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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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R. Lewis Dark

Founder & Publisher

Labs Have Strategies to Address Narrow Networks

IN TODAY'S EVOLVING HEALTHCARE SYSTEM, labs and pathology groups of all sizes in all communities are dealing with the issues of payers narrowing networks and the formation of ACOs, with all the unknowns about reimbursement that come with this new organizational model of healthcare

That is why you will be interested to learn more about a community hospital in New Hampshire that created a unique way to get its outreach lab program back into the provider network of the state's major health insurer and an anatomic pathology group in Alabama that assertively created a role for itself in an ACO that was first organized in 2012.

Each example of a lab developing a strategy to protect access to patients in its community is a reminder that the healthcare marketplace will reward lab organizations that are willing to be innovative and experiment with new ways to deliver lab testing services that meet the changing needs of health insurers and ACOs.

On pages 10-15 you will read about how 88-bed **Frisbie Memorial Hospital** in Rochester, New Hampshire responded when it found itself excluded from the site of service network of **Anthem Blue Cross Blue Shield of New Hampshire**. With the support of the hospital's CEO, a new, stand-alone lab company was created specifically to offer lab testing services at a more competitive price than what was charged by the hospital's lab. This lab earned provider status in Anthem's Site of Service network, even as the hospital itself remains out of network.

Pathologists and pathology practice administrators would do well to study the strategy and business thinking of **CytoPath, P.C.**, a five-pathologist group in Alabaster, Alabama, just a few miles from Birmingham. On pages 7-9, we describe how, back in 2012, when CytoPath learned that the local health system was forming an ACO, it acted decisively to ensure that its pathologists would be included as providers within the ACO. Not only did this require a willingness to accept a different model of reimbursement, but the pathology group needed to make ongoing investments in information technology in order to deliver the expanded sets of data required by the ACO.

Each of these market initiatives teaches lessons in how all labs can positively respond to the changes happening in healthcare. And, once again, it is THE DARK REPORT which is bringing you the news and analysis of these innovations. TDR

Beware Ides of March! Lawmakers Are in Session

Congress must address physician pay cuts and seek offsets that don't threaten clinical labs

CEO SUMMARY: Few pathologists and lab administrators know that, when the Protecting Access to Medicare Act of 2014 (PAMA) became law last April 1, language in the bill was scored to reduce Part B clinical laboratory test fees by $2.5 billion over 10 years. Congress used those lab fee cuts to patch the Sustainable Growth Rate (SGR) temporarily. The one-year patch expires on March 31, 2015. Now federal lawmakers must again address the SGR problem with some type of fix, including more spending offsets.

IN SHAKESPEARE'S PLAY, *Julius Caesar*, the new emperor is warned to "Beware the Ides of March." Indeed, when it comes to Congress, that may be good advice for the clinical laboratory industry.

In recent years, federal legislators have scurried in February and March to address the problem of crafting another one-year fix to the Sustainable Growth Rate (SGR) formula. Over the years, that fix has frequently resulted in significant threats or painful cuts to the Clinical Laboratory Fee Schedule. In 2012, CLFS took a 2% cut, paying for a substantial portion of the SGR one-year patch.

This cut happened because, to pay for extending the SGR for any amount of time, Congress must find budget offsets from other areas of healthcare spending. Every area of healthcare has been expected to support the offset, but after most areas of healthcare received significant cuts to pay for the Affordable Care Act in 2010, the tolerance for additional cuts to fix the SGR does not exist.

Last year, Congress took a somewhat different tact. Rather than simply pull from a list of offsets as they had in the past, congressional committees with jurisdiction over SGR sought to put together a policy bill that reformed payment systems. This included changing the way clinical laboratories are paid under Medicare.

The Protecting Access to Medicare Act (PAMA) emerged from that process. It included a section that, starting in 2016, requires certain labs to report to CMS private market prices by test code and payer,

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

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and their associated volumes. CMS will then use that market data to set prices for the Part B CLFS beginning in 2017. *(See TDR, April 7, 2014.)*

THE DARK REPORT has learned that the fee cuts specified in PAMA were scored by Congress to reduce spending on Medicare Part B lab tests by $2.5 billion over 10 years. This may be the first time that this number has been disclosed to the public, outside of possible communications by certain lab associations to their members.

Since the March 31, 2015, deadline for addressing the SGR cut to physicians is approaching, clinical laboratory associations, lab directors, and pathologists are meeting with federal lawmakers to ensure that additional cuts to lab fees are not imposed while PAMA is being implemented. They also want to address PAMA concerns and to identify other adjustments that can offset additional spending required to fund another temporary or permanent fix to the SGR formula.

Medicare Budget Cuts

This pattern for lawmaking and Medicare budget cuts has created a new problem for the profession of laboratory medicine. The House and Senate often work at a frenetic pace to craft the bill that addresses SGR.

Congress also wants to develop palatable legislation that would permanently address the SGR. However, that has a hefty price tag, currently estimated by the Congressional Budget Office at $119 billion. The major hold-back toward passage has been Congress' inability to identify enough offsets through provider cuts to pay for the legislation.

Whether it is a short-term patch or a permanent fix, Congress aims to minimize political opposition. It wants to write a bill that can receive the least amount of policial pressure, leaving opponents with little ability to fight individual provisions.

Last year, as Congress rushed to pull together an SGR bill, differences in the professional and economic goals of varying sectors of the lab testing industry surfaced.

In deciding to focus on labs as part of last year's legislation, lawmakers were influenced by several studies authorized by the U.S. Department of Health and Human Services that mainly looked for ways for Medicare to save money on what it pays for clinical laboratory testing.

