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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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Pathology Groups Respond to Eroding Finances

THESE ARE NOT THE BEST OF TIMES FOR ANATOMIC PATHOLOGY GROUPS. The various Medicare fee cuts enacted in the past couple of years have eroded the financial stability of a substantial number of the nation's 3,300 independent pathology practices and laboratories.

The consequences of eroding finances will become more obvious with each passing month of 2014. That's because the latest round of Medicare fee changes took effect on January 1 and, as the claims from that date forward are settled, pathology labs will be able to calculate the specific revenue decline their group is experiencing as a result of the new Medicare rules, given their test volume and test mix.

What I wanted to call your attention to is the fact that the anatomic pathology profession is now entering the first phase of a major cycle of transformation. The financially-weakest pathology groups will be first to fall. Most often, these will be pathology groups with five or fewer physicians, particularly those associated with a community hospital that is struggling with its own financial problems.

The early news about this cycle of transformation is not positive. Sources from coast to coast are telling THE DARK REPORT how certain pathology groups in their communities are restructuring their businesses. These developments are discussed in more detail in our intelligence briefing on pages 7-9.

However, not all the news is glum. Some pathology groups are actively refocusing their clinical services and business structures to meet the changing needs of hospitals, office-based physicians and payers. For example, I was fascinated to learn about **Spectrum Medical Group**, of Portland, Maine.

This group has 180 physicians and 22 of them are pathologists. Spectrum is a unique business model because it represents other medical specialities, including anesthesiologists and radiologists. This allows it to negotiate a single contract to provide nearly all hospital-based physician services to health systems, hospitals, and other providers in its service region. *(See pages 10-14.)*

The jury is still out as to whether Spectrum's business model will find success in the coming era of integrated clinical care organizations. But Spectrum's existence demonstrates to pathologists everywhere that different business models for anatomic pathology are taking root.

TDR

Clinical Labs Spending Money in New Ways

Five trends can be seen in today's market as labs respond to changes in healthcare system

CEO SUMMARY: In response to the many changes now unfolding in the U.S. healthcare system, labs are investing their scarce capital in different ways. Five trends in lab spending can be identified. They range from expanding the informatics capabilities of a lab organization to acquiring the hottest new diagnostic technologies. For lab industry vendors, some of these trends are welcome and mean more business. But other trends are negative and represent fewer orders.

By Robert L. Michel

MANY LAB ADMINISTRATORS report that the rate of change is accelerating in the healthcare communities and regions served by their lab organizations. Large lab industry vendors affirm this fact.

Lab organizations are reacting to this quickening pace of change in at least five primary ways. These are visible in the form of the strategies and actions clinical labs and pathology groups take to respond to change and keep their lab positioned as a provider of choice for the physicians and hospitals they serve.

In recent weeks, I have participated in several site visits and strategic sessions with a variety of lab industry organizations—both providers and vendors. Collectively, the vendors are serving several thousand hospitals and pathology groups with their products and services. Thus, region-by-region, they see the best and worst of what individual labs are doing to meet the challenges caused by various changes in the healthcare system.

1 TREND ONE

Expanding IT Capabilities

The first interesting trend involves the willingness of lab administration to invest money and management resources to buy and deploy information technology capabilities needed to keep their labs fully-integrated with the information systems of their parent hospitals and health systems.

At the same time, labs are spending the money required to build and maintain

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interfaces external to their parent organizations. Most frequently, this involves both LIS-to-EHR interfaces with their physician clients and interfaces with the health information exchanges in their regions.

The second, third and fourth trends center upon how clinical labs and pathology groups are purchasing and using lab instrumentation and lab automation differently than in past years.

2 TREND TWO

Longer Replacement Cycles

Trend number two is the willingness of labs to extend the replacement cycle for their instrument systems. A lab that traditionally replaced instruments every three years is now stretching that to five years. A lab that typically went five years may now extend that to seven years.

3 TREND THREE

Standardizing Lab Testing Across All System Sites

Trend number three is a bit contradictory to trend two because it represents more sales for the IVD manufacturers. Trend number three is associated with increased activity to standardize laboratory testing across a health system. Thus, in both physician office labs and within system laboratories, there are projects to equip each site with the same instruments and the same test methodologies. A similar thing may be unfolding across all the pathology groups serving an integrated health system.

4 TREND FOUR

Acquiring New Diagnostic Technologies

Trend number four represents another growth opportunity for instrument vendors. During the private strategic meetings and conferences that I attended in recent weeks, there was a consensus that many labs are generally willing to invest in new diagnostic technology that advances their clinical mission and may contribute to reduced costs and improved productivity.

Several examples were regularly mentioned. Automation in microbiology is an active segment of the lab instrument market. Similarly, there is growth in the number of labs acquiring mass spectrometry instruments, including MALDI-TOF systems. There is a willingness to invest in these new diagnostic technologies because they help labs deliver added value to clinicians, thereby improving their competitive position.

5 TREND FIVE

Use of Business Intelligence Software Solutions

The fifth trend can be called "business intelligence middleware." In the past few years, various companies have entered the lab marketplace with software products and services designed to give lab managers detailed data on lab operations, customer service performance, and financial metrics. These vendors offer solutions that allow lab managers to build customized dashboards that allow them to manage their lab's performance in real time.

Several of these vendors have enjoyed a steady increase in the number of lab customers who use their services. This demonstrates that—even during a time when budgets are shrinking and money is tight—smart lab administrators will invest scarce capital dollars when they believe an ample return on investment will result.

