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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Are Clinical Labs Prepared for What Is to Come?

IT IS TIMELY TO ASK THE QUESTION, "Are the nation's clinical laboratories prepared to deal with the multiple challenges already visible in the healthcare marketplace today?"

What leads me to ask this question is the unexpected number of deals involving the hospital lab outreach programs announced since the start of the year. Certainly the sale of **PAML** to **Laboratory Corporation of America** was not a surprise, as rumors had swirled about that deal for more than two years. Similarly, it was known that **PeaceHealth Laboratory** was being shopped by its parent health system.

But many lab managers were surprised to learn that **Mount Sinai Health System** in New York was selling its lab outreach business to **Quest Diagnostics Incorporated**. And few people knew that **Western Connecticut Health Network** was engaged in discussions to create of a lab joint venture with **Sonic Healthcare**.

Four significant transactions spaced so closely together is unusual. The important question for hospital-based lab administrators and clinical pathologists is whether these recently-announced transactions represent the leading edge of an emerging trend, or whether they are simply the coincidence of several transactions in which the parties were attempting to complete deals before the end of 2016, but the negotiations ran over and were finalized in early 2017.

You will read our coverage about the hospital lab outreach transactions on pages 3-12. Broadly speaking, there seems to be three elements motivating hospitals to assess what they might do with their clinical labs. One element is the financial squeeze hospitals and health systems are experiencing. The second involves payer cuts to lab test fees that reduce the revenue hospital lab outreach programs earn. The third is hospitals taking steps to deliver value-added care and finding ways to leverage their labs toward that goal.

Because of the keen interest in the financial sustainability of hospital laboratory outreach programs, this topic will be one of the significant themes at our upcoming *Executive War College* in New Orleans on May 2-3, 2017. Among the sessions will be a lab buyer panel with three of the nation's four largest lab companies confirmed to speak, along with another panel of successful lab outreach leaders sharing their strategies and successes. Other important sessions will address the financial consequences of the PAMA price reporting rule. TDR

LabCorp, Quest, Sonic Do Hospital Lab Deals

It is without precedent to see four major deals involving hospital lab outreach in just eight weeks

CEO SUMMARY: Is the New Year's spate of deals involving the sales of hospital lab outreach programs and a new joint venture the first tremors of an impending earthquake of similar transactions? In the first 10 weeks of 2017, Laboratory Corporation of America, Quest Diagnostics, and Sonic Healthcare announced significant agreements to purchase sizeable hospital lab outreach businesses and establish a laboratory joint venture. This is an unusual number of deals in such a short time.

IN THE FIRST 10 WEEKS OF 2017, hospitals and health systems have announced a surprising number of deals to sell off all or part of their clinical lab operations to the nation's largest commercial laboratory companies. These laboratory acquisitions involve several of the nation's biggest and most respected hospital-based clinical laboratory outreach programs.

The parade of transactions started Jan. 10, when **Laboratory Corporation of America** announced an agreement with **Mount Sinai Health System** in New York to acquire the assets of Mount Sinai's **Clinical Outreach Laboratories**.

One month later, LabCorp worked out a deal with **Providence Health and Services** in Renton, Wash., and **Catholic Health Initiatives** in Englewood, Colo., to acquire **Pathology Associates Medical Laboratories**, and PAML's interests in joint venture partnerships with **Colorado Laboratory Services**, **Kentucky Laboratory Services**, **MountainStar Clinical Laboratories**, **PACLAB Network Laboratories**, and **Tri-Cities Laboratory**. *(See pages 6-7 for details.)*

In February, **Quest Diagnostics Incorporated** agreed to acquire the outreach laboratory operations of **PeaceHealth Laboratories** in Vancouver, Wash., and manage 11 medical center labs that PeaceHealth will continue to own in Alaska, Oregon, and Washington. *(See, TDR, Feb. 20, 2017.)*

Also in February, **Sonic Healthcare USA** formed a joint-venture partnership with **Western Connecticut Health Network** in Danbury. Under the name **Constitution Diagnostics Network**, the

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partners will manage clinical and anatomic pathology testing in WCHN's three community hospitals (**Danbury Hospital**, **Norwalk Hospital**, and **New Milford Hospital**). Sonic will use its **Sunrise Medical Laboratories** in Hicksville, N.Y. for some reference testing. *(See pages 8 to 12 for more.)*

Another acquisition that happened since the new year was Sonic's purchase of **West Pacific Medical Laboratories** in Irvine, Calif. This deal was not disclosed publicly. In a separate agreement, Sonic said it will run the microbiology lab at **Baptist Memorial Health Care**, in Memphis.

THE DARK REPORT believes there is no precedent for four agreements involving the sale of three lab outreach businesses and the formation of a new lab joint venture among hospitals and health systems and three large national lab companies within just eight weeks.

➤Keen Interest In These Deals

Pathologists and lab administrators who operate hospital lab outreach programs are watching these developments with interest to understand if this number of agreements represents the first wave of a new trend, or whether these four major deals are a coincidence.

One argument in favor of the "coincidence" interpretation is that these announcements came shortly after the start of 2017. It is common for buyers and sellers to want to enter into sales agreements before year-end because of the tax benefits and other advantages. Thus, one school of thought is that the agreements were signed in January and February because the parties could not complete their negotiations in December.

There could be another motive that triggered these sales. Over the past 25 years, the most common reason for a hospital or health system to sell its lab outreach business to a commercial lab company was to convert the value of that asset into cash. In a substantial number of these transactions, the hospital or health system needed to bolster a deteriorating balance sheet, due to either outright losses or erosion in operating margins. The recent financial statements for each of the hospitals or health systems involved in these four transactions shows some evidence of financial pressure.

Weakening finances could be a factor in the Mount Sinai transaction, for example. The health system saw its cash and cash equivalents on hand shrink from $289 million at the end of 2014 to $194 million at the end of 2015, a decline of $85 million in just 12 months.