Report: Savings Are Possible

In one such report released in 2013, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings,* the federal Office of Inspector General wrote that Medicare paid 18% to 30% more than other insurers paid for 20 high-volume or high-expenditure lab tests. If Medicare had paid labs at the lowest established rates in each geographic area, the report's authors argued, it could have saved $910 million, or 38%, on these lab tests, OIG said. *(See TDR, June 17, 2013.)*

"All of these factors were in place when Congress began considering SGR offsets in late 2013 and early 2014," explained Julie Scott Allen, a Government Relations Director for **Drinker Biddle & Reath** and Senior Vice President for the firm's **District Policy Group**. She represents the **National Independent Laboratory Association** (NILA) and **American Association of Bioanalysts** (AAB).

"All signs directed at Congress convinced a few key congressional committee offices that there needed to be changes in how CMS paid for lab testing under Medicare," observed Allen. "A handful of congressional staffers dug in on the idea that they could get revenues from the traditional CLFS and simultaneously address coverage and payment concerns for newer laboratory tests that faced scrutiny and no coverage decisions by the Medicare Administrative Contractors (MACs).

"During this time last year, associations representing laboratories, including NILA, initially agreed that the lab community needed to push back against addi-

tional cuts," noted Allen. "Following years of negative adjustments to the CLFS that resulted from the ACA and SGR offset reductions, and in the face of a CMS effort to deliberately cut lab test payments based on undefined 'technological changes,' lab groups argued the additional cuts were unwarranted."

The Senate Finance Committee asked laboratory associations to prepare other proposals that could improve how Medicare paid for laboratory tests and that would address concerns of the committee and CMS.

"NILA deliberated on this issue, acknowledging that there were two key ways to address Medicare lab costs: Either adjust reimbursement, or affect volume in a smarter way," she said. "NILA issued a proposal to set forward something similar to 'appropriate use criteria' by instituting a process to ensure Medicare was paying for the right test at the right time.

Improving Test Utilization

"NILA's suggestion was that physicians could be guided more effectively on which tests to order for certain patients and when," she stated. "This would address the ongoing pattern of over-ordering or ordering lab tests that are not needed."

Under NILA's proposal, labs would not tell doctors what to order, but rather a system would be set up within the government to establish algorithms that could support physician understanding on which test to order at what intervals and in which chronological order to get to a diagnosis.

"NILA members often receive questions from physicians asking for expertise about which tests they should order," she stated. "NILA believes that instituting a process that could enhance the quality of the ordering process would help doctors improve their diagnostic accuracy and control Medicare costs too.

"This approach seemed to address everything that concerned members of Congress and CMS: higher quality, better patient care, and improved processes to boost efficiency and save costs," she explained. "NILA worked with members of the Senate Finance Committee to support having the proposal added to legislation that addressed the SGR.

Alternative Market Approach

"Ultimately, however, the **American Clinical Laboratory Association** (ACLA) and the large national laboratories opposed this approach and offered an alternative market approach with proposed funding attached," Allen said.

"When anyone offers a direct 'pay-for' to fund an SGR legislative proposal intended to seek pay-fors only, Congress gladly accepts," explained Allen. "Conversely, NILA's proposal could promise only savings over time, not a guaranteed hard number upfront.

"At this point, NILA, ACLA and a few other organizations were forced to sit as one group to engage congressional offices on how they could fairly assess the market to determine adjustments to Medicare laboratory payments," she said. "We all agreed that some limit needed to be imposed on how far cuts to the CLFS could go in any given year, and any assessment of the lab community needed to encompass the entire lab market, including hospitals and hospital labs," she noted.

Better Care, Lower Costs

"NILA argued that special consideration and financial adjustments needed to be given to certain laboratories serving niche markets within Medicare where cuts could affect patient's access to services," said Allen. "This is similar to what Congress has done for other healthcare services, including ambulance providers.

"The problem was that this legislation—and the policies being crafted within it—faced a looming SGR deadline," she added. "There was no time and little interest to develop such a proposal and run the numbers.

"A handful of congressional offices decided they would eliminate the current fee schedule for labs and replace it with a new, untested system in the absence of any congressional hearings, reviews by the Medicare Payment Advisory Commission, or evaluations on its feasibility," she stated. "This would allow them to say that they reformed lab payments and also met a pay-for obligation.

"The mission of the few congressional offices leading this charge was supported by ACLA and diagnostic equipment manufacturers," continued Allen. "Within a few days before the bill moved in the house, ACLA expressed support for the mandatory reporting of private lab payment rates by test volume, something NILA vehemently opposed.

"NILA not only feared the cost and administrative burden of mandatory reporting on small and mid-sized laboratories," observed Allen, "but it also opposed any system that would seek to collect and recalculate payment rates based on the very rates used to undercut the laboratory market for years because the largest labs in the market sought sole-source contracts with large commercial payers."

Adjustment to Part B CLFS

PAMA requires CMS to adjust the Part B clinical laboratory fee schedule beginning in January 2017, based on its evaluation of market rates reported by labs during 2016. Cuts to any of the codes on the fee schedule as a result of the evaluation are phased in at 10% for each of the first three years beginning in 2017 and then at 15% in each of the next three years. Following the first six years, there are no limits on how far CMS can make adjustments.

"NILA never supported such a drastic schedule for adjustments to the CLFS," noted Allen. "When the committee discussed phasing-in the adjustments, NILA and others in the lab community said that if such a process were undertaken, Congress needed to cap how much CMS could make in adjustments in any given year.

"For example, not permitting CMS to cut the CLFs in aggregate by more than 2% when making adjustments to codes based on a market evaluation would have given small independent labs some protection against CMS taking an ax to the fee schedule in any of the years after this process begins," she said.

Was It A Victory For Labs?

"Following enactment of this new law, some lab organizations explained the price cuts in PAMA as a victory for clinical labs because the cuts did not begin until 2017; the new law took CMS's technological adjustment effort off the table; and the lab community did not receive a direct cut to address the 2014 SGR patch," Allen said.