Investing In Their Labs

These five trends demonstrate that, across the entire lab testing industry, a significant number of laboratory organizations continue to invest in their business in order to maintain their clinical quality while positioning themselves as added value providers for their clients.

What is noteworthy is that their investment dollars are going into different priorities today than, say, three years ago. That is a rational response to shrinking lab budgets. These trends will be the topic of sessions at the upcoming *Executive War College* in New Orleans on April 29-30. TDR

Molecular Update

Better Data Needed to Support Pathologists as Consultants

MULTIPLE TRENDS ARE UNFOLDING that mutually reinforce the need for pathologists and PhDs to be experts and consultants in how physicians order and follow up on molecular diagnostics assays and genetic tests.

"Healthcare in the United States is approaching a tipping point that can greatly favor pathologists and PhDs as specialist consultants," observed Katherine Tynan, Ph.D., President of **Tynan Consulting LLC**, in San Francisco, California. "Today, treating physicians are being overwhelmed by the rapid advances in genomics and molecular medicine. They cannot stay up with all the changes to the state-of-the-art diagnostic tools in their specialty."

Tynan is a strategic consultant for diagnostics companies. She is engaged in developing the evidence needed to demonstrate the clinical utility of new molecular and genetic tests to physicians and payers.

"At the moment, payers are struggling to decide whether to cover these tests and how much to pay for them," noted Tynan. "At the same time, both physicians and patients are aware of these new diagnostic tests and they want information to guide clinical decisions.

"All of this is happening as the U.S. healthcare system is moving away from fee-for-service reimbursement," she continued. "The emerging new reimbursement models are centered around rewarding providers for value, bundled payments, and capitated or per-member-per-month payment—all based on outcomes rather than process steps.

"Thus, there is urgency for the laboratory medicine profession to step up and assert its role as the expert and the consultant in how diagnostics tests are ordered and used by clinicians," stated Tynan. "Pathologists and PhDs have a compelling argument to make that they are best-qualified to be consultants to physicians—and that the healthcare system needs to compensate them for this consultative role."

Tynan is not the first to make this argument. Pathologists have regularly asserted this point. But Tynan said that the time of opportunity for pathologists and PhDs to successfully make their case will be a short one, noting that "pathologists should take some cues from how other cognitive specialist physicians are establishing their value propositions as consultants who should be rewarded for that expertise with Medicare, private health insurers, healthcare administrators, and other physicians.

Explaining Value To Payers

"For example, infectious disease specialists are in a similar situation in that they too—like pathologists and PhDs—are working to explain the value of their work to payers, patients, and other providers," explained Tynan. "Pathologists and infectious disease (ID) doctors consult with other providers and so they are unlike proceduralists who get paid for each procedure they do.

"Last fall, I attended *ID Week* in San Francisco, which is a joint meeting for ID physicians, pharmacists, and others in the field," she said. "The **Infectious Diseases Society of America** (IDSA) recently retained consultants to help develop health economic arguments to justify their services. The results of the study give the IDs an opportunity to get politically active within their institutions.

"The activity-based payment system currently used in the United States healthcare system rewards physicians doing procedures disproportionally relative to those who are cognitive specialists, such as those in endocrinology and infectious disease," continued Tynan. "Recognizing the need for data that would demonstrate their value proposition as cognitive specialists, the IDSA undertook a project to obtain objective data about the value ID physicians bring to patient care.

"The results of the study will be useful for the IDSA and for the infectious disease physicians themselves for years to come," she noted. "By contrast, pathologists and the PhDs running molecular and genetic testing laboratories have not yet come together to fund and conduct a comparable study that would provide data that supports their value as cognitive specialists.

Right Discussions

"Yes, there are some diagnostic testing companies, such as **Clarient** and **Genoptics**, that communicate effectively the value of their professional services, but they do this as an integrated part of their differentiated service offerings," explained Tynan. "These are the right discussions to have in laboratory medicine, but not enough of them are happening, at least not yet.

"The challenge is that pathologists have always measured themselves on revenue, which works in an activity-based payment system," Tynan explained. "But it doesn't work in the new healthcare world into which we are evolving.

"Last year we saw what happened when the Medicare program introduced the new molecular CPT-codes system and that turned into a test by test coverage discussion with the payers," she added. "Now, molecular labs are being paid even less than they were under the old system and for far fewer tests.

"So, in conclusion, my recommendation to those pathologists and molecular geneticists who see the writing on the wall, is to work internally on the value of molecular testing," urged Tynan. "The profession of laboratory medicine must get hard data in front of physicians, administrators, and payers because healthcare today is data-driven." TDR

—Joseph Burns

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ID Study Presented Value of Cognitive Specialists

According to Katherine Tynan, Ph.D., a strategic consultant for diagnostics companies, to demonstrate their value as cognitive specialists, pathologists and PhDs should borrow a page from the infectious disease physicians.

Initiated by the Infectious Diseases Society of America (IDSA), a study designed to show the value of infectious disease (ID) physicians was published last year in *Clinical Infectious Disease*.

"Using administrative fee-for-service Medicare claims data, the researchers identified Medicare patients who were hospitalized in 2008 and 2009 and who had at least one of 11 infections," said Tynan, President of Tynan Consulting LLC. "This was a large study in which the researchers identified 101,991 inpatient stays with ID interventions and 170,336 stays without ID interventions.

