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The Dark Report

TOP TEN

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

Finding Lab Growth Opportunities Amid the Gloom

IN MANY WAYS, THE TRADITIONAL BUSINESS MODELS for laboratory testing services are proving deficient in the face of a swiftly-evolving healthcare system. I suspect that none of us fully understand how many laboratory organizations are already under extreme financial stress.

We intuitively understand that, somewhere out in the healthcare marketplace, clever and innovative pathologists are developing new business models for laboratory testing. They are discarding outmoded operational approaches and devoting attention to understanding the changing clinical needs of their client physicians. These laboratory professionals are finding lab growth opportunities amid all the gloom of declining reimbursement for lab testing services and unwelcome Medicare policy changes (like Medicare's announced reimbursement cut of 52% to CPT 88405-TC).

But there is even more to the good news part of this story. Here at THE DARK REPORT, we can find examples of lab entrepreneurs in different regions of the country who are founding clinical lab companies from scratch and enjoying steady growth. They are increasing specimen volume and revenue, enabling them to achieve break-even in a reasonable period of time. At the same time, they are disproving the conventional lab industry thinking that the only way to enter the clinical lab business is to acquire an existing lab company.

My point here is that our profession has two sides, a negative and a positive. I can paraphrase Charles Dickens and his famous opening sentence in *A Tale of Two Cities* and say this: we are seeing the best of times and the worst of times. We are at a moment in history when knowledge of the human genome will unleash an unprecedented flood of new diagnostic tests that pathologists can use to help physicians diagnose disease sooner and more accurately, then help with the selection of the most appropriate therapies.

At the same time, we are living in an age when demand for healthcare is outstripping the nation's ability to pay for it. That guarantees a gap in funding that will cause many lab organizations to merge, sell, or go out of business.

However, 320 million Americans continue to need lab testing services. Going forward, innovative labs have the opportunity to provide this testing and make money doing it. Your challenge is to stay alert to new opportunities, then help your lab deliver added value to physicians in a financially sustainable manner. TDR

2012's Top Ten Lab Stories Predict More Challenges

The year's list of important stories reveal how financial stress will intensify in coming years

CEO SUMMARY: It's been a year with more lows than highs, when viewed through the lens of THE DARK REPORT's "Top Ten Lab Stories of 2012." The end of the TC grandfather clause, new policies for prostate biopsy billing, and a dramatic 52% cut to 88305-TC fees were widely reported. But there was equally bad news for the clinical laboratory industry in other significant ways. The common link to many of these news stories is a reduction in what government and private health plans will pay for lab tests.

ON BALANCE, 2012 WAS NOT KIND to the laboratory industry. In particular, between Congress and federal healthcare agencies, new laws and several policy changes occurred.

Collectively, these actions are expected to be negative to the financial stability of the nation's medical laboratory organizations. But that's not the end of the bad news associated with the events of 2012.

In developing THE DARK REPORT's "Top Ten Lab Stories for 2012," there were few breaking news stories that represented good news for the nation's clinical laboratories and anatomic pathology groups.

One obvious bright spot was the call, by the **Institute of Medicine** (IOM), for all healthcare providers to transform themselves into "continuous learning organizations." This was the theme of a report the IOM issued in September titled "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America."

The IOM urges all providers to proactively go outside healthcare to identify technologies and innovations that can improve patient outcomes while lowering the cost of care. THE DARK REPORT selected this as the number one news story for 2012 because it represents a positive call for providers—including clinical labs—to become nimble at using Lean, Six Sigma, and the other methods of quality management. *(See page 5.)*

However, there is little good news to be found within the remaining "Top Ten Lab Stories for 2012." One example is news story number two on our list. 2012 is the year that private payers intensified their own war on what they deem to be

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unwarranted high costs for clinical laboratory testing. These payers are targeting small independent lab companies, hospital lab outreach programs, and community hospital-based pathology groups. Payers are actively working to exclude them from managed care contracts and approved provider networks. *(See page 5.)*

Although the efforts of payers to narrow their provider networks is a development that favors the largest national laboratory companies, 2012 delivered plenty of bad news for the giants of the lab industry. Story number five is the slowing of organic growth at the nation's two largest public lab companies. *(See page 7.)*

Another provocative development that surfaced during 2012 was the publication of a study that looked at the feasibility of a national competitive bidding program for Medicare Part B Clinical Laboratory Testing. *(See TDR, September 17, 2012.)* This is not an auspicious portent for the two blood brothers, should Medicare officials take action based on the findings of this study. That's because any price reduction resulting from a national competitive bidding program would decrease the money these labs currently get from Medicare fee-for-service pricing. *(See page 9.)*

Rapid Changes In Market

Other stories on our top ten list for 2012 include new laws and new regulatory policies. Each of these have been widely-reported due to the expectation that a large number of clinical labs and pathology groups will see a direct and negative financial impact.

Thus, story number four deals with the end of the TC grandfather clause. Congress, in its February bill to effect a temporary fix to the sustainable growth rate problem, took the money saved from allowing the TC grandfather clause to expire as of June 30, 2012. In the same bill, Congress also reduced Medicare Part B Clinical Lab fees by 2%. *(See page 6.)*

On the regulatory front, there were equally significant events. One Medicare carrier's new prostate biopsy policy caught the entire pathology profession by surprise. Just months later, the Medicare program released the 2013 Physician Fee Schedule that included a 52% reduction in the technical component for CPT 88305. *(See page 6.)*

Lab Deficiencies Identified

At a more strategic level, several small hospitals closed during 2012 as a result of serious CLIA deficiencies identified during inspections by state regulators. This is evidence that a day of reckoning is arriving. *(See TDRs, March 12, 2012 and October 8, 2012.)*

Many more small hospitals are at the brink of financial crisis due to years of declining reimbursement. That bill is now coming due and a hospital's laboratory is one of the first clinical services where deficiencies associated with inadequate hospital budgets becomes visible. *(See page 8.)*

Staying with the big picture, the list of top ten lab industry stories for 2012 provides powerful evidence that the entire lab testing profession is about to undergo years of severe financial stress. It is neither accident nor coincidence that both government health programs and private health insurers enacted severe policies that have in common the goal of reducing what is spent on lab testing services.

