Cuts

Will biggest lab companies be forced to ask health insurers to increase contract lab prices?

CEO SUMMARY: Just as Nero is reputed to have fiddled while Rome burned, officials at CMS seem to be doing their own fiddling as their planned deep price cuts to Medicare Part B lab tests could begin driving lab companies out of business. In recent weeks, the owners of two lab companies decided to sell their labs before the fee cuts go into effect Jan. 1. One lab executive predicts the Medicare cuts will cause the national lab companies to ask health insurers for higher contract prices.

SOME LAB COMPANIES ARE NOT WAITING until Jan. 1, 2018—when the deep cuts to Medicare Part B lab prices take effect—to put themselves up for sale. Just in the last 60 days, the owners of two well-established labs sold their companies.

The first sale was on Sept. 22, when **Avista Capital Partners**, a private equity company, bought **Miraca Life Sciences.** This sale was notable because the price Avista paid was almost $500 million less than what Miraca Holdings paid for the lab company in 2011. *(See page 8.)*

Retail Lab Assets Sold

In the second sale, on Oct. 31, **Laboratory Corporation of America** purchased the retail lab testing assets of **Vista Clinical Diagnostics** of Clermont, Fla. The terms were not disclosed. *(See pages 9-11.)*

The sale was significant because the owners of Vista will continue to provide lab testing services to 150 skilled nursing homes and more than 200 assisted living facilities in Florida and other states. Essentially, Vista is selling its most profitable clients while keeping its least profitable client accounts.

These could be the first dominoes to fall as Medicare's lab test price cuts erode the revenue of independent lab companies and hospital outreach lab programs.

Big Price Cuts Coming

In September, the federal **Centers for Medicare and Medicaid Services** said it would cut what it pays clinical labs and pathologists by $628 million in 2018. This amount is just under 10% of the $7 billion that CMS pays for such testing each year.

Under the final CLFS for 2018, CMS intends to pay 20% to 28% less than it pays now for some of the most common lab tests. *(See TDR, Oct. 9, 2017.)* As a result of such steep cuts, one third of the nation's independent labs could be forced to close, estimated Joe Plandowski, the co-founder of **In-Office Pathology**, a lab consulting firm in Lake Forest, Ill.

The proposed 2018 CLFS will slash what CMS pays to labs by $628 million in 2018. The reductions will continue in the following years as CMS can lower the price of specific lab tests by a maximum of just 10% per year in 2018, 2019, and 2020; and a maximum of 15% per year in 2021 and 2022.

Will CMS Regret Slashing Part B Test Prices If It Causes Small Labs to Go Out of Business?

FOR THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES, it may seem like good business to cut severely the prices it pays for Part B clinical lab testing. After all, CMS needs to be diligent about how it spends taxpayers' money.

But what happens if the Part B clinical laboratory fee cuts are so deep that one third to one half of the nation's small and mid-sized independent laboratory companies go out of business? Independent lab companies have already put themselves up for sale after they studied the negative financial effects that the 2018 Medicare price cuts would have on their labs.

Since September, two lab companies were sold. One was Miraca Holdings, a national pathology lab company. The other was Vista Clinical Diagnostics, in Clermont, Fla., a lab serving office-based physicians and nursing homes. In both cases, the Medicare Part B lab price cuts were a primary reason for the sales.

The nation's larger lab companies are likely to fill at least some of that void, said Joe Plandowski, the co-founder of In-Office Pathology, a laboratory consulting firm in Lake Forest, Ill.

But the larger lab companies are not expected to take on all of the lab businesses that may come up for sale. That means CMS may not be able to serve the 55 million beneficiaries it currently cares for in the Medicare program as existing patient access to quality lab testing disappears in many communities and rural areas.

The other wild card associated with the Medicare lab test price cuts is how the lab industry might use a lawsuit to seek redress. The larger labs, meaning **Quest Diagnostics** and **Laboratory Corporation of America,** may be considering a legal challenge against CMS for cutting what it pays so deeply. Recently, in response to questions submitted by THE DARK REPORT, Quest, LabCorp, and **BioReference Laboratories** all said they were not considering filing or joining a lawsuit against CMS.