"Some people have said labs got a deal that was better than what CMS was planning" she added. "I don't see it that way. Cuts in the magnitude of 75% to any given lab test are significant to NILA's labs. Also, there are no promises in politics. Already, we are hearing that Congress could consider adjustments to labs on top of these cuts.

"If Congress permanently repeals the SGR later this year and needs $113 billion or more to pay for that fix, copayments for lab services or 20% coinsurance likely will be on the table," warned Allen. "Additional drastic and devastating cuts to labs come in many different forms.

"Such potential sources of cuts include imposing copayments, coinsurance, and other Medicare payment reforms that could happen in addition to the 'market-based' pricing requirements," concluded Allen. "Such actions would threaten the financial health of community laboratories and reduce access of Medicare patients to laboratory testing services in their localities." TDR

—Joseph Burns

Contact the National Independent Laboratory Association at 314-241-1445.

Early ACO Experience Has Lessons for Pathologists

Five-pathologist group wins ACO contract, Learns importance of managing patient data

CEO SUMMARY: To date, many of the nation's 500 accountable care organizations have launched with little involvement by independent pathology groups and clinical laboratories. That was not the case with an ACO in Alabama, however. From its inception in 2012, the ACO has contracted with CytoPath, P.C., a five-pathologist group in Alabaster, Alabama. CytoPath's pathologists are currently paid on a fee-for-service basis and must provide detailed and timely data to the ACO.

MORE THAN 500 ACCOUNTABLE CARE ORGANIZATIONS now operate nationwide. To date, however, few independent pathology groups and clinical labs have successfully negotiated lab testing contracts with these ACOs.

This often happens because, for many reasons, independent pathologists and clinical laboratories have not been part of the initial mix of primary care, specialty physician groups, and hospitals that launched these new contracting entities.

In fact, independent laboratories and pathology groups were often left off of ACO planning committees altogether. Frequently, hospitals participating in an ACO contracted with their in-house laboratories, freezing out independent labs and pathology groups.

Today, however, more independent pathology groups and clinical labs are participating in the development and operation of ACOs. Their early experiences in these entities offer lessons for other labs and pathology groups seeking to contract with ACOs.

One such pathology group that has been part of an ACO since 2012 is **CytoPath, P.C.**, a five-physician group in Alabaster, Alabama, just south of Birmingham.

About 60% of CytoPath's volume comes from its contracts with hospitals in the Birmingham area and about 40% comes from its outreach efforts to physicians' offices. The group offers histology and cytology in house and has been operating in central Alabama since 1989. CytoPath also has a lab in Selma.

Big Demand for Big Data

In 2012, CytoPath had an opportunity to negotiate a contract for pathology services with the **Baptist Physician Alliance** (BPA), an ACO that the **Baptist Health System** formed a year earlier. "In 2011, the health system formed the ACO and began contracting with about 400 physicians the following year," stated Bill Warren, CytoPath's administrator. "The aim of the ACO was to improve the quality of care and to control costs as well.

"In some parts of the country, shared-savings and shared-risk ACO models are developing, but after surveying its 400 physicians, BPA found the doctors had an aversion to financial risk," he said. "Therefore, BPA formed an ACO in which payment was based on fee for service. If there were any savings, then BPA would share those savings with the providers.

ACO Puts Demands on IT

"But before any savings were possible, BPA spent those first two years—meaning 2012 and 2013—setting up the infrastructure of an ACO, including the IT systems needed to collect the data on patient care," he noted.

"In fact, BPA controls all the data generated by the ACO," he added. "As a pathology group, we pass the data to them. That is part of the agreement with the ACO.

"The importance of data was one of the first lessons we learned," he continued. "All ACO arrangements are driven by the data collected by participating medical groups.

"That is why, before a lab or pathology group signs a contract with an ACO, it should recognize that the IT team will be closely involved in the relationship with the ACO," stated Warren. "IT is needed to collect and report patient data to the ACO. The ACO then takes that data to the insurers to show how it improved quality or reduced the costs.

"Initially, we were not sure how to deliver that data to BPA," he recalled. "We discovered that we could not extract the necessary data from our existing electronic billing system as it was configured.

"Our solution was simple," said Warren. "We could collect the necessary data through our billing system via its Medicare Physician Quality Reporting System (PQRS). As long as we coded every bill using PQRS, we would have the data the insurers needed to manage patient care appropriately.

"During those first two years, this approach allowed us to collect and transmit the necessary data to the ACO through the PQRS system," stated Warren. "This was a critical time for the ACO because it wanted to assemble the data required to demonstrate both the quality and savings it was delivering before it went out to negotiate with other private payers."

This strategy has apparently worked for Baptist Physician Alliance. "We've been told that a lot of payers are now interested in contracting with this ACO," he said. "Later this year some payers are expected to offer contracts to BPA and its participating physicians, clinical labs, and to pathology groups like ours.

"The PQRS system allowed us to demonstrate the quality of care delivered by our pathologists," noted Warren. "To improve the accuracy and completeness of this data, we actually slowed our billing timeline a bit to ensure that every bill we submitted contained all the necessary PQRS data. The billing department we use is **McKesson Business Performance Services**, which sends our bills directly to the payers.

"In order to use the PQRS reporting system as a source of data for the ACO, there was a reason why we slowed all billing related to those quality metrics," he continued. "Take the example of patients with breast cancer. If those claims were submitted without any information on special stains, for example, then the PQRS coding on those bills would be incomplete.

Billing Adjustments Needed

"We worked closely with McKesson to hold those claims until we collected all the data needed for a complete bill," added Warren. "That was probably the single biggest change we needed to make to help ensure that we were submitting all of the PQRS codes prior to billing the case and getting credit in the PQRS system."