The money has run out, particularly at the federal level. To make it from one fiscal year to the next, both legislators and regulators will be squeezing dollars from any and every source they can find.

This is one important message to be gleaned from a study of THE DARK REPORT'S "Top Ten Lab Stories for 2012." It would be a strategic mistake not to study the most significant events of the year as a way to understand the evolutionary forces now reshaping healthcare as we have known it. **TDR**

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TOP TEN LABORATORY STORIES OF 2012

1 Institute of Medicine Issues Call For Culture of "Continuous Learning"

HEALTHCARE EXPERTS say that the **Institute of Medicine's** (IOM) latest report and call to action may be every bit as significant as the IOM's "To Err Is Human" was in 2009.

The IOM is calling on all healthcare organizations to adopt a culture of "continuous learning." It directs healthcare administrators to become proactive about identifying innovations within other industries, then be swift about adopting them in ways that improve both workflow and patient outcomes.

This new report is titled "Best Care at Lower Cost: The Path to Continously Learning Health Care in America." It was issued in September by the IOM. *(See TDR, October 8, 2012.)*

In the words of the IOM, "Americans would be better served by a more nimble healthcare system that is consistently reliable and that constantly, systematically, and seamlessly improves... In short the country needs healthcare that learns by avoiding past mistakes and by adopting newfound successes."

This is a clear and unmistakable message. As the American healthcare system moves toward value-based reimbursement, all providers—including clinical laboratories and anatomic pathology groups—will need to develop organizational cultures that embrace continuous improvement. This means more use of Lean, Six Sigma, and quality management systems (QMS).

TOP TEN LABORATORY STORIES OF 2012

2 Payers Get Serious About Cutting What They Spend on Lab Testing

FOR MANY REASONS, THIS WAS THE YEAR that some of the nation's largest health insurers took aggressive actions to exclude many regional and local laboratories as network providers.

Their goal is to significantly reduce what they spend on laboratory testing services. Too often, this means payers look for ways to exclude smaller independent laboratory companies, hospital lab outreach programs, and local pathology groups from their provider networks.

Aetna, Inc.'s efforts to significantly cut back on the number of clinical labs and pathology groups holding provider contracts is probably the best-known example of this trend. There are reports that Aetna has effectively purged as many as 400 regional and local laboratory providers from the various provider networks it operates throughout the United States.

Similarly, the **Blue Cross Blue Shield Association** (BCBSA) enacted new requirements for its Blue Card program. Several lab industry groups recognized these changes as designed to exclude large numbers of small lab providers from having access to Blue Card patients. *(See TDR, July 16, 2012.)*

By no means is this trend limited to just Aetna and the Blues. Other health insurers are taking similar actions that make it tougher—if not impossible—for small labs to be an in-network provider.

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➤ TOP TEN LABORATORY STORIES OF 2012

88305 and Prostate Biopsy Policies Send Message to Pathology Labs

EFFORTS BY MEDICARE OFFICIALS to reduce reimbursement for anatomic pathology services is a major news story for this year. Regarding CPT code 88305, one of the most commonly used codes in pathology labs, the bad news came in two forms.

First, in August, **Palmetto GBA**, the nation's largest Medicare contractor, issued a new policy for Part B prostate biopsies that restricted what labs could bill for these claims.

The effect of this policy was a cap on reimbursement for a 12-core prostate biopsy using code 88305 at about 47% of its former level. However, as of press time, it appears that Palmetto's policy may not stand, for several important reasons. *(See TDR, September 17, 2012.)*

The second attack on 88305 commences on January 1, 2013. On that day, the Medicare program will cut payment for labs billing the technical component on the 88305 CPT code by 52%, while raising the fee for the professional component by 2%. *(See TDR, November 19, 2012.)*

It is possible that both reimbursement policy changes can be revised through effective lobbying by the laboratory industry. That would be good news.

However, such industry wins would not change the significance of this Top Ten Lab Industry Story for 2012. These actions by Medicare carriers and federal regulators are a direct result of growing financial pressure. That is why more budget cuts can be expected.

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➤ TOP TEN LABORATORY STORIES OF 2012

End of TC Grandfather Triggers New Dynamics in Pathology Market

IN AN EXAMPLE of "robbing Peter to pay Paul," last February Congress eliminated what labs call the pathology "TC grandfather provision." This was done to find the funds necessary to pay for the temporary fix to the physician Sustainable Growth Rate formula.

Effective July 1, 2012, independent laboratories could no longer bill Medicare directly for payment for the technical component (TC) of certain surgical pathology services done for Medicare Part A patients. Instead, pathologists had to bill hospitals for these services. *(See TDR, April 23, 2012.)*

What is significant about this story is that the pathology profession had managed, for almost two decades, to gain extensions to the TC grandfather provision. Now, because of the federal government's desperate fiscal problems, Congress is grabbing any source of funds it can to patch the financial crisis of the moment.

This situation is exacerbated by the continuing federal budget deficit that is at record high levels. It means that Congress has a shrinking number of options as it attempts to plug different budget gaps.

For the anatomic pathology profession, we are entering what experts predict will be a grim time. Congress will aggressively pursue every opportunity to cut spending. It is reasonable to expect deeper and more painful cuts to reimbursement for lab testing.

