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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Healthcare's Ongoing Struggle: Patients or Profits?

ALL THE MISPLACED INCENTIVES OF A HEALTHCARE SYSTEM that uses fee-for-service to reimburse providers continue. The diverse spread of lab industry business intelligence presented in this issue of THE DARK REPORT vividly demonstrates that there continues to be a "best" and a "worst" in provider motives and behaviors during the last days of fee-for-service payment.

On the "best" side, we present the experience of a quality improvement team at **Intermountain Healthcare** in Salt Lake City. At the inception of a project to attack severe sepsis and septic shock in its emergency departments and ICUs, Intermountain's sepsis mortality rate was already at the lowest end of the national average, at 20.2%. You'll read how the team, after it engaged the expertise of phlebotomy and the clinical lab professionals, drove down the septic mortality rate to under 9%! *(See pages 6-9.)*

Similarly, our interview with Matthew Hawkins, President of **Sunquest Information Systems**, delivers insights about how the nation's most progressive healthcare systems are moving forward with patient-centric clinical care. In every case, better use of lab test data is a linchpin to these efforts. He describes the opportunities clinical labs have to leverage lab test data to help clinicians deliver better patient outcomes. *(See pages 10-15.)*

On the "worst" side, you'll read about two different bills working their way through the Florida Legislature. Our lead story on pages 3-5 provides the details of a remarkable play by one or more of the national lab companies to get the Florida Legislature to pass a bill that would retroactively change a long-standing state law on Medicare pricing—and would thus make a state whistleblower lawsuit moot. As you will read, the state's Attorney General showed up at a subcommittee to call attention to the brazen nature of this bill.

The second story on pages 16-19 deals with an effort by physicians in Florida to support a bill in the legislature that would restrict the use of clinical decision support and laboratory benefit management systems in certain circumstances. This bill is associated with the physician dissatisfaction with **UnitedHealthcare's** requirement that they must use **LabCorp's BeaconLBS** system before ordering about 80 lab tests.

Judge for yourself whether the main motive behind each of these bills in the Florida legislature is "patient" or "profit." TDR

Florida AG Opposes Bill Over Customary Charges

Bill would change Medicaid price definition and retroactively kill ongoing whistleblower suit

CEO SUMMARY: It was a surprise to the Florida Attorney General that a bill had surfaced in the Florida Legislature to amend the existing state law's definition of usual and customary pricing to the Medicaid program. The bill would even make that change in definition retroactive. If this bill clears the legislature and becomes law, it would render moot an ongoing whistleblower lawsuit that accuses the two national lab companies of overcharging the Florida Medicaid program.

WHAT IS A LAB COMPANY TO DO when it is a defendant in a lawsuit accusing it of violating state Medicaid laws governing discounted pricing for lab tests? Why, simply go to that state's legislature and get a bill passed that retroactively makes your lab company's pricing practices legal—thus making the ongoing lawsuit moot!

This appears to be exactly what **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** are attempting to do in Florida. The two lab companies are defendants in a *qui tam* case alleging that they violated Florida law in how they charged the Medicaid program for laboratory tests.

Representatives of the two lab companies recently appeared at a house committee hearing on January 13 to support the bill in question, HB 421 or SB 526, Reimbursement of Medicaid Providers. This bill would change the existing language defining "usual and customary charges" to now mean "the amount routinely billed by a provider or supplier to an uninsured consumer for services or goods before application of any discount, rebate, or supplemental plan. The term does not include free or discounted charges for services or goods based upon a person's uninsured or indigent status or other financial hardship."

Also attending this House committee hearing was Pam Bondi, Attorney General for Florida. She minced no words in telling the committee not to advance a bill that would undermine the ongoing state *qui tam* lawsuit against LabCorp and Quest Diagnostics.

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

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At stake are millions of dollars from a scheme to defraud the state's Medicaid program, Bondi declared in her testimony. Bondi interprets existing Florida law as requiring providers to charge the state Medicaid program the lowest rate they receive from any third-party payer.

The *qui tam* case in question was filed by Chris Riedel and **Hunter Laboratories** against Quest Diagnostics and against LabCorp. The State of Florida has joined the case as a plaintiff against the two labs. The case is *State of Florida ex rel. Hunter Laboratories, LLC, and Chris Riedel v. Quest Diagnostics, Inc., et al*, in the Circuit Court for the Second Judicial Circuit in and for Leon County, case number 2007-CA-003549.

Millions of Dollars at Stake

In her statements, Bondi alleged that Florida House Bill 0421 would undermine her case against Quest and LabCorp. An identical bill, Senate Bill 526, is pending in the Florida Senate.

During the hearing conducted by the House Health Innovations Subcommittee on January 13, Bondi said that if the bill becomes law, it would cost Florida taxpayers tens of millions of dollars. The committee took no action that day, deciding to temporarily postpone a vote on the bill. As of press time, committees in the house and senate had not acted on the bill.

"I am here to tell you today that, as your chief legal officer for the State of Florida, I have an obligation to be standing here in front of every one of you here today and tell you that we have very active litigation pending involving massive healthcare fraud," Bondi told the members of the Health Innovations subcommittee.

"You would be legislating one case pending in Florida currently and it's by LabCorp and Quest," she said. "And Mr. Huey, who I respect, is here representing LabCorp and this is his legislation." J. Michael Huey, an attorney with **Gray Robinson** in Tallahassee, represents LabCorp in the case of *State of Florida ex rel. Hunter Laboratories, LLC, and Chris Riedel v. Quest Diagnostics, Inc., et al.*

'Defrauding Your Taxpayers'

"So if this bill passes your committee, you will be an unwitting facilitator to potentially costing our taxpayers millions of dollars. Millions!" emphasized Bondi. "This is big because these two companies are defrauding your taxpayers.