"When the ID physicians intervened in these cases, the patients had significantly lower mortality and readmissions compared with those cases in which there was no ID physician intervention," she said. "The researchers reported improved patient outcomes when ID specialists intervened, and early interventions were associated with reduced costs for beneficiaries with certain infections."

The journal, *Clinical Infectious Disease*, published an article on the study, "Infectious Diseases Specialty Intervention Is Associated with Decreased Mortality and Lower Healthcare Costs," online September 25, 2013 (doi:10.1093/cid/cit610).

Anatomic Path Business Faces Uncertain Future

Payer cuts to pathology reimbursement and hospitals buying medical groups are key factors

CEO SUMMARY: There's a day of reckoning on the way for the traditional business model of the private pathology group practice. At most risk are smaller pathology groups that typically have five or fewer pathologists. Blame it on the reduced prices that Medicare and private insurers are paying for pathology services. Another factor is the trend of office-based physicians selling their medical practices to hospitals and insurers. The pathology profession is poised for a new cycle of consolidation.

NOT SINCE THE MID-1990S has the private practice business model of anatomic pathology seen such competitive market pressures as in the last 30 months.

At that time, it was the entrance of national pathology lab companies like **Dianon Systems**, **Impath**, and **UroCor** that disrupted the private practice business model of pathology. Organized as national pathology companies, from the mid-1990s forward, they took business away from local pathology groups by sending in their national sales teams to scoop up specimen referrals from office-based specialist physicians in communities across the nation.

This time around, changes to the pathology marketplace are being triggered by the Medicare program and private health insurers. In recent years and as a result of their repeated and collective actions, public and private payers have substantially reduced the payments earned by anatomic pathology labs and group practices. These changes range from the elimination of the TC grandfather clause in 2012 and the substantial reduction in Medicare reimbursement for CPT 88305-TC in 2013 to the new Medicare coverage guidelines and prices that became effective on January 1, 2014.

Similarly, the coverage decisions and prices posted during 2013 for the new molecular test CPT codes by the Medicare administrative contractors represent substantial reductions in payments for many molecular tests. These coverage and pricing decisions are often mirrored by private health insurers, thus compounding the negative financial impact of this situation for a large number of pathology groups and lab companies.

Shrinking Path Revenue

At the same time that payers are reducing what they pay for anatomic pathology services, another trend is reinforcing the revenue shrinkage seen at many pathology groups. Over the past eight years, a substantial number of office-based physicians have sold their medical practices to hospitals, health systems, and health insurers.

Post-sale, pathology groups can lose the specimen referrals from these office-based physicians. That is because the new owners of these physician groups frequently redirect the pathology specimens to their favored anatomic pathology lab providers.

Each of these marketplace dynamics is a contributing factor as to why a sizeable number of private pathology group practices in communities across the nation are experiencing significant reductions in revenue and operating margins.

Widespread Financial Pain

This financial pain is widespread. Pathology groups large and small throughout the United States report significant decreases in the amount of money they now collect for the same volume of surgical pathology services and molecular/genetic testing. In some cases, the revenue drop has been dramatic and has caused some lab companies to close their doors. *(See TDRs, May 28, 2013 and July 18, 2013.)*

THE DARK REPORT is hearing from pathologists and pathology practice administrators throughout the United States and they have a common problem. They say that the revenue decline at their laboratories has been so rapid and deep that it now costs them more money to provide some anatomic pathology services than the amount they are reimbursed by government and private payers.

Moreover, most of these anatomic pathology groups have yet to identify a viable strategy for coping with the decreased payment they receive for certain significant anatomic pathology services. That also includes developing a new business model they can use to deliver value and maintain financial stability.

Pathology Advisors Agree

These facts are affirmed by pathology consultants and attorneys with longstanding connections to the pathology profession. They acknowledge that a growing proportion of their pathology clients are actively considering radical business options in response to shrinking revenue and declining profitability.

These business options run the full spectrum of possibilities. One of the most common actions being reported is the reduction in the number of pathologists employed by a group. With revenue shrinking, these pathology groups are taking the opportunity to release the less productive pathologists in their group practice.

Pathologists who were considered average contributors in terms of productivity and/or revenue generation are finding that their partners don't want to renew their contracts. One consequence of this situation is a definite increase in the number of pathologists seeking jobs at this time.

Some pathology groups that own a technical laboratory are exploring how to sell the lab to an interested buyer. But it is a situation where there are many sellers and few buyers—at least not at a purchase price that the selling pathology group is willing to accept. Therefore, this strategy is not working for these lab sellers.

Best Business Strategy

In response to these developments, pathology groups are looking for the right business strategy or some type of exit plan. Their pathologists and practice administrators want to take action before the current market value of their pathology group or laboratory is eroded by further reductions in revenue.

However, today's anatomic pathology marketplace is a tough environment. There are few buyers for a pathology practice and those buyers are refusing to pay prices that the selling pathologists deem as acceptable.

It is also true that smaller pathology groups—as measured by revenue and the number of pathologists—have fewer restructuring options. These pathology groups lack the economies of scale, a broad base of clients, and the range of subspecialty expertise that would make

them an attractive acquisition or merger candidate for any pathology super-practices located within their regions.

Given the realities in today's pathology market described above, THE DARK REPORT predicts that the pathology profession will soon see a cycle of mergers and consolidations. However, this consolidation cycle will be different than those seen in the last two decades.

