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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

Will Hospital Labs Anchor Integrated Care?

STEP BY STEP, HEALTHCARE IN THE UNITED STATES is moving toward a system in which clinical care is fully integrated and providers are reimbursed for the value they provide. This trend presents clinical laboratories and anatomic pathology groups with a challenge and an opportunity.

The challenge comes because being a value-added contributor requires labs to adopt a new mindset and working culture. To be successful, labs will need to move beyond the common goal of simply reporting an accurate test result within a set time. Failure to evolve beyond this basic form of lab test services will result in shrinking revenue and smaller budgets as funds are redirected to labs that add value.

The opportunity for labs is to be at the forefront of supporting the health system's newest needs. To meet these needs, lab professionals must get out of their labs to collaborate with clinicians. Such collaborations will help physicians use lab tests more efficiently, become more effective at using lab test results to select the most appropriate therapies, and to monitor each patient's progress. Innovative labs will offer services that support physicians in delivering care that is proactive rather than reactive and that allows health systems to integrate all care to support value-added payments.

On pages 10-15, you will read about an ambitious lab regionalization project in Michigan. For this project, lab managers for **Ascension's** seven organizations, 14 hospitals, and 18 laboratories throughout the state are working to standardize instruments, assays, test menus, reference ranges, and work practices at every site where lab testing is performed. Obvious goals are to increase productivity, reduce lab costs, and improve quality. Of equal significance in this statewide lab initiative is a goal to align lab services to meet the needs of physicians and patients. Thus, a standardized test menu and methodology, with consistent reference ranges, will help Ascension's physicians and other providers to serve individual patients, no matter where in the health system they show up for care.

The lab division at Ascension Michigan is taking steps to standardize lab test services in ways that allow it to serve the strategic and clinical goals of Ascension. This project is an early example of how hospital labs can remake themselves to be essential diagnostic assets as their parent institutions take the steps necessary to integrate care and become added-value providers. TDR

Theranos Will Dissolve, Seeks to Settle Claims

Discredited lab company wants to dissolve as better solution than filing a bankruptcy action

CEO SUMMARY: It appears that the final chapter in what many call Silicon Valley's biggest investor fraud will conclude this week. Theranos, Inc., the once high-flying lab testing company, is to be dissolved and its remaining cash and intellectual property will be distributed, according to CEO and General Counsel David Taylor. Meanwhile, Theranos founder Elizabeth Holmes and former COO Ramesh "Sunny" Balwani face federal criminal charges of wire fraud and conspiracy to commit wire fraud.

SOMETIME THIS WEEK, the blood-testing company **Theranos Inc.** will be dissolved. In an email to shareholders on Sept. 5, CEO and General Counsel David Taylor explained that the company had only about $5 million in cash on hand and would distribute this amount to its unsecured creditors.

Writing in *The Wall Street Journal* that same day, reporter John Carreyrou explained that Theranos Inc., of Palo Alto, Calif., has been tainted by scandal and accused of perpetrating Silicon Valley's biggest fraud.

"The big-name investors who poured money into Theranos will get nothing," Carreyrou added. "All told, investors in Theranos have lost nearly $1 billion."

The dissolution comes after federal prosecutors filed criminal charges in June against Elizabeth Holmes, the founder and Chairman of Theranos, and against Ramesh "Sunny" Balwani, the company's former chief operating officer. Holmes and Balwani were each indicted on nine counts of wire fraud and two counts of conspiracy to commit wire fraud. *(See TDR, June 18, 2018.)*

If convicted, Holmes and Balwani could face prison sentences that would keep them behind bars for the rest of their lives and fines totaling $2.75 million each, the *Associated Press* reported. The two executives have denied the charges and face a criminal trial. Attorneys for Holmes and Balwani are scheduled to be in U.S. District Court in San Jose for a status conference before Judge Edward J. Davila on Oct. 1, *Ars Technica* reported.

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The once high-flying Theranos is dissolving because the company breached a covenant governing a $65 million loan it received last year from **Fortress Investment Group**, a private-equity firm in New York, Carreyrou reported. "Under the loan terms, Fortress was entitled to foreclose upon the company's assets if its cash fell beneath a certain threshold," he wrote.

Two Dozen Employees

Most of the two dozen employees who remained at Theranos worked their last day on Aug. 31, Carreyrou reported. "Only Mr. Taylor and a handful of support staff remain on the payroll for a few more days," he added.

On top of the $65 million that Theranos owes to Fortress, the company owes at least $60 million to its unsecured creditors, according to an email that Taylor wrote to investors on Sept. 5.

While pursuing a settlement with Fortress, Taylor explained that Theranos would enter into what's called "an assignment for the benefit of creditors" under California law. Under an assignment, all assets of the company other than its intellectual property would be assigned to a third-party to be held in trust for the company's creditors, he wrote. "We expect that the full assignment process may take approximately six to 12 months," he added.

In his email to creditors, Taylor explained that the company's cash was not nearly enough to pay all of its creditors in full. Therefore, there would be no distributions to shareholders, he added. After assets are assigned, the company would file a certificate of dissolution under Delaware law, he wrote.

Before reaching the decision to dissolve the company, Taylor explained in the email, Theranos had retained **Jefferies Group LLC**, an investment bank and financial services company in New York, to sell the company. Over four months, officials from the Jefferies Group contacted more than 80 potential buyers, 17 of which signed nondisclosure agreements.

"We assisted those parties with diligence and had numerous follow-on conversations," Taylor wrote. "Unfortunately, none of those leads has materialized into a transaction. We are now out of time. Despite our careful cash management, we are in default under the Fortress credit facility.