"We are alleging tens of millions of dollars [of fraud] here in Florida," she continued. "You all know we are a bellwether state and I am telling you now the eyes of the entire country are on us because LabCorp and Quest know other states in the rest of the country are looking at this.

"This is very active litigation. In my five years I have never seen anything like this about to happen," she explained. "The proper forum for this to be heard is in sworn court testimony where it [this lawsuit] is ongoing.

"This [bill] is an end-run, desperate attempt… in a potentially multimillion case that impacts Florida and other states around the country," commented Bondi. "This is very serious. And you also need to know that there is a federal component to our case.

'To Kill Active Litigation'

"I am confident this [proposed bill] is being done… to kill our active litigation," she continued. "It is highly inappropriate to be handled in the middle of litigation that affects all of our constituents and our taxpayers especially.

"By passing this bill, by voting yes today, you will be giving these companies an open checkbook to raid our Medicaid program," Bondi charged.

Also, she addressed an amendment that was added to the bill to make any change in state law regarding usual and customary charges retroactive. "The amendment is the icing on the cake. It's

not even hiding anymore. They [the defendant lab companies] want it to be retroactive. This [law] alone would be damaging enough. But to make it retroactive, it's basically in your face saying it's about our litigation," added Bondi.

Bondi went on to explain that attorneys general in other states, such as California and Nevada, have settled similar cases for hundreds of millions of dollars. Lab directors and pathologists are familiar with the similar case in California. In 2011, Quest Diagnostics agreed to pay $241 million to settle allegations that it overcharged Medi-Cal, California's Medicaid program. That same year, LabCorp agreed to pay $49.5 million to California in a similar settlement. Neither company admitted guilt.

LabCorp's Representative

Following Bondi's statement, Huey addressed the committee, saying healthcare providers in Florida are under no obligation to charge the state Medicaid program the lowest amount that they receive from any third-party payer. He stated that he had never heard of the definition of usual and customary in which all providers—including labs, physicians, hospitals, and others—would have to bill Medicaid the lowest charge that was paid by any third-party payer.

In his comments, Huey said, "When LabCorp came to me, they asked, 'What do you know about this? We're being sued on a Medicaid fraud claim.' I have been representing providers in Florida for over 40 years and I've never heard of this."

Looking into the issue raised by LabCorp, Huey said that he asked other provider organizations about how they handled usual and customary charges. "Hospitals use their charge master rate. The doctors use whatever their normal charges are. They get paid the Medicaid rate because Medicaid establishes a rate for every service for every provider," he told the House committee members.

Defining the Meaning of "Usual and Customary"

AT ISSUE IN THE WHISTLEBLOWER LAWSUIT that Florida Attorney General Pam Bondi joined is the definition of "usual and customary" charges. Under state law, the term, "usual and customary" is defined as noted below.

Florida statute 59G-5.110(2) took effect May 9, 1999. It is also known as the "lowest charge rule" and says:

"Charges for services or goods billed to the Medicaid program shall not exceed the provider's lowest charge to any other third party payment source for the same or equivalent medical and allied care, goods, or services provided to persons who are not Medicaid recipients.

"Any services or goods customarily provided free of charge to patients may not be billed to Medicaid when provided to Medicaid recipients. Any payment made by Medicaid for services or goods not furnished in accordance with these provisions is subject to recoupment and the agency may, in such instances, initiate other appropriate administrative or legal action."

Huey further stated that, twice he took his findings to the state's administrative court and an administrative law judge ruled in his favor each time. Yet, stated Huey, after each ruling, Attorney General Bondi sought to insert her definition of usual and customary as a rule for the state's Medicaid department, the **Agency for Health Care Administration**, he said. It was for this reason that he brought the matter to the legislature and asked for this bill, concluded Huey.

During this committee hearing, Doug Russell, the representative from Quest Diagnostics stated that "Quest waives its support for this bill." As of press time, there no additional developments regarding this bill. **TDR**

—Joseph Burns

Phlebotomy Contributes To Drop in Sepsis Mortality

Phlebotomist's expertise on the team helped program cut the death rate from sepsis in half

CEO SUMMARY: When Intermountain Healthcare began a quality improvement program to address sepsis, its sepsis mortality rate was 20.2%, among the lowest in the nation. By 2007, all 15 of its hospitals had deployed this program. A breakthrough came in recent years, when a phlebotomist was added to the team and contributed new insights into how to diagnose "tweener" patients early, meaning those who have yet to show all the symptoms of sepsis. Intermountain's sepsis mortality rates fell to under 9%.

EIGHTEEN MONTHS into its nationally-recognized quality improvement program for managing severe sepsis and septic shock in the emergency department and ICU, the team at **Intermountain Healthcare** in Salt Lake City had hit a wall. But after adding a phlebotomist to the team, a wave of impressive gains was realized.

"That phlebotomist and the suggestions he offered to our team made such a difference that the initiative showed improvements in compliance with the program's protocols almost immediately," stated Todd Allen, MD, who started with the original program at Intermountain in 2004.

Saving Hundreds Of Lives

"The other significant benefit was that, soon thereafter, sepsis mortality rates started to drop as well," added Allen, who is the Program Chair of the Emergency Department Development Team within Intermountain's Intensive Medicine Clinical Program.

When the program commenced, Intermountain's sepsis mortality rate was 20.2%, which was among the lowest in the nation. But Allen believed Intermountain could do better. The numbers tell the story. As a result of the sepsis-management protocols Allen and his team instituted, Intermountain has cut the mortality rate in half. Today that rate is less than 9% and Intermountain's program saves more than 100 lives annually, according to *Hospitals & Health Networks* magazine.

Pathologists and lab professionals can use the lessons learned and experience gained at Intermountain Healthcare to inform similar efforts to improve the diagnosis and management of sepsis at their own hospitals throughout the nation.