Cycle Of Consolidation

The pathology profession is likely to see smaller—and financially weaker—pathology groups seek to merge with the stronger pathology groups in their community. Little money will change hands in these transactions. Rather, the smaller group will be happy to fold itself into the larger group and gain whatever additional financial security results from being part of that larger laboratory operation.

Remember that there are thousands of private pathology practices in the United States that have five or fewer pathologists. These smaller groups lack the financial staying-power to survive the ongoing reductions in revenue that both Medicare and private payers are pushing down on anatomic pathology.

In fact, should the nation's smallest pathology groups delay action on restructuring their business affairs, they are likely to end up in either a Chapter 7 or a Chapter 11 bankruptcy. Certain pathology vendors have told THE DARK REPORT that, over the past 24 months, they have lost customers through Chapter 7 bankruptcy actions—something that these vendors have not seen in prior years.

Less Money, Less Time

These predictions are based on a reasonable interpretation of market forces that are clearly visible today. The window of opportunity for smaller pathology groups to reposition themselves is growing smaller as payers continue to reduce what they pay for pathology services. TDR

Aurora Diagnostics: It Shares Industry Woes

BECAUSE MOST PATHOLOGY GROUP PRACTICES are privately held and do not regularly report their financial earnings, it can be difficult to obtain objective information about the state of the anatomic pathology marketplace.

However, there is one pathology company that does report its quarterly financial performance because its debt is held by the public. That is **Aurora Diagnostics, Inc.**, of Palm Beach Gardens, Florida. Founded in 2006, it has acquired and currently operates about 20 community pathology practices in 12 states.

In its public financial filing for the third quarter of 2013, Aurora Diagnostics reported a decline in revenue of 10.5%, from $69.4 million Q3-2012 to $62.1 million in Q3-2013. Similarly, for the full nine months of 2013, Aurora Diagnostics' revenue declined 12%, from $211 million to $186 million.

Aurora stated that its average revenue-per-accession through September 30, 2013 "was approximately $114, down from $128 in the quarter ended September 30, 2012." This is a decline of 11% .

Company officials attributed this decline "primarily to Medicare reductions, including changes to the 2013 Fee Schedule and sequestration, as well as lower reimbursement from private insurance, the BlueCard program, and a change in service mix."

As a side note, for those watching the collapse of the business of providing lab testing to nursing homes, in this filing, Aurora explained that it had sold a clinical laboratory business in August 2012. This business served primarily nursing homes and long term care facilities. Aurora said that, for the "three and nine months ended September 30, 2012, the discontinued operation had net revenue of $0.8 million and $3.8 million, respectively, and net losses of $0.3 million and $2.2 million, respectively."

Meeting the Changing Needs of ACOs, Medical Homes, and Hospitals

Maine's Spectrum Med Group Offers Multiple Specialties

CEO Summary: ***Pathologists looking for a viable future in a healthcare system marked by integration of clinical care and value-based reimbursement will be interested to learn about Spectrum Medical Group based in Portland, Maine. This 180-member multispecialist group includes 22 pathologists (but no primary care physicians). It has found a way to serve ACOs, health plans, hospitals, and patient-centered medical homes by providing a variety of specialist physician services.***

MANY PATHOLOGISTS AND LAB DIRECTORS today are considering how they can become part of accountable care organizations and patient-centered medical homes.

This is a fundamental question of business strategy for pathology groups. Healthcare is moving toward integrated care organizations and away from fee-for-service reimbursement. Thus, every pathology group practice in the United States is confronted by a basic clinical and financial survival issue.

Currently there is no obvious organic way for anatomic or clinical pathology groups to become part of ACOs or PCMHs without getting an invitation to participate from the ACO administrators or the PCMH's primary care physicians.

But in Maine, **Spectrum Medical Group** has found a way to include pathologists in traditional and non-traditional contracting arrangements with hospitals, health systems, ACOs, and PCMHs, said David Landry, Spectrum's CEO.

Formed in Portland, Maine, in 1996, the Spectrum Medical Group is an organization of 180 specialty physicians in Maine. The group contracts with hospitals, health systems, other physicians groups, and third-party payers.

"Our group has no primary care physicians," emphasized Landry. "Instead, it has hospital-based specialists: anesthesiologists, radiologists and pathologists along with office-based groups such as physiatrists, radiation oncologists, neurologists, and surgeons.

"Upon Spectrum's formation in 1996, it was comprised of two anesthesia groups, two radiology groups, and a pathology group," continued Landry. "Today we have 11 practices. All practices operate under one corporate identity but participate in what I call a federated governance structure. By that, I mean each group has local control of its practice."

"Several years ago, Spectrum decided it would not get involved in adding primary care physicians," he stated. "Rather, it would develop the capability to plug into existing primary care groups or health systems as they develop their own strategies—whether they are ACOs, PCMHs, or other contracting entities.

"One of our key strategies is to develop what we call a 'plug and play specialty solution,'" Landry noted. "This allows us to go to any ACO being developed with an offer to deliver a range of specialist-physician services customized to its needs.

"We simply plug into that ACO and deliver the specialty physician services—including pathology—that they want," he said. "The beauty of the plug-and-play strategy is that it allows us to contract with other ACOs as the opportunities arise.

Plug-And-Play Service

"Two examples show the interest in our plug-and-play service," added Landry. "We are currently speaking with a primary care group in southern Maine that wants us to plug in as their ACO partner to deliver all the specialty services that we offer. At the same time, we are having similar conversations with a big hospital system that is developing an ACO.