TOP TEN LABORATORY STORIES OF 2012

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Growth Slows for Nation's Two Largest Public Lab Companies

SUSTAINING ADEQUATE LEVELS OF ORGANIC GROWTH in revenue and specimen volume has been an elusive goal for the nation's two largest public lab companies in recent years. Quarterly financial reports throughout 2012 showed the continuing nature of this challenge.

For the first nine months of 2012, **Quest Diagnostics Incorporated** reported a decline of 2.9% and 1.1% in revenue and patient requisitions, respectively, when compared to the same nine months of 2011.

For **Laboratory Corporation of America**, during the first nine months of 2012, there was 2.2% growth in revenue and an increase of 1.3% in patient requisitions, compared to the same period in 2011. Allowing for the contribution of acquisitions during this period, LabCorp executives noted that organic growth was positive for third quarter.

For almost 15 years, the two blood brothers have regularly posted rates of growth that pleased Wall Street investors. Much of this growth came from the strategy of acquiring other lab companies to gain their revenues and specimens.

But, with fewer opportunities to acquire clinical labs and pathology groups, the financial results for the first nine months of 2012 provide an indication that both national lab companies may need different business strategies if they are to perform to the expectations of shareholders and financial analysts.

TOP TEN LABORATORY STORIES OF 2012

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California Labs Sue Health Insurers and Quest for Sherman Act Violations

NOVEMBER SAW THE FILING OF A PRIVATE LAWSUIT with the potential to establish powerful legal precedents in how clinical laboratory companies and health insurers may contract to do business with each other.

Defendants in this case are: **Quest Diagnostics Incorporated, Aetna Inc., Blue Shield of California,** and the **Blue Cross and Blue Shield Association (BCBSA)**. They are accused of conspiring to monopolize and restrain competition for routine, molecular, and specialty testing services in California.

This lawsuit was filed in California in November. The plaintiffs are four independent laboratory companies: **Hunter Laboratories LLC** (Burlingame), **Pacific Breast Pathology Medical Corporation** (Novato), **Rheumatology Diagnostics Laboratory Inc.** (Los Angeles), and **Surgical Pathology Associates** (Los Gatos). *(See TDR, December 10, 2012.)*

The key legal issues in this case center around allegations that the defendants acted to unreasonably restrain competition in violation of federal and California law and that these actions constitute unlawful, unfair, and/or fraudulent business practices under California law.

This is believed to be the first time that a private lawsuit has been filed that raises these specific claims as they pertain to the managed care contracting practices between large labs and big insurers. Thus, a favorable outcome for the plaintiffs could establish new legal precedents.

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➤ TOP TEN LABORATORY STORIES OF 2012

Lab Deficiencies Cause Closure of Small and Rural Hospitals

DURING 2012, MANY SMALL HOSPITALS struggled financially. In some cases, in response to deteriorating cash flow, some of these hospitals failed to adequately fund their clinical laboratories.

The New York State Department of Health (NYSDOH) uncovered two examples of this problem during the past year. One hospital was shut down permanently while the other reopened and continues to operate.

In February, NYSDOH ordered a 30-day closure of the clinical laboratory at the 173-bed **Peninsula Hospital Center** in Queens, New York. In 2011, the hospital had filed a bankruptcy action. The closure order was issued after state inspectors found nine pages worth of deficiencies in the clinical lab. When the bankruptcy court did not okay a restructuring plan, the hospital closed permanently. *(See TDR, March 12, 2012.)*

Another lab closure order was issued in September to 37-bed **E.J. Noble Hospital** in Gouverneur, New York. NYSDOH officials found 14 deficiencies in the hospital's clinical laboratory. Again, reports indicated the hospital had financial problems affecting the clinical lab. *(See TDR, October 29, 2012.)* This hospital later reopened.

There are similar examples of poor laboratory compliance with CLIA requirements at other financially-strapped small hospitals. These are sentinel events that portend tougher times ahead for rural and small hospital laboratories.

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➤ TOP TEN LABORATORY STORIES OF 2012

Lab Market Welcomes Real-Time Management Dashboard Software

ANY NUMBER OF VENDORS NOW OFFER clinical laboratories and pathology groups software solutions designed to deliver real-time information to managers and lab staff.

This is a fast-moving new development. It demonstrates that the nation's more innovative clinical laboratories continue to seek ways to improve workflow and achieve greater productivity.

Further, use of real-time management dashboards is a logical progression for clinical laboratory operations. First came automation of the high volume core chemistry and hematology laboratory. As labs implemented automated solutions, they next began to purchase middleware solutions that help to further automate manual work flow activities. Examples of this are autoverification and managing the movement of specimens through the lab. Call this the second stage on the automation curve.

Today's third stage of automation involves use of middleware solutions to more fully integrate all the information systems within the lab—from the lab information system (LIS) to the billing systems. *(See TDR, June 25, 2012.)*

Call it the stage of "enterprise-wide solutions." These products are laboratory-specific CRMs (customer relationship management) and are capable of giving lab managers continuous and real-time data about workflow in their laboratory, as well as customer service levels.

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TOP TEN LABORATORY STORIES OF 2012

CLIA PT Test Referral Issue Subject Of Newly-Enacted Federal Law

HAVING CONGRESS PASS a legislative fix for one part of the CLIA statute was a significant victory for the laboratory medicine profession this year.

It was December 4, 2012, when President Obama signed into law the Taking Essential Steps for Testing (TEST) Act of 2012. This was legislation intended to provide clarity to the **Centers for Medicare and Medicaid Services** (CMS) in how to interpret the language of the Clinical Laboratory Improvement Amendments (CLIA) that pertain to the inadvertent referral of proficiency testing specimens.