What will be particularly inspiring to hospital laboratory administrators is how, after including a phlebotomist and his frontline expertise on the team, the sepsis management program could achieve further, ongoing improvements in reducing mortality from sepsis and septic shock that have saved hundreds of lives.

The challenge presented by sepsis is huge. The mortality rate in most hospitals is 25% to 50% of patients with severe sep-

sis, and the condition kills 220,000 patients annually, H&HN reported. As of January 1, the federal **Centers for Medicare & Medicaid Services** put new rules in place for the treatment of patients with sepsis and septic shock, called SEP-1.

"When I started the work of improving our diagnostic and treatment reliability on patients with sepsis and septic shock, I didn't fully appreciate the importance of how blood tests were collected and processed," Allen said in an interview with THE DARK REPORT. "My approach to labs was simplistic: I thought I would order a lab test and get a number back.

"I didn't think carefully about all the steps of ordering a lab test, collecting the specimen, sending the order to the lab, and incorporating those results back into the process of care," he noted. "I didn't see that each was a critical step in our process-improvement effort.

"Consequently, when the team was organized, it did not include a member of the lab staff, and, in particular, phlebotomy was left off of our team," continued Allen. "For that reason, despite lots of effort in the first 18 months of the program, we made almost zero progress. By excluding that key part of the process—phlebotomy—it seems like I doomed myself from the beginning.

Adding A Phlebotomist

"During those 18 months when we weren't seeing much progress on our sepsis management goals, we tried many different kinds of improvements," recalled Allen. "First we worked harder, then we worked smarter. Then we got more educated and then looked for an IT solution. Then we went back to get more education. Then we hoped and prayed. But nothing seemed to click until we finally added a phlebotomist to the program."

More months might have passed if the phlebotomist, Ryan Black, hadn't asked to work with Allen. "Ryan Black was preparing to go to medical school and wanted to add some activities to his application in order to show that he did more than just work as a phlebotomist," Allen said. "He wanted to help in any way he could and so I suggested he join the sepsis project.

"As I recall, I said something like, 'I don't think you'll have much to add,'" Allen explained. "'But come along, you'll learn something, and I'm happy to certify that you participated on this team.'

"So he did and he was polite and professional and tried not to interrupt," noted Allen. "But then, at one point, he said, 'I think we're missing an important piece in the process of identifying patients with potential sepsis and getting an earlier start on their diagnostics and treatment. Here's my idea. What do you think about it?'

Identifying Sepsis

"As a phlebotomist working on the clinical team, he had a sense—through his experience with our patients—of when people are potentially septic or not," Allen said. "He saw that we were very good at identifying those patients who definitely have sepsis and excluding those who definitely do not have sepsis. The signs of sepsis are sometimes obvious, such as fever, low blood pressure, clear infection, and tachycardia.

"But he also saw that we had a difficult time with patients you might call 'tweeners.' By that, I mean patients who may not have developed a fever yet, maybe their complaint isn't the productive cough or painful urination," stated Allen. "These patients may have weakness, dizziness, malaise, nausea—all of which can be early nonspecific signs and symptoms of sepsis.

"In a busy emergency department, I'm often in a hurry," he continued. "So I take a brief history, do a focused exam, and I may not pick up all the clues that are there. But Ryan noticed that all of these patients were at least ill enough to require some diagnostics and so we ordered lab tests on almost all of them. That meant he would get involved to do the blood draw.

"Ryan then observed that most of these who turned out to be septic were intravascularly depleted and it was tough to find a good vein to access," he explained. "So in order to find that good vein, he had to get really close to the patients and spend some time with them, touching, warming, and looking carefully at the skin. Sometimes it took him three minutes or so to find the vein. Ryan started to notice subtle changes in capillary refill and skin warmth that, in his experience, correlated with sepsis.

Reading Signs, Symptoms

"Then Ryan told me this: 'As a result of the thousands of patients from whom I've drawn blood, I think I can tell when patients are sick by the touch, by their skin turgidity, by the cap refill rate. These are all signs of a potentially more serious illness,'" noted Allen.

"Ryan was worried that, whenever he noticed these signs, my orders did not always reflect that same level of concern," noted Allen. "If my orders didn't include a blood culture or a lactate test, it meant I was not thinking about the possibility of sepsis in these patients. Ryan could tell when his suspicions did not match mine!

"He asked if I were willing to expand the test-ordering permissions and governance to allow him to start the approved sepsis diagnostic pathway as long as I gave my confirmation later," he explained. "A physician must sign off at some point. He saw that I was busy and he did not want to wait to start the diagnostic process if he suspected sepsis. We agreed that we would start a trial of initiating the sepsis diagnostic bundle independent of my approval.

"That's when I had my 'aha moment' about phlebotomy," declared Allen. "I had almost completely ignored that part of the process and the expertise of the phlebotomist, both as a member of the core team and at the bedside. So, I took his suggestion and implemented it as soon as possible, and it made all the difference in our sepsis management program.

"We instituted a standing directive that he (or his trained phlebotomy colleagues) could initiate lactate and blood culture tests as long as the treating physicians approved them later," added Allen. "The quid pro quo was a promise that I wouldn't get mad at him if he was wrong. Essentially, he would bail me out and I would keep him safe. After all, he was looking out for me and our patients.

"That one change gave us the extra intelligence we needed on those tweener patients," he said. "Thereafter, we began to see improvements in compliance with all steps in our sepsis bundle.

"Improved compliance with the bundle means that: 1) we drew the blood culture test before antibiotics were administered and, 2) that the serum lactate test was done for patients with potential early sepsis and septic shock," observed Allen. "After Ryan got involved, we saw those numbers improve almost immediately. And they continued to improve whenever we made adjustments to the bundle.

