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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

Medicare Overstepped With Proposed Rules

FOR SEVERAL YEARS NOW, officials at the federal **Centers for Medicare & Medicaid Services** (CMS) have signaled their unhappiness with the status quo in how coverage guidelines and prices must be established for clinical laboratory testing and anatomic pathology services.

These pages have chronicled some of the analyses and reports commissioned by CMS over the past 24 months. Each had one thing in common: they concluded that Medicare pays too much for clinical laboratory testing.

Let me remind you of two examples. One is the study of national competitive bidding for Part B Clinical Laboratory Tests. This was published in May 2012 and authored by **RTI Technologies** of Research Triangle Park, North Carolina. The conclusion was that substantial savings would be realized.

The second was made public this spring. It was a study by the **Office of the Inspector General** and determined that, if Medicare charged the lowest price paid by any state Medicaid program for each lab assay, Medicare could save $910 billion annually over what it currently pays. *(See TDR, June 17, 2013.)*

So should anyone be surprised at how boldly Medicare officials acted when they released their proposed rules in the 2014 Medicare Physician Fee Update draft that was published in the *Federal Register* on July 19?

However, this time, our public servants at CMS may be guilty of a serious overreach in their effort to slash what Medicare pays for clinical lab tests and anatomic pathology services. Now, less than 90 days after publishing these proposed reductions in lab test reimbursement, we see the first round of lab company sales, along with the bankruptcy filing of a sizeable lab company.

More financial blood will soon be spilled on the streets of the laboratory testing industry. Many small lab companies will close their doors for good. I expect a substantial number of private pathology group practices will cease to exist and their pathologists will end up in other practice settings.

Who will be the loser in all of this? CMS, definitely. It will see beneficiary access to lab testing diminish significantly. This will be particularly true for patients in nursing homes, because it is small, independent labs that serve this sector. Ultimately, however, if CMS persists in its actions to substantially reduce lab test fees from current levels, it will be the physicians and patients across the nation who must cope with reduced access to lab testing services in their cities. TDR

Medicare Price Cuts Drive Labs to Sell or File BK

It is the first wave of lab restructuring and is market evidence of deteriorating lab finances

CEO SUMMARY: Professional investors are smart with their money. Thus, it is no surprise that clinical lab and pathology companies owned by private equity firms are the first to be sold or closed. These investors are acting in response to the cumulative negative financial impact of recent cuts to lab test prices. Even more worrisome to the entire profession of laboratory medicine is the consequence of Medicare's proposed cuts to pathology testing and Part B Clinical Lab Prices for 2014 and 2015.

OCTOBER SAW THE FIRST WAVE of sales and bankruptcies among laboratory companies in reaction to both the actual and proposed cuts to the prices the Medicare program pays to clinical laboratories and anatomic pathology labs.

In just the past four weeks, a lengthening list of laboratory companies have either been sold or filed a bankruptcy action. Each of these transactions is evidence that successive cuts to lab test reimbursement are undermining the financial stability of a large number of laboratory companies across the nation.

At the same time, it is appropriate to remind everyone of the invisible damage done by these price cuts to the quality and the integrity of the lab test results produced by laboratories. Most directly, it can mean that financially-struggling labs begin reporting inaccurate lab test results that can negatively affect patient care and may go undetected for months or years by CLIA inspectors or assessors from lab accreditation organizations.

Another negative consequence to the sale and/or closure of individual lab organizations is reduced patient access to lab testing in many communities. These negative consequences will be particularly true for those lab organizations that make bad decisions as to where to cut costs in response to being paid less per test by government and private health programs.

Each time a laboratory company is put up for sale or a lab bankruptcy is filed, additional evidence is produced about the negative impact that recently-imple-

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mented and proposed price cuts are having on different clinical laboratory companies throughout the United States.

This wave of lab sales and bankruptcies began on October 7. That is the day when the sale of **ConVerge Diagnostic Services, LLC**, to **Quest Diagnostics Incorporated** was announced. Terms of the sale were not disclosed.

Pathology Lab Sold To Quest

ConVerge is an anatomic pathology company in Peabody, Massachusetts. Public sources indicate that it has annual revenue of $15 million, 22 employees, and nine pathologists.

Just 15 days later, on October 22, it was disclosed that **Plus Diagnostics, LLC** of Union, New Jersey, would be acquired by **Miraca Life Sciences**, of Dallas, Texas. There were 26 pathologists at Plus, a company that did a national business in anatomic pathology services.

Both Converge and Plus were owned by **Water Street Healthcare Partners**, a private equity company based in Chicago, Illinois. It is reasonable to assume, in the wake of cuts to pathology fees in recent years—and factoring in the impact of the proposed Medicare fee cuts as published in the 2014 Medicare Physician Fee Update—that Water Street's principals could see no way to achieve their financial goals going forward.

Thus, the rapid sale of both anatomic pathology companies allowed Water Street HealthCare Partners to take the losses immediately, write off these investments, and redeploy the capital into other industries. It can be expected that other professional investors will make similar decisions to end their investment in lab testing companies.

Loss Of Investor Confidence

Loss of investor confidence in the clinical laboratory and anatomic pathology business was widely predicted last spring. These predictions were made after the Medicare program proved unprepared to administer claims submitted for the 114 new Tier 1 and Tier 2 molecular diagnostics CPT codes that became effective on January 1, 2013. *(See TDRs, April 15, 2013, and June 17, 2013.)*

It was a similar story in another laboratory sale. Also on October 22, the acquisition of **Shiel Medical Laboratories** by **Spectra Laboratories, Inc.**, was announced. Shiel is based in Brooklyn, New York. It was founded in 1919, which made it one of the oldest clinical laboratory companies still operating in the United States.

Over the past decade, Shiel consistently posted solid rates of growth in the highly-competitive New York City market. It currently employs more than 630 people and is owned by CEO Jack Basch. The reason for the sale was not announced. Spectra Laboratories is a business division of **Fresenius Medical Care AG & Co KGa**, the national dialysis company. Spectra primarily provides testing for dialysis patients.