What spurred Congress to act was the fact that nationally-respected laboratory organizations were being hit with severe penalties in response to incidents where lab staff had inadvertently referred a proficiency test (PT) specimen in violation of CLIA requirements.

This summer, CLIA officials sent a sanction letter to the laboratory at **Ohio State University Wexner Medical Center** (OSUWMC) in Columbus, Ohio. In response to the disclosure of inadvertent referral of PT specimens, OSUWMC was told that it would lose its CLIA license and its laboratory director would be barred from serving in this role at any lab for two years. *(See TDR, August 6, 2012.)*

This and similar severe sanctions to other labs motivated Congress to pass the TEST Act in just four months!

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TOP TEN LABORATORY STORIES OF 2012

Is It Serious? National Competitive Bidding Study Published by Medicare

AS A CONCEPT, COMPETITIVE BIDDING for Medicare Part B Clinical Laboratory Testing Services is back again! This time around, the idea is to conduct a national competitive bidding program.

This is an important story. But it seems to have gone unnoticed by many in the clinical laboratory testing industry. The feasibility of conducting a national competitive bidding program was the subject of a study titled "The National Market for Medicare Clinical Laboratory Testing: Implications for Payment Reform."

This was published last spring in the *Medicare & Medicaid Research Review*, a peer-reviewed journal published by the **Centers for Medicare and Medicaid Services** (CMS). The study was conducted by **RTI International, Inc.**, of Research Triangle Park. *(See TDR, September 17, 2012.)*

Authors of the study wrote "In this study, we conduct an empirical analysis of the national Medicare Part B FFS [fee for service] clinical laboratory market, *which could inform future efforts to implement Medicare clinical laboratory competitive bidding* or other payment reforms." *(Italics by THE DARK REPORT.)*

RTI's commission to produce a feasibility study of national competitive bidding shows that certain officials within the federal establishment continue to see this approach as a useful way to reduce what Medicare spends on lab testing. TDR

Price Cuts, Long Delays in Payment Are Expected

Revised policies for molecular CPT codes, prostate biopsies, and 88305 may cause confusion

CEO SUMMARY: In addition to a steep cut in the 88305 CPT code, anatomic pathology laboratories can expect cuts in the payment from Medicare for molecular and prostate biopsy testing. Two national experts in lab billing and reimbursement warn labs to expect confusion in how both public and private payers implement these new policies. Overall, 2013 will be a tough environment when it comes to ensuring full compliance with all the new billing and reimbursement policies for this testing.

EVERY CLINICAL LABORATORY and pathology group faces an uncertain environment for billing and reimbursement during the coming year. That's because labs are poised to be paid significantly less for certain important CPT codes as a result of new polices that take effect on January 1, 2013.

Three primary issues are getting the most attention. But there are associated issues that, if unaddressed, have the potential to trip up laboratories and create unwelcome Medicare compliance violations.

The three policy shifts expected to have a major impact on laboratory finances have been widely reported to date. They are: 1) new molecular diagnostics CPT codes and associated coverage guidelines and prices; 2) price adjustments for surgical pathology tests billed under CPT code 88305; and, 3) prostate biopsy testing.

Further, because some of these policy changes have been challenged by lab industry groups, there is some uncertainty about how the federal **Centers for Medicare & Medicaid Services** (CMS) will pay for prostate biopsy and molecular diagnostic testing. This uncertainty is likely to lead to payment delays and denials, according to lab billing experts.

"What has the full attention of anatomic pathology groups is the sizeable decline in payment from Medicare for tests billed under 88305," stated Donna Beasley, DLM(ASCP). She is the Laboratory Specialty Vice President at **McKesson Corporation's** Revenue Management Solutions.

88305 Payment Decline

"The payment cut for 88305 will come primarily from a reduction of 52% in the technical component (TC) of testing for CPT code 88305, according to CMS," explained Beasley. "Since this new policy will reduce payments by millions of dollars, it is going to have considerable impact on many labs.

"This will happen because CPT 88305 is the most frequently billed code in many anatomic pathology labs," noted Beasley. "It is believed that, at least for some labs, the resulting reduction in revenue may force them to close.

"One class of labs expected to be financially hurt most by the 88305 change

will be in-office pathology labs owned and operated by specialty physicians," stated Beasley. "Examples of these labs are those operated by physician specialists in gastroenterology, dermatopathology, and urology groups. These in-office labs lack the diversity of specimens needed to easily absorb the deep cuts to 88305."

Prostate Biopsy Confusion

Whereas the announced fee cuts to 88305 are relatively straightforward, the situation with new reimbursement policies for prostate biopsies is more complicated. Important questions remain unanswered.

"According to the CMS physician fee schedule (PFS) announced for 2013, it looks like CMS is saying that when labs submit one to four prostate biopsy specimens, they should code with CPT 88305," Beasley said. "And when billing for 10 to 20 specimens, labs should use the G0416 code. This part is fairly straightforward.

"The confusion comes when billing for five to nine prostate biopsy specimens," explained Beasley. "This change in the 2013 Medicare Physician Fee Schedule (PFS) seems to indicate that CMS expects biopsy specimens of five to nine to be coded with 88305, while 10 or more biopsy specimens are to be coded with the 'G' code series.

"This assumption is based on the fact that—with the new G0416 code descriptor—specimens five to nine have no specific direction within the 'G' code descriptors," she said. "The assumption is that 88305 would be used for five to nine prostate biopsy specimens."

How Labs Should Bill

"There has been no further instruction from CMS nor any publications from Medicare contractors on how they will treat these services," added Beasley. "Lacking such instruction, there is likely to be confusion as to how labs should bill for prostate biopsies when submitting five to nine specimens."