"This phlebotomist helped us break through our self-imposed glass ceiling in terms of bundle compliance," emphasized Allen. "Once we got that compliance moving up toward 80% in all 22 hospitals, then our mortality rate from sepsis started to drop as well.

Appointed Lead Phlebotomist

"Looking back on it, I saw that Ryan had a special combination of skills and knowledge and that's why we made him our lead phlebotomist," he added. "We now recognize that most well-trained and experience phlebotomists can do what he did.

"Let me add that the phlebotomists I've met and worked with at Intermountain are a special bunch," he enthused. "They have a special skill set and if you treat them as healthcare professionals and allow them to use their skills maximally, then you'll get good results. The same is true of nurses or patient care technicians. If you give people the opportunity to excel, they will."

Reducing Mortality from Sepsis is Multi-Year Effort By Improvement Team at Intermountain Healthcare

IN 2004, A CLINICAL TEAM at Intermountain Healthcare in Salt Lake City began developing an evidence-based protocol for the aggressive detection and treatment of sepsis. The goal was to start in the ED, then expand use of the protocol into the intensive care units.

Nationally, it is recognized that mortality rates for sepsis cases that enter the hospital through the emergency department can vary from 20% to 50%. In 2004, Intermountain Healthcare was recording one of the lowest sepsis rates in the nation, at 20.2%.

Under the direction of team leader Todd Allen, MD, Program Chair of the Emergency Department Development Team within Intermountain's Intensive Medicine Clinical Program, an initial bundle of 11 elements was developed. In a story published by *Hospitals & Health Networks*, Allen explained that "Four typically are implemented in the ED, four in the ICU, and three can be applied in either setting. The bundle addresses the following elements: (in the ED) serum lactate, blood cultures, broad-spectrum antibiotics and fluid resuscitation; (in either setting) vasopressors, CvO2 measurement, and inotropes and/or blood transfusion; (in the ICU) steroids, glucose control, rAPC use in eligible patients and a lung protective ventilator strategy." These elements were reduced to seven in 2011 to reflect changes in clinical practice.

Implementation began in 2006 and by 2007, all 15 IHC hospitals were using the protocol in their emergency departments and ICUs. Allen reported that, by 2010, compliance with the sepsis protocol bundle had reached 80%—meaning that, 80% of the time, 100% of the appropriate bundle elements were followed by the clinical team.

Allen wrote that: "As a result of the 80% compliance, Intermountain achieved the following care and cost improvements from a study cohort of 4,329 patients from 2004 to 2010:

- The rate of survival increased from 20.2% mortality to under 9%.
- The average length of hospital stay was reduced by 20 hours.
- The average cost per patient declined by nearly $3,000."

Because of this quality improvement program, Intermountain has reduced the sepsis mortality rate to under 9%. It saves the lives of more than 100 patients annually because of better compliance with guidelines.

In addition to serving as a team member who could order preliminary diagnostic tests, Black served as a liaison to the clinical lab, a factor that led Allen to work more closely with pathologists. "Once I got smarter about lab testing, I reached out to our laboratory leaders, the pathologists, to make sure they knew what I was trying to do. It was important, for example, to ensure blood cultures were drawn before antibiotics are given and the pathologists helped us achieve the lab test result turnaround time our sepsis team needed.

"Improving TAT was just a matter of helping them identify the specimens we care about most and having them make those specimens a priority," recalled Allen. "Everyone in the clinical lab was very willing to help us.

"Today, the 22 hospitals in the Intermountain system use our sepsis protocol," he continued. "Because we have such a variety of facilities, each hospital and each emergency department had to somewhat customize how sepsis patients' laboratory tests flowed from those departments to our regional labs or to the local laboratories. But from central lab leadership on down and throughout the system, every lab and every person seemed fully invested. All that helped us figure out how to be more timely and accurate with these tests." TDR

—Joseph Burns

Contact Todd Allen, MD, at 435-792-1950.

NEWSMAKER INTERVIEW

Assessing Healthcare's Need for Advanced Laboratory Informatics

CEO SUMMARY: By now, most pathologists and clinical laboratory administrators recognize that effective use of information technology will be a critical success factor as healthcare systems transform to do population health management and to use "big data" with value-based payment models. As the provider of laboratory information systems to hundreds of the nation's major hospitals, health systems, and academic systems, Sunquest Information Systems is engaged with its clients to add functionality in support of these goals. Editors Robert Michel and Joseph Burns conducted an interview with Sunquest President, Matthew Hawkins to learn more about what market trends are driving lab test services, how hospitals are leveraging lab test data, and how labs can prepare for the coming market transformation.

AS PART OF HEALTHCARE'S ONGOING TRANSFORMATION, clinical laboratories and anatomic pathology groups will need to become more sophisticated in their use of information technology. Supporting interconnectivity with hospitals, physicians, and payers is just the starting point. Labs will have greater roles in helping clinicians improve patient outcomes.

To provide perspective on the informatics trends in healthcare and the clinical laboratory and pathology markets, THE DARK REPORT spoke with Matt Hawkins, President of **Sunquest Information Systems**, based in Tucson, Arizona. Sunquest sells laboratory information systems (LIS) and related informatics services. Hundreds of clinical labs, hospitals, health systems, and anatomic pathology groups use these systems.

EDITOR: Matt, thank you for taking the time to discuss these issues with us. Let's start with what you see as the most significant trends unfolding in the healthcare system today?

HAWKINS: Three macrotrends are driving change and having the biggest impact. The first macrotrend is the tremendous amount of market consolidation taking place among hospitals and health systems. The second is the need to offer patient-centric care. The third trend is the shift away from fee-for-service in favor of value-based and budgeted payment arrangements.