CytoPath pathologists also engaged the ACO's physicians to improve lab test utilization. "To save money for the physicians,

Alabama Pathology Group Needed to Retain Its Corporate Structure in Newly-formed ACO

ONE OF THE FIRST accountable care organizations in Central Alabama was the 400-member Baptist Physician Alliance (BPA), which was formed in 2011.

In 2012, BPA began contracting with four hospitals, which have a combined number of 885 beds. Those hospitals serve a region with a population of 1.2 million people.

BPA and its four hospitals contracted to serve approximately 6,000 people. One contract was with Medicare to serve about 1,000 members of a local Medicare Advantage plan in Birmingham. The second contract was to serve about 5,000 employees and their family members from the four hospitals. Being self-insured, the hospital contracted with **Blue Cross Blue Shield of Alabama** to administer the health insurance program to the employees and their family members.

During the formation of this ACO, the five pathologists of CytoPath P.C. in Alabaster, Alabama, saw the opportunity to gain experience in working with a multi-payer ACO.

"Initially, BPA wanted to contract with the individual pathologists," explained CytoPath Administrator Bill Warren. "But we are a five-man group and if you want to contract with these five pathologists, we believed it would be best to contract with CytoPath rather than the individual pathologists.

"There were tax implications to consider during the contract negotiations with the ACO," he explained. "One issue is associated with the employment agreements we have with our pathologists. BPA wanted to set up the ACO so that they could run all the revenue back to the individual providers rather than to CytoPath, PC, which is our corporate entity.

"Our corporate documents require that all revenue flows to the corporation and not to the individuals," emphasized Warren. "Thus, if a pathologist contracts with an individual hospital, any revenue paid to that pathologist must go back into the group.

"So, when BPA came along, CytoPath needed to negotiate terms in the contract that would not violate the employment agreements it has with the pathologists," he observed. "There was another benefit to this contracting approach with the ACO. Under our current agreement with BPA, CytoPath can have all five pathologists deliver care whenever and wherever it is needed."

we recommended that the physicians switch from one reference lab to another," he said. "Once we were part of the ACO, we saw that the physicians and hospitals were spending too much on reference lab work. Switching the esoteric testing from one national reference lab to another produced substantial savings without any loss of quality. This contribution of the pathologists was recognized by the ACO.

Sharing the Savings

"Activities during those first two years were designed to collect the data needed to show that the ACO could deliver quality care and cut costs for those 6,000 members of the ACO," Warren concluded. "After two years, the ACO was able to show substantial savings and some of those savings were passed along to us.

"CytoPath's share of the savings was just under $20,000," he recalled. "This was like found money because we had already been paid for doing this work under the ACO's fee-for-service arrangement.

"The other reward is to see the quality of patient care, as documented by the ACO data," said Warren. "CytoPath's experience shows how an independent pathology group can make worthwhile contributions as part of an ACO." TDR

—Joseph Burns

Contact Bill Warren at 205-664-9797 or bwarren@cytopathpc.com.

Strategy Allows Community Hospital to Compete in Outreach Market

Locked Out of Payer Network, NH Hospital Opens Lab Company

CEO SUMMARY: Since Anthem launched its site of service program in New Hampshire in 2010, labs in the state's hospitals have mostly been excluded from its network and have lost market share. Recently one community hospital developed an unusual strategy to win back those patients. Last year, Frisbie Memorial Hospital in Rochester, opened a stand-alone independent lab company that became a provider in the Anthem network. To date, the independent lab has been gaining patients steadily, hospital officials say.

ACROSS THE NATION, managed care plans are using narrow networks to exclude most clinical laboratories and pathology groups as providers. However, one community hospital in New Hampshire pursued a strategy that allowed it to get its lab back into the network of one the state's largest health insurers.

Administrators at 88-bed **Frisbie Memorial Hospital**, located in the small community of Rochester, created a stand-alone laboratory company called **Granite State Lab, LLC**. Rochester is a town of 30,000 residents in the southeastern corner of the state.

The new lab company negotiated competitive outreach lab test prices with **Anthem Blue Cross and Blue Shield in New Hampshire** and was added to the payer's lab network, despite the fact that the hospital itself remains outside the Anthem network.

Long-time clients of THE DARK REPORT know that, in New Hampshire in 2010, Anthem introduced a "site of service" change to its health plan. Seeking to steer members to low-cost clinical labs (and ambulatory surgery centers), Anthem BCBS in New Hampshire eliminated co-payments and deductibles for members who use in-network labs.

This motivated patients to use only the labs shown on Anthem's web site. Listed prominently are **Quest Diagnostics Incorporated, Laboratory Corporation of America,** and **NorDx**.

When members use any of these and other in-network labs for clinical lab testing, the members pay nothing out of pocket. "That means no deductible or coinsurance," Anthem says on its site. (See "Trend in New Hampshire Is to Engage Lab Patients," *TDR April 2, 2012*.)

Anthem also lists other in-network independent labs and in-network hospital labs. Out-of-network facilities are not listed.

After Anthem launched this site of service program in New Hampshire, out-of-network clinical laboratories, including those operated by hospitals, lost market share. One example was **Speare Memorial Hospital**, a 25-bed critical access hospital in Plymouth, New Hampshire.

Not only did Speare lose patients who had regularly used its hospital lab outreach program, but it experienced another problem. In 2012, Michelle McEwen, FACHE, President and CEO of Speare Memorial Hospital, told THE DARK REPORT that her hospital was dealing with a spike in the number of patients who were requesting that the hospital collect their blood and other laboratory specimens, but then were telling the hospital to send those specimens to the independent lab companies in Anthem's network for testing.

She further stated that, "While Anthem's new product is pulling the lucrative outpatient services—such as lab and ambulatory surgery—away from hospitals, Anthem still expects us to provide important urgent, emergent, and inpatient services to their patients."