Further complicating this situation is the fact that different lab industry challenges have been raised about the new polices for both 88305 and prostate biopsy testing. Labs will need to track the success of multiple lab industry challenges to these revised guidelines.

"Once the new policies were made public, several lab associations immediately stepped forward and challenged the rules regarding how to bill for prostate biopsies and the reduction in fees for 88305," noted Rina Wolf, Vice President of Commercialization Strategies, Consulting & Industry Affairs, for **XIFIN, Inc.**, in San Diego, California. "These challenges may lead CMS to make changes in these policies in the coming months. For that reason, all labs should follow events as they unfold."

New Molecular CPT Codes

Wolf also cautioned laboratories performing molecular diagnostic testing to expect plenty of confusion among payers about how to handle the new molecular test codes. "CMS contractors have been instructed to price the new codes utilizing the 'gap-fill' process," she said. "This is a very laborious process. Some contractors may not be familiar with the tests that are represented and, for that reason, will be delayed getting this done in time for the January 1, 2013, deadline.

"Also, CMS released a Clinical Lab Fee Schedule with zeros in the pricing column," continued Wolf. "That spills over into the private payer sector because private payers often purchase these fee schedules from CMS to use as a basis for their pricing. This likely means uncertainty as to pricing with the commercial payers as well. We have called the private payers, but none had any guidance for us.

"Under the gap-filling method, Medicare contractors determine reimbursement based on local pricing patterns," added Wolf. "Then CMS may use the various regional reimbursement determinations to arrive at a final national reimbursement rate that it would implement in 2014.

"Because the gap-filling process is so complex, it may not be completed by all the contractors on time," she observed. "This could potentially give CMS a reason to delay this policy and have Medicare contractors use the old stack codes to pay labs for molecular tests. Use of stack codes is not ideal for payers because they do not provide transparency.

"For its part, Palmetto plans to use the Z codes or its PTI codes and has received inquiries from other payers about possibly sharing these codes," noted Wolf. "If a delay in implementation of the new molecular codes does happen, CMS and other payers may require labs to submit the new code—if there is one—along with the old stack code. We may even see the use of temporary G codes that are created as an interim pricing fix.

"CMS contractors are obligated to adjudicate claims according to mandated timelines," concluded Wolf. "Therefore, it is imperative for a payment mechanism to be set in place to avoid delays for CMS and for laboratories."

Coding Molecular Tests

Beasley explained the issue further. "At one point it was questionable—but the Z-Code Identifiers associated with Palmetto's MolDx program are in effect and are being continued," said Beasley. "At recent speaking events, Palmetto has publicly addressed key points on this issue.

"The MolDx program is a separate contract between CMS and Palmetto GBA," she explained. "It is therefore separate from the Medicare J1 contract. The Z-Code Identifiers and the McKesson Diagnostics Exchange exist as technology components of the MolDx program.

"Therefore, were Palmetto to lose the J1 contract (which is a possibility but is under appeal and won't be settled for months), the MolDx program would not be affected," she said. "Therefore, coverage policies and edits that use the Z-Code Identifiers and are used in Local Coverage Determinations would remain in effect.

"Palmetto has said publicly that it intends to roll out the MolDx program nationally," added Beasley. "As well, several commercial payers are considering licensing the Z-Code Identifiers."

Payers May Follow CMS

Commercial payers often follow the lead of CMS on such issues, Wolf said. "Once CMS sets its fee schedule, then the **Blues plans**, **Aetna**, **UnitedHealthcare**, **Humana**, **Cigna**, and other commercial payers purchase those fee schedules and load them into their own payment systems.

"The commercial payers then use those fee schedules to create their own allowable rates," she continued. "But if payers purchase the fee schedules from CMS with zeros in the amount column, what will the commercial payers do then? So far, that question is unanswered, which means there could be as many different fee schedules as there are Medicare contractors!

"At present, Palmetto is the only Medicare carrier with a procedure in place to pay for molecular tests," said Wolf. "Another contractor, **First Coast Service Options**, has requested information from labs on how to price molecular tests, but we have not yet seen a payment policy in place. First Coast Service is the Medicare Administrative Contractor (MAC) that serves Florida, Puerto Rico, and the U.S. Virgin Islands.

"All this uncertainty in how CMS and commercial payers will process claims for molecular tests represents a big downside for laboratories," advised Wolf. "That's because many labs have no way of modeling their expected payments for 2013.

"The large national labs, and other labs with commercial payer contracts, are likely to see less impact with the commercial payers because they have contracts in place with assigned payment levels for these tests," commented Wolf. "However, if their contracts are based on a percentage of

When Payment Declines for Certain Tests, Labs Will Need Data on Costs for Each Code

LABS THAT UNDERSTAND THEIR EXACT COSTS for each CPT code may succeed when others fail, said Donna Beasley, Laboratory Specialty Vice President, McKesson Revenue Management Solutions.

"When revenue declines, labs need to understand their per-test costs," said Beasley. "That is an essential element to calculate if you are profitable and are developing a strategic plan to gain market share."

Some industry observers predict that the recent dramatic reductions in the reimbursement for certain pathology CPT codes may cause some in-office pathology labs operated by specialist physicians to close.

"Should specialty in-office pathology labs close, local hospital labs and independent labs may pick up that additional testing. That's why it's essential for a lab to have accurate costs," Beasley said. "When labs don't know their cost for each CPT code, they have no strategy to stay profitable.

"In addition, it's essential to focus on improving revenues and not simply on reducing operational costs," she advised. "Every dollar due to your laboratory must be worked for collection. For hospital outreach labs, this point is often difficult to monitor because typically they use the hospital's central billing office and these systems lack lab-specific reporting.