First Known Lab Bankruptcy

The first lab company known to have filed a bankruptcy petition is **Laboratory Partners, Inc.**, of Palo Alto, California. On October 25, it filed a Chapter 11 bankruptcy petition in the United States Bankruptcy Court, District of Delaware.

Laboratory Partners is a substantial lab company. Under the name **MedLab**, it operates 12 laboratories in Ohio, Indiana, Illinois, Missouri, Michigan, Kentucky, Virginia, Maryland, and Washington, DC.

The majority of MedLab's revenue comes from its long-term care clients. In Indiana and Illinois, it serves office-based physicians. In Indiana, MedLab also provides lab testing services to two hospitals.

In its bankruptcy documents, MedLab described the reasons for its financial problems. It said the major reason for shrinking revenue was the result of "government-imposed permanent reductions in rates of reimbursement."

Shrinking Reimbursement for Clinical Lab Tests Is Major Reason Lab Owners Are Deciding to Sell

OVER THE COURSE OF 2013, several substantial laboratory organizations either put themselves up for sale or ceased operations and went out of business. A common theme in these decisions has been the dramatic and sustained reduction in reimbursement for lab testing services by Medicare and private payers.

Take California, as an example. Two major hospital laboratory outreach programs were put up for sale during 2013. In April, **Dignity Health** disclosed that it would sell its clinical laboratory outreach business in California and Nevada to Quest Diagnostics Incorporated. The transaction included the sale of 56 lab sites and patient service centers.

Dignity Health operates 40 hospitals. The sale involved a significant volume of lab testing. For example, the *Stockton Record* wrote, in a story it published about the 25th anniversary of Dignity Health's **HealthCare Clinical Laboratories**, that "it was reported the 26,000-square-foot facility employed 365 workers... served customers from Long Beach to Mount Shasta; handled 3 million transactions a year; and earned gross revenue of approximately $80 million annually."

Another major lab sale involved **John Muir Health** in Walnut Creek, California. On September 3, 2013, it agreed to sell its **MuirLab** business to **Laboratory Corporation of America**.

Reduced Lab Test Prices

This laboratory outreach program was struggling to maintain financial stability. Along with the reductions in Medicare Part B clinical lab test fees, as an out-of-network laboratory for a number of private payers, it was hit with the requirement that patients had to pay more out-of-pocket when their lab testing was done by MuirLab.

LabCorp acquired the 26 patient services centers operated by MuirLab, along with its client list. LabCorp did not purchase MuirLab's core lab facility in Walnut Creek (which John Muir Health closed). It also did not acquire the nursing home clients that were being served by MuirLab. It was estimated that MuirLab's annual revenue was about $70 million.

It should not be overlooked that, on January 2, Quest Diagnostics announced that it had completed its purchase of the laboratory outreach program of the **UMass Memorial Medical Center**. Annual revenue of this lab outreach program was believed to be about $90 million.

Two Lab Companies Closed

Also during 2013, the lack of payment or unfavorable coverage decisions by Medicare contractors for tests billed under the new molecular test CPT codes has played a role in causing at least two lab companies to close their doors.

It was in April when **Pathwork Diagnostics, Inc.**, of Redwood City, California, ceased testing operations and closed permanently. Low reimbursement for its proprietary cancer tissue-of-origin test was one reason why its investors decided to pull the plug on the lab company, which had been founded in 2006. *(See TDR, May 28, 2013.)*

Another private laboratory company caught in the molecular CPT code fiasco was **Predictive Biosciences** (PB) of Lexington, Massachusetts. It closed its doors for good on May 31, 2013, despite the fact that almost 1,000 urologists were regularly ordering its proprietary molecular tests for bladder cancer.

Upon learning that the Medicare contractor had made an unfavorable coverage decision for the most important of its three proprietary molecular tests, the investors on Predictive Biosciences' board of directors voted to close the laboratory and cease doing business. These investors recognized the intent of payers to further reduce the prices paid for lab tests. *(See TDR, July 8, 2013.)*

More specifically on this point, MedLab stated in the court documents that it operates "under a Medicare Clinical Laboratory Fee Schedule. In 2010, Congress reduced reimbursement rates under the schedule for clinical laboratory services, which directly affected the Debtors. This year the Medicare Physician Fee Schedule Proposed Rule was released, proposing additional cuts in laboratory reimbursement rates. Further cuts to the Fee Schedule will go in effect in 2014 and 2015. As expected, the reimbursement rate cuts are negatively affecting the company's revenues."

The laboratory businesses for which it filed Chapter 11 Bankruptcy petitions are:

- **Pathology Associates of Terre Haute, Inc.**, Terre Haute, Indiana.
- **Terre Haute Medical Laboratory, Inc.**, Terre Haute, Indiana.
- **Biological Technology Laboratory, Inc.**, St. Louis, Missouri.
- **Suburban Medical Laboratory, Inc.**, Cuyahoga Falls, Ohio.
- **MedLab Ohio, Inc.**, Cincinnati, Ohio.
- **Kilbourne Medical Laboratories, Inc.**, Cincinnati, Ohio.
- **Laboratory Partners, Inc.**, Palo Alto, California.

The CEO of MedLab is Bill Brandt. He is a turn-around expert who granted an interview to THE DARK REPORT. His comments about the reasons for the decision to file a Chapter 11 bankruptcy action are found on pages 7-9.

In Operation Since 2004

MedLab's owner is **Laboratory Partners, Inc.**, of Palo Alto, California. Founded in 2004, Laboratory Partners' CEO is Richard Daly, a former executive at several lab and diagnostic companies. He has kept a low profile in the laboratory industry since his firm acquired its first laboratory company about seven years ago.