Anthem's site of service requirement had a similar effect on the lab test volume at Frisbie Memorial Hospital. Its administrators, however, recognized the need to maximize the volume of specimens coming into the hospital's laboratory. Increased volume allows labs to run an expanded on-site menu of tests, thus cutting turnaround time and contributing to improved patient care. The increased specimen volume also contributes to a lower average cost-per-test for inpatient and outpatient services.

Rising Monthly Volume

Frisbie's new clinical lab company helps the hospital to meet both of those goals. "Last year the hospital established **Granite State Lab** (GSL)," stated Brenda Niland MT(ASCP), Director, Laboratory Services. "The lab opened a drawing station here in Rochester on Route 202 at Exit 13 off Route 16."

"This patient service center is staffed with one phlebotomist five days a week," she said. "In its first month of operation, it served 74 patients. Since opening, patient volume has increased every month. In January, the center had about 500 lab tests from 188 patient visits.

"GSL refers these specimens to the Frisbie hospital laboratory so that the hospital lab benefits from the volume," noted Niland. "Frisbie continues to own and operate three additional patient service centers that are not affiliated with GSL."

A Workable Strategy?

Pathologists and lab directors at community hospitals in other markets may want to consider whether this strategy would be an effective way to retain or regain status as in-network providers. Since so many insurers are developing narrow and limited networks, this method of contracting may be one way for community hospitals to retain lab test volume and attract cash-paying patients who have high deductible health plans and so want to pay lower prices.

Another important question for lab directors and pathologists to consider is whether Anthem Blue Cross Blue Shield will introduce this site of service benefit design in any of the other 13 states in which it operates. Those states are California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New York, Ohio, Virginia, and Wisconsin. If Anthem does introduce site of service plans in these states, many hospitals and their labs would probably be excluded from the network due to high lab test prices.

Outreach Lab Strategy

Frisbie Hospital President and CEO John Marzinzik supports the strategy to operate an independent outreach lab company. "As a business model, the independent Granite State Lab is working for us, even though it's not making any money yet," he noted. "But the overhead is modest and lower than the overhead we have in the hospital lab. So any test volume we generate from the GSL patient service center goes into the hospital lab because Granite State Lab contracts with our hospital lab to do that testing."

Niland explained that the Granite State Lab has only one phlebotomist working from 6:30 a.m. to 3:00 p.m., five days a week. "Once patients find out about this new drawing station, they love it because—if they are self-pay or have high deductibles—they are looking for low prices," she said.

"Further, because the Granite State Lab prices are low compared with the prices in our own hospital lab, some of our physicians now direct their patients to GSL," added Niland. "These physicians know that patients are concerned about getting the lowest price.

Hospital Lab Runs Tests

"Equally important is the fact that Anthem patients can go to GSL, with no out-of-pocket expense and our hospital lab still runs those lab tests," emphasized Niland. "If Frisbie did not have GSL, it would lose that volume entirely because the hospital itself is not on the state's insurance exchange (that covers New Hampshire) for Anthem.

"Last year, Anthem was the only health insurer operating on the state exchange," noted Niland. "As of January 1, four other insurers began operating on the New Hampshire exchange, and Frisbie is in those networks.

"Frisbie can't take patients who enroll in Anthem on the state insurance exchange because, of the 26 hospitals in New Hampshire, Anthem left 10 hospitals out of its network and Frisbie was one of them," explained Niland.

"As a consequence, each time we had a patient who previously came to us for doctor visits and lab work, we had to send that patient to another hospital," she said. "We were losing those patients.

How Frisbie Memorial Hospital Created a Growing Independent Lab Company

SOME ENLIGHTENED HOSPITAL ADMINISTRATORS at community hospitals are recognizing the importance of a dynamic laboratory outreach program—even if it means lowering the prices of lab tests to be competitive in their region.

Last year, administrators and the finance staff at Frisbie Memorial Hospital in Rochester, New Hampshire, put in motion a plan to develop a freestanding independent clinical laboratory with its own patient service center (PSC). They formed a limited liability corporation under the name Granite State Lab, LLC, and rented space for the PSC in a new mixed-use office building located at the intersection of two major highways. The PSC opened in July.

Brenda Niland MT(ASCP), the hospital's Director, Laboratory Services, worked with the materials director to get the chairs, desks, and all equipment needed for the patient service center. A phlebotomist was hired and Granite State Lab contracted with RCM, a private billing company, to process claims.

"The director of finance set up the pricing for lab tests based on reimbursement from insurers," stated Niland. "In an effort to appeal to price-conscious patients, GSL set its lab test prices lower than those offered at the hospital. Doing so allowed GSL to contract to be a network provider with all five of New Hampshire's health insurers.

"At first, we did a lot of advertising on radio, on billboards on Route 16, in newspapers, and on the patient vans that deliver patients to doctors' offices," she said. "In those ads, we didn't mention that GSL was associated with Frisbie in any way. We just said that GSL had lower prices.

"What we learned was that many of our patients were loyal to Frisbie and didn't want to go elsewhere," continued Niland. "So we began to educate them to the fact that— while GSL is a separate company— all the clinical laboratory testing is done here in the hospital.

"Administrators at Frisbie Memorial Hospital recognize the importance of growing the volume of lab specimens through Granite State Lab," she concluded, "Volume lowers our average cost-per-test for inpatient, outpatient, and outreach testing. The good news is that GSL is experiencing an increase in test volumes each month because the word of mouth from our patients is positive."

"No lab wants to lose volume," continued Niland. "Our hospital lab has a staff of about 50 who cover three shifts, seven days a week, and we perform about 450,000 billable tests per year. So, we want to find ways to boost volume and retain the specimen volume we have.

Growing Volume In New PSC

"The volume in the new standalone drawing station is not high compared with that of our other drawing stations," she stated. "At one of our PSCs, we draw more than 100 patients a day, and we might have 80 people before 9 a.m. This PSC is open until 5 p.m. on Monday and Tuesday and until 3 p.m. on Wednesday, Thursday, and Friday. It is staffed with four phlebotomists."