"Fortress has the legal right to foreclose upon, and to sell or take ownership of, all of the company's assets, including the company's intellectual property (which is owned by a 'special purpose subsidiary' of the company)," he wrote.

In an effort to benefit investors, Taylor wrote, the company was negotiating a settlement with Fortress to allow the equity investors to acquire the company's interests in the special purpose subsidiary and any intellectual property the subsidiary would retain, but Theranos would relinquish its rights to the remaining cash, subject to certain conditions.

Only $5 Million to Distribute

Under this settlement, Theranos would distribute the $5 million to unsecured creditors, rather than to Fortress, Taylor wrote. "We believe that this result would benefit the company's creditors more than any other achievable one, including a bankruptcy, in which we believe no material assets would be available for distribution to creditors," he added.

In closing the email, Taylor wrote, "On our current path, we intend later this week to seek the necessary board and shareholder consents for the Fortress settlement, the assignment, and the corporate dissolution, and, assuming consent, to proceed with those actions beginning next Monday, September 10. Following these actions, the company will send a letter to stockholders confirming that there will not be a liquidating distribution to stockholders, and providing a copy of the certificate of dissolution, for use for tax-loss purposes." TDR

—Joseph Burns

Biggest Lab Firms Diverge on Hospital Lab Strategies

Public lab companies want new agreements to acquire or manage labs owned by hospitals

CEO SUMMARY: Almost half of the nation's hospitals and health systems are rethinking how to use their clinical labs to support clinical and financial strategies. Options range from outright sale of their lab outreach businesses to lab management agreements or joint ventures with one of the nation's three billion-dollar public lab companies. Each of the three big companies—Laboratory Corporation of America, Quest Diagnostics, and Sonic Healthcare—has a different approach to these deals.

One common strategy that executives voice regularly at the nation's three largest public lab companies is to expand their management or ownership of the clinical laboratories in hospitals and health systems.

National lab companies discuss this strategy during conference calls with analysts and at conferences with Wall Street investors. Their oft-repeated message in recent years is that significant numbers of hospitals and health systems are willing to explore how they can cut lab testing costs by engaging with commercial lab companies. *(See TDRs, Feb. 21, 2017, and Aug. 20, 2018)*

Hospital Lab Transactions

Regularly, The Dark Report has assessed the most significant agreements between hospitals or health networks and commercial lab companies. Most often these agreements involve either a sale of a hospital's laboratory outreach business or a contract for the public lab company to manage the hospital's inpatient lab.

When viewed retrospectively, however, only a small number of such sales and management agreements are negotiated each year. And, most such transactions involve a financially-strapped hospital or health network selling its laboratory outreach business to raise capital.

Raising capital was one goal when **PeaceHealth System** of Vancouver, Wash., sold its substantial lab company, **PeaceHealth Laboratories**, to **Quest Diagnostics** in 2017 and when **Providence Health/CHI** decided to sell their **PAML** lab company to **Laboratory Corporation of America** that same year.

Timing was a factor in each sale because each seller expected the profitability of their respective outreach lab companies would decline when Medicare cut what it paid for Part B lab tests as of Jan. 1, 2018. *(See TDRs, Feb. 21 and Mar. 13, 2017).*

Some hospitals and health networks, however, view their inpatient, outpatient, and outreach laboratory activities as valued points of clinical advantage that can and do contribute revenue to the parent organization. **ProMedica Health** of Toledo, Ohio, held this view when it announced a laboratory joint venture (JV) last month with **Sonic Healthcare USA**.

ProMedica wants the new lab JV to support its operational and clinical integration with other hospitals and office-based physicians in the three states it serves. An integrated clinical laboratory service is a key element in ProMedica's effort to deliver precision medicine and improve patient outcomes to support value-based payments from health insurers.

After ProMedica and Sonic announced their lab joint venture, THE DARK REPORT interviewed Sonic's Vice President of Hospital Affiliations Noel Maring. Almost half of the nation's hospitals and health systems are rethinking their lab-testing strategies, he said, and many are considering ways to work with or sell outreach testing operations to one of the big three lab-testing companies.

Each of the three companies—LabCorp, Quest Diagnostics, and Sonic—works with hospital labs differently, he said, and it's useful for lab directors and pathologists, to understand each approach.

"From a strategy standpoint, with each deal these companies make, I can see the dividing lines among the three billion-dollar public lab companies," Maring commented. In discussing the various objectives, he started with Quest Diagnostics, followed by LabCorp, and Sonic.

"Quest seems to want to both buy outreach programs and—where possible—manage the hospital's inpatient laboratory," explained Maring, "It will off load all the outreach testing business it acquires to a Quest facility. Additionally, in past inpatient lab contracts it has aggressively moved as much of the less time-dependent testing volume to a Quest facility offsite."

In Massachusetts, there's a recent example of this strategy where Quest acquired the outreach lab testing business of **Cape Cod Healthcare** last year and now manages the inpatient laboratory, he added.

During a conference call with Wall Street analysts on July 24, Quest Chairman, President and CEO Steve Rusckowski explained Quest's plans to accelerate growth. "The first element of our growth strategy is to grow 1% to 2% through strategically-aligned accretive acquisitions," he said. "We completed our previously-announced acquisition of the outreach laboratory services business of Cape Cod Healthcare in Massachusetts."

That system includes Cape Cod Hospital in Hyannis, which has 283 beds, and Falmouth Hospital in Falmouth, with 95 beds. Quest runs what it calls the 'lab of the future' in Marlborough, Mass., a new, state of the art facility of 200,000 square feet about 95 miles from Hyannis. In an arrangement announced last year, rapid-response tests are done in the hospital labs in Hyannis and Falmouth, and other tests go to Marlborough.