It should be noted that the sales of several laboratory companies and the lab bankruptcy action mentioned above are only those that have been publicly disclosed. Other lab closures and sales are occurring, but have been kept out of the public eye.

For example, THE DARK REPORT knows of two pathology group practices, reportedly in the Northeast United States, where the pathologists are negotiating to become employees of the hospitals that their respective pathology practices have served for many years. This news has not been made public because the final agreements have yet to be finalized.

A Toll On Lab Finances

Lab administrators and pathologists across the United States will want to track these developments. Aggressive price cutting by the Medicare program and the national health insurers is about to take its full toll on the clinical lab organizations and anatomic pathology practices that so capably serve patients in this country.

There will be more bankruptcies. There will be more forced sales of clinical lab organizations. With their deep pockets, the two national laboratory companies will be waiting to pick up these assets at bargain-basement prices. However, given past and proposed lab test price cuts, this may turn out to be a Pyrrhic business strategy for the nation's largest lab companies.

For anatomic pathology, it will be a similar story. Because the majority of the nation's 3,300 independent pathology group practices currently operate with four or fewer pathologists, they will be particularly hard hit due to the reduced reimbursement for their technical and professional services.

It may take some time before the deeper impact of multiple price cuts to various pathology services can be assessed. One reason why that is true is because the majority of pathology groups are private, are small, and tend to be slow in restructuring their core business activities. TDR

MedLab CEO Discusses Changes in Lab Market

Erosion in lab test reimbursement caused investors to shy away from investing in lab firm

CEO SUMMARY: Two factors combined to cause executives at Laboratory Partners and its MedLab business division to file a Chapter 11 bankruptcy petition on October 25. One was the sustained and continuing cuts to lab test reimbursement. The other was the reluctance of Wall Street investors to continue to fund the company. The majority of MedLab's specimen volume and revenue comes from long-term care facilities and the lab company hopes to sell virtually all of its remaining assets as part of the restructuring.

DECLINING LAB TEST REIMBURSEMENT was given as a major reason why **Laboratory Partners, Inc.** filed its Chapter 11 bankruptcy petition on October 25. The Delaware bankruptcy filing included both the parent company, Laboratory Partners, Inc., and all of its subsidiaries, including **MedLab**.

It is a story that has useful insights for pathologists and clinical laboratory managers. Along with the sustained reductions in lab test reimbursement that occurred in recent years, Laboratory Partners said it faces other significant issues. In the documents it filed with the bankruptcy court, it identified the negative effects of the recession and its continuing high cost of capital as additional contributing factors.

Investors Getting Gunshy

Another reason identified by Laboratory Partners is the general reluctance of investors to continue funding a lab testing venture during a time when reimbursement for lab tests is falling. An equally significant factor is that the lab company derives a majority of its specimens and revenues from one of the most expensive market sectors in the lab testing business: long-term care. MedLab says that approximately 900 of its 1,050 employees serve long-term care clients.

Laboratory Partners has specific goals for its Chapter 11 bankruptcy action. The company has appointed William A. Brandt, Jr., as President and CEO of its parent corporation, Laboratory Partners, Inc., as well as all of its subsidiaries. Brandt is a specialist in turning around or reorganizing businesses. He is also the President and CEO of **Development Specialists, Inc.**, of Chicago.

"MedLab is operating its business in the usual fashion and remains totally committed to providing the highest quality of timely and accurate service to its patients and clients," stated Brandt in an interview with THE DARK REPORT. "That said, it is probably time to actively entertain bids for the sale of the remaining constituent parts of the business, and to arrange for those sales to occur on an operating basis with no interruption in service.

"At this time, there are several parties interested in bidding on portions of our business," he said. "I would expect that in the near term we will sell off the remaining operations and divisions of the company."

In addition to its largest lab in Cincinnati, Ohio, MedLab operates 23 lab facilities in Illinois, Indiana, Kentucky, Maryland, Michigan, Missouri, Virginia, and Washington, D.C. It also has more than 500 phlebotomists and its labs perform about 6 million tests annually. *(See story on pages 3-6.)*

"In recent years, CMS and some commercial insurers have tightened up on reimbursement," explained Brandt. "That puts financial pressure on all labs and is a significant factor for MedLab. But MedLab also faces other issues.

"From the creation of Laboratory Partners in 2007, its MedLab business unit had sought, by starting with a large regional footprint, to become a national player in the lab business," he noted. "At its inception, the business truly flourished, but shortly thereafter came the recession and a sustained weakened economy. As a result of these factors, as well as the continuing tightening up of reimbursements, MedLab has struggled and has been in a recent mode of selling off some of its business units."

In a Restructuring Mode

"In the past few months, MedLab was dealing with creditors and was in a restructuring mode," stated Brandt. "As part of that restructuring, the company reassessed its strategic vision regarding becoming a national laboratory company.

"MedLab also talked with the investors—such as institutional investors and others—that originally got behind the business when it looked like it was going to be an obvious growth endeavor," he continued. "But as the numbers changed over time, many of those investors changed their expectations and their outlook. They could see that the business model MedLab had developed needed more growth in order to flourish.

"But as the lab testing market changed, investors began hedging their bets on whether more growth was possible," continued Brandt. "With a business like this, you either get to a certain size that is sustainable or you find that the lab business model you've built may not be developing the way you envisioned it. As a result of these developments, we've seen many investors become concerned about investing in the lab business.

Factors Plaguing Labs

"Right now, a host of factors are plaguing clinical labs," he said. "Two such factors include the uncertainty surrounding the implementation of the Affordable Care Act and the constant pressure on lab test reimbursement.

"The strategic vision MedLab had was of consolidating many labs into a larger platform where the economies of scale would be significant," observed Brandt. "In the middle of that rollout, we started to see reimbursement for lab tests go down.

"Suddenly the prospect of getting MedLab to grow to the size where the economies of scale makes sense isn't as realistic as it once was," he explained. "That causes everyone—including professional investors—to take another look at things and reconsider their investment plans.