➤Hospitals' Money Problems?

At PeaceHealth, financial performance has been stable. One big expenditure has been $352 million to implement an EHR in both the ambulatory and inpatient settings in recent years. The need to beef up capital could be one factor in the timing of PeaceHealth's decision to sell its outreach business.

Providence Health and Services is feeling financial pressure and announced in November 2016 that it planned an undisclosed number of layoffs. At that time, officials said this action was a response to reductions in payment and increased costs.

Catholic Health Initiatives is experiencing similar declining reimbursement and higher costs. For its year ending June 30, 2016, CHI reported a loss in net income of $699 million.

➤Razor-Thin Profit Margins

Also, times are tough for WCHN. This three-hospital system reported a $12.8 million operating margin, or about 1%, for 2015. Last year, *Modern Healthcare* reported, "For the current year [2016], the WCHN board approved a budget that envisions no margin whatsoever, but [CFO] Steven Rosenberg said even that might be optimistic. 'We're not at a break-

Financial Analyst Comments on Strategies Quest Diagnostics Is Pursuing to Fuel Growth

IN A NOTE TO CLIENTS, AMANDA MURPHY, a stock analyst with **William Blair & Company**, explained the latest growth strategies Quest Diagnostics is pursuing.

One avenue is to work with hospitals to run clinical labs in those facilities. Quest describes this strategy as professional lab services (PLS) agreements. When seeking a PLS arrangement, Quest Diagnostics targets the inpatient and outpatient lab testing markets, she wrote.

"This setting is reimbursed under bundled payments beneath the DRG, and thus these labs serve as cost centers for the hospital, potentially tying up capital the hospital would prefer to use elsewhere," she explained. "When labs are viewed as cost centers and revenue is declining, hospitals are likely to want to jettison those assets.

"PLS arrangements could save 10% to 20% for a given hospital," she wrote. One disadvantage to PLS arrangements is that they take time to put in place. Yet, she added, "Lab management arrangements, particularly focused on inpatient/outpatient testing, have typically not been a focus for independent laboratory companies and thus, while lower margin, represent a greenfield opportunity."

Quest also is pursuing opportunities to sell medical lab data to pharmaceutical makers and other companies, she added. "Given Quest's national footprint and swath of testing data, the company is able to identify the locations with high disease-specific patient concentrations (thus providing a benefit for those interested in site selection/clinical trial enrollment)," she wrote.

even pace this year, and we're really struggling with what to do,' he said."

Among hospital administrators, interest in discussing the options for their clinical laboratories has never been higher, according to LabCorp and Quest Diagnostics. During presentations at investment conferences, lab executives from these two companies express great optimism about their respective prospects to do more clinical lab deals with health systems this year.

These dynamics leave unanswered a critical question: Is the lab industry at the beginning of a new trend in which significant numbers of hospitals and health systems are considering selling their lab outreach businesses and allowing commercial lab companies to manage their inpatient labs?

One factor forcing this question into the open is that hospitals and labs will continue to endure drops in reimbursement. This trend will work against most hospital and health system laboratories. For hospitals, less reimbursement for patient care will necessitate increasingly radical steps to bring costs in line with falling revenue. That would be one reason why selling an outreach lab business and outsourcing management of inpatient labs might appeal to hospital administrators.

Double-Whammy Hits Profits

At the same time, falling reimbursement for lab tests will erode the profitability and return on investment that lab outreach programs have produced. Reduced profitability will make it even easier for hospital administrators to consider selling their laboratory outreach operations and/or outsource inpatient lab testing.

Recognizing the importance of these developments, this year's *Executive War College* on May 2-3 will include sessions from lab administrators and executives involved in these lab sale deals. TDR

—Joseph Burns

Sale to LabCorp to End Most of PAML's Lab JVs

Buyer and seller disclose some hospitals will sell their interests and exit joint ventures

CEO SUMMARY: It will take several years to understand how the market for lab testing services will change in Seattle and the Pacific Northwest, once Laboratory Corporation of America becomes the owner of PAML, based in Spokane, Wash. Price and financial terms of the sale were not disclosed. The announcement of the agreement also reported on the disposition of six of the eight lab joint ventures that PAML operates with its hospital partners.

ONCE MORE, THE NATION is about to lose another of its largest and most respected independent lab companies. When this lab sale closes, the buyer will become the dominant lab company in the Seattle metropolitan area, and in several other regions in the Northwest and other states.

These outcomes will result from the acquisition of **Pathology Associates Medical Laboratories** (PAML) by **Laboratory Corporation of America** if the proposed sale clears regulatory review.

Another consequence of this sale is that four of PAML's eight lab joint ventures will end. Partner hospitals in two of the remaining four JVs are considering their options. No public information about the fate of the other two lab JVs has been released.·

In terms of sales price, this proposed deal is expected to be a large transaction even though neither party has provided a sales price or financial terms of any kind. Based on information from a variety of sources, PAML's annual revenue, including that of its eight lab joint ventures, is believed to be about $300 million to $315 million. The largest JV is PACLAB, with annual revenue of about $105 million. Taken together, the seven other lab joint ventures generate $50 million to $60 million annually. That would put PAML's yearly revenue in the range $140 million to $150 million.

For Lab JVs, The End Is Near

LabCorp and PAML's two owners, **Providence Health and Services** and **Catholic Health Initiatives,** described the disposition of PAML's eight lab joint ventures with various hospitals in a news release. *(See sidebar for a list of the JVs.)*

In three of the eight lab JVs, LabCorp will acquire PAML's interest and the hospital co-owners will sell their interests to LabCorp. These JVs are: **PACLAB Network Laboratories**, **Colorado Laboratory Services**, and **Kentucky Laboratory Services**.