Lab Costs Are Triple

At the time, Michael Lauf, CEO of Cape Cod Healthcare, said, "The costs of providing lab services to our patients is roughly three times that of Quest."

For LabCorp, its strategy differs slightly. "LabCorp also wants to acquire hospital lab outreach businesses," Maring said. "At the same time, LabCorp is providing services under technical service agreements (TSAs), in which LabCorp helps with reference testing and couriers. However, compared with Quest, LabCorp seems less interested in managing hospital labs.

"Both public lab companies seem to be avoiding joint ventures—at least for now," he added. "While each company has existing JVs, they do not seem to be actively pursuing new joint ventures, possibly because they do not want to cannibalize existing revenue they currently control around a prospective JV partner's medical campus.

"At Sonic, our approach is more varied," continued Maring. "We'll consider agreements that call for us to manage inpatient labs. However, we prefer a more comprehensive partnership with healthcare systems that have a strong strategic position in their communities.

"Because our goal is a long term strategic partnership with hospitals and health systems, we are more willing to contribute our existing lab testing volume into those joint ventures when it makes financial sense to do so," Maring commented. "That's what we did with ProMedica by shifting about two million lab tests per year to the joint venture lab, which is the **ProMedica Pathology Laboratories** (PPL) core laboratory.

Contributing Lab Test Volume

"To date, I am unaware of arrangements where Quest and LabCorp have contributed significant outreach lab volume into a joint venture with a hospital, and I'm not sure they will," he said. "At this time, therefore, there is a clear delineation of where these two lab companies are willing to go."

Maring affirmed that the CEOs of many hospitals and health networks are considering options for their clinical laboratories. "These hospital leaders are reacting to the changes in how they are reimbursed, the slowing growth of inpatient admissions at the same time that outpatient services are increasing, and the need to further integrate care delivery.

"These factors motivate them to seek the highest and best use of their laboratories," he added. "For example, they're asking if their lab outreach businesses will be profitable in the future. They know that lower reimbursement is coming from Medicare and other payers, that cuts in lab test payments are in place under the Protecting Access to Medicare Act (PAMA), and that the cuts under PAMA will accelerate in the coming years.

"In addition to asking if their outreach businesses are profitable, health system administrators also want to know if they should remain in that business," he commented. "Some hospitals have no choice but to sell their outreach lab businesses. They have short-term financial needs and the outreach business is an asset they can sell easily. When they sell that asset, they gain capital right away.

"Both Quest and LabCorp are talking to the administrators at those hospitals, and Sonic is too, but to a lesser extent," he explained. "From our conversations with these same administrators, we know they will sell their outreach businesses and consider some form of a lab management deal. They will do so because a lab-management deal can save them 10% to 20% on inpatient lab expenses.

"On the other end of the spectrum are the large, well-run health systems—such as **Northwell Health** on Long Island—that have their own lab strategies," added Maring. "Because of their strong finances, these systems are least likely to consider a joint venture, a lab management deal, or a sale of their lab outreach businesses. Certainly not in the near future.

"In between those two extremes, as many as 40% of hospitals—or about 2,000 facilities—in the United States need to refine their lab strategies," he added. "These hospitals know they need to cut costs and to either improve or exit their lab outreach businesses. And many recognize they may need help achieving these goals.

Stable Finances

"Then there are hospital systems that are relatively large and do not have short-term financial needs that require them to sell their lab outreach businesses," continued Maring. "But they want to reposition themselves strategically and they want that repositioning to happen in a stepwise fashion over time.

"Instead, these hospitals have an interest in other options for their labs, such as a joint venture," noted Maring. "If they can, they want to keep their lab outreach business and grow it with the help of someone who's savvy about how to do that." TDR

—Joseph Burns

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Hospital Market Update

Morgan Stanley Report Shows 8% of Hospitals at Risk of Closure

AMONG THE ROUGHLY 6,500 HOSPITALS OPERATING in the United States, only about 125 (2.5%) have closed in the past five years. But in the coming years, some 450 hospitals are at risk of closing. Analysts at **Morgan Stanley** said 600 other hospitals have weak finances that could lead them to close.

In the report, Morgan Stanley, an investment bank and financial services company in New York, reviewed the financial strengths of about 6,500 U.S. hospitals and ranked 8% (450) as being at risk of potential closure and 10% (600) as being weak financially. Morgan Stanley rated the remaining 4,950 hospitals as being healthy financially.

For hospitals, much of the news in recent years has centered on mergers and acquisitions. M&A activity is slowing, however, and will give way to news about closures, the report said.

"We think hospital closures will increasingly drive the debate on healthcare disruption," the report said. "After the Affordable Care Act of 2010, hospitals saw improved finances, and merger activity shot up for several years. But hospital profitability has been trending downward recently as management teams learn that bigger isn't necessarily better."

In addition, there are fewer buyers for single-facility hospitals because many health systems are focusing on integration from recent mergers, the report said, adding, "While potential disruption from the new **Amazon** venture has been grabbing headlines, we think closures will enter the narrative on hospitals during the next 12 to 18 months."

Morgan Stanley's report, *Hospital X-Ray: Fractured Foot(print)*, used public data sources to assess the financial health of individual hospitals and explain why the number of hospitals that close will rise. Although the report was prepared to help investors, its conclusions are nonetheless revealing about the level of disruption that managers and pathologists in hospital labs may face in the coming months.