"Another problem for MedLab was that the capital it raised in the first few years was borrowed at rather high interest rates," added Brandt. "Simply said, and with the economy in a sustained weakened state, our continuing costs of funds became difficult to justify, particularly because MedLab's existing overhead structure was built to support a larger volume of testing. When factors conspired to prohibit MedLab from getting any larger, these high costs began to be an impediment.

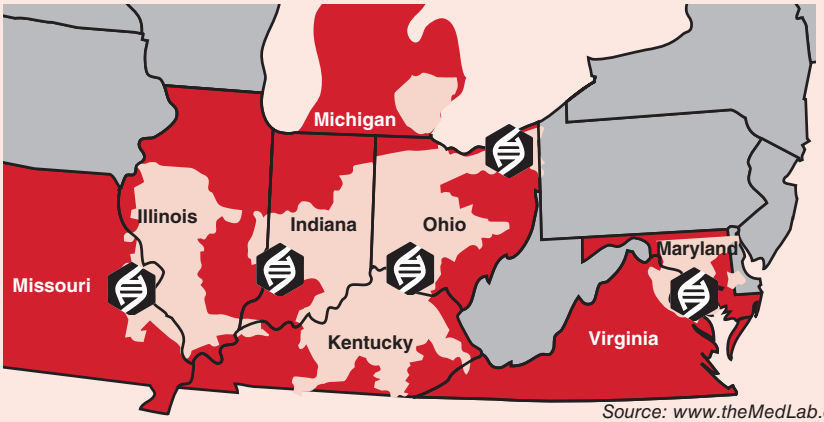
"Of course, these are common issues in the lab testing industry" he said. "Many

Laboratory Partners Quietly Expanded Operations to Provide Lab Test Services Across Midwest

FROM ITS INCORPORATION IN **2004,** Laboratory Partners, Inc., quietly acquired a number of laboratory companies across the Midwest. Operating under the name MedLab, the company eventually grew to 12 laboratories located in seven states and the District of Columbia.

It has raised tens of millions in venture capital funding. Public filings indicate that investors have included **Aquilo Partners**, **Chrysalis Ventures**, **Oxford Bioscience Partners IV LP**, and **Primus Venture Partners**. In documents filed with the bankruptcy court, Laboratory Partners said it is seeking court permission to sell its laboratory division in Terre Haute, Indiana. It hopes to complete these transactions as early as December using such sales methods as auctions.

Service Region for MedLab



Source: www.theMedLab.com

These are the business units of Laboratory Partners, Inc. that were included in the Chapter 11 Bankruptcy action:

- **Pathology Associates of Terre Haute, Inc.**, Terre Haute, IN.
- **Terre Haute Medical Laboratory, Inc.**, Terre Haute, IN.
- **Biological Technology Laboratory, Inc.**, St. Louis, MO.
- **Suburban Medical Laboratory, Inc.**, Cuyahoga Falls, OH.
- **Kilbourne Medical Laboratories, Inc.**, Cincinnati, OH.
- **MedLab Ohio, Inc.**, Cincinnati, OH.
- **Laboratory Partners, Inc.**, Palo Alto, CA.

lab organizations are dealing with these issues and some are doing it better than others. But clearly, a shakeout is coming to the clinical laboratory industry and this bankruptcy is one sign of that shakeout.

"So in the current market environment, the math of the lab testing business doesn't make sense for some organizations like MedLab," concluded Brandt. "The need is for volume production, and for MedLab the economies of scale are simply not there. To serve nursing homes and LTC facilities, it would make all the difference to have a lower overhead structure as well as a better set of logistics, but at the present time, MedLab doesn't enjoy these advantages." **TDR**

—Joseph Burns

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CEO SUMMARY: Tasked with cutting $2 million from their lab's annual operating budget, the lab team at Broward Health System instituted changes that included a lab test formulary and ordering algorithms. In collaboration with physicians, these changes reduced the use of outmoded tests while ensuring that the correct test or blood product was ordered for the right reasons. The lab produced savings of $871,000 in the first 12 months.

Lab's collaboration with physicians generates significant cost savings

Broward Health's Lab Pursues Multiple Ways to Cut Lab Costs

TODAY, PRIORITY NUMBER ONE at clinical labs in hospitals and health systems across the country is to cut costs. Thus, a $2 million cost reduction target at the nation's 10th largest public healthcare system did not surprise the new lab administrator when he arrived in July 2012 to start his new duties.

But how to achieve this $2 million cost reduction from the system's annual lab operating budget was the question Leo Serrano, FACHE, DLM(ASCP), faced in his new role as Corporate Director of Laboratory Services at **Broward Health System** in Fort Lauderdale, Florida. Broward Health Medical Center, at 700 beds, is the largest hospital in the health system.

It will surprise many pathologists and clinical lab managers that the primary strategy Serrano used to cut almost $900,000 in lab costs in just 12 months was to implement appropriate blood product utilization and a lab test formulary. The formulary was supported by the introduction of algorithms and computerized physician order entry (CPOE) for lab test orders.

This strategy is counter-intuitive. That's because the conventional wisdom holds that requiring physicians to adhere to laboratory test formularies and new lab test algorithms is a sure-fire way to incite resistance from physicians.

Physicians often view these actions as impinging on their ability to practice medicine as they see fit. Such physician resistance could have surfaced at Broward Health. How this was successfully handled and avoided by the clinical laboratory team has much to teach other clinical lab organizations.

However, the toughest challenges often produce the most spectacular results and this was true of the lab cost-cutting initiatives at Broward Health. Attacking lab test utilization was recognized to be the single biggest opportunity to shrink lab costs while improving patient care.

"When I arrived at Broward Health, I saw that there were no constraints on lab test ordering," recalled Serrano, who was speaking at the *Lab Quality Confab* last month in New Orleans. "Physicians ordered whatever tests they wanted—even very expensive tests—regardless of whether there was any indication of clinical need."