The process is slightly different for **Alpha Medical Laboratory**. The hospital co-owner intends to acquire PAML's interest in Alpha, after which it will sell

Hospital Lab Partners in Joint Ventures with PAML To Follow Different Paths Following Sale to LabCorp

OVER THREE DECADES, Pathology Associates Medical Laboratories was unique in its development of commercial lab-hospital joint ventures. Only **International Clinical Laboratories**, a company that **SmithKline Beecham Clinical Laboratories** (now **Quest Diagnostics**) acquired in 1988, had comparable success in developing multiple commercial lab-hospital lab JVs. The lab joint ventures PAML organized and serves as general partner are:

- **PACLAB Network Laboratories:** Founded 1996 in Seattle and Puget Sound. Hospital partners include Providence Health System-Washington, Providence Everett Medical Center, Franciscan Health System, Overlake Hospital Medical Center, Evergreen Healthcare, Valley Medical Center.
- **Alpha Medical Laboratory:** Founded 1996 in Coeur d'Alene, Idaho. Partner is Kootenai Medical Center.
- **Tri-Cities Laboratory:** Founded 1999 in Central Washington. Joint Venture includes Kadlec Medical Center, Trios Health, Lourdes Health Network.
- **Treasure Valley Laboratory:** Founded 1999 in Boise, Idaho. Joint venture includes Alphonsus Regional Medical Center.
- **MountainStar Clinical Laboratories:** Founded 2008 in Salt Lake City. Joint venture includes St. Mark's Hospital and Lakeview Hospital.
- **Colorado Laboratory Services:** Founded 2010 in Denver. Joint venture with 11 hospitals of Centura Health.
- **California Laboratory Associates:** Founded 2010 in Burbank. Joint venture with Providence Health and Services-California.
- **Kentucky Laboratory Services:** Founded 2011 in Lexington. Joint venture with Saint Joseph Health System.

the joint venture interests to LabCorp, following a vote by its board. LabCorp is expected to have full ownership of Alpha.

For **Mountain Star Clinical Laboratories** and **Tri-Cities Laboratory,** LabCorp will purchase PAML's interests in each JV. The hospital co-owners of these two JVs are evaluating their options, which may include selling their interests to LabCorp. PAML's partner in the MSCL venture is a seven-hospital health system that **HCA**, the for-profit hospital company, owns.

Unaddressed is the disposition of two of the laboratory joint ventures: **California Laboratory Associates** in Burbank, Calif., and **Treasure Valley Laboratory** in Boise, Id.

"After the staged transactions are complete, Providence, CHI, and the hospital joint venture owners will continue to provide all existing inpatient hospital laboratory services," the news release said. "LabCorp will then continue to provide the outreach testing services and reference laboratory services currently provided by PAML and the joint ventures that are part of the overall transactions."

It may be noteworthy that, from the information disclosed to date, neither of the health system owners of PAML or any of the lab JV hospital partners, have contracted with LabCorp to manage their inpatient laboratories. TDR

Sonic, WCHN Announce New Lab Joint Venture

By keeping WCHN's lab testing in state, partnership aims to boost TAT, cut testing costs

CEO SUMMARY: To prepare for the transition from fee-for-service to value-based payment, Western Connecticut Health Network, a three-hospital health system, announced a laboratory joint venture with Sonic Healthcare. Benefits will include lower test costs, more competitive prices, and the ability to offer same-day turnaround in Western Connecticut. Another benefit is that physicians in towns WCHN serves will continue to work with pathologists they've known for years.

ONE BENEFIT OF THE LAB JOINT VENTURE PARTNERSHIP that the **Western Connecticut Health Network** announced last month with **Sonic Healthcare** is that as much as 80% of clinical lab testing will remain in WCHN's three-hospital network.

Keeping lab testing local will allow WCHN to compete more effectively against labs in Connecticut that send tests out of state, stated Noel Maring, Sonic's Vice President of Hospital Affiliations. Running tests in Western Connecticut will allow WCHN to offer same-day turnaround, which its competitors can't match, he added. Also, of course, physicians in the towns WCHN serves will continue to work with pathologists with whom they have long-standing relationships.

"This joint venture is a hybrid lab model," Maring told THE DARK REPORT. "It's not a commercial lab model, and it's not a hospital lab model. It is designed to serve WCHN's outreach business and inpatient testing in a number of ways.

"The joint venture partnership which is called the **Constitution Diagnostics Network**, will leverage the benefits of a hospital lab with local testing because 75% to 80% of the tests will be done in the local communities, meaning Norwalk, New Milford, and Danbury. That's our goal: keep as much of the testing local as possible.

"In addition, we will optimize the integration between the hospital laboratories in western Connecticut and our lab operations at **Sunrise Clinical Laboratories**, our northeast regional laboratory in Hicksville, N.Y., on Long Island, and our Sonic Reference Lab in Austin, Texas," he explained. "Large lab companies prefer to move as much testing as possible out of the local markets and send it to their own large labs. Our model is different from that because we will keep as much of the outreach lab testing within the local market.

Additional Lab Cost Savings

"The highest cost in any lab is labor and we will address that cost as well," he continued. "Staff reductions are not anticipated. The JV partners project that increased outreach volume coming into the hospital lab will optimize the labor already in place. Doing that will reduce the labs' average cost per test, including inpatient tests as well as the out-

reach volume. This is how the existing labor force in the WCHN hospital labs will become more productive.

"Next, for most hospital labs, the second highest cost after personnel is supplies, equipment, and reagents," Maring commented. "We will use our global cost structure to reduce the cost of testing at the WCHN laboratories.

"Outreach volume will increase because Sonic will introduce the skillsets it has in sales and marketing for lab testing," added Maring. "Also, additional lab sales reps will be added to the market.

Bolstering Lab Sales Effort

"Sonic does have some existing sales staff in this region," he said. "Expectations are that at least three more salespeople could be added in Western Connecticut in the coming years. That decision will be based on test volume and growth in market share.