Hospital Finances

Morgan Stanley's report is similar to one that **Alvarez & Marsal, LLC**, a restructuring and consulting firm in New York, produced in 2008. For that report, A&M studied the financial operations of 3,861 of the 4,900 acute-care hospitals operating in the United States. Among those 3,861 hospitals studied, 2,044 (53%) were not making a profit on patient care. *(See TDR, May 27, 2008.)*

As THE DARK REPORT noted at the time, the A&M report, *Hospital Insolvency: The Looming Crises*, showed the hospital industry was due to change dramatically and such a shift could affect the clinical laboratory and anatomic pathology professions. Since publication of the A&M report, hospitals have continued to struggle financially.

For its report, Morgan Stanley divided all hospitals into three groups: healthy, weak, or at risk. "Our analysis distinguishes healthy hospitals from weak ones, and goes further to break down the weak hospitals into a smaller subset of facilities that could potentially be at risk of closure or downsizing," the report said. "We esti-

mate 10% of hospitals in the US are weak and 8% could be at risk of closure."

Morgan Stanley showed that nonprofit hospitals are in better shape than for-profit hospitals and that hospitals in the 32 states that expanded their Medicaid programs under the Affordable Care Act are stronger than hospitals in non-expansion states.

In the market for healthcare services, several factors are squeezing hospital profits, including competition from alternative sites of care, Morgan Stanley reported. As health insurers acquire outpatient facilities and physician networks, payers can drive members away from high-cost hospitals to lower-cost urgent care and ambulatory surgical centers and to freestanding emergency rooms, the report said.

The growing prevalence of high-deductible health plans reduces hospital revenue and increases bad debt when patients cannot afford to pay for care. For hospitals, more outpatient revenue and an increasing senior population will mean more government reimbursement at lower margins, the report said.

The Case Mix Factor

Other factors that determine a hospital's financial strength are the case-mix among patients (because sicker patients require more resources and thus their care generates more revenue); bed capacity, characteristics of the market for healthcare services, cash flow, and level of government reimbursement.

Among for-profit hospitals in cities and towns with low healthcare utilization, profit margins become crucial, the Morgan Stanley analysts reported, adding, "underperforming facilities that drag down systemwide margins become targets for divestitures or, in extreme cases, closures for the publicly-traded, for-profit names." When all other factors are equal, there is higher risk of closure among for-profit hospitals relative to nonprofit facilities, the Morgan Stanley analysts reported.

Among the for-profit hospital companies cited in the report were **Tenet Healthcare** (THC), **Community Health** (CYH), and **Quorum Health Corp.** (QHC), all of which have high debt levels, the report said. Those with high debt levels have the "time pressure of dealing with weak and at-risk facilities." These for-profit companies are interested in divesting facilities to improve margins and reduce debt, but, "a recent slowdown in the pace of announced divestitures, coupled with reported closures, are a sign that the market for low-margin facilities is getting smaller," the analysts explained.

Under-Performing Hospitals

Although prospects for nonprofit hospitals were less grim, the report suggested that those who invest in nonprofit hospitals should be wary. "Better balance sheets don't make them immune from operating challenges, and our work shows that even the highest-rated systems have plenty of underperforming hospitals," the report said.

As Morgan Stanley noted, cash flow is a significant factor that determines a hospital's financial health. Ten years ago, Alvarez & Marsal also noted the importance of cash flow, reporting that 744 hospitals in its study earned so little that they could not fund day-to-day operations, make needed repairs, or support basic capital expenditures. In addition, A&M reported, access to sufficient numbers of patients was a big reason so many hospitals were failing to generate adequate revenue.

At the time, TDR wrote, "For many hospital-based laboratory managers and pathologists, A&M's conclusions are not good news." The same could be said of the Morgan Stanley report. As the A&M report said, "A 'flight to (perceived) quality' is occurring by both physicians and patients—creating a bigger gap between the fiscally strong and fiscally weak hospitals in a given market." TDR

—Joseph Burns

Goals are common test methods, menus, practices

Michigan's Ascension to Standardize Labs Throughout the State

CEO SUMMARY: Two trends are driving a movement to standardize laboratory operations across large regions: the integration of clinical care and the need for hospitals and health networks to improve patient outcomes continuously. In Michigan, Ascension Health is an example of a lab team working to standardize lab testing activities among seven organizations, 14 hospitals, and 18 laboratories. The goal is to use standard instrumentation, tests, and best practices across all sites while sustaining growth in Ascension's laboratory outreach program.

ONE-BY-ONE, MAJOR HEALTH SYSTEMS in the United States are recognizing the need to evolve into fully-integrated care delivery networks. Integration makes it possible to eliminate gaps in care, maintain a complete health record of all patients, and improve patient outcomes while reducing healthcare costs.

An essential step in these integration efforts is to standardize and consolidate clinical laboratory services throughout the health system. Pathologists and lab administrators know that a complete record of a patient's lab test data allows physicians to identify gaps in care and be more effective in how they diagnose, treat, and monitor patients.

All of these reasons are in play at one of the nation's largest projects to standardize clinical lab testing services. For the Michigan region of **Ascension Health**, an ambitious integration of clinical laboratory testing services is underway. This project involves seven member organizations, including 14 hospitals and 18 laboratories.

During a presentation at the THE DARK REPORT'S *Executive War College* in May, Carlton Burgess, MSM, Vice President of Laboratory Services at Ascension Health's **St. John Providence Clinical Pathology Laboratory** in Grosse Pointe Woods, Mich., outlined six primary goals for this ambitious lab program. They are:

1) Faster workflow and shorter cycle times;
2) Improved identification and elimination of non-value-added processes;
3) Increased adoption and use of continuous improvement, Lean, and similar methods;
4) Better use of sophisticated informatics and real-time analytics;
5) Collaboration with other providers to deliver more value from lab test results; and,
6) Measurable improvements in patient outcomes and lower costs of care.