In deciding to tackle lab test utilization, Serrano, Lab Medical Director Fred Reineke, M.D., and the lab team knew that many cards were stacked against them. "This is one of the hardest tasks I've ever taken on," Serrano stated. "We fully expected there to be physician resistance as the lab worked to introduce these new processes.

"However, our lab team believed it could overcome that resistance by insisting that physicians be responsible for making most of the clinical decisions," noted Serrano. "These clinical decisions would not be made by the pathologists and the lab staff."

This approach proved to be quite effective. The first positive outcome came as Serrano and Reineke presented physicians with the clinical and financial reasoning behind the lab's recommendations for controlling the ordering of expensive esoteric tests. They did this by introducing an approval process, a lab test formulary, and lab test algorithms.

"It turned out that our physicians were open to the input from our laboratory professionals," explained Serrano. "They are aware of the changes happening in healthcare and medicine. They realize that, in order to improve patient safety and patient outcomes, they will benefit from increased precision in the ordering of the rapidly-growing number of laboratory tests at the appropriate time and for the right clinical reason."

But being open to the introduction of a new lab test formulary and associated algorithms is not the same as changing physicians' habits day in and day out when they are ordering medical lab tests. The lab team at Broward Health ran straight into this obstacle.

"Our lab's job was to begin to control lab utilization," recalled Serrano. "But we are lab people dealing with clinicians. We felt it would be inappropriate for laboratorians to tell physicians what to do in their environment. That is why we adopted another approach.

"We explained why we would like to include or exclude specific tests from the formulary," he continued. "The Physician-led Lab Formulary Committee would make the decisions, consult with their peers, and share with their peers."

This step included several elements. "We outlined all the reasons behind our actions,"

noted Serrano. "We explained that reimbursement pressures are stronger than ever. At Broward Health, we have many uninsured and underinsured patients who leave our health system with unpaid bills. This meant we could easily justify our initial efforts at monitoring high cost, esoteric tests.

"Next, we addressed the fact that several tests on the test menu were unnecessary, outdated, or inappropriate," he added. "Not only do these tests incur costs to our lab, but, when ordered, they may also increase the cost of care. Yet, doctors don't want the lab to take away tests with which they are comfortable!

"There is a separate issue that must be addressed if a lab like ours is to control utilization effectively," noted Serrano. "It is the regular introduction of new lab tests. That happens continuously these days. Pathologists know all too well what comes with many of these new lab assays.

Introducing New Lab Tests

"As a new test is introduced, the company that developed the test goes to physician offices and explains how wonderful their proprietary lab test is," noted Serrano. "The challenge comes from the fact that many of these tests may have little or limited clinical value and they increase costs. Physicians have no idea if these tests are useful or not, nor how much they cost the patient or the insurance company.

"This is the opportunity for every hospital laboratory to step in because clinicians treating patients today get information from a wide variety of sources," noted Serrano. "Our job in the lab is to filter this information. This is where the lab staff, the medical director and the pathology group need to work with clinicians.

"Keep in mind that, along with the cost pressures that labs and hospitals face, physicians have time constraints," he commented. "Their time with patients is shrinking. That means they need help sorting through the maze of tests available today.

Focus on Patient Care

"Our first step in controlling utilization was to establish our lab formulary," stated Serrano. "From the beginning, we understood that the lab and the pathologists could not dictate how to make these changes. Any attempt by the lab to tell physicians how to practice would trigger a revolt.

"As treating physicians, they bear the ultimate responsibility to improve the outcomes of their patients," he continued. "Our lab's job is to help them do so by communicating to them how we can help them. That's it in a nutshell: We need to communicate with them. And you can never have too much communication.

"How did we do so?" he asked. "We used a simple approach. A multispecialty committee of physicians was created and the lab simply facilitated communication within this committee. Our role was to offer assistance, guidance, and support. We were not voting members of the committee.

"This role as a guide to the committee increases receptivity," he added. "As guides, the lab team helps physicians to see that this is not a mandate from administration.

Computerized physician order entry (CPOE) played a big role in the lab's effort to cut costs. CPOE use was linked to "best practices" initiatives at Broward Health.

"Best practices turned out to be a key because, at that time, Broward Health was installing a CPOE system," recalled Serrano. "As part of the CPOE introduction, the hospital had made a commitment to follow best practices.

"At the start of the CPOE process, Broward Health created two committees," he said. "One was the Evidence-Based Care (EBC) committee and the other was the Physician Advisory Committee (PAC).

"The EBC, a committee composed of a variety of healthcare professionals, was

Effective Use of Lab Formulary Committee Engages Physicians to Improve Utilization

ONE MAJOR CHANGE instituted by the laboratory at Broward Health Services in Fort Lauderdale, Florida, was the creation of a system-wide lab test formulary.

"It is true that runaway lab test ordering cannot be controlled without collaboration between the laboratory and the physicians," stated Leo Serrano, Corporate Director of Laboratory Services at Broward Health. "That is why our lab took several steps to engage physicians in this process.

"One thing we did was create a lab test formulary committee," he said. "This is a medical staff committee, not an administrative committee. Thus, it reports to the Combined Medical Executive Committee because we presented it as a quality management tool of the medical staff.

"Committee members are physicians from a variety of settings and are nominated by the various medical staff chiefs," observed Serrano. "Two pathologists serve on the committee, but they are nonvoting members. Their primary duties are to offer expertise in laboratory medicine.

"The lab test formulary is developed by physicians at our health system," he added. "It is the responsibility of the physicians to write the formulary along with help from the senior laboratory staff. Each hospital nominated two physician volunteers to sit on the committee.

"Members of the committee," he continued, "include a physician from community health, an emergency physician, a pediatrician, a surgeon, an ob-gyn, a family practice physician, two nephrologists, two internal medicine specialists, a pulmonologist, and a hospitalist. Also on the committee are representatives who work within the hospital and who work in ambulatory settings.