EDITOR: Would you explain trend one, the consolidation of hospitals and health systems. Why is this consolidation happening now?

HAWKINS: We see three factors motivating hospitals to consolidate. One is to achieve larger scale that enables these hospitals to have more leverage when they negotiate with payers. The second is to add the resources needed to provide more clinical services for their patients. The third is to improve geographical coverage to better serve the outpatient market, which is growing more than twice as fast as the inpatient market.

EDITOR: Would you speak to the second macrotrend, that of patient-centric services?

HAWKINS: Hospitals and health systems are taking steps to get closer to patients. For example, consolidation of hospitals helps to achieve this goal within the community or the metropolitan area they serve. This consolidation is consistent with the progress hospitals and physicians are making to create integrated clinical delivery systems that are specifically designed to deliver patient-centric care.

EDITOR: Would you discuss patient-centered care in more detail?

HAWKINS: The message is getting through to hospitals, physicians, insurers, and others that the patient—the consumer—will be front-and-center in tomorrow's healthcare system. To prosper in this environment, health systems must learn from the banking, retail, and travel industries, for example, to identify patients' expectations and then to meet and exceed those expectations with higher quality, improved timeliness, and lower costs.

EDITOR: How is Sunquest responding to this patient-centric trend in healthcare?

HAWKINS: Sunquest believes that consumerism will influence the way clinical care is provided in the future as patients become more and more responsible to directly pay their providers, including medical laboratories. The trend is definitely to require

patients to have higher deductibles and to take a more active role in their healthcare.

EDITOR: What do you see happening with the third macrotrend?

HAWKINS: This trend is related to the shift to value-based care. Your readers are aware that the transition from fee-for-service reimbursement to value-based and budgeted payments is accelerating. That requires every clinical service—including the clinical lab—in every health system to adopt a razor-sharp focus on cost reduction and quality improvement.

EDITOR: Could you add some detail to this, please? As this macro trend involving the transition to budgeted payments plays out, what do you see providers doing differently in response?

HAWKINS: Hospitals and health systems are recognizing that there are significant direct costs that can be reduced. Indirect costs are also getting scrutiny.

EDITOR: This makes sense. If a hospital is getting paid a fixed sum for patient care, similar to a Medicare DRG, then everything becomes a cost.

Matthew Hawkins

➤"Sunquest believes that consumerism will influence the way clinical care is provided in the future as patients become more and more responsible to directly pay their providers, including medical laboratories."

HAWKINS: Yes. Most of our hospital customers are already devoting more resources to identifying unnecessary costs, then working to reduce or eliminate those costs. Don't overlook the fact that, to succeed in providing value-based care, the provider must add services in support of population health management. Both smart cost-cutting and population health management require sophisticated data collection and information systems to optimize care delivery. That is why providers are spending more in information technology, which is essential to support these activities.

EDITOR: Obviously these three healthcare macrotrends are critically important trends to clinical laboratories. What are the drivers and primary trends changing today's market for clinical labs and pathology practices?

HAWKINS: In the clinical lab marketplace, consolidation is ongoing. In the independent lab sector, there continues to be plenty of buyers for any lab company that comes up for sale. As hospitals consolidate, they will take the obvious steps to consolidate lab test services, then use that critical mass to boost their outreach lab programs.

EDITOR: What other market forces are reshaping the clinical lab marketplace?

HAWKINS: What doesn't get much attention, but is a powerful trend is the much faster growth of the outpatient service market. Revenue from inpatient admissions is shrinking. Thus, as healthcare systems buy more hospitals, clinics, and primary care practices, they put more attention into serving patients in outpatient and ambulatory settings.

EDITOR: That is an interesting answer. Would you explain in more detail?

HAWKINS: The statistics tell a compelling story. Since 2007, there's been a cumulative 33% increase in outpatient procedures even as inpatient procedures declined by a cumulative 17%! What this means for hospital-based clinical labs and pathology practices is that they need to reach outside the hospital setting and into the community to build volume and market share.

EDITOR: What are your lab customers doing to improve their outreach programs?

HAWKINS: One need is for them to bring their basic customer service levels up to a level that equals how the national labs serve office-based physicians. For example, we see more hospital lab out-

reach programs improving specimen collection and tracking of those specimens to ensure accuracy and to prevent errors.

EDITOR: This reflects the reality of where most lab errors originate, correct?

HAWKINS: Yes. Decades of clinical studies demonstrate that labs are excellent at the analytical stage. It is in the pre- and post-analytical activities where most errors affecting lab tests occur. Therefore, labs need to ensure order accuracy on the inbound side. Then, on the post-analytic side, they need to ensure the physicians are interpreting the results they send them correctly.

EDITOR: How is this changing clinical lab operations?

HAWKINS: In the post-analytical stage, we see labs investing in informatics tools that make it easier for physicians to understand the test results. This often includes creating capabilities that allow lab professionals and pathologists to regularly interact and consult with providers to ensure that all ordering physicians understand the test results labs sent to them.

EDITOR: What other trends in the marketplace are affecting clinical labs and pathology groups?

HAWKINS: One big factor is that our lab clients now see increased competition from lower-cost patient service centers and labs that do testing at very low rates. **Theranos** is a well-known example. This lab company entered Arizona and offers very low prices for lab testing. Who knows if those low rates are sustainable or if Theranos will be successful outside of Arizona? What is true is that Theranos has stirred up more interest among consumers for low-cost testing—particularly if they have no health insurance or high deductible health plans.

EDITOR: If you see falling lab test prices as a trend, do you also see cost-cutting in labs as a trend?

HAWKINS: Yes, that is definitely true. Many of our client labs now put greater emphasis on finding ways to lower costs of basic and complex tests as much as possible. They do this while at the same time making changes designed to improve the patient care experience.

EDITOR: Can you provide examples?