"Essentially, all the Ascension labs in Michigan are working to align their mission and values with those of the parent organization by improving the quality of care and cutting needless spending," stated Burgess. "In addition, our labs are working to implement the Ascension quadruple aim at about the same time that the health system itself is doing so.

"Ascension Michigan's quadruple aim involves: 1) delivering the highest quality care; 2) improving the patients' experience; 3) improving the providers' experience; and 4) delivering care at the lowest possible cost," said Burgess.

From Costs to Revenue

Another goal in this statewide reorganization and standardization of these laboratories involves generating revenue. "When fully implemented, this project will transform clinical laboratory operations from a financial cost into a revenue generator," he added. "Our first target is to deliver $5.3 million in additional net revenue annually.

"These four goals are a challenge for a system as large as Ascension in Michigan," noted Burgess. "In just our one state, we have seven member organizations, 14 hospitals, and 18 laboratories. In addition, we have six different LIS systems, myriad different registration and electronic medical record systems, and an enterprise master patient index.

"Our pursuit of Ascension's quadruple aim puts our labs at a crossroads between quality and finance," Burgess commented. "Does that mean finance or quality will drive these initiatives?

Low Costs or High Quality?

"The commitment to the quadruple aim forced us within the organization to look at the financial opportunity versus the effect on quality," he noted. "When we did, we found there was much support from senior leadership to lean toward quality. This means our lab initiative is never to affect the patients' or the providers' experience negatively just for the sake of getting down to the absolute lowest cost.

"Once we knew that, it became much easier to get buy-in from senior leadership for

our proposed lab standardization project," he added. Plus, he explained later, the accounting department showed that the project would help increase revenue.

In support of the quadruple aim, the path to regionalizing and standardizing Ascension's 18 Michigan labs required all labs to work together. "To achieve this, the labs will be linked in four regions, a process we describe as regional integration," he said.

"Each region has a core lab and rapid response labs and each region will be responsible for building lab volume through increased outreach testing," he added. "In addition to changing how labs serve each region, our statewide standardization project has three objectives:

1) "Repatriate existing send-out lab testing back into Michigan;
2) "Establish standard test menus for each facility; and,
3) "Renew each lab's focus on growing lab outreach business.

"To accomplish these goals, Ascension Health in Michigan has eight labs operating as rapid response labs (RRLs) and this number will rise to 12 RRLs," he said. "The lab at the **Saint John Hospital and Medical Center** (SJHMC) in Detroit will be expanded into that region's core lab.

"In addition, we are already nearly standardized on **Roche** automation equipment," Burgess explained. "This will help us standardize test methodologies and reference ranges across all laboratories. This automation also will handle the increased volume that will come from repatriating tests that are currently sent outside of Michigan, as well as handling the increased volume from growth and consolidation.

"Currently, Ascension Health labs sends more than 25,000 tests annually outside of Michigan," he stated. "By bringing those tests back into our labs, we can save those costs.

"Other parts of the project include integration of our informatics systems," he noted. "We will interface the SJHMC **Atlas** system to all of the EMRs in use at Ascension facilities in Michigan. We plan to use the **Cerner** PathNet LIS at all labs and the **MedSpeed** courier service to manage the logistics of moving testing. In addition, the sales and marketing teams at SJHMC will expand to grow the outreach business statewide.

A Goal of Full Integration

"At the start of this project, lab leadership had a high-level perspective of what it wanted to accomplish," he said. "That included full integration within the four regions and the 18 laboratories, supported by a modern core laboratory in every region."

Burgess used Ascension's term "ministries" for each region: **Borgess** in Kalamazoo; **Mid-Michigan-Genesys** in Grand Blanc; **Saint Joseph Health System** in Tawas City; **Saint Mary's of Michigan** in Saginaw; **Crittenton** in Rochester Hills, and **Saint John Providence** in Detroit and the surrounding areas.

"It is not in our plans to upgrade a core lab in Detroit to handle highly-esoteric tests," he added. "We don't want to replicate what a lab like **ARUP** already does, for example. On the other hand, we definitely want to keep the right testing in Michigan.

Right Test at the Right Time

"We are like many other health systems in that way because we want to do the right test at the right time in the right location," Burgess added. "Our goal is to keep our lab testing in our system.

"Another goal is ensure that each facility has rapid response capabilities commensurate with the medical services that facility offers," Burgess said. "Doing so will help us expand lab outreach programs in each region and regionalization will improve outreach program efficiency at each site.

Ascension's Lab Team to Regionalize Testing in All Michigan Hospitals and Laboratories

IN RESPONSE TO THE TRENDS OF INTEGRATED CARE AND FULLY-INTEGRATED HEALTH NETWORKS, the laboratory team at Ascension Health in Michigan has embarked on a program to fully regionalize, standardize, and consolidate laboratory services. What makes this a particularly ambitious project is that there are seven system organizations involved, not to mention 14 hospitals and 18 laboratories.

The map of Michigan below shows the location of the member health networks. The bullets below identify the manner in which the laboratory team will reorganize existing clinical laboratory facilities throughout Michigan, along with the primary goals for this ambitious laboratory regionalization initiative. Nationally, Ascension Health is the largest Catholic health system and is one of the largest non-profit health networks. It will take several years to achieve full regionalization of lab testing services throughout Ascension's facilities in Michigan.