"I don't want to give details specific to this partnership, but generally, our experience is that there is a 12% to 20% overall cost reduction opportunity in the hospital laboratory when we deploy Sonic's global cost structure, labor optimization programs, and efficiency improvements in these types of partnerships.

"Another element of this lab JV that works in WCHN's favor is WCHN's outreach business will use our pre- and post-analytical capabilities," continued Maring. "This will address the need for the hospital lab outreach program to have robust electronic interfaces with those doctors sending in outreach tests who may not use the hospital's electronic health record (EHR) system.

"Sonic has existing interfaces with multiple EHR vendors," he explained. "The result is that physicians in Western Connecticut will be able to order outreach testing on our pre- and post-analytical systems. So before the patient gets to the patient service center, the order from the doctor's office will already be in the system. Then after the test is run, the results will get sent back to the physician's EHR whether they're using **Cerner's** EHR (used by WCHN), or some other EHR.

"Collectively, these capabilities mean that the JV will get the most out of the WCHN lab in Danbury, which runs seven days a week, 24 hours a day," observed Maring. "For a select menu of routine tests ordered from a physician's office, the lab will report these test results back to the doctors that same day.

"We call this service, 'In by noon, out by 5 pm,'" Maring said. "That select menu includes routine tests, chemistries, CBCs, drug levels, and other similar assays.

"Doing that can give us a competitive advantage over other commercial labs that send those tests out of state. Because we can keep tests in state, other labs will be unable to match our turnaround time," Maring predicted. "Local testing will allow us to extend the network's ability to grow throughout Connecticut.

"In fact, it would be possible to use WHCN's core lab in **Danbury Hospital** to provide a higher level of lab services to the physicians in Western Connecticut and beyond," he explained. "Currently, all commercial lab work is exported out of the state.

Local Competitor Acquired

"The one local lab competitor to WCHN was **Connecticut Laboratory Partners** in Newington. It ran the laboratory testing for **Hartford Healthcare**," Maring said. "But last year, **Quest Diagnostics** acquired CLP, downsized that lab, and moved that testing to Massachusetts.

"Our lab JV can counter that move easily because it will do much of its testing locally, within Connecticut," he added. "This better serves value-based healthcare, because a faster-turn-around time for lab test results helps physicians improve patient care." TDR

—Joseph Burns

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Value-Based Care One Goal Of WCHN-Sonic Lab JV

➤Partnership with Sonic will help Western Connecticut Health System compete statewide

➤➤CEO SUMMARY: Announced last month, the new laboratory joint-venture partnership with Sonic Healthcare's Sunrise Clinical Laboratories will allow WCHN to compete with other health systems and prepare to respond to health insurers' requests that hospital systems offer lower rates in value-based payment models. WCHN has already seen payers shift to low-cost providers. For this reason, it expects its lab partnership with Sonic Healthcare to help it cut costs while supporting patient-centric lab testing.

IN FEBRUARY, the **Western Connecticut Health Network** and **Sonic Healthcare** announced a clinical laboratory joint venture. WCHN is creating this JV to integrate clinical lab testing services more efficiently as the three-hospital health system makes the transition from fee-for-service to value-based payment.

In the joint venture—called **Constitution Diagnostics Network**—Sonic's **Sunrise Medical Laboratories** in Hicksville, N.Y., will do the esoteric testing while the clinical laboratories in WCHN's three community hospitals (**Danbury Hospital**, **Norwalk Hospital**, and **New Milford Hospital**) will run the more routine clinical and anatomic pathology testing for the three facilities.

➤Three Hospital Labs Involved

The three hospitals have a combined revenue of $1.1 billion and 882 beds. About two-thirds of those beds are in the New Milford and Danbury hospitals which operate under one license. The other third are in the Norwalk Hospital, stated WCHN's Chief Strategy Officer Michael Daglio.

The partnership will allow WCHN to compete more effectively with other health systems in state, such as **Connecticut Laboratory Partners**, which **Quest Diagnostics** acquired from **Hartford Healthcare** last year. *(See TDR, March 21, 2016.)*

"We expect that this lab joint venture will help WCHN be better prepared when health insurers look for hospital systems that can offer lower rates, meaning those designed for a health system built on a model of value-based care," observed Daglio.

In an interview with THE DARK REPORT, Daglio explained that the partnership addresses several pressing financial questions that the network couldn't fully answer with its own resources. Each of WCHN's three hospitals has a lab, though the ones in Norwalk and New Milford are enhanced stat labs. The joint venture will develop a core lab at Danbury Hospital.

The challenge for Sonic and WCHN is how to reshape that traditional community-hospital structure to serve an environment that wants lower costs and greater efficiency while maintaining quality.

Health System's Move to Value-Based Care Designed to Meet Needs of Patients and Payers

WHILE THE U.S. CONGRESS considers whether to repeal the Affordable Care Act, one of the goals behind the act will always remain in place, stated Michael Daglio, the Chief Strategy Officer for Western Connecticut Health Network.

The ACA was built on a value-based care delivery model, and patients and payers will always want care delivered in this model, Daglio explained.

"We don't know what's going to happen with the ACA, but we do know that achieving high quality at low cost is a value proposition that's never going away," he said. "Regardless of what model prevails in the future, we will always need to increase quality and lower our costs.

"That's what payers want; that's what patients want," emphasized Daglio. "Today, payers foot the bill. But patients increasingly are becoming aware of the cost of healthcare through high-deductible health plans. Patients are no different than anyone else. They want high quality care at a low cost. That's what we want to provide and so that's our strategy here at WCHN, even if that means that we don't always fill our beds.