For Marzinzik, the freestanding facility not only generates volume for the hospital lab, but it provides benefits to local patients that other independent labs cannot. "Granite State Lab delivers cost-effective, high-quality care and gives us a venue to serve a niche in the community and the region we serve," he said.

"We wanted to create a private label lab that could negotiate with insurance companies," he explained. "That is why

we established the outreach lab as an LLC that was separate from the hospital, but yet subcontracted back to the hospital.

"This arrangement allows Granite State Lab to have the hospital do the work in a CAP-certified laboratory and this lab testing is done very close to the hospital's cost," added Marzinzik.

"The Granite State Lab has different contracts with health insurers than the hospital has," he said. "Because the freestanding lab has lower overhead, it can charge less. We were willing to accept the insurers' fee schedule and the hospital lab would still get the volume. The only difference is that GSL does not get the same price for lab tests that the hospital would get.

"We wanted to do something because Anthem and other commercial insurers were directing patients to private labs, such as LabCorp and Quest Diagnostics," observed Marzinzik. "They were literally steering patients away from the hospital based purely on price. While these insurers were doing what's best for them, we were losing business, which is not good.

"Also, this arrangement disrupted the ability to get those test results back into the patients' charts," he added. "For that reason, we created GSL as a way to contribute to improved patient care.

Fee Schedule Accepted

"Our analysis of the Granite State Lab business model showed that GSL could accept the retail laboratory fee schedule for reimbursement," he continued. "Additionally, GSL has the capability to assure that all lab test results would go back into the physicians' electronic health record charts electronically.

"Most independent labs send their results back on paper, usually by fax," stated Marzinzik. "That fax gets scanned into the chart in the EHR. The problem is that the physician then has only an image of the results in the EHR.

"This is not discrete data physicians can use easily if they want to extract results to show trends over time, for example," he continued. "GSL's ability to transmit lab test results in the EHRs is a benefit and contributes to improved patient care."

It is important to emphasize that low prices for lab testing is a significant benefit for the growing number of patients who are self-pay or have high-deductible health plans. "The fact that GSL can do lab testing inexpensively is important, particularly for those patients who have no coverage and pay out of pocket," he said.

Goal Is Quality Care

"It's too soon to tell if GSL is going to make money, but we may know that in another six or seven months," predicted Marzinzik. "The proforma says it will make some money but that's not our first goal.

"Our first goal is to provide good quality care to patients who may have no health insurance or have an incentive to go to a private label lab and pay less than they would elsewhere," he emphasized.

Marzinzik did not know how many hospital patients were affected when Anthem excluded Frisbie Memorial from its exchange network and didn't know how much the exclusion affected the hospital financially.

"Where it hurt was among those patients who had long-standing relationships with doctors they had seen for 25 years," observed Marzinzik. "Suddenly those patients needed new doctors and those doctors were not affiliated with Frisbie Memorial."

With the creation of Granite State Lab, LLC, the hospital has addressed that problem for patients. At the same time, it is now increasing its lab outreach test volume while meeting the needs of patients with no coverage or high-deductible health plans. TDR

—Joseph Burns

Contact Brenda Niland at 603-335-8451 or B.Niland@FMHospital.com.

In New Hampshire, Hospital Lab Administrator Sees More Price Competition for Laboratory Testing

IN NEW HAMPSHIRE, COMPETITION for medical laboratory tests has increased in recent years, say several lab directors working in the Granite State. They point to the numerous radio, newspaper, and billboard advertisements that tout the low prices that hospital labs and freestanding labs offer as they compete for patients

Anthem Blue Cross and Blue Shield in New Hampshire has fostered competition by eliminating copayments and deductibles for members who use low-cost labs listed in Anthem's Provider Finder. In its marketing literature, Anthem calls these in-network sites "zero-cost labs." Under their Anthem health plan, patients are free to use any medical laboratory. But if they use a lab that's not listed in the Provider Finder on Anthem's web site, the patient's out-of-pocket cost may be higher.

Anthem is using a strategy in which an in-network health benefit costs nothing to the patient. *(See TDR, April 2, 2012.)* In recent years, this strategy has forced hospital labs in New Hampshire to compete on price, but not all are doing so. One lab administrator who asked not to be named said both commercial labs and hospital labs have been competing fiercely since the Affordable Care Act went into effect last year.

Patients Are Price-Shopping

"In the last year or so, we've seen a lot of interest among patients to shop for low-price lab tests," he stated. "A high proportion of patients now have high deductible plans and so naturally they want low-cost lab testing.

"At our hospital, the options for our lab are limited," continued the lab administrator. "Advertising a price too low would put our contracts in jeopardy and our lab cannot discount below the New Hampshire Medicaid fee schedule.

"Our lab team has recommended opening a free-standing patient service center as Frisbie Memorial Hospital has done, but the administration here is reluctant to do so," he explained. "In the meantime, we are watching our outpatient lab test business erode. We'd like to mitigate that erosion. However, our lab team does not feel it can compete on price with the labs advertising low prices."

This lab administrator further pointed out that several lab firms in New Hampshire do not require a physician's order and these lab companies use the patient service centers and lab testing facilities of the two national labs. One such site is **Health Testing Centers** (at *www.healthtestingcenters.com*).

Its web site states, "You do not need an order or a prescription from your doctor. All our tests include everything you need to have the test performed. After ordering, simply bring the requisition form to a LabCorp or Quest Diagnostics location close to you. Present that form and they will collect the proper specimen for your tests. There is no additional payment to LabCorp or Quest. We receive the results and send them directly to you (usually in 1-2 days)."