"Because the hospital's central billing department posts payment at the patient-account level, labs don't see cash collections for each CPT code," she explained. "Understanding profitability at the test level is vital to the fiscal viability of the lab. Developing a strategy as to specific tests to send out and specific tests to keep in house requires this level of business intelligence.

"Also, the hospital's central billing is typically organized by payer and focuses on the high-dollar claims of other specialties," she said. "That means they may write off small balances, such as lower-dollar claims for lab tests.

"When linked to high volume tests, small balance write offs add up quickly," Beasley explained. "In this new reimbursement environment, every dollar will count. Many labs cannot afford to absorb or write off small balances as they do now. Therefore, labs should consider billing solution alternatives that help them collect every dollar that is legally reimburseable."

Medicare rates, they could be impacted and they could certainly see changes in payment for Medicare beneficiaries.

"Remember, we are talking about new molecular CPT codes and not new tests," Wolf noted. "Therefore, any lab that has a contract with a commercial payer that specifies how the lab will be paid for these tests will likely be fine. But most labs do not have such contracts.

"When it comes to getting paid for molecular tests, labs are likely to experience a logistical headache and endure long delays in getting paid," predicted Wolf. "Therefore, we recommend that labs make billing personnel available to answer payers' questions. Also, be prepared for payment denials and delays."

Beasley agreed that CMS will use the gap-fill method, and she acknowledged that it is a less than ideal way to pay claims. "The gap-fill method has not been used often and when it has been used, it has not worked well because there is no consistency from one Medicare contractor to another," Beasley concluded. TDR

—Joseph Burns

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Ascend Clinical Acquires PathCentral Lab Business

➤Both companies intend to partner in delivering testing & informatics services to pathology groups

➤➤CEO SUMMARY: Ascend Clinical and PathCentral see an opportunity to provide sophisticated services to community pathology groups. Ascend Clinical will expand the molecular diagnostic and gene sequencing business it is purchasing from PathCentral. PathCentral will concentrate on marketing its cloud-based anatomic pathology LIS solution and launching a pathology professional network early in 2013. Each company said its goal is to help pathologists nationwide compete more effectively.

SEEKING TO EXPAND ITS MENU of reference and esoteric tests, **Ascend Clinical, LLC**, has purchased the diagnostics laboratory operated by **PathCentral Inc.** of Irvine, California.

This is not a large acquisition when measured by annual revenue. However, it is notable as an example of an emerging trend: that of creating companies focused on offering national reference/esoteric testing services specifically in support of anatomic pathology groups and labs.

The acquirer is Ascend Clinical, of Redwood City, California. Until now, Ascend has been an end-stage renal disease (ESRD) lab testing company serving independent dialysis clinics.

➤PathCentral's Lab Business

Ascend Clinical has acquired the lab testing business of PathCentral. PathCentral keeps its anatomic pathology laboratory information system (APLIS), currently used by 20 of the nation's largest regional and national anatomic pathology labs, along with almost 200 community pathology groups throughout the United States.

Now that the acquisition is complete, PathCentral will continue to operate its pathology informatics services and will focus on further development of its information technology solutions for anatomic pathology labs and group practices. Ascend Clinical will continue to use PathCentral's information technology solutions to provide continuity to existing clients and to take advantage of PathCentral's online tools for TC/PC testing options.

➤Expand Into New Areas

"Our interest in acquiring PathCentral's laboratory business was motivated by our need to expand into other areas of the clinical lab testing market," commented Paul Beyer, who is the CEO at Ascend Clinical. "Currently we have strong market share in serving independent dialysis clinics. At the same time, we've watched the steady growth in molecular diagnostics. That is why acquiring PathCentral's laboratory testing business gives us a good platform for further growth in this market sector."

Beyer observed that the majority of the nation's 3,300 pathology groups are small

PathCentral Uses Cloud Technology as a Way To Level Playing Field for Community AP Groups

PATHCENTRAL WAS FOUNDED IN 2009 by Matt Watson and Dan Angress. Within a year, PathCentral had acquired eTeleNext, a pathology informatics company that had been created in 2002. Its primary product was an anatomic pathology laboratory information system (APLIS).

At the time when PathCentral acquired the assets of eTeleNext, the company marketed its APLIS only as a client-server model. Watson and Angress then developed a cloud-based version of the APLIS. In this form, as software-as-a-service (SaaS), it was a reliable, fast, and low-cost solution for local pathology groups that wanted the capability to handle sophisticated molecular diagnostics and gene sequencing data.

"In 2011, PathCentral added an esoteric pathology testing laboratory," stated Jaye Connolly, PathCentral's CEO. "This allowed PathCentral to offer both esoteric testing and an enhanced APLIS service to local anatomic pathology group practices.

"The beauty of putting the APLIS in the cloud is that it leveled the playing field for community pathologists," added Connolly. "The APLIS did this by providing a scalable and flexible workflow solution at a reasonable cost.

"Many local pathologists provide H&E testing but do not do any molecular diagnostics or gene sequencing," explained Connolly. "One option is to send those tests to some of the larger national labs, but these labs have their own pathologists and they often try to cut out the community pathologists by going directly to oncologists.

"Further, by having our APLIS in the cloud, pathologists who referred specimens to our esoteric lab could request that the technical component and professional component be split, providing another source of revenue and control of the case," she noted. "This pathology informatics solution makes it easy for them to access the data they need in order to sign out the case."

and often lack adequate capital to establish sophisticated in-house testing services. "It takes high-tech analyzers and specialized lab medicine skills to perform advanced molecular testing and gene sequencing," he said. "We see a strong business opportunity in providing those sophisticated testing services to pathology practices nationwide in ways that help local pathologists compete more effectively against larger labs.