"It would be interesting to see what Quest, LabCorp, and other labs would do regarding a lawsuit, but I wonder why any of them would do that because a number of independent lab companies and hospital outreach labs will disappear," predicted Plandowski. "When community labs and hospital lab outreach programs go out of business, Quest and LabCorp will selectively pick up some of that business.

"Therefore, they might be saying, 'Let the market get rid of our competitors because if we sue, we're only helping our competitors.' For that reason, suing the federal government doesn't make any sense," he said. "If I were running one of the nation's largest lab companies, I'd say, 'Goodbye to all those small lab competitors.' In the meantime, Quest and LabCorp would get bigger by gaining more market clout because there would be fewer choices in the marketplace.

"As small labs disappear, Medicare officials will discover that beneficiary access to lab testing in many regions has disappeared entirely. What will CMS do then?" he asked.

CMS published the proposed 2018 CLFS prices in September and issued the final rates last week with some minor changes. *(See page 15.)*

"During the next five years, if the lab test price cuts CMS is talking about come to pass, that would be disastrous for pathologists and clinical lab owners," Plandowski said. "What's going to happen is that—while Medicare rates come down—pathology groups and clinical labs will attempt to charge dramatically higher

rates to commercial payers to make up for the Medicare cuts.

"But the market doesn't work that perfectly," he added. "As Medicare does its chop job on lab test prices, a number of labs will go out of business. It won't surprise me if we see the number of anatomic pathology groups and independent lab companies shrink by 50% or more during the next three years.

Asking Insurers To Pay More

"Over that time, the remaining labs will hang on by attempting to boost the rates they charge to private payers," Plandowski explained. "They have to do that because many of the nation's largest labs have contracted with large health insurers to do lab testing at deeply-discounted prices, sometimes at or below the marginal cost to perform those tests.

"**UnitedHealthcare** is a good example," he continued. "It pays its biggest network lab companies just half the Medicare price for many lab tests. Those lab companies will be forced to say, 'We can't do this testing anymore because it's not economical,' and UnitedHealthcare will have to respond in some way.

"Honestly, I don't know where UnitedHealthcare, **Aetna**, **Anthem**, and other big health insurers will get the testing done at the current fees their reference labs offer unless they open up their own laboratories, and they are not likely to do that," he added. "Insurers might buy some labs and have them do their own testing if they think they can get it done cheaper, but no health insurers have done so yet.

"The problem for insurers is that there will be fewer labs to contract with," Plandowski said. "Maybe that's what they want. But look at it this way: labs are facing a cut in Medicare reimbursement of at least 20%—depending on the tests they offer.

"Most community labs and hospital lab outreach programs already operate on very low profit margins," he added. "So, if one-third of their business comes from Medicare and they get a 20% cut, that translates into a 6% reduction in total revenue. The year-end profit margins of small labs are generally under 10%—most labs are at just 2% to 6%. So, expect that profit margin to become an annual loss.

"It's even worse for labs that have one-third of their business with Medicare," stated Plandowski. "They will get hammered financially, particularly the smaller ones that have a high Medicare mix. That's why I say those labs will be forced to close.

"One reason labs face such steep reductions in Medicare lab test fees is because the nation's larger lab companies charged CMS rates that were much too high compared with the deeply-discounted lab test prices these same lab companies charged third-party payers," he said.

Living Rich On Medicare

"The bigger lab companies did it to themselves," he continued. "They were living rich on Medicare because Part B lab prices were relatively high. But at the same time, they discounted the prices they offered to all third-party payers to be the exclusive or semi-exclusive in-network laboratory providers.

"Of course, bigger lab companies simply could have charged Medicare less," he mused. "But nobody in their right mind would do that because the Part B lab test prices Medicare paid brought a lot of profitability to the biggest lab companies," he concluded. "After doing well with what they made from Medicare, those big lab companies aggressively cut the lab test prices they charged private payers. Once Medicare saw that, it was only a matter of time before Medicare would slash what they pay. So now, the day of reckoning has come!" TDR

—Joseph Burns

Contact Joe Plandowski at 847-840-3077 or iopathology@gmail.com.

CLFS Update

CMS Publishes Final CLFS Rates, Labs Prepare to Cut Staff or Close

MEDICARE OFFICIALS PUBLISHED the final Part B Clinical Laboratory Fee Schedule for 2018 last Friday. Some changes clinical labs will welcome. The rates remain deeply flawed, however, and will cause many labs to lay off staff and others to close, experts said Saturday.