"The other day I was asked: Isn't your goal to fill the beds? And I said, 'No. Our goal is not to fill the beds," responded Daglio. "WCHN's goal is to care for the population in a meaningful way.' If that means a patient has to come in because they're acutely ill or they have a traumatic event, then yes, we want that patient in a bed. But if there are other alternatives to treat that patient outside the hospital, such as if patients have surgery and we can discharge them to home, that's what we will do.

"Those are the goals that we have now because we are caring for the population," Daglio concluded. "To do that, we need to deliver high quality care at a low cost."

"We want to move toward being a value-based health network but our roots are in traditional hospital-based models," Daglio noted. "Our laboratory is a hospital-based model with hospital-based rates. Even though we serve physicians in the community through an outreach program, there's no way we can do it at costs and prices comparable to those of Quest Diagnostics or **LabCorp**. But we know that we need to move in that direction to succeed in the value-based world.

Four Issues To Address

"To be effective with value-based care, there are four primary issues we need to address," he added. "They are: 1) convenient access to testing and results; 2) high quality; 3) greater patient and physician satisfaction; and, 4) lower cost.

"Our health system needs to hit each of those four goals," Daglio said. "In particular, we must achieve the first three while simultaneously reducing our costs. That will enable us to compete on a lower price and thus be more competitive in a value-based world. WCHN absolutely must find a way to lower pricing to insurance companies and employers to remain competitive with lab services.

"Our joint-venture partnership with Sonic will allow us to move toward those goals," he continued. "Sonic and Sunrise Laboratories will connect us more closely with our physician offices. And they will run the patient service centers so that we can provide a more convenient patient experience on the front end.

"In addition, as our joint venture partner, they will help us move to value-based pricing to meet that final piece of it, which is the cost side," noted Daglio. "How we get to the cost side of value-based care is by accessing the scale and efficiencies that Sonic brings to the partnership.

"Sonic will manage our health system laboratory on the inpatient side and as they do, we will be able to leverage their expertise in lab productivity," he stated. "By that I mean, they have the expertise to establish more efficient laboratory workflows that we do not have now.

Helping To Lower Lab Costs

"Also, we will connect to their supply chain which will allow us to get supplies for the lab for a much lower cost than we can get now," he said. "Supplies are the second highest line-item expense in any lab. So, that could bring us significant savings on the inpatient side that we would otherwise not achieve on our own as a three-hospital system.

"For example, maybe our labs run tests that could be done just as effectively and with the same level of quality, but at a much lower cost at a laboratory that does much higher volumes of these same types of tests," Daglio added. "One goal with the lab JV is for Sonic to help us achieve lower test costs while maintaining essential access and turnaround times for inpatient, outpatient, and outreach tests.

"Another major goal for this partnership will be the data we will pull from our laboratories," he said. "Right now, we do a good job of managing utilization. However, with Sonic we will have access to more sophisticated data that will allow us to manage utilization more effectively."

More Effective Competitor

All of the benefits WCHN gets from its joint venture with Sonic will allow the hospital system to compete more effectively against other hospital networks in the Nutmeg State, predicted Daglio. "With this partnership, we can compete with the other big labs in Connecticut on price, service, and local quality," he said.

"Before joining this partnership, we never felt there was an option for us to compete with commercial lab companies because they have such scale and such competitive pricing," Daglio said. "Now, with our partnership, we also have the sophistication of a large laboratory company behind us, and we have the scale we need to grow and compete successfully.

"Another benefit to the lab JV is that we believe we can be more competitive with other hospitals that haven't converted to a value-based model," he added. "They may continue to see an erosion of their lab test volume just as we have seen in recent years.

"The trend we see is that health insurers are slowly steering patients away from those laboratories and imaging centers that are too expensive," observed Daglio. "Generally, the more expensive providers are hospital-based and oriented to serve fee-for-service payment systems. This is why we've already seen some steerage from payers toward lower-cost providers.

Preparing For Shift To Value

"The payers are not going to shift everything tomorrow," he noted. "But we think—over the next five years or so—that price and volume erosion will eat into our ability to afford to offer healthcare services effectively.

"This partnership with Sonic helps us get out ahead of the curve while also becoming more competitive with other hospital-based laboratories that haven't moved in that direction yet.

"As this model proves successful, other hospitals could consider joining our laboratory joint venture," Daglio said. "Laboratory testing is the kind of service that we can offer to other hospitals. Doing so would mean that—instead of always competing with other hospitals—we have a way to share certain services, such as lab testing. If we can build a company here that other hospitals can share in, I would welcome that opportunity." TDR

—Joseph Burns

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Health Insurers Want Data On Tests' Clinical Utility

For genetic tests, payers also cite the need for regulation and concerns about price variation

CEO SUMMARY: Genetic tests that lack two essentials are troublesome for the nation's health insurers. Those essentials are clinical validity and clinical utility. During a recent webinar, two executives from major health insurers stressed the need for genetic testing labs to provide acceptable evidence that their genetic test is accurate and that it produces information that is clinically-actionable and improves patient care. The variability of prices charged by different labs for the same genetic test is another area of concern.

CONFRONTED LITERALLY WITH TENS OF THOUSANDS of new molecular and genetic tests, health insurers are getting increasingly tougher when asked by labs for coverage and reimbursement decisions. Labs should demonstrate the quality and clinical utility of their tests and the quality of their laboratory operations, according to executives from two major health insurers who described what they want from genetic testing labs during a recent webinar.

Few clinical laboratories provide data to support claims that their tests are better than those of other labs, stated Lee N. Newcomer, MD, Senior Vice President, Oncology and Genetics, for **UnitedHealthcare**. Newcomer was one of two health plan executives on the webinar. The other was Henry Garlich, Director of Enhanced Clinical Programs for **Blue Shield of California**.

America's Health Insurance Plans, the trade association for health insurers, sponsored the webinar, along with **Concert Genetics** (formerly **NextGxDx**), a company in Nashville, Tenn., that collects and reports data on genetic testing for providers, labs, and health insurers.