"Our value proposition to hospitals, health systems, ACOs, PCMHs, and others is that we can deliver high quality services at a lower cost than these organizations could do if they built their own network of specialty physicians," emphasized Landry. "So far it has been successful. We have not been displaced out of any relationship because a primary care group wants to in-source its pathology services or a hospital decides it can do it better if it controls these services."

At this time, the majority of Spectrum's pathology services are still delivered in support of hospitals. "Most of our pathology work is based in hospitals," stated Landry. "By that I mean that our 22 pathologists work in eight or nine different hospitals. Most of these hospitals have their own internal labs—both clinical and histology labs—where our pathologists work.

"Spectrum's 22 pathologists represent about 50% of all pathologists in the state," he added. "They do about two thirds of all the anatomic pathology work in Maine and about 50% of the clinical pathology work in the state.

Cross Border Services

"In addition to serving eight or nine hospitals in Maine, we also do work in New Hampshire at several hospitals, and in Massachusetts at **Anna Jaques Hospital** in Newburyport," he noted.

"Some days we send pathologists to be onsite at Anna Jaques Hospital," Landry continued. "We will also transport specimens from that location up to our subspecialist pathologists, depending on the need and the case involved. For all of the hospitals Spectrum serves, it does a combination of hospital-based work and outpatient work.

"Of course, we contract with commercial labs, such as **Quest Diagnostics Incorporated** and **Converge Diagnostics** in Walpole, Massachusetts, which is now part of Quest," stated Landry. "We also have a partnership with **Aurora Diagnostics**, based in Palm Beach Gardens, Florida, for outpatient work done in physician offices. Aurora does the technical component and we do the professional component.

Lab Relationships

"Because we do not own clinical pathology or anatomic pathology labs, we work out of the laboratories in other facilities, such as hospitals," he explained. "Spectrum also has relationships with third-party labs where our pathologists serve as medical directors and we have several joint-venture business relationships with third-party labs."

At this time, most of the pathology services Spectrum provides to its client hospitals are done in a traditional arrangement. But Spectrum—because of its regional coverage and its subspecialist pathologists, is already in the early stages of operating a distributed, regional pathology service. Regardless of where the tissue is processed, the glass slides or images will be sent to the appropriate subspecialist-pathologists, wherever they are located.

"Yes, in a traditional arrangement, our client hospitals outsource the physicians staffing to us, and we deliver that service," noted Landry. "However, we have multiple value propositions for our clients.

"For example, if it is a smaller hospital, Spectrum will offer to put someone onsite a couple days a week to be the medical director of the lab and to manage the clinical laboratory," he explained. "We can then send the anatomic pathology work originating at that hospital to our subspecialist-pathologists wherever they are around the state.

Specimens Shipped Out

"We ship pathology specimens everywhere—depending on the site of service and the specific subspecialist pathologist who will to review those specimens," added Landry. "That way we can leverage our subspecialty physicians to best advantage.

"If it's a dermatopathology case, it goes to our dermpath," he continued. "If it's a breast case, it goes to our breast pathologist, and so on. We have coverage in most of the major subspecialty areas: gynecology, genitourinary, gastroenterology, and breast. Plus, we have five hematopathologists. In terms of subspecialties, we are well diversified.

"As a result of having these subspecialists, we can deliver high quality specimen review and better turnaround time than any other group and we can do it at a lower price than others can do it," he said.

"In Maine, our pathology group is the largest," added Landry. "We compete against one other group, **Dahl-Chase Pathology Associates,** in Bangor."

Dahl-Chase has 13 pathologists. It provides anatomic and clinical pathology

Various Settings for Pathology Work Require Spectrum to Use Different Payment Structures

FOR SPECTRUM MEDICAL GROUP, payment for its speciality physician services is as varied as the types of contracting arrangements it has, says CEO David Landry.

"By working in different settings, such as hospitals, ACOs, patient-centered medical homes, and others, the question of how we get paid needs to be addressed each time," he said. "Like most other groups, we contract directly with Medicare, Medicaid, and with commercial health plans. In those contracts, we have a whole range of payment arrangements. These include traditional fee-for-service payment and various forms of risk-based contracting with health plans.

Pathology Services

"In pathology, our typical hospital-based relationship involves a services agreement contract to provide the pathology services or to be the medical director of the clinical lab or both," explained Landry. "We also provide other services to these hospitals as needed. For example, our pathologists offer teaching services to residents in certain hospitals.

"For all of the clinical services, which are primarily anatomical pathology services, we bill directly to patients and to third-party payers," he stated. "The hospital might provide some compensation for certain services we provide that are not related to patient care and, of course, the hospital pays us if we serve as the medical director of the clinical laboratory.

"In most of the reimbursement arrangements we have, we pay our physicians on a fee-for-service model," Landry noted. "We also do earn capitated reimbursement from certain health plans. We track the utilization of various services, whether it's pathology or other specialty physician services.

"We then distribute the payment using fee-for-service combined with some type of relative value measurement and a factor that recognizes quality improvement or utilization management," he continued. "We also compensate pathologists for their work in developing algorithms in the clinical lab or for conserving blood if they work in the blood bank. Those fees are pulled out of the capitated payments that are made to Spectrum."

and subspecialists in breast pathology, cytopathology, dermatopathology, gastrointestinal pathology, genitourinary pathology, hematopathology, molecular pathology, and transfusion medicine.