How CMS set the rates remains problematic, stated Julie Khani, President of the **American Clinical Laboratory Association** and Mark Birenbaum, PhD, Administrator of the **National Independent Laboratory Association**. Both ACLA and NILA called for a delay beyond the scheduled implementation date of Jan. 1 for the new rates.

The 2018 CLFS was established under the Protecting Access to Medicare Act of 2014. Ironically, rather than protecting access to lab testing for Medicare patients, PAMA may have the opposite effect. The new rates are likely to force many labs to close, making it difficult for Medicare beneficiaries to access lab testing services, NILA said.

Lab Staff Layoffs Expected

"If these payments are not corrected, laboratories will be forced to lay off thousands of workers across the United States, eliminate services, or close their businesses altogether," NILA predicted. After analyzing the proposed rates in September, ACLA, NILA, and **XIFIN** were unanimous in their criticism, saying the rates CMS proposed were deeply flawed.

Clinical lab directors, pathologists, and experts who analyzed the proposed rates were encouraged to explain their concerns to CMS. *(See TDR, Oct. 9, 2017.)* "CMS clearly did not listen," Birenbaum said.

The intent of PAMA was to establish private market-based lab test rates. "CMS constructed a system where data from national laboratories with the highest test volumes and highest discounts in the private market dominate the data reported," NILA charged. Also, CMS excluded data from labs that have high test volumes and higher payments from private insurers, the association added.

For a few clinical labs, however, the final rates were not universally bad. "Some changes are consistent with recommendations ACLA made in its comments on the preliminary rates, and we acknowledged these minor changes," Khani said. "However, these changes do not address the failure of CMS to implement PAMA according to the intent of Congress."

Lâle White, founder, Executive Chairman and CEO of XIFIN, a healthcare IT company serving clinical labs, agreed. "It looks like they took a number of the comments into consideration," White said. "For example, the preliminary CLFS release did not cap codes that did not have a national limitation amount (NLA) at 10%. That cap was applied in the final release.

"The General Health Panel, which is not a payable Medicare benefit, was deleted from the new release," she noted. The definitive drug G codes, which were materially changed in description in 2017, were not ignored as they should have been since they do not match the 2016 usage of those codes. However, CMS did cap the reduction on the G codes at 10%."

—Joseph Burns

FDA Clears Waived CBC For Near-Patient Testing

➤Sysmex Granted First-Ever FDA Clearance of a CLIA-Waived CBC Analyzer for Hematology

➤➤CEO SUMMARY: Market clearance of the first-ever CLIA-waived analyzer for complete blood count and three-part differential tests could cut time-to-answer from days to mere minutes for one of the top 20 tests by volume performed at core laboratories. Developer Sysmex America, Inc., foresees its analyzer as a complement to central labs. Basic diagnostics would be performed in physician-operated laboratories while larger central labs continue to provide in-depth analysis and repeat testing.

FOR THE FIRST TIME in the United States, a CBC (complete blood count) lab test can be performed by in-house staff at CLIA-waived locations. On Nov. 6, the **Food and Drug Administration** cleared the **Sysmex** XW-100, making it the first CLIA-waived CBC hematological system available for use in near-patient settings.

While not intended to replace moderately complex laboratory testing, the analyzer is the latest example of a trend to bring more lab testing capabilities to the near-patient environment. The goal is to reduce time to answer while improving both the speed and accuracy of patient care.

"This undertaking was thoroughly researched and well thought through," stated Ralph Taylor, CEO of **Sysmex America, Inc.**, in an interview with THE DARK REPORT. "Sysmex worked closely with a number of groups to identify the needs and requirements for a CLIA-waived CBC test that would support clinical care for all the right reasons."

Some in the clinical laboratory profession will be concerned that a waived CBC test now has FDA clearance. In part, that's because there are examples of waived tests where untrained operators performed tests that produced inaccurate results for reasons ranging from an analyzer out of control and use of outdated reagents to failure to properly perform quality control.

These experiences are a reason why it is important to understand the story behind the FDA's clearance of a waived CBC. "Test processes were stripped to the essentials during the design process to meet requirements for ease-of-use, and to reduce risk, user error, and erroneous test results. Sysmex worked very closely with the FDA to obtain the CLIA-waiver," noted Taylor. "The objective was to develop diagnostic technology to meet well-documented, unmet needs that exist with how the current healthcare delivery model treats patients."