During the hour-long session, both speakers explained that they have developed good working relationships with some genetic testing labs but they were concerned about the lack evidence on clinical validity and clinical utility.

The speakers noted that payers also are concerned about consistency—meaning the ability of a lab to do the same test in the same manner each time it's run—and the lack of evidence supporting the quality of lab tests and lab operations. The lack of standards could lead health insurers to require compliance with regulators, they added.

10-Fold Price Variations

One other problem health insurers want to address is the lack of understanding among physicians who order genetic tests, Newcomer and Garlich said. In addition, health insurers are particularly concerned about the cost of genetic tests and the wide variation in what labs charge for similar tests. Variation in what labs charge

for these tests could lead insurers to force labs to compete on price, Newcomer said.

Each of these problems offers clinical lab scientists an opportunity to explain the quality, clinical utility, and validity of their tests. Also, the fact that ordering physicians don't always understand the genetic tests they're ordering, means labs have a responsibility to educate these providers.

Demonstrate Quality

For pathologists and clinical lab directors, Newcomer said, "You need to find a way to demonstrate your quality that is uniform so that we definitely can compare [your tests with those of other labs]. Without that, we have to make assumptions that price is the only thing that should differentiate you. And I know that every lab will say, 'We're better,' but no lab comes to us with data that demonstrates that."

Newcomer and Garlich were critical of labs that promote their CLIA certifications as proof that they provide quality testing. "CLIA is not a guarantee of analytic validity," Newcomer said. "CLIA simply says that you have certain laboratory procedures in place, but CLIA tells us nothing about the individual test. For next-generation sequencing that's a crucial, crucial gap."

Evaluation Of Genetic Tests

Both Blue Shield of California and UnitedHealthcare evaluate genetic tests the same way they evaluate all new diagnostic and treatment technologies. "Clinical utility is still king and that is best proven in some kind of a cohort comparison trial," advised Newcomer. "The randomized trial would be ideal but our greatest interest is in evidence of clinical utility—meaning that those tests actually affect a treatment decision and improve health outcomes.

"Without that, a genetic test starts to rapidly fall off on the evidence scales and therefore the ability to provide coverage," he added.

Asked to estimate how many genetic tests have data on clinical utility, both Garlich and Newcomer said the number was extremely low. "Some estimates suggest that—of all the thousands of tests that are out there—maybe 400 to 500 diagnostic tests have any level of evidence or evidence-based guidelines of clinical utility," Garlich commented. "It's a small fraction and, as the number of tests increases, that fraction becomes lower and lower."

Newcomer agreed, saying, "You're talking about a single-digit percentage of all lab tests that truly have good clinical utility studies. When you look at the vast categories of spending, I would take out some of the tests that have obvious clinical value, such as cystic fibrosis carrier screening and perhaps even BRCA testing. But beyond that, the data drops off dramatically."

Issue Of Analytical Validity

Another issue of critical concern is analytic validity, noted Newcomer. "In molecular testing, analytic validity is an absolutely critical element. This is particularly true in the area of next-generation sequencing. There seems to still be a very wide variation in reports submitted by the same labs and different labs," he explained. "Today, unfortunately, there isn't a good national standard for labs that do NGS." As a result, he said, UHC has trouble deciding what level of quality to accept to approve coverage for NGS testing.

Perhaps equally troubling is another issue. "Regarding genetic tests, there's a huge knowledge gap among doctors," Newcomer said. "I think every physician would tell you that they wished they knew more about this topic."

Blue Shield of California has similar problems. "It is a tremendous issue to have many of our providers order genetic tests even though they don't know much about those tests," observed Garlich. "That's where a genetic counselor can

Health Plans Want to Support Interaction Between Physicians, Patients for Genetic Tests

WHEN MAKING DECISIONS about whether to cover a genetic test or not, health insurers do not want to come between providers and their patients, two health plan executives said recently. But when making those decisions, insurers need help from somewhere, they added.

"Regarding the decision-making process between the patient and the physician, we don't want to be in the middle of that activity," stated Lee N. Newcomer, MD, Senior Vice President, Oncology and Genetics for UnitedHealthcare. "We will, however, take a larger population view about the test and look at evidence and ask, 'Is this evidence here or not? And if the evidence is there, then we will provide coverage and those genetic tests will be available to a physician.

"What we've discovered in this field of genetics is we need help here," he added. "We don't know this field well. Health insurers will need to rely on someone else to help us understand which genetic tests have good performance, which tests are reasonably priced, and, sometimes, how to identify the right clinical situations where a test would be appropriate.

"Thus, as we build our prior authorization system [at UHC], we are incorporating some of that decision support to say [to a physician], 'here are the questions we need to ask, and here might be an alternative for you,'" explained Newcomer. "One of those alternatives always is the genetic counselor.

"More and more physicians find that they may need extra help in this particular area and so we make genetic counselors available to our patients—either telephonically or in the networks themselves," added Newcomer. "These counselors will be a critical member of the team for a lot of these molecular and genetic test decisions."

Garlich agreed, saying, "As the health plan we certainly don't like to get involved in that decision between a physician and patient. We want to provide as much information as we possibly can to the member with decision support tools, decision aids, videos or infographics—anything that will help that patient with informed decisions.

"Again, that's a provider responsibility and our view is that we won't interfere with that," noted Garlich. "However, we do work very closely with our providers. When our providers ask us to evaluate a specific genetic test because they feel it would be beneficial for their patients, we will evaluate it and we will certainly look at the merits of the evidence," added Garlich.

"We will look at clinical utility and the downstream healthcare impact as a whole from a population health standpoint," he said. "If there is a reason for this test to be covered, and if there is enough evidence for us to feel confident that this test will benefit our members or providers in terms of access and it will benefit us in terms of the cost of healthcare, then we will consider making a policy on that test."

come in and provide enough information to help guide some of those decisions. And so education is absolutely a key."