"Molecular diagnostics is transforming many aspects of cancer testing and the practice of medicine," noted Beyer. "We think there is an untapped demand to provide advanced molecular diagnostics to the nation's small anatomic pathology practices.

"At the same time, this acquisition also allows Ascend Clinical to diversify and expand its existing test menu to serve this rapidly-growing market," explained Beyer. "Our existing lab specializes in running routine tests and has a national client base. We have a staff of about 200, including 30 software developers. Adding the PathCentral laboratory provides us with more sophisticated equipment and the expert staff to do molecular diagnostics and gene sequencing."

Offering Leading-Edge Tech

For Ascend Clinical, one of the attractions of PathCentral software is its ability to accommodate pathology groups that want to split the technical component (TC) and professional component (PC) of each case. "The referring pathologist can choose to split the work, thereby allowing him or her to bill the professional component or have us do the test globally," said Beyer.

"We know pathologists around the country need to have more esoteric testing done, and we believe they will be interested in using our laboratory," he added. "That's our growth model."

Achieving economies of scale was another factor in Ascend Clinical's decision to purchase PathCentral's laboratory business. "We already have substantial infrastructure in place, so we don't expect there is much we will do differently now that the sale is closed," commented Beyer. "For example, we have the staff, such as billing and administration, which will allow us to operate the new lab assets more efficiently and at a lower cost.

"Further, we have capital to invest if needed," he continued. "It can cost $200,000 to $500,000 just to validate an instrument that may handle only a few samples per week.

"This up-front cost is why it is difficult for local pathology groups to build up in-house capabilities to offer their clients the latest molecular diagnostic assays," added Beyer. "That's another reason we believe there is a need for a national anatomic pathology reference and esoteric testing service."

Assessing Its Strengths

On the other side of this acquisition is PathCentral. It had been a company with two distinct business lines. One business line involves providing an anatomic pathology laboratory information system (APLIS) to pathology groups through its cloud-based solution. The second business line is the clinical laboratory business that is being sold to Ascend Clinical.

PathCentral's executive team was faced with a fundamental question. "We asked ourselves whether our core strength is as a lab testing company or as a technology company," explained Jaye Connolly, PathCentral's new CEO.

"The pathology informatics side of our company is over 10 years old and formerly operated under the company name of **eTeleNext**," Connolly noted. "This was a client-server based APLIS and had a number of big reference labs as clients, including **Clarient**, **Genoptix**, **Genzyme**, and **NeoGenomics**.

"Three years ago, we developed a strategy to make this same APLIS technology available to community-based pathologists via the cloud," noted Connolly. "Our APLIS is designed to link with the lab testing component, making it possible for pathologists to order sophisticated genomic testing with the click of a mouse. However, it also meant we were running two different businesses.

Robust Testing Added

"One was the lab testing business and the other was an information technology company," Connolly explained. "Each business requires substantial capital and specialized staff and each captures market share in different ways.

"That's when we made the strategic business decision to be strictly a technology company," she continued. "A majority of our employees worked in this area. We also recognized that the emerging market in digital pathology would be a strong and ongoing growth opportunity.

"That's why it made sense to divest our esoteric testing laboratory," observed Connolly. "But we wanted the buyer to be a willing partner to help us extend our APLIS to pathologists everywhere.

"We believe Ascend Clinical will be a good long-term partner for us," she concluded. "And we believe community pathologists will be interested in using the services of an advanced molecular diagnostics and gene sequencing laboratory that is partnering with an APLIS company offering a proven cloud-based informatics solution that delivers value to our common customers." TDR

—Joseph Burns

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Preserving Competition Is Goal of Calif. Lawsuit

Plaintiffs' lawyer discusses legal issues involving Sherman Act, Cartwright Act violations

CEO SUMMARY: Once again, the use of deeply-discounted lab test pricing to win exclusive managed care contracts is involved in a court case. However, this latest private lawsuit is different from earlier cases because it seeks to preserve competition in the lab testing and the managed care contracting marketplaces, said an attorney for the four plaintiff labs that brought the case. Citing the Sherman Act and the Cartwright Act, the latest case seeks to preserve competition and stop allegedly unlawful business practices.

BY ALLEGING that a national laboratory company and several national health insurance organizations have violated the federal Sherman Act and California's Cartwright Act, plaintiffs in a recently-filed lawsuit are raising new legal issues that involve pricing and managed care contracting practices that are commonly used by lab companies and health insurers.

It is a lawsuit without precedent in the clinical lab testing industry. That's because one component of this legal case accuses the defendants of having engaged in behavior that violates federal anti-monopoly and restraint of trade laws.

The second component of the lawsuit involves claims that the defendants took actions that constitute unlawful, unfair, and/or fraudulent business practices under California law.

To learn more about the legal strategies of this lawsuit, THE DARK REPORT spoke with Justin T. Berger. He is an attorney with **Cotchett, Pitre & McCarthy, LLP,** and represents the four plaintiff lab companies in this case. They are: **Hunter Laboratories LLC** (Burlingame), **Pacific Breast Pathology Medical Corporation** (Novato), **Rheumatology Diagnostics Laboratory Inc.** (Los Angeles), and **Surgical Pathology Associates** (Los Gatos).

"Antitrust laws were enacted in the United States and in California because it was recognized that healthy competition outweighs whatever benefit there may be from the short-term efficiencies that might result from a monopoly," explained Berger.

Antitrust & Monopoly Issues

"In healthcare, price is an issue, but that does not justify squashing competition," he said. "Monopolies are unhealthy for consumers and the economy."