As cleared by the FDA, the Sysmex system provides both a CBC and a three-part White Blood Cell Differential—a technology that Sysmex says, "is built on the company's reliable, trusted, and proven technology honed by Sysmex scientists over nearly 50 years."

The CLIA-waiver does limit the range of diseases and patient profiles for which the machine is cleared for testing. The intended use for the XW-100 states it is "Not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases or disorders, oncology patients, critically ill patients, or patients under the age of two."

The new analyzer incorporates similar diagnostic technologies currently used in Sysmex-equipped hospital laboratories. However, it is simplified for the physician office laboratory (POL) environment or other Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver facilities where use by operators at CLIA-waived locations is likely.

In its press release about the FDA action, Sysmex said the device "uses a 15µL sample size of venous blood to provide a CBC with a three-part white blood cell differential, offering 12 clinically useful results, all of which are available in as few as three minutes."

Speedy Result For Doctors

Sysmex sees opportunity in providing physicians with a CBC test that can generate a result in as little as three minutes. "For example with this system, patients can leave the doctor's office with a prescription written and waiting at the pharmacy," said Taylor. "We believe this helps serve an unmet need among healthcare providers in POL settings due to the ability to support the diagnosis of the patient and decide on therapy during the same visit, ultimately providing a better level of care."

Medical technologists working with hematology systems will notice key differences in the new Sysmex analyzer compared to moderately complex analyzers. Missing are bulk processing, comprehensive reporting, and integration with the LIS and/or EHR. "This was by design," noted Taylor.

The FDA clearance as a waived test allows operators in CLIA-waived facilities to operate the system. The new CBC analyzer has several innovative features. "This

Multi-Year Road to Obtaining Clearance for Waived CBC

"CLEARANCE OF THE **XW-100** as a waived test required rigorous scrutiny from the FDA," stated Peter Shearstone, Vice President of Regulatory Affairs, Quality Assurance, and Clinical and Medical Affairs at Sysmex America, Inc. "This is the result of multiple exchanges across multiple years to ensure no one was put at risk by bringing CBC tests to CLIA-waived facilities."

Sysmex followed a two-step process to work with the FDA to achieve clearance for its analyzer for use in waived testing. In 2015, the XW-100 Automated Hematology Analyzer was originally cleared through the 510(k) pathway for use at the patient's point-of-care. The second step was to demonstrate to the FDA that the CBC waived test was substantially equivalent to the 2015 model, and, as stated in the FDA press release about the clearance, "that the submitted data demonstrated the test's ease of use and low risk of false results when used by operators at CLIA-waived locations."

"To support the CLIA-waiver application, Sysmex conducted a clinical study that paired six moderately complex clinical laboratory testing sites with six CLIA-waived testing sites," noted Shearstone. "Both Sysmex and the FDA analyzed CBC and three-part differential test results to compare accuracy and quality. Following an FDA-approved protocol, Sysmex gathered an extensive number of samples collected from patients ranging in age from two- to 92-years old.

"As part of this study, the CLIA-waived sites had a diverse population of patients covering a wide range of specialties, including family practice, internal medicine, and pediatrics," he continued. "The staff at each site were required to multi-task, and no individuals had formal laboratory training."

benchtop analyzer requires no additional training to set up upon arrival," explained Taylor. "Operator training consists of a brief video outlining basic features. Everything else is handled through on-screen prompts that walk operators step-by-step through the initial data-entry processes and starting the CBC test.

"When started, the analyzer connects to Sysmex to verify reagent authenticity and expiration dates, and check control values," he continued. "The instrument also stays connected to Sysmex and rechecks these after every eight hours of laboratory use, and when reagents are changed. "

Unlike more complex hematology analyzers, this system does not report to Sysmex outside of routine data checks. It also does not transmit data locally within the healthcare setting. Instead, it produces paper printouts of CBC and three-part differential results, which the physician uses to support diagnosis and treatment decisions. In addition to the print-out, the XW-100 stores the results of the last 100 tests on a first-in/first-out basis.