"The lab formulary committee established three testing tiers," explained Serrano. "The first tier is the largest one. It includes routine tests that any provider could order and has some guidelines for frequency of ordering.

"The second tier of tests is much smaller," he added. "It is limited and these tests can only be ordered by specialists, senior fellows, or consultants. On the third tier are the most expensive tests. These require the approval of the medical laboratory director or designee.

"Immediately, the formulary had the desired effect by limiting the ordering of esoteric and questionable tests first," observed Serrano. "It had a direct effect on reducing costs and yet it still gave physicians as much clinical leeway as possible.

"This approach helped us avoid telling physicians how to practice," concluded Serrano. "By using the formulary, peer physicians are providing useful guidance to their colleagues on how to more appropriately order laboratory tests."

charged with streamlining processes and reducing variation," noted Serrano. "The PAC was a committee in which only the physicians could vote. It was designed to review and approve the recommendations of the EBC.

"To do this job, the EBC collected standing orders from all facilities and combined them and standardized them," said Serrano. "The committee then compared these with evidence-based best practices. If there were any disagreements, the EBC and the PAC would meet to solve any problems. Then the PAC could implement the best practice guidelines as powerplans.

"Our laboratory contributed to this effort by designing lab test order sets that allowed for standardization in practices and a reduction in variation," stated Serrano. "We did this by removing outdated and duplicative tests.

Cardiac Panel

"One example was a cardiac panel the physicians had used for many years," he noted. "That panel included tests that were essentially duplicates. We advocated the elimination of tests that experts recommend should be dropped while still providing physicians with some flexibility in ordering.

"We gave physicians much leeway," emphasized Serrano. "But for certain tests, such as comprehensive metabolic panels, frequency recommendations were established. For example, a physician could order certain tests only once every other day.

"When a physician wants to order that test more often, the CPOE system issues a warning and makes a recommendation," he said. "Should the physician want to override the warning, he or she can do so but then the system would flag the physician as an outlier.

"Implementation and use of this CPOE system was timely because expenses for repeated and unnecessary testing were out of control." recalled Serrano. "It created the opportunity for our lab team to consult with specialists in all of the various clinical disciplines to discuss high-cost esoteric tests. In those meetings, we explained what we were paying for lab testing. We also explained that high costs for testing could have a detrimental effect on financial performance. We further stressed that patient outcomes trumped costs.

Shifting Authority

"At that point, physicians asked us to write a policy," he stated. "They also agreed to give the Department of Pathology and the medical laboratory director the authority to approve or not approve the ordering of high-cost tests.

"We established a policy in which any high-cost non-standard esoteric test of $1,000 or more would require the approval from the medical laboratory director or his designee," noted Serrano. "As part of this approval, the medical director or designee would contact the ordering physicians to discuss the reason for the test. They would need insurance prequalification and have to answer this question: Does this test change the treatment or outcome for the patient?

"Acceptance of this policy by physicians was not universal," added Serrano. "Despite the fact that the physicians themselves had given us the approval to make these changes, some clinicians were unhappy about having to order high-cost tests in this manner.

Ordering High-Cost Tests

"Next, we explained the reasons behind these policies and also the consequences of ordering these tests in the inpatient setting and the outpatient setting," commented Serrano. "With that explanation, they understood that by taking these extra steps, the physicians were helping us get paid for high-cost lab testing.

"This gave our laboratory a big win," said Serrano. "In its first six months of implementation, just this one policy on high-cost testing saved the hospital nearly $100,000. That was significant and health system administration took notice of this success.

"One lesson we have learned is that the primary activity of the Lab Formulary Committee is to communicate this information regularly and repeatedly," he continued. "A lab formulary will have very little effect on ordering unless there is active engagement between the physicians and the clinical laboratory.

"One example of how our lab test algorithms affected lab test ordering involved flow cytometry, FISH, and cytogenetic testing," noted Serrano. "Before the lab utilization process took effect,

physicians would check all the boxes on a requisition.

"Our first action was to explain to the physicians how much unnecessary cost was inflicted on the entire organization because of this ordering practice," he said. "Physicians quickly understood the need to voluntarily give up ordering and have the pathologists do it instead, in accordance with newly-established guidelines.

Controlling Lab Test Costs

"This was significant in controlling costs," Serrano observed. "Today, whenever bone marrows or biopsies are done, it is our pathologists who order the flow cytometry, the cytogenetic tests and the FISH tests.

"Having made all these changes, we counted up the savings that resulted from our efforts over the first 12 months of this cost-cutting program, starting in July 2012 and ending July 2013," he stated. "The total was $871,000—about 40% of our cost-cutting goal."

Serrano listed the specific activities and the amount saved. "Just on esoteric test approvals and unnecessary test reductions, the savings were $220,000," he noted. "Our lab increased revenue $68,000 by shifting, in an appropriate manner, some tests away from inpatient orders and over to outpatient orders.

Other Sources of Savings

"Other significant sources of savings came from reduced send-out testing that saved $74,000 and reduced in house testing that saved $97,000," he continued. "We also reduced platelet waste and cut costs for red blood cells by a total of $412,000.

"While our lab hasn't quite reached $2 million in savings, we are well on the way and lab utilization is a huge part of the savings," said Serrano. "It is the foundation for our next wave of cost-cutting efforts." TDR

—Joseph Burns

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Broward Health Lab Team Provides Enriched Data

GIVING MORE INFORMATION and enriched data to physicians was one element of the lab's strategy to control lab test costs at Broward Health System.

"As part of our lab's cost-cutting efforts, we decided we should give something back, such as test ordering assistance," stated Leo Serrano, Corporate Director of Laboratory Services at Broward Health. "You can't keep taking away without giving something back.