This lawsuit was filed in the U.S. District Court for the Northern Division of California in San Jose in November. The plaintiffs accused **Quest Diagnostics Incorporated**, **Aetna Inc.**, **Blue Shield of California**, and the **Blue Cross and Blue Shield Association** (BCBSA) of conspiring to monopolize and restrain competition for routine, molecular, and specialty testing services.

Berger and his law partner, Niall McCarthy, represented one of the plaintiffs in an earlier case. In 2005, the CEO of Hunter Laboratories, Chris Riedel, alleged in a whistleblower case that seven California lab companies billed the Medi-Cal program improperly. The defendant labs paid more than $300 million last year to settle the case with the California Attorney General *(See TDRs, April 6, 2009; February 7, 2011; and June 13, 2011.)*

Although some of the alleged market actions are similar to the earlier case, the legal claims at issue in the current lawsuit involve different federal and state laws. "The earlier State of California case focused quite narrowly on the low-price rule and *not* on the issue of preserving competition in the market," said Berger.

"The low-price rule requires providers to give the state [and its Medi-Cal program] the lowest price that they offer other customers for comparable services," he noted. "And that low price is part of an effort to win other business from customers.

Sherman Act Violations

"Our current lawsuit focuses on discounted pricing in the context of how it is used by the defendants in violation of the Sherman Act and the Cartwright Act," he said. "These two laws specifically address competition.

"This latest case also is different in that it has some national implications," continued Berger. "We cited the federal antitrust laws because certain of these business practices affect small and mid-sized laboratories throughout the United States.

"Another issue of this lawsuit also has national implications," he stated. "It addresses the changes the Blue Cross Blue Shield Association has made to the Blue Card program. Even though the Blue Card program changes were only recently implemented, they are having a definite and traceable effect on labs.

"To minimize the negative impact of the Blue Card program changes, laboratories are attempting to get into the networks of Blue Cross and Blue Shield plans in those states where they have patients and referring doctors," said Berger. "But so far, they are not able to gain entry to those networks for reasons described in the lawsuit.

"The results of all the actions we cite is that our plaintiffs have been harmed—and continue to be harmed—by losing accounts and by not being able to get new accounts," Berger said. "That's why we will seek injunctive relief to stop some of the more egregious practices." TDR

—Joseph Burns

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Complaint Alleges Efforts to Cut Labs From Networks

HEALTH PLANS NATIONWIDE are narrowing their provider networks by eliminating some local and regional labs from the panel of contracted providers available to patients. *(See TDRs, April 2, 2012; June 4, 2012; and December 10, 2012).*

Four California clinical lab companies are challenging these exclusionary business practices in a complaint filed in the U.S. District Court for the Northern Division of California, in San Jose. The plaintiffs claim that such actions are in violation of anti-monopoly and restraint-of-trade laws of the U.S. Government and the State of California.

One example alleged in the lawsuit is that Quest Diagnostics persuaded Aetna and Blue Shield of California to terminate the in-network status of Quest's smaller competitors in exchange for Quest offering financial and other incentives. The complaint also describes how Quest and Aetna entered into a contract whereby Aetna agreed to terminate 400 regional contracts across the United States, thus increasing Quest's dominance in multiple markets.

All the defendants have denied the charges of the lawsuit and stated that they will defend themselves vigorously.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It is likely that the latest lab acquisition by **Bio-Reference Laboratories, Inc.** (BRLI) is for the purpose of building its new Hispanic laboratory business, called **Laboratorio Buena Salud**. *(See TDR, November 19, 2012.)* Earlier this month, BRLI announced an agreement to purchase **Meridian Clinical Laboratory Corporation**, located in Miami, Florida. It's a small transaction, with a price of approximately $1.85 million. Meridian was founded in 2000 and 100% of the shares are owned by Maria Acosta. With its acquisition of Meridian Clinical Laboratory, BRLI's Laboratorio Buena Salud gains a physical presence in Miami and South Florida, a region with a large population of Spanish-speaking people.

STERLING BUYS TWO TOX LABS

Sterling Reference Laboratories, of Tacoma, Washington, has acquired two toxicology lab companies. One is **Graham-Massey Analytical Labs, Inc.**, of Shelton, Connecticut. The other acquired lab is **SECON Laboratories** of Worcester, Massachusetts. Sterling is a SAMSHA-certified lab and was itself acquired last April by a private equity firm. These acquisitions demonstrate the heightened interest by professional investors in drugs of abuse testing and testing in support of pain management.

TRANSITIONS

- Ken Cerney is now CEO of **Manhattan Labs** in New York City, New York. He has served in executive roles at **Strand Diagnostics**, **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

- Michael Tarwater is the new Vice President of Information Technology for **Atherotech Diagnostics Lab**, located in Birmingham, Alabama. Tarwater has held executive positions with **MuirLab**, **DSI Laboratories**, and **Impact Information Technologies**.

- **Sonic Healthcare USA** hired Noel Maring for the position of Vice President, Hospital Affliations. Maring's career includes positions with **aLabs**, **PAML**, and **Damon Clinical Laboratories**.

- Mark Mylinski has joined **Saladax Biomedical, Inc.**, of Bethlehem, Pennsylvania, as its Chief Commercial officer. He was formerly President and CEO of **RedPath Integrated Pathology, Inc.**, and held positions at **Ortho-Clinical Diagnostics** and **Veridex, LLC**, both **Johnson & Johnson Companies**.

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DARK DAILY UPDATE

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

...the findings of a study that included lab test data on 200,000 people and suggests that fasting may not be needed for cholesterol testing. The study was conducted by the **University of Calgary** and **Calgary Laboratory Services**.

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That's all the insider intelligence for this report. Look for the next briefing on Tuesday, January 22, 2013.

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