"Here in Maine, there are still hospitals that employ pathologists directly and there are a few small pathology groups that still work with hospitals as we do," observed Landry. "But no other arrangements like ours can be found in Maine.

"As a group, Spectrum is completely specialist driven. In that way, we are different from other multi-specialty groups—in part because we have no primary care physicians," he stated. "Instead, we have both the traditional hospital-based physician groups as well as outpatient practice groups.

"Each group of specialists is an operating division and produces its own profit and loss statement every year," added Landry. "Also, each group has autonomy over the usual issues that concern physicians.

Physicians Have Autonomy

"In pathology, for instance, pathologists make the decisions about staffing, compensation and call schedule," he stated. "If the pathologists want to contract or provide certain services to a hospital, they make that decision. In those cases, we will facilitate the execution of the contract from the corporate perspective.

"In some hospitals, we just have one of our physician specialties and in other hospitals we have multiple specialties,"

observed Landry. "It should be noted that, when we have multiple specialties in one hospital, Spectrum will have a single contract with that hospital.

Improving Stickiness

"One competitive advantage to having many different types of specialists is that we can offer a variety of services to any hospital," he said. "About 10 years ago, Spectrum was invited to provide radiology services to a hospital with which we had no previous affiliation. After some time, the administration was pleased with our work and invited us to solve a problem the hospital had in the pathology lab. That was easy for us to do.

"Many times since then, we have seen this happen: We provide one specialty service to a hospital and then the hospital asks about other services we provide," noted Landry. "As a strategy, the more services we can deliver to each hospital, the more stickiness it creates for us. And that's one key to our ongoing success."

Model of Integrated Services

Pathologists should not overlook the clinical and financial success of Spectrum Medical Group over its 18-year life. At a time when healthcare is evolving away from the traditional clinical silos and toward various models of integrated clinical care, Spectrum is offering multiple clinical services via its own integrated organization.

Private pathology group practices, particularly those with just a handful of physicians, will find it increasingly difficult to offer ever-more sophisticated diagnostic services while maintaining financial stability. One viable strategy is for pathology groups to consolidate into larger regional groups or find new collaborators, such as the specialist physicians have done at Spectrum Medical Group. TDR

—Joseph Burns

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Specialty Physicians in Maine First Came Together in 1996

FOR DAVID LANDRY, marketplace defensiveness and serendipity were behind the 1996 formation of Spectrum Medical Group.

"When Spectrum first launched in the 1990s, that was during the first wave of managed care," recalled Landry, who is Spectrum's CEO. "All of our physicians saw what was happening in the nearby Boston market. They noticed that traditional health insurance was giving way to managed care.

"At that point, our specialty physicians realized that—if they were going to be relevant in a managed healthcare marketplace—they had to either negotiate with managed care companies or establish their own systems and just get bigger," he explained. "At the time, there were two independent conversations going on simultaneously about mergers involving two radiology groups and two anesthesia groups.

"When they discovered those conversations were occurring independently, the physicians decided to all join together as a collaborative," continued Landry. "That was the serendipitous spark that formed Spectrum. Later a pathology group joined our group.

"Today we see similar arrangements starting to pop up in other regions," he said. "We know of specialist physician organizations like ours that are in talks about forming in New Hampshire, Philadelphia and Chicago.

"When asked to explain our business model, I describe it as either a collaborative specialty care organization or as plug-and-play specialty physician services firm that is available to a range of customers, including hospitals, health systems, health plans, and primary care groups," concluded Landry.

Spectrum's 180 physicians include specialists in the following areas: anesthesiology, medical rehabilitation, neurology, pain management, pathology, radiology, radiation oncology, and surgery.

Acquisition Update

Quest Gets Into Wellness By Acquiring Summit Health

An early example of how the national lab companies may use acquisitions to diversify their revenue base

IT IS NO SURPRISE THAT THE NATION'S largest laboratory companies are looking for new revenue opportunities now that fee-for-service payment for lab tests is soon to end.

One striking example of this trend was the move last week by **Quest Diagnostics Incorporated** to acquire **Summit Health,** a company in Novi, Michigan, that provides on-site illness prevention and wellness programs for employers. Neither party disclosed the terms.

Summit Health uses a network of nurses to staff on-site wellness programs for employers, health plans, retail clinics, and other organizations. In its press release about the purchase, Quest stated that, in these clinics, nurses do biometric and other health screenings primarily by finger stick specimen collection. They also provide immunizations, wellness coaching, and conduct educational seminars.

In its work providing on-site wellness programs, Summit Health sends nurses to client companies' offices to test cholesterol, blood pressure, and body mass index levels of employers. The nurses also have workers complete a health risk assessment survey.

Some useful analysis of the deal came from Amanda Murphy and J.P. McKim at **William Blair & Company LLC** in Chicago. "We estimate Summit Health generated revenue of roughly $50 million in 2012 and $80 million in 2013 (60% growth)," Murphy and McKim wrote. "We project it to generate revenue of $100 million in 2014 (25% growth), adding 1% to Quest's revenue growth annually."

Summit's growth is driven in part by provisions in the Affordable Care Act, which provide incentives to employers to establish wellness programs.

Estimated Purchase Price

"Assuming Quest paid somewhere between 2.0 times and 2.5 times 2014 revenue (which seems reasonable given higher growth rates of Summit and historical lab multiples), that implies a purchase price of $200 million to $250 million," Murphy and McKim added.