"Thus, we started publishing a monthly newsletter called *Laboratory Info for Physicians*," he continued. "In this newsletter we provided information about our pathologists, including their clinical background, and even some details about their family lives.

"We also provided clinicians with ongoing updates about lab tests," he stated. "This explained why certain tests are so outdated that the results are of little use in clinical care. We included recommendations on which lab tests should replace the outdated assays.

"The newsletter proved to be an effective way to publish lab testing algorithms," he added. "One of the first algorithms we published helped physicians sort through the issues involved in thyroid testing.

"That caused physicians to ask us for more algorithms," recalled Serrano. "To get more algorithms, we asked **ARUP Laboratories** and the **Mayo Clinic** if we could use their algorithms and they both agreed, saying their information was available to the public and free to use. We now have an entire file of lab test algorithms that we make available on the physician portal."

Most Colorado Labs Now Connected to State's HIE

➤Since launching operations in 2011, CORHIO manages health data on 2.8 million state residents

➤➤CEO SUMMARY: One trend getting little publicity is that of health information exchanges (HIEs). Since its founding in 2009, the Colorado Regional Health Information Organization (CORHIO) has grown steadily. Today, most of the state's independent lab companies and hospital laboratories are connected to CORHIO. Real-time access to laboratory test data is one feature that has high value to participating providers. This is particularly true for emergency room physicians.

ONE TREND IN HEALTHCARE operating quietly in the background is that of health information exchanges (HIEs). Across the nation, clinical labs and pathology group practices are "hooking up" to their regional HIEs and providing lab test data in real time.

HIEs represent a transformational force in healthcare because they give participating providers immediate access to patient data when a patient shows up for care. In turn, this access to patient information often leads to improved patient care within the region served by the HIE.

➤Launched Operations in 2011

Founded in 2009, the **Colorado Regional Health Information Organization** (CORHIO) demonstrates how a sustainable health information exchange can work to benefit both providers and their patients. CORHIO is a nonprofit, public-private partnership that was funded with more than $9 million in grants from the **Office of the National Coordinator for Health IT**. It launched operations in 2011.

All of Colorado's largest hospitals and laboratories are now connected or in the process of connecting to CORHIO. Currently there are 1,800 office-based physicians, 100 long-term and post-acute care facilities, and 13 behavioral health centers participating in the network, along with skilled nursing facilities, home health services, health clinics, health plans and public health departments.

"The overall goal of CORHIO is to help providers provide better patient care," noted Kelly Joines, CORHIO interim CEO and Vice President of Operations. "Our HIE changes workflow in a positive way. For example, it helps to avoid unnecessary tests and facilitates sharing of patient histories among attending physicians."

Laboratory test data has an important role within the HIE. "Our exchange delivers quick lab results for more appropriate intervention," explained Joines. "Physicians can also trend data, and this enables them to observe a specific population over time."

Physicians participating in CORHIO agree that the HIE is beneficial. Jesse Flaxenburg, M.D., is a Nephrologist at

Pikes Peak Nephrology in Colorado Springs and has used CORHIO for nearly a year. He said the HIE "hasn't changed the way I practice medicine, but it has markedly improved the efficiency with which I do."

In particular, Flaxenburg noted that quick access to lab test results dramatically improves his ability to monitor his patients' status. "I receive test results on a more timely basis and in a more usable format than I had previously," he said. "As a result, I more quickly catch things that require my attention."

Quicker Interventions

Flaxenburg noted that this is especially important in monitoring kidney transplant patients, as it enables him to identify organ rejection earlier and intervene quicker. He also pointed out the benefits of CORHIO's data trending feature.

"The ability to collect and trend large quantities of data allows medical practitioners to much more easily and dramatically improve the lives of our patients," said Flaxenburg. "This is key to the identification of best practices and helps us, as practitioners, see how we are applying these best practices. Without it, this would be a much more difficult task.

"CORHIO also allows the sharing of information with other physicians in the community," Flaxenburg continued. "Five years ago, physicians practiced more or less independently of one another. Information was scattered across multiple platforms—some paper-based and some electronic.

"That's far less common today," he stressed. "With EHRs and information hubs like CORHIO, information sharing is seamless. In most physicians' offices, there exists instantaneous access to patient medical information.

"There are many benefits to this," continued Flaxenburg. "It can prevent medical errors, like drug interactions between medications prescribed by separate providers. Those kinds of errors are far less common than they used to be.

CORHIO Supports Full Menu of Functions and Services

IN ITS THIRD YEAR OF OPERATION, the Colorado Regional Health Information Organization (CORHIO) now has the medical histories of 2.8 million people in its database. This is just over half of Colorado's population.

The health information exchange (HIE) gives participating providers access to:

- lab and pathology test results;
- radiology reports;
- transcript notes, including discharge summaries, H&Ps, and operative and ED reports;
- admits, discharges and transfers.

CORHIO also provides automated referral and consult requests. It facilitates the sharing of patient medical histories and HIPAA-compliant data with other providers. This includes secure messaging, and community- and state-wide connectivity.

The HIE assists providers in meeting and qualifying for Medicare and Medicaid EHR incentives and reduces administrative and overhead costs.

Future plans at CORHIO call for providing electronic ordering of laboratory, pathology and radiology tests. The HIE intends to support public health alerts and notifications. It also wants to support continuity of care documents.

"Additionally, it's important for physicians of various specialties to communicate, so they don't repeat tests or prescribe inappropriate medications," Flaxenburg added. "This not only prevents potentially harmful errors, it reduces costs."

Pathologists and clinical lab managers will be interested to learn that physicians, more so than in years past, are considering cost before ordering tests and other healthcare services. "Patients today bear a larger portion of healthcare-related costs—whether it be through higher insurance pre-

miums, deductibles or co-pays," noted Flaxenburg. "Therefore, the challenge becomes how to provide a higher quality of care at a lower cost than in the past."