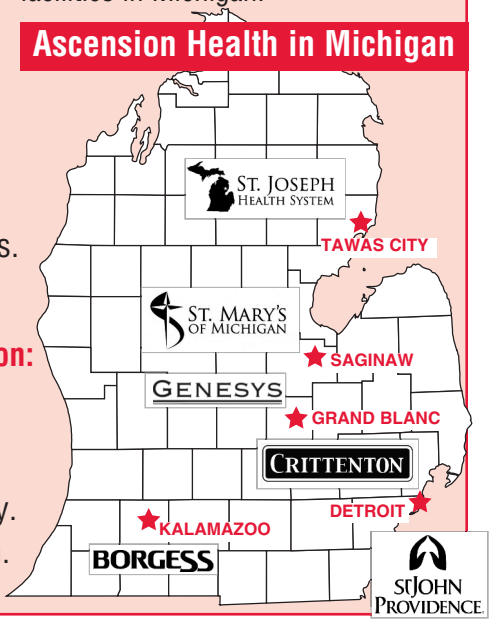
Delivery Model:

- Regional lab integration.
- Regional core laboratory.
- Facility-based rapid response labs.
- Regional market lab outreach.

Goals of Laboratory Regionalization:

- Repatriate send-out testing back into Michigan.
- Regionalize through rationalized testing menus for each lab facility.
- Renew focus on outreach growth.

Ascension Health in Michigan



"We plan to expand the outreach program to cover the entire state," he explained. "In fact, the lab at SJHMC is a model for what we could do with our outreach program in each region.

"In our core laboratory at SJHMC, we have a system that is highly standardized on the Roche platforms, and that's true in most of the regions," he added. "While we do not yet have 100% of our facilities on Roche automation equipment, we are a long way toward standardizing in that way.

"As we look toward the future, we aim to standardize on our instrumentation as much as possible," he continued. "That will help us avoid the problems that result when reference ranges come from different platforms.

"As mentioned, one of our goals is to repatriate all of the more than 25,000 tests

that we send outside of Michigan each year," he said. "To do this, we do not need to make a new or substantial investment because that testing capacity is already available in the Detroit core laboratory. But in the other regions, that testing is getting referred outside the system to external reference laboratories. Therefore, repatriation is the low-hanging fruit that we can do quickly and with no added investment."

After discussing the basic strategies for lab regionalization, Burgess discussed how information technology would support standardization.

"One of the most important aspects of this project involves how the labs interface with Ascension Health's EMRs," he said. "For our interface, we use Atlas LabWorks as our primary connectivity product at SJHMC. We plan to use that same system in the other regions so that we can bring connectivity to the facilities that don't have it already.

"Also, we're considering standardizing on Cerner's PathNet as our common LIS," he said. "Right now, standardizing on Cerner PathNet is a long-term reach. We have a few different LISs in the system and five different versions of Cerner PathNet. As a health system, Ascension is heavily invested in Cerner, so there's a natural fit to use those products going forward. Converting all of the LISs may take some time.

Vendor Integration Too

"For our couriers, we have standardized throughout Ascension and within Michigan on MedSpeed," he said. "We did that under a partnership formed a few years ago. Not only does MedSpeed provide courier services, but it also transfers supplies from point-to-point among facilities and departments as needed. Therefore, MedSpeed is a tightly integrated operation already."

Following his discussion of the logistical aspects of standardization, Burgess explained the project's expected financial results.

"When we first considered standardization, all of our discussions were at a very high level," he explained. "But over time, we looked at the effect the project would have on our test menus, equipment at each location, staffing, and IT options.

Assessing Staff Needs

"We needed to know if we had the staff to support this project and if the people on staff would have challenges with it," he said. "We also needed to know what kind of referral options we had and what those referrals would cost. Also, of course, we needed to know the IT status at each location so that we could determine what each location needed.

"For each facility, we needed detailed information, including the LIS in each organization and the lab equipment in each facility," he said. "We also needed to know how much point-of-care testing each facility did, how the POC testing was done, how those results were disseminated, and how much the lab was involved.

"To help us with this aspect of the project we got support from the finance department and we brought in business analysts as early as possible," Burgess said. "We also needed people who could help us with cost accounting and we invited in people from Ascension Health's internal group purchasing organization, called The Resource Group. They do a lot of contracting across the Ascension Health system and they have an active lab subcommittee.

"Getting the finance people involved early was important because they helped us answer a lot of questions that were bound to be asked," he explained. "At this point, we're getting into the gritty details of the project. For example, when we looked at standardizing the testing menu, we needed to know if we could do so based on the equipment in each facility. If the goal was to standardize or regionalize electrophoresis testing, we had to have the same equipment in each hospital.

Ascension's Finance Dept. Helped Lab Team Evaluate Different Aspects of Regionalization

"IT IS INTERESTING TO NOTE that we often hear how cost accounting is not a strength in many hospitals or in hospital laboratories," said Carlton Burgess, Vice President of Laboratory Services at Ascension Health's St. John Providence Clinical Pathology Laboratory.

"But as we developed our regionalization plan for the 18 laboratories at Ascension Health in Michigan, the folks in finance made a significant contribution in analyzing one difficult question after another," he stated. "With their help, we could do deep-dive cost accounting on every test that we perform, including those in the core laboratory.

"They helped us consider whether changing a referral pattern would increase or reduce costs," noted Burgess. "Together, we could analyze whether moving testing from one lab to another, or bringing it into the core laboratory, would make sense financially. For certain tests, we learned that it would cost more to do them in the core laboratory, than keeping those tests at one of our sister labs.

"This team approach with finance helped us evaluate tests that we send out," he added. "We learned it would be better to keep some tests in-house. For some of these tests, the GPO had negotiated the contracts for us and we asked it to renegotiate based on what we learned from finance about how we could do those tests in-house at a lower cost than what we were paying when we referred them out.

"For us, there were clear benefits of doing a deep dive on cost accounting with the finance folks," Burgess commented. "Because the laboratorians were collecting the data for our analysis and sending that data to finance, the accountants could develop a *pro forma* look at what financial results we might expect from this laboratory integration."