HAWKINS: To improve the patient care experience, labs are moving to faster turnaround times for reporting results. Another strategy is to upgrade patient portals so that patients can access their lab test results in an easy-to-understand dashboard or report.

EDITOR: As a trend, how do you see the trend of steady growth in the use of molecular diagnostics and genetic testing playing out for clinical labs and pathology groups?

HAWKINS: That question strikes to the heart of a bigger trend we see unfolding in the lab testing marketplace. Yes, increased genetic testing is happening. However, this trend is interwoven with healthcare's ongoing movement toward personalized medicine and precision medicine. Using genetic tests in support of precision medicine is having a profound impact on how the nation's most innovative laboratories think about how they can add value to their parent hospitals, physicians, and payers.

EDITOR: By that, are you saying that you already see some clinical laboratories, in order to deliver more value to physicians and payers, moving to a new model of care delivery?

HAWKINS: Yes, absolutely! That's a very important issue to address today. Labs must become proficient at collecting lab test data, storing it, and analyzing in ways that contribute to improved patient outcomes and patient safety.

EDITOR: This is also consistent with the trend toward the patient-centric delivery of healthcare, right?

HAWKINS: You are correct and we also find that one of the most important vari-

ables in the delivery of care for any patient is time. By that I mean, how much time is required for an integrated health system to either prevent disease or to cure disease. So if you want to take costs out of the healthcare delivery process, we believe that more care coordination will be accompanied by faster diagnoses of patients. That is consistent with the goal of preventing illness.

EDITOR: Taken together, your comments are that the successful lab of the future will deliver fast and accurate lab test results, offer an appropriate menu of genetic tests, and have the informatics capabilities to analyze large amounts of data in support of both population health management and precision medicine.

HAWKINS: That captures much of what we see in the healthcare marketplace today.

EDITOR: Then this is a good place to shift our conversation away from the trends you are tracking with the healthcare system and the clinical laboratory marketplace. Instead, let's talk about what your most innovative LIS customers are doing to be ahead of these trends. Can you explain how your LIS clients are building the infrastructure for value-based care and population health? By that, I mean, what is the role of the clinical lab in fostering these trends?

HAWKINS: When you think about the role of the lab, much of the critically important clinical information that ends up in a patient's health record comes directly from the lab. So, as large health systems think about how to care for populations of patients, they are starting to see the value of that information.

EDITOR: Do you have examples of health systems moving down this path?

HAWKINS: The **University of Pittsburgh Medical Center** and the **Henry Ford Health System** (in Detroit) are two examples of innovative health systems that are using diagnostic laboratory information to serve their patients. **Partners Healthcare** (in Boston) and **Carolinas HealthCare System** (in Charlotte) are two other examples of health systems that have been innovative in connecting physician offices to lab test data. Both health systems asked us for information systems that will help them manage populations of patients.

EDITOR: What are the hurdles to achieving this?

HAWKINS: What these health systems want is a richer flow of data, which already exists in our LIS. Sunquest's challenge, then, is to help our clients manage that tremendous volume of rich clinical, HIPAA-compliant data so it can be used to control costs, identify patients who need more intensive care, and to improve the quality of care. By bringing that together, our LIS can contribute enhanced value to our clients.


Matthew Hawkins

➤ "...individual health systems... in general terms, now use lab orders and test results to determine how to optimize care and how to reduce duplicate orders."

EDITOR: Do you have examples of the innovations taking place at these health systems?

HAWKINS: It would not be appropriate to discuss what these individual health systems want from data. But I can tell you that, in general terms, they now use lab orders and test results to determine how to optimize care and how to reduce duplicate orders. Thus, they have a common goal of optimizing the ordering of tests.

EDITOR: Do you see these health systems working to improve utilization of lab tests?

HAWKINS: Yes, and this is just the first goal with lab testing that the systems are pursuing. As you know, there is much overuse of lab tests and significant underuse of tests. One job we have is helping our LIS clients to eliminate both overuse and underuse by getting to optimal use. In addition, they want laboratory information sys-

tems and companies like Sunquest to collect and store all that data in a way that is useful for identifying methods to improve care going forward, not just for today.

EDITOR: Is this so the health systems can add richer sets of lab test data to contribute to their "big data" efforts?

HAWKINS: Yes, but don't overlook the practical use of data from the lab that can help the parent hospital improve throughput in the emergency department. We also see hospitals using lab test data to assess what is happening in the primary care clinics that they own. The health systems want to know if physicians are following up on their patients appropriately and if the primary care clinics are moving patients efficiently.

EDITOR: So there is a dual use of lab test data. One use is to improve patient flow. The other use is to better support physicians at selecting the right test for the right patient at the right time.

HAWKINS: Better utilization of lab tests is especially true for diagnoses for high-risk patients in certain disease states. Our clients are asking for more detailed information from the lab about specific disease states.

EDITOR: Do you have examples?

HAWKINS: I've seen that, once one of these innovative health systems begins feeding a richer stream of lab test data into their EHRs, there is more focus on ensuring that appropriate follow-up actually happens. Health systems want to know that any treatment that was prescribed was appropriate based on the lab test results, or that the lab results were used to correctly diagnose the patient's condition.

EDITOR: Is it becoming more common to see the parent hospital electronically match diagnoses, like ICD-10 codes, with the lab test results that would be appropriate for patients, then alert physicians to gaps in the care of patients?

HAWKINS: That is happening, yes. In other words, if a patient has diabetes, the health system wants to know that there are hemoglobin A1C test results in the EHR and that the doctor is taking appropriate steps to manage that patient's care.

EDITOR: Is this evidence that more health systems are getting "data savvy" in how they assemble clinical information, including lab test results, then analyze it to identify the best ways to help physicians improve patient care?