PersonaLabs (at *www.personalabs.com*) appears to offer a similar service, saying, "Let PersonaLabs be your Online Resource. Get the same professional tests you'd get through a doctor, at a fraction of the price. No need to go into debt, just find out what you need to know. Take charge of your healthcare with PersonaLabs: Convenient, Confidential, Affordable Lab Tests & More." All suggested locations on the PersonaLab web site in New Hampshire are LabCorp sites.

One problem hospital labs face when patients use an independent lab such as Quest Diagnostics or LabCorp is that the patients' test results usually are not transmitted to the patient's electronic medical record, said the lab administrator. "To us here at the hospital, that's a patient safety issue," he stated. "But I'm not sure patients even care about that because they're looking for a low price."

UnitedHealth Sets April 15 to Start Claims Impact of Lab Program

Pathologists get reprieve on second-opinion rule; two common tests removed from decision support

APRIL 15 IS THE DATE when UnitedHealthcare will begin denying laboratory claims in Florida that do not meet the requirements of its unpopular laboratory benefit management program.

The health insurer sent out notices last month to alert physicians and laboratories that it will implement what it calls the "claims impact" phase of the program. Effective April 15, physicians must follow the procedures in the **BeaconLBS** decision support program or claims will not be paid for certain laboratory tests. The program applies to laboratory services for fully insured UnitedHealthcare commercial members.

Apparently the strong opposition that many physicians and societies have expressed to UnitedHealthcare has caused the insurer to back down on some aspects of the program. There was some positive news in the announcement. For example, UnitedHealthcare made it easier for pathologists to comply with the BeaconLBS program, saying it would accept a single review from a sub-specialist or a secondary review from an anatomic pathologist for dermatopathology, cytopathology, and hematopatholog.

Last year, the **Florida Society of Pathology** estimated that about 40% of pathology practices would have trouble meeting the second-opinion pre-certification requirement. Pathologists said that few groups in Florida have the size or composition of subspecialists to meet UHC's requirement.

UHC also said it would extend the deadline for dermatologists who perform in-office pathology services to comply with the accreditation requirements of the **College of American Pathologists**. UHC did not announce a new deadline for dermatologists, however.

In another change, UHC removed two routine clinical lab tests from the 80 or so tests listed as requiring pre-notification or pre-authorization. The two tests removed from the decision support list were prenatal profile and gestational diabetes, UHC said.

EHRs With Interfaces

To address physicians' concerns about which electronic health record systems work with the BeaconLBS system, UHC listed the EHRs from the following system vendors as being compatible with its physician decision support system: **Allscripts**, **aprima**, **eClinicalWorks**, **Emdeon**, **HelloHealth**, and **Advanced Data Systems**.

By issuing this announcement, UnitedHealthcare demonstrates its determination to push forward with its laboratory benefit management system. It remains to be seen how clinical labs and physicians in Florida will react to the rejection of lab test claims if referring physicians do not follow the requirements of the BeaconLBS system when the tests are ordered. TDR

PerkinElmer Launches Lab Venture in China

New lab to provide prenatal and newborn screening and also infectious disease testing

CEO SUMMARY: PerkinElmer is the latest U.S. organization to open a clinical laboratory business in China. Last December, it formally opened its new Suzhou PerkinElmer Medical Laboratory. The new lab is located about 60 kilometers (37 miles) west of Shanghai. It will provide neonatal and prenatal screening along with infectious disease testing. PE's new venture hopes to leverage relationships developed from providing newborn and prenatal screening in China throughout for the past 20 years.

DRAWING UPON RELATIONSHIPS developed over two decades, **PerkinElmer Inc.** of Waltham, Massachusetts, formally opened a new medical laboratory in Suzhou, China.

With this step, PerkinElmer becomes the latest U.S. organization to launch a clinical laboratory in the world's most populous nation. Suzhou is located about 60 kilometers (37 miles) west of Shanghai in the southeastern section of Jiangsu Province.

"The **Suzhou PerkinElmer Medical Laboratory** will provide patients with neonatal and prenatal screening as well as infectious disease testing," stated Johnson Zhang, PerkinElmer's Vice President and General Manager for Diagnostics in the Asia-Pacific region. "This includes molecular cytogenetics testing, screening for inherited metabolic diseases, and viral load testing."

PerkinElmer already offers these types of clinical laboratory testing services in the United States. For example, **PerkinElmer Genetics** operates a CLIA laboratory in Bridgeville, Pennsylvania, that provides state-mandated testing for newborns as well as services in prenatal risk assessment and neonatal screening.

"It was almost 20 years ago when PerkinElmer started a newborn screening project with China's Ministry of Health," explained Zhang. "About 15 years ago, again working with the Ministry of Health, PerkinElmer started a prenatal screening project.

Newborn Screening Rate

"Today, newborn screening coverage has reached more than 80% of the population," he said. "This means that most newborns in China are now given two basic assays."

"Each year in China, about 16 million babies are born and between 12 million to 13 million of those babies are screened," noted Zhang. "About 70% of this screening is currently done by PerkinElmer."

Because of this ongoing program, "PerkinElmer has strong business relationships with more than 400 prenatal and neonatal screening centers," commented Zhang. "In addition, PerkinElmer has

existing relationships with more than 2,000 infectious disease screening laboratories across China."

SYMBIO Acquisition In 2009

Along with its ongoing newborn and prenatal screening programs performed in China, PerkinElmer has a significant diagnostics business. "In 2009, PerkinElmer paid $6.7 million to acquire **SYMBIO Lifescience Co., Ltd.**, of Shanghai," said Zhang. "This company provides diagnostics instruments and reagents to hospitals in China."

At the time, PerkinElmer said the acquisition doubled the number of hospitals it could reach in China. It thus offered an opportunity for PerkinElmer to expand its prenatal and newborn screening business in China.

"The business model now is to increase our investment so that we can provide the infrastructure, the instruments, and the software for these hospitals to do newborn and prenatal screening," explained Zhang. "Along with PerkinElmer's established presence in this lab testing market for more than 20 years, we have very strong sales teams to cover all provinces here in China."