Flaxenburg's experience in working with a health information exchange and an electronic health record shows pathologists and clinical laboratory managers how the integration of healthcare informatics can contribute to improved patient care in several important ways. It is also provides examples of how laboratories can deliver more value to clinicians using lab test data and integrated informatics.

Flaxenburg believes that the fully-digital electronic health record is essential if healthcare is to succeed with implementation of the Affordable Care Act and the evolution toward integrated clinical care. "I think there will be a steep learning curve between now and then, but we can't continue to practice medicine like in the 1950s," he said. "To improve the quality of care and better control costs, we must coordinate care, and we can't do that with a paper-based system. That is why the data exchange facilitated by CORHIO is essential as healthcare transforms itself."

Changes In Practice Patterns

Clinical laboratories feeding data into CORHIO are noticing similar changes in clinical practice patterns—all to the benefit of patients. "Real-time access to lab test data through the HIE delivers real benefits," stated Amery Ray, Laboratory Outreach Coordinator, **Memorial Hospital** at the **University of Colorado Health** (UCHealth) in Colorado Springs. "In our hospital, we see it every day as physicians in the emergency room are able to use CORHIO to view the patient's lab test data and see his or her cumulative lab test results."

Because Colorado Springs is a military and college town, Ray sees the practical value of CORHIO daily. "If a person working at a different military base or a student gets into a car accident here and he or she has been seen in the UCHealth system previously, the attending physician can obtain immediate health data from the patient's record from earlier visits to any of our facilities along the Front Range," she explained. "The physician no longer has to make calls to multiple providers to gather needed information because the information—including lab data—comes directly from CORHIO into the hospital or physician's electronic health record system."

Patient Satisfaction

Another factor that is important to hospitals is patient satisfaction, which is measured in surveys and is part of the hospital's accreditation. "Studies show that the ability of providers to access medical information quicker results in greater patient satisfaction," observed Ray.

"There are big benefits when a physician has quick access to lab results," she continued. "It allows the physician to treat patients for a condition while they're still at the physician's office, so they don't have to return another day to be treated."

There are other practical benefits for the clinical laboratory participation in an HIE. "Partnering with CORHIO is very forward thinking," emphasized Ray. "It improves even simple things. For example, we save money because paper has been eliminated. We save time because we no longer need to scan documents and fax them to doctors. These savings are small on a per-test basis, but compound over thousands of tests and become significant over time."

Stage 2 Meaningful Use

Another factor that should not be overlooked is that compatibility with HIEs is a key component of Stage 2 Meaningful Use. Therefore, Colorado providers participating in the federal EHR Incentive Programs will find it easier to meet this requirement and qualify for their incentives. TDR

—Patricia Kirk

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Who would have guessed that Angelina Jolie would do a multi-million-dollar favor to **Myriad Genetics, Inc.**? Jolie caused quite a stir earlier this year when she went public with the news that she had done a prophylactic double mastectomy after she had learned the results of her BRCA test for breast cancer risk. That news event was a financial bonanza for Myriad Genetics. When the company reported its third quarter earnings, its revenue exceeded the Wall Street consensus by tens of millions of dollars, surprising analysts. And the reason for this surge in revenues? Myriad executives attribute as much as $35 million of the company's $208 million in Q-3 revenue to women asking to be tested in the weeks following the news of Jolie's double mastectomy.

MORE ON: *Myriad*

Myriad Genetics will be closely watched by investors going forward. That is because, since the Supreme Court decision on the patenting of genes earlier this year, other laboratory companies have announced their intent to offer their own BRCA genetic tests. Such lab companies include **Ambry Genetics**, **Bio-Reference Laboratories**, **Quest Diagnostics Incorporated**, and **GeneDx**.

FDA ISSUES REPORT ON PERSONALIZED MEDICINE

Lab executives interested in the latest thinking within the **Food & Drug Administration** (FDA) about personalized medicine, companion diagnostics, and laboratory-developed tests may find useful insights in a new report issued by the federal agency. It is titled "Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development." Released last month, the FDA report covers efforts by the agency "to advance regulatory standards, methods, and tools in support of personalized medicine."

GENE TEST FIRMS INVOLVED IN IPOS

CardioDx of Palo Alto, California, is preparing an initial public offering (IPO). It hopes to raise as much as $92 million for its molecular assays used in diagnosis of cardiovascular disease. Earlier this fall, **Foundation Medicine, Inc.**, of Cambridge, Massachusetts, raised $102 million with its IPO. It offers molecular products to aid in the diagnosis and treatment of various cancers.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how private insurers are joining with large healthcare systems to create ACOs. One recent example is a new **UnitedHealthcare** partnership in Wisconsin with three large health systems that created one of the state's largest ACOs.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, December 2, 2013.

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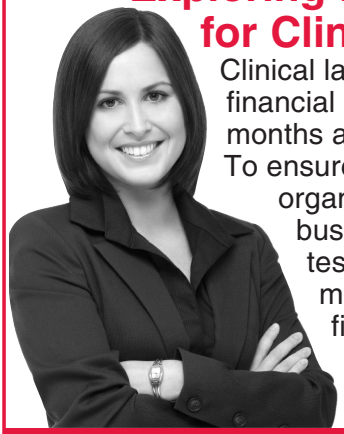
Exploring New Business Models for Clinical Laboratory Testing



Clinical labs have been hit with multiple financial hammerblows over the past 24 months and more price cuts are predicted. To ensure financial stability, innovative lab organizations are developing new business models to deliver clinical lab testing in a financially-sustainable manner. Join us for the lab industry's first look at the likely new business models that will allow clinical labs to grow and prosper.

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- **With Lab Companies Up for Sale, What Motivates Buyers in this Tough Financial Environment?**
- **Assessing the Impact of Medicare's Final Rules for Lab Test Pricing that Take Effect on January 1.**
- **Negotiating with ACOs: How Labs Can Deliver Added Value Services that Improve Outcomes.**

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