This lesson is an important one, Burgess suggested. "Having a financial analysis of the project helped to lower the barriers for justification when we presented our plan to senior leadership," he said. "And, having the financial people present when we made our presentation to leadership meant that when we got a question about any of the content, we could ask the finance staff to provide the answer.

"As a result of this experience, I recommend that if your lab has a good relationship with your institution's finance department and you can get them involved in analyzing the financial aspects of a lab project like this, then include those people in your planning," recommended Burgess. "They will be very, very helpful moving forward.

"For our lab project, they created a five-year financial model on the effects of regionalization and standardization," stated Burgess. "The model included a snapshot of an optimized financial statement for fiscal years 2018, 2019, 2020, 2021, and 2022. The report included fully-loaded costs, including the costs of staff and benefits and all other expenses."

"Using that approach, we recognized that—instead of having seven electrophoresis instruments around the system—we needed two in the regional laboratory," he explained. "Assuming that was done, how much could we get in potential savings by dropping service contracts and repair expenses on those extra pieces of equipment that were no longer needed? What's the future value of dollars for that instrumentation that would no longer be needed? These are questions that the team in finance is helping us answer." TDR

—Joseph Burns

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Under Audit, Labs Need Statistics on Their Side

More payers are using statistical sampling and extrapolation to extract payments from labs

CEO SUMMARY: When commercial and government payers use auditors to review a lab's claims, they often use statistical sampling and extrapolation to limit the time needed to review claims. But proper sampling and extrapolation require following the rigorous scientific methods to produce a representative sample of claims to draw conclusions they can apply to the universe of claims. A lawyer involved in such cases cautions that payers cannot simply plug in numbers to produce a result in their favor.

THREE YEARS AGO, federal auditors cited at least three genetic testing lab companies under federal law, saying the labs had filed false claims totaling multiple millions of dollars for molecular and genetic tests.

In each case, the lab companies protested that federal auditors unfairly used statistical sampling to identify a small number of potentially fraudulent claims and then, from those numbers, the auditors extrapolated a much larger number that reflected the actual amount the labs owed.

In these cases, the use of statistical sampling and extrapolation was damaging and costly to the lab companies involved. Now, a lawyer who often works with labs in these cases has cautioned clinical, genetic, and molecular testing laboratories that all auditors must follow proper procedures when using statistical sampling and extrapolation to produce accurate audit results.

"The key to defending against any false claims charges that stem from an auditor's use of statistical sampling and extrapolation is to understand the mathematical and scientific principles behind these techniques," advised Jeffrey J. Sherrin, a lawyer who represents labs in these cases. Sherrin is President of **O'Connell & Aronowitz** in Albany, N.Y.

Is Sampling Done Correctly?

"The use of statistical sampling and extrapolation in government overpayment audits is well accepted," Sherrin explained in an interview with THE DARK REPORT. "It is a given that the government can do this. The question becomes whether they do it correctly. That's where labs can make their case.

"In my work with labs, I have been very involved in cases where auditors have used statistical sampling and extrapolation," he added. "Actually, both have come up in several contexts. Typically, sampling and extrapolation come up in Medicare and Medicaid overpayment audits.

"In those cases, the auditors will look at whether you crossed the 't' or dotted the 'i', and if you didn't, they take those examples and calculate how much your lab owes," stated Sherrin.

"Increasingly, the use of statistical sampling and extrapolation is growing," he warned. "Commercial payers are using these techniques and the government is using them in false claims cases to prove either liability or damages or both.

"Among commercial payers, it is not well established that they can use statistical sampling and extrapolation," Sherrin commented. "Instead, the use of these techniques is a subject of debate among lawyers and others.

"The reasoning behind the debates is this: If it's just an audit case that's not related to criminality, then the burden of proof is on the plaintiff, meaning the person who says you owe the money," he explained. "In these cases, the plaintiff normally has to prove that your lab breached one or more contracts.

"Sampling and extrapolation are allowed for government audits because the process is more efficient and less costly," Sherrin explained. "Using these techniques, the Medicare and Medicaid programs have a legitimate interest in reducing the cost to determine how much money is owed so that the cost of carrying out this government function isn't prohibitive.

An Open Question for Payers

"If an auditor were to review 100% of, let's say, 10,000 claims, you'll know exactly how much is owed," he added. "But, the cost of reviewing 10,000 cases would be prohibitive. On the other hand, if you review 1% of 10,000 claims, then you're using statistical theory to arrive at a number that will approximately equate to what you would get if you reviewed 100% of the cases.

"That's why commercial payers don't necessarily have the same public policy requirement to be as inexpensive and cost efficient when going after a provider," he added. "In some cases, lawyers will accept the idea that commercial payers can use sampling, and in other cases, lawyers will argue they can't.

Labs Suffered When Auditors Used Sampling, Extrapolation

IN RECENT YEARS, at least three pharmacogenomics testing laboratories reported that federal auditors targeted their company's labs with audits and multi-million dollar recoupment demands.

In these cases, auditors from the federal Zone Integrity Program Contract (ZIPC) identified a small number of claims as being paid improperly and rejected those claims. Then, the auditors extrapolated from that small number of rejections to all claims filed over a period of years. The result was that the auditors demanded that each targeted lab company pay tens of millions of dollars. *(See TDRs, Jan. 7 and 30, 2017, and April 3, 2017.)*

In 2016, **Pharmacogenetics Diagnostic Laboratory** (PGxL), of Louisville, Ky., was forced to file for bankruptcy protection after such an audit of its Medicare claims.

"While it's still an open question, commercial payers are increasingly moving in that direction," he added. "That means it's an important issue for all providers, including laboratories.