"We believe Summit has roughly 175 full-time employees and 100 to 150 temporary workers," they wrote.

Interestingly, Murphy and McKim noted that the Summit deal was announced one day after Quest Diagnostics completed its acquisition of **Solstas Lab Partners Group**, a commercial laboratory in Greensboro, North Carolina. Quest paid $570 million for Solstas.

"Quest is trading at 13.2 times next-12-months' earnings, above its three- and five-year averages of 12.6 and 12.7 times, respectively," Murphy and McKim wrote. "The acquisitions (of Solstas and Summit Health) play into our thesis that a tough operating environment for labs, especially on the reimbursement front, will drive consolidation in the space to low-cost providers, Quest and LabCorp, particularly as larger labs seek top-line growth."

TDR

Eastern Canada's Latest Lab Errors Get Attention

Breast cancer testing under scrutiny again after nine patients need new treatment plans

CEO SUMMARY: Authorities for Eastern Health in Newfoundland and Labrador province in Canada are conducting a root cause analysis after finding discrepancies in breast cancer testing that affected nine patients. Health officials said these cases were discovered as a result of an improved quality assurance testing program and are unrelated to problems that plagued Eastern Health labs between 1997 and 2005 when 386 patients received wrong results for hormone receptor testing.

ERRORS IN BREAST CANCER TESTING at the **Eastern Health** pathology lab in St. John's, Newfoundland, have generated news headlines in the province and nationally across Canada. This is the same health region that mishandled breast cancer testing between 1997 and 2005.

This situation is a reminder to all pathologists and lab executives that public trust in the accuracy of lab test results is essential for a lab organization to stay in operation.

The story has elements of both bad news and good news. The bad news is that, for breast cancer testing done at the St. John's lab between April and December, 2013, discrepancies were discovered in the test results reported on some patients.

The good news is that the new procedures and improved quality control/quality assurance protocols instituted after the lab's earlier problems were uncovered in 2005 had a role in the discovery of these recent test problems. As a result, the number of lab test errors was limited and notifications of the test problems were sent to both the patients who were affected and their physicians.

Because of the lab test errors, nine patients with breast cancer were treated with Herceptin, but a review of their test results by an outside laboratory suggested that they were in fact negative for overexpression of the Her2. Eight of the nine patients had begun treatment because of physicians believed these patients had aggressive cases of breast cancer, provincial health authorities stated.

Discrepancies Were Found

After discrepancies were found and retesting was done early this year, the health authorities changed the treatment for these nine patients and apologized for mischaracterizing their test results.

In a press conference on February 13, officials at Eastern Health said these cases were discovered as a result of quality assurance testing and are unrelated to problems that plagued Eastern Health labs between 1997 and 2005. That was when 386 patients received wrong results for hormone receptor testing. Some of those patients possibly died as a result of a lack of proper treatment.

Those 386 cases of wrong breast cancer test results led to an extensive investi-

President of Canadian Association of Pathologists Weighs in on the Issues at the St. John's Lab

MUCH HAS CHANGED IN LAB TESTING at Eastern Health's St. John's laboratory since the Cameron Inquiry in 2009 identified extensive problems with breast cancer testing during the years 1999 through 2005. A more rigorous program of quality assurance (QA) and quality control was implemented.

"Changes have been made to the funding of pathologists and the testing system, along with the level of transparency in the system," stated Martin J. Trotter, M.D., Ph.D., President of the Canadian Association of Pathologists and a Professor in the Department of Pathology and Laboratory Medicine at the **University of Calgary**. "In addition, a comprehensive quality-assurance program was added since the 2009 inquiry. Pathology quality programs in Newfoundland have improved at least 100%.

"What's different in this most recent episode at the St. John's laboratory is that these latest errors were discovered as part of a quality assurance process, as all labs do now," Trotter explained. "The laboratory participates in several external quality assessment (EQA) programs and discrepancies were discovered on one of these external tests.

"That QA assessment was done specifically to assess performance of the Her2 Dual *in situ* Hybridization (DISH) tests that the Eastern Health lab has been running," he said. "These chromogenic ISH slides are difficult to interpret, with considerable interobserver variation.

"The external quality assessment suggested that two cases that were interpreted by Eastern Health pathologists were discrepant with the reference lab result," stated Trotter. "A review of testing protocols was recommended, and, on a subsequent EQA challenge, further retesting was advised.

"Eastern Health requires labs to participate in quality assessment, and the QA process quickly identified a potential issue," noted Trotter. "A review of assay protocols demonstrated that there were no technical problems with tests. The issue seems to have been interpretative variability. These EQA cases are often very challenging and not straightforward.

Discrepant Test Results

"Our position at the Canadian Association of Pathologists (CAP-ACP) is that—when pathologists participate in quality assurance activities—policies and procedures need to be in place to define the actions to be taken if test results are discrepant," added Trotter. "The CAP-ACP position is that a lab should make sure its processes are complete and accurate, then retest a subset of cases within a recognized EQA program.

"Unless a systemic problem is discovered after a root cause analysis, then retrospective review of patient cases is not the correct approach to EQA discrepancies," observed Trotter. "I don't know of any lab that would retrospectively review 100% of patient cases. The correct approach is to continue with all components of the Newfoundland quality assurance programs, including EQA testing, continuing medical education, and continuous improvement processes."

gation called the Cameron Inquiry in 2009. It was conducted by Margaret Cameron, a Supreme Court judge in the province.