For coverage decisions, Blue Shield of California relies on the clinical assessments from the **Blue Cross Blue Shield Association**, Garlich explained. In addition, the insurer has developed close relationships with some clinical labs.

"One thing we do that may be a little different than some of our other Blue partners is that we take chances on some genetic tests," he explained. "We are bringing the labs in to have them describe all of the evidence that's been done to date. We want to see if there are areas where we can say, 'This is a genetic test that could benefit our providers.' If we want to give access to that

genetic tests, we're going to take a chance that this [test] will improve the quality of healthcare and possibly reduce the costs."

Garlich cited a new test for prostate cancer that another Blue plan studied and determined that the test had a role in reducing the number of radical prostatectomies and radiation therapies these patients needed. "Obviously, that test contributed to significant quality improvement and, of course, the cost to the healthcare was positive as well," he said.

Newcomer warned, however, that he is skeptical about early study results from new lab tests. "Many laboratory manufacturers will say, 'Look, this information is available. All docs will use it now.' And that just isn't true," he stated. "They'll price the test based on the assumption that 90% of docs will use it, when only about 5% or 10% do. As a result, the economics don't work out."

Genetic Test Costs

The cost of genetic testing is a significant issue, particularly the wide variation in what labs charge, said Garlich. Blue Shield of California uses **Concert Genetics** to identify market prices for tests and thus reduce variation, Garlich said.

"For BRCA testing, in particular, prices range anywhere from $500 per test upwards to $3,500 per test, even when different labs are looking at the same genes," he added. "That variation in price is a real concern for us. That's why we develop narrow networks and negotiate very hard with our genetic labs to make certain that they offer fair market value for our health plans."

UHC takes a slightly different approach to paying for genetic tests, Newcomer explained. "Our contracting team is integrated with those people who do the economic analysis for us," he said. "So we might decide that a test could be cost effective at 'X' price but not at 'Y' price.' There is a huge opportunity within lab testing because, with the onslaught of tests that look similar, pricing variation can be 10- to 20-fold and physicians are unaware of those pricing differences.

"One of our challenges in the future will be to develop policies as to what is the right test [for specific health conditions]," he added. "The next step is to decide what is the most cost-effective or economical test in that area that still delivers good quality."

Worrisome Lack of Oversight

When deciding whether to cover a new molecular or genetic test, Garlich said, the lack of evidence of analytical validity and the lack of regulatory oversight are worrisome to his health insurer.

"There are no regulatory bodies that govern this today, so it's a concern for us to make certain that the quality of genetic testing is high," he said. "That's hard to do and that's why it's very important for us at Blue Shield to have strong relationships with labs so we can talk to medical directors at the labs about the evidence that supports analytic validity and clinical validity and make certain that they have the compliances that are required by the **College of American Pathology** or various other organizations.

Lab Accreditation

"We are looking into requiring accreditation through the **College of American Pathology** and making certain that labs comply with laboratory accreditation requirements in proficiency testing programs for next-generation sequencing," noted Garlich. "That's the only thing we can rely on to make certain that there's consistency with the quality of the lab tests that we provide for our members and providers."

"Absolutely," Newcomer agreed. "I don't know which [laboratory accreditation] organization that might be, but we would all benefit from having standards that need to be met in the areas of molecular and genetic testing." TDR

—Joseph Burns

Legal Update

Labs Ask: Does PAMA Statute Prevent Legal Challenges?

Although the law prevents labs from challenging its provisions, avenues of challenge are possible

SINCE MEDICARE OFFICIALS PUBLISHED the final rule for lab test market price reporting of private payer prices last year, clinical lab industry consultants and lawyers have raised serious criticisms of the rule.

The critics recognized that CMS officials wrote a final rule for the Protecting Access to Medicare Act (PAMA) that excluded from reporting large numbers of clinical labs that receive higher payments from private health insurers than other labs do. This discrepancy will mean that CMS will set lower fees because the data it collects will come from labs that get paid less from health insurers.

One example offered of this bias is the final rule's requirement that each hospital lab must have a National Provider Identification number to submit market price data to the federal government. The problem with this NPI issue is that only a few hospital labs have their own NPIs because they operate under their parent hospitals' billing numbers when submitting claims to CMS.

Cuts Higher Than Expected

Another concern is that CMS expects the cuts to the Medicare Part B clinical lab fee schedule to total $400 million during 2018 and $5.4 billion over 10 years. Critics point out that these amounts are twice as high as the fee cuts that Congress planned when it passed the law in 2014.

But what will surprise many lab administrators and pathologists is a little-known fact about the PAMA statute and the final rule for market price reporting: Both include language that some say limits the legal challenges that the clinical lab industry could mount against that law.

To address these questions, THE DARK REPORT sought clarification from Jeffrey J. Sherrin, a lawyer who is President of **O'Connell & Aronowitz**, in Albany, N.Y. He represents the **National Independent Laboratory Association**.

Immunized from Lawsuits?

On the issue of whether the wording in the law prevents lawsuits, Sherrin said, "There is a section in the PAMA statute that prohibits legal challenges to the rates that CMS establishes. The PAMA provision that states '[t]here shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the establishment of payment amounts,' is codified in 42 USC 1395m-1(h)(1) as well as in corresponding regulations in 42 CFR §414.507(e).

"It is disappointing that this provision is present, because it can have the effect of allowing CMS to set rates that are actually inconsistent with the data collected," he added. "It may even immunize CMS from challenges to the methodology used to decide upon who has to report, and what data needs to be recovered, in what format.

"There is precedent for these statutory provisions that limit the available remedies, including in the context of Medicare rates," Sherrin explained. "The theory is that if Congress creates the right, Congress has the power to determine and limit the remedies. The exception is if there is a claim of a deprivation of a constitutional right.