As the first multinational laboratory company to focus on newborn screening in China, PerkinElmer is well positioned, Zhang continued. "Since those two basic tests were introduced, PerkinElmer has added more advanced assays. Combine that with our strong presence in diagnostics and we are in a good position to guide doctors in how they treat patients."

Will Past Serve as Prologue?

"Having such a long history here in China, means that we have a good infrastructure in place. We also have all the logistics worked out and a good location that is not far from Shanghai," he concluded. "Throughout China, PerkinElmer has over 1,000 employees. For all of these reasons, we are well positioned for now and in the future in China."

China's Ministry of Health Supports Newborn Screens

BECAUSE NEWBORN AND PRENATAL SCREENING IS A PRIORITY for the Chinese government, there is plenty of opportunity for the new clinical laboratory PerkinElmer opened in Suzhou last December.

"With China's newborn population exceeding 16 million per year and prenatal screening at 40%, the Chinese government is increasingly focused on investing in maternity and child care institutions for birth defects prevention," observed Xuming Bian, M.D., Professor in the Department of Obstetrics and Gynecology at **Peking Union Medical College Hospital**.

"Chinese regulations on maternal and child health administration are improving, the national birth defects prevention network is evolving, and prenatal screening and diagnosis systems have been established," Bian explained. "To respond to the needs of its residents, the Chinese government continues to support third-party labs such as PerkinElmer's Suzhou facility."

China is one of the fastest-growing lab testing markets in the world. IVD manufacturers are experiencing double-digit growth in their sales to Chinese labs.

Several clinical laboratory and anatomic pathology businesses have been launched in China that involve labs in the United States. The pathology departments at **UCLA** and **UPMC** have joint venture agreements with lab organizations in China, for example. Also, UCLA is opening a clinical laboratory company in Shanghai with China-based **Centre Testing International Corp.** *(See TDR, April 28, 2014.)* **TDR**

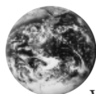
—Joseph Burns

Contact Nicky Xu at +86-13910295554 or nicky.xu@perkinelmer.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report



Many laboratory professionals are closely watching the development of **Theranos**, the lab testing company based in Palo Alto, California, that claims it has technology and a business model that will disrupt the clinical laboratory testing market. Recently *Forbes* announced its annual list of the 400 wealthiest people in the world. Theranos CEO Elizabeth Holmes made her debut on this year's list. With a net worth of $4.5 billion, *Forbes* ranked her number 122nd among the world's wealthiest 400 people.

FRANKIE THE DOG CAN SMELL CANCER

It's one more demonstration of the potential for dogs to play a role in the early detection of cancer. Researchers at the **University of Arkansas** in Little Rock presented a paper recently about how Frankie, a German Shepard mix, was able to detect thyroid cancer cases from the urine samples of patients. In 2013, our sister publication *DarkDaily.com* wrote about how Cliff, the Beagle, could sniff out *Clostridium difficile* in a research project performed at **Vrije University Medical Center** in Amsterdam, The Netherlands. Another example is in the United Kingdom, where, in 2012, Daisy the Golden Labrador's ability to smell cancer launched a study known as the "Medical Detection Dogs" in that country. Each of these examples triggered an ongoing project to further assess whether these capabilities in canines can be developed into reliable ways to identify individuals who have undetected cancers.

TRANSITIONS

- Rick Panning, MBA, has assumed the position of Senior Administrative Director for the **HealthPartners and Park Nicollet Care Group Laboratories** in Minneapolis, Minnesota. Prior executive positions held by Panning include **Fairview Health Services**, **Allina Hospitals**, and the **American Red Cross/St. Paul**.

- **hc1.com** of Indianapolis, Indiana, announced the appointment of pathologist Charles Miraglia, M.D., as Chief Medical Officer. Miraglia has held executive positions with **Sonic Healthcare USA**, **Esoterix Coagulation Laboratory**, **Laboratory Corporation of America**, **PA Labs**, and **Methodist Hospital of Indiana**.

DARK DAILY UPDATE

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

...research at the **University of Bradford** in England that showed how, when blood cells get exposed to ultraviolet light (UVA), cancer cells can be differentiated from healthy cells. Armed with this revelation, the team developed the "lymphocyte genome sensitivity (LGS) test." Efforts are now underway to develop diagnostic tests using this technology.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 30, 2015.

SPECIAL SESSION!

How UCLA's Pioneering Integration of Radiology and Pathology Services Delivers More Diagnostic Value to Physicians & Patients

William "Dean" Wallace, M.D., Chief, Pulmonary Pathology
Corey Arnold, Ph.D., Assistant Professor of Radiology

Learn how patients benefit from what is the nation's first regular clinical service that truly integrates pathology and radiology diagnostic services!

Exciting things are happening at UCLA's David Geffen School of Medicine. The Department of Pathology and the Department of Radiology have come together to develop the nation's first integrated diagnostic service where radiologists and pathologists deliver a single integrated report to oncologists.

This is the first public discussion of how, in the initial phase of this program, the pathologists and radiologists at UCLA are collaborating on lung cancer cases. You'll learn the role for a special software system, called UCLA RadPath which helps manage workflow and enables pathologists and radiologists to see each other's images and clinical findings. Join us and explore UCLA's vision of anatomic pathology's future!

It's our 20th Anniversary!

Executive War College

Conference On Laboratory & Pathology Management

UPCOMING...

- ***Next in a Series: Laboratory Value Pyramid's Level Four Helps Labs Deliver Added Value.***
- ***What Is the True Amount of Lab Test Fraud? Revealing the Scale & Scope of What Payers See.***
- ***New Ways to Use Lab Automation to Cut Costs While Boosting Productivity of Lab Staff.***