"When a government or commercial payer uses statistical sampling and extrapolation in any false claims case, the issue of intent comes into play," he explained. 'The payer has to prove unlawful intent and that raises the question of whether an auditor can use sampling and extrapolation to prove intent. It's not yet clear whether the courts will allow it or not.

Courts Are Split

"Because some courts will allow it and other courts do not, eventually it might get to the U.S. Supreme Court," he predicted. "In the meantime, that battle is being fought a little bit more all the time.

"If we assume that statistical sampling and extrapolation are allowed, then you get into the difficult questions as to whether it was done properly, and there is

no single way of doing it correctly," Sherrin explained. "Since there are many ways to do it, lawyers representing labs need to ask if the result is reliable.

"Reliability of the data will depend on the total number of claims in question and the number of claims used to review," noted Sherrin. "These two numbers create a lot of litigation for this reason: the bigger the number of samples, the more precise (or less error) there will be, or should be, in the projections.

"To understand how this works, consider how a Gallup poll will produce a result showing an error rate of, say, plus or minus 2%," he said. "That error rate reflects a statistically-sound confidence level. In other words, Gallup will say it used statistical methods to reach that level of confidence.

Confidence in Results

"With statistical sampling and extrapolation, the commercial or government payer will need to show that it has confidence in its results," Sherrin said. "Auditors have to arrive at a number that represents their level of confidence, and they usually use 95% as the confidence level. Typically, they derive that number from a 100-case sample. Depending on the type of audit, they actually might require many more than 100 cases.

"But many commercial payers do not use 100 cases at all," he added. "Instead, they might use 20 cases. So, the first thing a lab's lawyer should look at is how many cases are in the sample. In a case where the auditor uses five cases rather than, say 1,000 cases, then the margin of error will be huge.

"Next, the lab's lawyer needs to know how the claims were chosen for review," he said. "The auditors might say the cases are chosen randomly. However, that doesn't mean the auditors put all the numbers in a hat and picked some arbitrary number.

"Auditors should use computer programs and algorithms that have been tested to confirm whether the numbers chosen are, in fact, random," he advised. "If the numbers are not random, and the auditor can't prove they're random, then those numbers have no value whatsoever.

"For this discussion, let's say the numbers are random and the auditor has a sample of 10, 100, or 10,000 claims," he added. "Whatever number they choose will affect the confidence level. A low number will reflect a low-level of confidence and a higher number will reflect a higher level of confidence.

"If the lab accepts the lower number, then the risk of doing it wrong is on the auditor and not on the lab," he commented. "But if the parties choose the higher number, then the risk is on the lab and not on the auditor.

"The point is that in every case of statistical sampling and extrapolation, there are certain conditions that auditors must meet statistically to accept the low point," he said. "Yet, in many cases no one considers these conditions.

"Instead, the parties argue about whether the sample was big enough or small enough or whether it's okay to sample or not sample," he warned. "They're not looking at whether the auditors met the conditions that they need to meet.

Eliminating Sample Bias

"Auditors have to look at whether the sample itself is large enough to at least trigger the appropriateness of using the sampling method," he concluded. "Also, the claims in the sample have to represent the claims in the universe, meaning there should be no bias in the statistical sampling. The sample has to provide a real picture of what the universe would be.

"If auditors don't follow these parameters, then they're not doing the sampling or extrapolation correctly," he said. "If that happens, then the lab in question can needlessly suffer a great loss." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

News that a laboratory's courier truck was highjacked in broad daylight with patient specimens aboard puts the spotlight on whether the security practices labs use to protect drivers, vehicles, and the patient specimens they may be carrying are adequate. On Aug. 3 in Durham, N.C., a driver of a courier vehicle owned by **Laboratory Corporation of America** was confronted by an armed gunman. He took the vehicle and drove off. The LabCorp driver was unharmed. The vehicle was later recovered. However, local police are mystified because the 79 patient samples in that courier vehicle had disappeared.

MORE ON: *Courier Car Robbery*

LabCorp has notified physicians about the missing specimens. It is also offering to pay for identity protection services because personal information was with some of the samples. This episode demonstrates why it is useful for clinical labs and pathology groups to review both their security practices and their procedures before a breach involving protected patient data occurs.

AAFP ASKS DOCS TO FILL OUT SURVEY ABOUT IMPACT OF MEDICARE CUTS

Physicians who are members of the **American Academy of Family Physicians** (AAFP) are being asked to complete a survey on how the PAMA lab test price cuts are affecting their ability to serve their patients. In its bulletin, the AAFP said, "The goal is to persuade Congress to fix PAMA so that in-office labs can afford to stay open and patients can continue to benefit from point-of-care testing services." This survey demonstrates that the PAMA price cuts are creating a financial pinch for physicians who operate in-office laboratories.

TRANSITIONS

• Roland Diggelmann, Chief Operating Officer of **Roche Diagnostics** and a member of the Roche Corporate Executive Committee, will leave the company, as of Sept. 30. He joined Roche in 2008 and assumed his current position as head of Roche Diagnostics in 2008. Formerly, he held executive positions at **Zimmer**, **Sulzer Orthopedics**, and **AllPro AG**.

• **Roche** appointed Michael Heuer to be interim CEO of Roche Diagnostics and a member of the Roche Corporate Executive Committee. Heuer moves up from position as Region Head of Roche Diagnostics' division covering Europe, Middle East, Africa, and Latin America. He joined Roche in 1998 and formerly worked at **Boehringer Mannheim**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 1, 2018.

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Our Multi-Year Journey to Achieve Six Sigma Quality in Reducing Lost Specimens!

Charles D. Hawker, Ph.D., MBA
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