The inquiry's report cited numerous flaws in lab testing procedures in Eastern Health and resulted in extensive changes in Eastern Health's pathology laboratory processes and administration. *(See TDR, May 18, 2009.)*

Although the recent cases involve breast cancer treatment just as the cases that led to the Cameron Inquiry did, the recent errors were different from those that occurred from 1997 to 2005, reported Barb Sweet in the St. John's *Telegram.*

Here's what unfolded: On December 9, the quality assurance initiative of the Laboratory Medicine Program at Eastern Health identified a discordant test result between a result produced by the Eastern Health lab and the result done by an outside quality assurance lab.

Additional Testing

A quality assurance review of 68 cases done between April and December indicated the need for additional testing, and of these tests, 34 required additional testing at a lab in Miami, stated Eastern Health CEO Vickie Kaminski at the February 13 news conference.

On January 31, 34 of the 68 samples were sent to a Dual ISH expert in Miami for review. The name of the Miami lab has not been released, and, during an interview with THE DARK REPORT, Dr. Martin Trotter, President of the **Canadian Association of Pathologists**, said that he did not know the name of that lab.

Among the 34 results sent to Miami, Eastern Health had determined that 22 were HER2 negative and the Miami lab agreed. Among the 12 samples that tested positive, the Miami lab confirmed the findings for three results, but reported nine cases as discordant, the Telegram reported.

Quality Assurance Review

"The authority knew something was amiss in December due to a quality-assurance check, but said it did not have confirmation of the nine errors in the immunohistochemistry lab until Tuesday (February 12), after consulting an expert in Miami, Florida, and having further testing done in an outside lab," reported the *Telegram.*

Provincial health officials stated that, while a quality assurance test identified the need for retesting and the retesting identified results that did not match, the source of the mismatched results remains unclear. The fact that the mismatched results were caught as a result of a quality assurance review indicated improvement from the problems uncovered between 1997 and 2005 when lab testing errors were common, officials said.

The *Telegram* reported that, as of mid February, health officials did not know the source of the error and that they would conduct a root cause analysis. Also, HER2 testing has been discontinued in the province until the results of the analysis are known. This will lengthen the time before patients know the results of their lab tests for breast cancer.

Kaminski admitted that while it was bad news that nine patients were affected negatively, the QA program caught the problem quickly, the newspaper reported. "This is a very distressing time for our patients and their families and we are offering whatever support they need at this time," she said at the time.

Detecting Discordant Results

"However, this incident demonstrates that Eastern Health has a quality assurance program in place in its laboratory medicine program that is working," Kaminski said, according to The Telegram. "It allows us to detect any discordant results early; that we put a process in place to determine whether there is an issue and, most importantly, that we can adjust treatments for our patients if required. That is what we have learned from the errors in estrogen and progesterone receptors."

The regional and national news stories that appear in Canada following the disclosure of lab errors that may have negatively affected patient care, such as those described above, demonstrate the level of trust citizens place in their medical laboratories. That is why it is significant news whenever a respected laboratory organization must acknowledge to the public that, due to errors, it must notify the patients affected and provide additional testing. TDR

—Joseph Burns

Contact Dr. Martin Trotter at 403-770-3202 or Martin.Trotter@cls.ab.ca.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

People walking down a street in Weatherford, Connecticut on March 10, found lab test reports for at least 16 patients, according to a news report by a local television news station. This is a breach of protected health information (PHI) under the federal HIPAA statute. Reporters from WSFB contacted one of the patients whose lab test report was found. Not surprisingly, she stated that "This is too much information on it... personal information. I don't think this should have happened." It was reported that the lab test reports came from **Clinical Laboratory Partners, LLC**, of Newington, Connecticut, a lab company owned by **Hartford Healthcare**.

ADD TO: *PRI Breach*

This incident is a reminder to all clinical laboratories and pathology groups that breaches of PHI can happen in unexpected ways. In 2012, THE DARK REPORT covered the break-in and theft of 700 patient records at a patient service center operated by **Health Care Clinical Laboratory** in Stockton, California. *(See TDR, May 14, 2012.)* Earlier, in 2010, 67,000 pathology test reports were discovered at a public dump in Georgetown, Massachusetts. In this case, the billing company for four pathology groups had sent the records to be destroyed. The parties involved in this PHI breach paid $140,000 penalty to resolve this case. *(See TDR, August 23, 2010.)*

PRESIDENT'S BUDGET CUTS LAB FEES OVER 9 YEARS

It is not a good omen for the lab testing industry. When President Obama submitted his proposed federal budget for 2015 to Congress in recent weeks, it included an item that called for reducing Medicare Part B clinical laboratory test fees by 1.75% annually for the years 2016 through 2023. This would be an overall 14% reduction in reimbursement. It is now up to Congress to develop and pass its own budget, so the lab industry has time to educate elected officials about the consequences of enacting such lab test fee cuts.

TRANSITIONS

- Michael Laposata, M.D. Ph.D., has been selected to be the next Chair of Pathology at **University of Texas Galveston Branch**, in Galveston, Texas. He will assume these duties on July 1, 2014. An academic pathologist, Laposta has held faculty positions at **Vanderbilt University Medical School** and **Harvard University** (**Massachusetts General Hospital**).

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That's all the insider intelligence for this report. Look for the next briefing on Monday, April 7, 2014.

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