"Values outside of the normal ranges are flagged and reported. For results outside of critical ranges, the numerical results are not reported to the operator and follow-up steps are recommended instead, such as referring the specimen to a core laboratory for test completion," noted Taylor. "This ensures that erroneous data is not used to support the diagnosis or treat conditions."

Should tests return abnormal results due to machine error, or if the operator cannot bring the analyzer within standard control ranges, the machine locks out all operators, blanks out all viewable test data, and reports to Sysmex.

"What happens next is a unique feature of this system," added Taylor. "Sysmex will deliver a replacement analyzer the next day. Physicians return the malfunctioning unit using the box in which their new unit was delivered. This reduces maintenance and training requirements, ensures proper operation of the analyzer, and minimizes downtime for the physician."

What Taylor neglected to mention is that Sysmex has adopted the same replacement policy that consumers expect with their computers, printers, smart phones, and similar devices. Call the company, report the malfunction, and a replacement is immediately shipped with a return label so that the malfunctioning device can be sent back to the manufacturer.

Although the XW-100 is the first CLIA-waived hematology system available, it is not the first laboratory diagnostics analyzer to receive a CLIA-waiver or to be cleared to market by the FDA. For moderately complex labs that may worry about demand for one of its highest-volume tests shifting to POL and CLIA-waived environments—and taking revenue streams with them—Sysmex understands those concerns.

Samples To Core Lab

"This analyzer is designed so that samples will still be referred to central labs for either repeat testing or more detailed hematology tests that will give a greater level of information back to clinicians," stated Taylor. "Our goal with this analyzer is to deliver information within the POL environment that allows clinicians to respond quickly and rapidly to begin treatment. Meanwhile, central labs will continue to provide detailed information that will be used to further refine treatment. This doesn't change our commitment to the core lab market."

Value-based payment to physicians is one factor in the Sysmex strategy to introduce a CLIA-waived CBC test. Such payments encourage doctors to increase the efficiency of office visits by reducing time to answer and improving patient satisfaction. Thus, the ability to do CBC testing while patients are still in the office and to provide them with a diagnosis and a prescription before they leave is expected to be an important reason why clinicians may decide to adopt this system. TDR

—Jon Stone

For further information, use this URL: www.waivedcbctesting.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last Friday, **Roche** announced an agreement to acquire **Viewics, Inc.**, of Sunnyvale, Calif., in a transaction that, subject to regulatory clearance, is expected to close on Nov. 21. Viewics sells a middleware analytics solution to clinical labs. Terms of the sale were not announced. Viewics was founded in 2010.

SUNQUEST IN DEAL WITH N-OF-ONE

Earlier this month, **Sunquest Information Systems, Inc.**, said it had entered a partnership with Concord, Mass.-based **N-of-One**. The two companies want to integrate N-of-One's capabilities in the clinical interpretation for next generation sequencing (NGS) panels with Sunquest's Mitogen, "a laboratory information management system (LIMS) and genetic analysis and reporting software suite for molecular diagnostics and precision medicine." This partnership shows the speed with which next-generation gene sequencing is gaining acceptance in diagnoses and treatment decisions, particularly involving cancer.

CYTOPATH SELLS TO AURORA

On Nov. 1, **Aurora Diagnostics** of Palm Beach Gardens, Fla., announced its acquisition of **CytoPath, PC**, of Alabaster, Ala. Aurora said CytoPath serves eight hospitals in Alabama and public records show six pathologists in the practice. Aurora stated that it now has 30 "affiliated local pathology practices." Aurora Diagnostics was founded in 2006.

TRANSITIONS

- Ted Snelgrove was appointed Chief Commercial Officer for **Guardant Health** of Redwood City, Calif. He previously held executive positions at **Counsyl**, **Jazz Pharmaceuticals**, **CellScape Corporation**, **Crescendo Bioscience**, **Genomic Health**, **Amgen**, and **Immunex Corporation**.

- **Pacific Biosciences** announced that Kathy Ordoñez is its new Chief Commercial Officer. She worked previously at **RainDance Technologies**, **Quest Diagnostics**, **Celera**, and **Hoffmann-La Roche**.

- Huntington Willard was selected as the Director of the new **Geisinger National Precision Health Initative**, launched by **Geisinger Health System**. Willard was founding Director of the **Duke Institute for Genome Sciences & Policy** and is a former President of the **American Society of Human Genetics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 11, 2017.