HAWKINS: Yes, that's exactly right! This is a significant development relative to the macrotrend we discussed earlier about how a growing number of institutions want a richer flow of data from the lab back to the health system's information system. This makes it possible for the health system to drive population health initiatives while also helping physicians identify the most appropriate lab tests required to support the practice of precision medicine.

EDITOR: Matt, to close this interview, what recommendations would you make to lab executives and pathologists who want to keep their labs in the forefront of clinical care going forward?

HAWKINS: I have two key suggestions. First, leverage data to quantify not just the cost of laboratory operations, but also the reimbursement and revenue that laboratory services contribute. The ability to quantify value will help laboratory executives have a much different conversation with their leadership teams with regards to investments for the laboratory. Second, closely align laboratory strategies with the broader organization's strategic priorities. With approximately 80% of physicians' diagnoses resulting from lab tests, every laboratory can uniquely impact priorities associated with care quality and population health. TDR

—Joseph Burns

Contact Stephanie Clohessy at 520-570-2599 or Stephanie.Clohessy@sunquestinfo.com.

Matthew Hawkins

Lab Benefit Management Bill Advances in FL Senate

Senate bill would set some restrictions on use of clinical decision support systems for lab orders

CEO SUMMARY: To date, a bill to restrict how health insurers use lab benefit management systems such as UnitedHealthcare's BeaconLBS, has been favorably received in the Florida Senate. But the bill may face opposition when presented to the Senate's Appropriations Committee. In a report, the state Office of Insurance Regulation said that restricting the use of clinical decision support and laboratory benefit management programs could raise costs to the state Medicaid program.

In recent weeks, two committees in the Florida Senate gave favorable votes to a bill to restrict the use of clinical decision support and lab benefit management programs.

Hearings on the bill were conducted by the Banking and Insurance Committee on January 20 and the Health Policy Committee on February 1.

Supporting the bill have been such state physician associations as the **Florida Society of Pathologists,** the **Florida Society of Rheumatology**, and the **Florida Medical Association**. FSP is working with lobbyist Amy Young of Ballard Partners, according to FSP President Margaret Neal, MD, FCAP, of **KWB Pathology Associates** in Tallahassee.

As currently written, the bill would limit how clinical decision support systems and laboratory benefit management programs—such as the program **UnitedHealthcare** introduced in Florida—can be used. On April 15, 2015, UHC required physicians serving its commercial HMO patients to use the **Beacon Laboratory Benefit Solutions** system when ordering any one of about 80 clinical lab tests. BeaconLBS is a business division of **Laboratory Corporation of America**.

Physicians must use BeaconLBS when ordering certain tests and wait for an authorization from BeaconLBS before sending lab test requisitions to one of 20 "labs of choice" that UHC and BeaconLBS designated as in-network labs. LabCorp owns eight of those 20 labs. *(See TDRs, July 21 and November 24, 2014, and January 5 and March 9, 2015.)*

Concern About Costs

Supporters of the bill may face opposition when SB 1084 is presented to the Senate's Appropriations Committee in the coming weeks. The Department of Management Services in the state Office of Insurance Regulation, Division of State Group Insurance, has said that restricting the use of clinical decision support and laboratory benefit management programs could raise costs to the state Medicaid program.

In a report on this matter, the DMS wrote, "Further, the DMS states that the

provision in the bill that prohibits HMOs from requiring healthcare providers to use a clinical decision support system or a laboratory benefits management program, to direct or limit provider's decision-making ability could affect the state group health insurance program. Changes to current medical management procedures that cause an HMO's medical costs to increase would result in higher negotiated premiums for the state-contracted HMOs."

This report is titled: "Senate Bill 1084 Fiscal Analysis *(January 14, 2016)."* It is on file with the Senate Committee on Banking and Insurance.

Two Committee Hearings

During two committee hearings, no opposition has been raised and no support has been introduced regarding the section of the bill that would limit how health insurers can limit the use of decision support or lab benefit management systems. To date, all of the debate has focused on another section of the bill that addresses the protocols health plans use to manage physicians prescribing prescription drugs.

State Sen. William Gaetz who introduced SB 1084, said he expects the decision support and lab benefit management portions of the bill to be debated and he expects opposition from health plans. The Senate's Appropriations Committee will be next to consider the bill, but no date was set as of press time.

Robert W. Levin, MD, a rheumatologist in Dunedin, Florida, is prepared to defend the bill if there is any opposition. As the President-Elect of the Florida Society of Rheumatology, Levin is a staunch opponent of BeaconLBS.

"Rheumatologists are very much affected by the BeaconLBS system because the tests we order are needed for many reasons," he said. "The most ridiculous example from the BeaconLBS program is the requirement to get authorization for testing for lupus, specifically, ANA testing.

There Is Plenty of Resistance to UHC, BeaconLBS System

FROM THE FIRST ANNOUNCEMENT by UnitedHealthcare in early 2014 that it would require Florida physicians serving beneficiaries enrolled in UHC's commercial HMO to follow the requirements of its laboratory benefit management program, there has been much dissatisfaction and outright opposition.

Several of Florida's specialty medical associations wrote to UnitedHealthcare describing their objections to the program, including: Florida Society of Pathologists, Florida Society of Rheumatology, Florida Medical Association, and the **Congress of Obstetricians and Gynecologists**, District XII (Florida).

Even **COLA** took objection because it was excluded as a laboratory accreditation organization for UHC's laboratories of choice network.

"The diagnosis of lupus is very hard to make," observed Levin. "It combines lab criteria with the patient's signs and symptoms from a physical exam. I've been trained to do this diagnosis through medical school, internship, residency, and a rheumatology fellowship, and I can't figure out how a computer or a decision support system would trump my clinical impression of whether the patient needs a workup for lupus. This diagnosis requires an objective evaluation combined with an expert opinion and there is no way a computer can do that. It's absolutely insulting!