A Right To Payment?

"Congress has much less authority to restrict someone's right to challenge an unconstitutional act," he said. "In the Medicare context, however, it has been held that there is no constitutional right to a certain level of Medicare payment.

"A different result may be reached where CMS does something in the process that is inconsistent, or contrary to, congressional intent," he said. "There, the claim would be that CMS is violating the principle of separation of powers, and defeating the intent of Congress. There may be a viable argument that the prohibition on challenges to rates would not bar challenges to administrative action that is actually contrary to the language or intent of the PAMA statute, or other federal law."

Next Sherrin addressed the question most lab directors would have: can a lab challenge how CMS sets rates under the law? "The next question becomes whether it also bars challenges to the methodology that CMS uses to arrive at the rates," he said. "Recent decisions have held that when the methodology is inextricably intertwined in the rates, one cannot challenge the methodology either.

Are Challenges Barred?

"Thus, this provision could be seen as barring challenges to the methodology," he added. "But, as with the observation above, if the methodology itself violates some other congressional language, the challenge might still be viable. So, I think that the jury is still out whether all challenges are barred."

The question about whether clinical labs that lack an NPI would need to collect data retroactively to comply with the law is more complex. "The issue of retroactive data gathering is a problem for all laboratories, not just hospital labs," Sherrin explained.

"CMS could have set compliance dates with the PAMA regulations that allowed labs to put the systems in place first, to enable them to capture prospective data," he said. "But CMS did not and the PAMA statute itself did not require that. Apparently, Congress and CMS failed to understand the problems and difficulties laboratories would face in collecting private payer price data, and assumed that labs had the systems and capabilities to retrieve this data retroactively. Unfortunately most do not.

"A legal challenge to setting the compliance timetables in a manner that is impossible to meet, therefore, might be viable on the ground that the demands in the regulations are arbitrary and capricious," he added. "It would be a difficult case, and the remedy if the labs won might be just a delay in implementation.

Uncertainty Among Labs

"A big problem I see is that labs cannot really be sure in the initial reporting that their data is complete and accurate," observed Sherrin. "Yet—not only is the lab subject to heavy sanctions if it fails to report—but the lab must also have a certifying officer who certifies to the completeness and accuracy of the data submission. They are subject to personal sanctions if they falsely certify. So, in some ways, these certifying officers are caught between a rock and a hard place.

"Hopefully these dilemmas will be recognized and fixed before the deadline for reporting," he concluded. "Labs need clarity on these important issues." TDR

—Joseph Burns

Contact Jeffrey J. Sherrin at 518-462-5601 or jsherrin@oalaw.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's bad news for clinical labs and pathology groups that lack the capability of collecting copays, deductibles, and out-of-pocket payments from patients at time of service. As of October, 2016, four out of every 10 Americans under the age of 65 with health insurance had a high-deductible health plan. That means these patients are responsible for paying most or all of their lab test costs before the HDHP insurance coverage kicks in. This new data is from the federal **Centers for Disease and Prevention** National Health Interview Survey, which found that 39.1% of people under 65 with private insurance were enrolled in a high-deductible health plan.

MORE ON: *HDHPs*

Enrollment in HDHPs is increasing at a steady pace. As of 2010, the CDC reported that 25.3% of people under 65 with private health insurance had an HDHP, compared to the 39.1% number as of last fall. That's a 54% increase in HDHP enrollment. Innovative labs are implementing the capability to collect payment from these patients at time of service because they understand that these patients are typically responsible for annual deductibles of $3,000 to $5,000 as individuals and $5,000 to $10,000 as families.

HEALTH SYSTEMS TO BUILD NEW LAB IN NEW YORK CITY

As part of their clinical laboratory joint venture, **Northwell Health** and **NYC Health and Hospitals** announced plans to build a 36,000 square foot lab in Little Neck, N.Y. It will cost $47.7 million, will perform 50 million tests annually, and is expected to open in 2018.

PAUL MANGO MAY RUN FOR GOVERNOR OF PENNSYLVANIA

In Pennsylvania, news sources report that Paul Mango is considering running for governor of that state. Mango recently resigned from **McKinsey & Company**. He is familiar to long-serving clinical laboratory executives as the architect of the Pittsburgh-based **Reference Laboratory Alliance**. Launched in 1995, during the heyday of closed-panel gatekeeper HMOs, this was a regional hospital laboratory network with 40 participating hospitals that won managed care contracting status for its member hospitals' lab outreach programs. *(See TDR, Sept. 25, 1995.)*

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...a urine test developed by researchers in the United Kingdom that can quickly reveal the health of an individual's eating habits and that might eventually create a new market that could be served by clinical labs.

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, April 3, 2017.

SPECIAL SESSION!

Confronting the Diagnostic Industry's Structural Problems!

Girish Putcha, MD
Chief Medical Officer, Freenome Inc.

How Molecular/Genetic Testing Labs Can Address Payer, Regulator Concerns of Analytical Accuracy, Clinical Utility

Every lab developing and performing assays in support of precision medicine will find this presentation to be of compelling interest. Dr. Putcha is doing work in support of the Medicare MolDx program and the FDA. He is engaged in activities to define the standards for demonstrating the analytical accuracy of the biomarkers being measured, along with how labs should provide evidence to demonstrate the clinical utility of their tests.

You'll hear about the concerns that these federal agencies have relative to quality, reproducibility, and clinical usefulness. Federal officials have legitimate concerns about the absence of quality in the methods with which many labs are performing molecular and genetic tests. This session will explore some of the specific issues of quality, including the technologies used for liquid biopsies and in gene sequencing. Expect a candid look at the strengths and weaknesses that are observed in today's laboratory medicine profession. Guarantee your place by registering today!

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- ***Update on Fraud and Abuse in Certain Sectors of Lab Testing and Payer Strategies to Stamp It Out.***