Diagnosing Lupus

"I understand that insurers will say there is some inappropriate ANA testing," he continued. "The truth is that ANA testing is not appropriate for every elderly patient who comes in with degenerative arthritis. There is no reason to do an ANA on those patients. But for a patient you suspect has lupus, then an ANA test is the most helpful lab study we can do.

"In addition, we also need to do the follow up lab testing—which is called an ANA profile—to see if you can confirm the diagnosis," explained Levin. "There's no way a computer can do that. It's impossible because the diagnosis is not an automatic 'yes' or 'no' answer to a list of questions from a computer. Yet, that is required by the BeaconLBS system and it's a total waste of time for physicians.

"Physicians also need to use the BeaconLBS system to order vitamin D tests as well," he said. "Vitamin D deficiency has been associated with bone disease, such as osteoporosis, general malaise, and fatigue.

Infringing on Patient Care

"Many patients have low levels of vitamin D and when you test and have them take vitamin D every day, about half the time it solves the problem," stated Levin. "If the system doesn't allow vitamin D level testing, those patients are at risk of harm, and a large proportion of patients are vitamin D deficient."

A significant proportion of Florida physicians believe the use of a decision support system as designed by Unitedhealthcare infringes on a physician's medical judgment. This issue is likely to be among the arguments proponents of SB 1084 make.

Levin added that another issue ordering physicians complain about is the requirement to use the BeaconLBS system in addition to their own electronic health record system.

No EHR–Beacon Interface

"In our office, the BeaconLBS decision support system doesn't interface with the computer system we use," he said. "Thus, we must go into a totally different computer screen to enter all of the patient's demographic information and then answer the questions needed to get an authorization that will allow the lab to draw the blood. It's another impediment to getting things done on behalf of our patients."

Recently, Levin had a patient who had to wait two to three hours to see if the BeaconLBS system would authorize Levin's request for ANA and vitamin D testing. "We just wanted to draw her blood so we could start the testing, and yet the authorization took all afternoon," he said. "That's ridiculous.

"Another concept to consider involves the issue of the obstacles going up against patients who need care," Levin added. "The insurers have put so many prior authorization hurdles in front of physicians and patients, that both physicians and patients have become extremely frustrated by these roadblocks to care.

"What happens is that physicians and patients simply give up trying to fight the system," he explained. "Therefore, appropriate and needed diagnostic testing and treatments are never authorized. When that happens, patients end up being the big losers.

"But physicians also lose with this system because we need to spend so much time and effort to get authorizations for things that we know are reasonable and medically necessary," Levin concluded.

Interesting Battlelines

The proposed bill creates interesting battlelines. Florida physicians are encouraging passage of a law that would restrict the ways that health insurers can require physicians to use clinical decision support systems and laboratory benefit management programs.

Will the health insurance industry decide to oppose this bill with great vigor? Or might health insurers decide to save their lobbying clout in the Florida legislature for issues that are of greater importance to them? However this plays out, clinical labs and pathology groups in Florida will follow these events with great interest. TDR

—Joseph Burns

Contact Robert Levin, MD, at 727-734-6631 or rwlevin@msn.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Microbiology's most important reagent is undergoing a supply crunch and becoming more expensive. Agar production is being affected by two factors. One is the increased global demand for seaweed. The second are new restrictions on the trade of seaweed, intended to protect natural stocks of seaweed. In December, **Thermo Fisher Scientific** of Waltham, Massachusetts, said it had ceased the sale of certain raw agar products. This would allow it to maximize production of products used by microbiology and research labs that use agar with growth nutrients. **Millipore Sigma** in Billerica, Massachusetts, also announced that it was halting sales of raw agar for a period of time.

MORE ON: *Agar Supply*

Microbiology labs are seeing a substantial increase in the price of supplies that utilize agar. News stories report that the price of raw agar has nearly tripled in recent months. Currently a kilogram of agar is priced at between $35 to $45. It is being reported that the direct cause of the current agar shortage is due to Morocco enforcing a production cap on Moroccan Gelidium of 6,000 tons, with an export cap of 1,200 tons. Morocco has previously harvested as much a 14,000 tons per year. The country wants to protect a dwindling population of Gelidium.

IVD CONSOLIDATION CONTINUES WITH TWO BIG DEALS

Two big acquisitions demonstrate that consolidation continues among *in vitro* diagnostics manufacturers. On January 21, **Abbott Laboratories** announced an agreement to acquire **Alere, Inc.**, for a price of $5.8 billion. Following completion of this transaction, Abbott said its annual revenue would exceed $7 billion. It was January 8 when news broke that **Thermo Fisher Scientific Inc.**, had agreed to acquire **Affymetrix Inc.**, in a deal valued at about $1.3 billion.

TRANSITIONS

- **Neogenomics** of Fort Meyers, Florida, appointed Mark Machulcz as its new Vice President of Operations. Machulcz first arrived at Neogenomics in December, after the acquisition of **Clarient Diagnostic Services**. Prior to Clarient, he had previously held executive positions at **PLUS Diagnostics** and **Quest Diagnostics Incorporated**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

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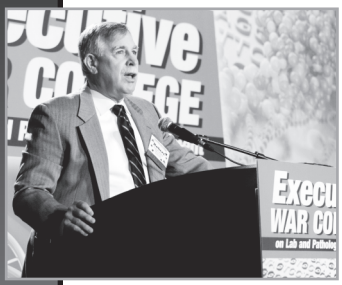
That's all the insider intelligence for this report. Look for the next briefing on Monday, February 29, 2016.

By Demand!

Private Practice Pathology's Present and Future:

What's Working… What's Not… with Strategies To Protect and Enhance Pathologist Income



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