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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

Giving Back to the Clinical Lab Profession

MANY OF US ARE CONCERNED about how the next generation of clinical lab and anatomic pathology leaders will be trained and prepared to step up and assume responsibility for the clinical excellence and financial performance of their respective lab organizations.

To contribute to the training of promising young lab managers, in the past two years THE DARK REPORT has invested significantly to offer high-quality leadership development training at our *Executive War College* program and our *Lab Quality Confab* conference. This is one way we can give back to the profession of laboratory medicine that has been so good to us since our founding in 1995.

In this spirit, I am happy to report that there is a cadre of promising leaders among the Gen X and Gen Y lab managers currently employed in labs throughout the United States. For example, at last year's *Executive War College*, our full-day leadership conference attracted more than 100 participants. It was a day of superb learning and instruction, provided by Colonel Jeffery A. McCausland, retired, U.S. Army, the former Dean of Curriculum at the **U.S Army War College** in Carlisle, Pennsylvania.

That program went so well that, at the upcoming *Executive War College* on April 26-27, we've engaged McCausland and his colleague, W. Brad Johnson, PhD, Professor of Psychology at the **U.S. Naval Academy**, to offer coaching and instruction to lab administrators who are mentoring and the individual managers who are their mentorees. Participants signing up for this exceptional learning opportunity are enthusiastic and already engaged in preparing for their time with McCausland and Johnson later this month. (It's not too late for you to sign up and bring your mentoree!)

Similarly, for lab managers who are the up-n-comers in their organization, the *Executive War College* is offering full scholarships, including travel costs, to the program. **McKesson Corporation** is funding one of this year's scholarships. The good news is that the number of applicants was the highest ever.

Another way THE DARK REPORT is giving back to the lab profession is by conducting the first-ever National Lab Sales Achievement Awards. The nominations represent amazing performance by lab sales reps responsible for ethically generating more specimen volume from new client physicians. The awards will be announced later this month at the 21st Annual *Executive War College*. TDR

Just 66 of 742 Labs Submit Rate Data to Calif. DHCS

Does this 9% compliance rate predict what CMS will see with its PAMA lab price reporting?

CEO SUMMARY: Federal officials tasked with implementing the PAMA lab market price reporting requirement would be well-served to study what happened in California when the Department of Health Care Services mandated market price reporting. According to DHCS, last year, only 9% of the state's 742 labs submitted price data! This is evidence that requiring a lab to report every payer's price for almost every test is not only a huge burden on most labs, but nearly all labs lack the technology needed to assemble the data.

CAN THE FEDERAL GOVERNMENT succeed in its effort to require clinical labs to report market price data, as mandated under the Protecting Access to Medicare Act? If the experience of California's **Department of Health Care Services** is a useful precedent, then this experience is evidence that the federal reporting effort will be a dismal failure.

THE DARK REPORT is the only lab industry news source to report on the fact that just 9% of clinical laboratories in California submitted data to the state Department of Health Care Services (DHCS) for its rate-setting program, according to DHCS data. The data were based on what third-party payers paid the laboratories in 2014.

At this moment, the clinical lab industry awaits the publication of rules from the federal **Centers for Medicare & Medicaid Services** to implement PAMA lab test price reporting. This is a controversial section of the PAMA law, for many reasons. One reason is the heavy burden needed for labs to gather and report the lab test price data for each type of test and for each health insurance plan.

If California only could get 9% compliance with its lab test price reporting requirement from almost 750 labs, does this fact support a credible argument that, assuming CMS goes forward with the PAMA laboratory test price reporting requirement, it may get compliance of just 10% or lower? This is particularly true since CMS must require labs throughout the United States to report even more complex test price data than what was required of laboratories in California.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

The data-collection effort of the California DHCS last year was phase one of a two-phase program. In phase two, labs have been asked to submit data on what third-party payers paid them in 2015. The deadline for submitting data under phase two was March 18.

No Phase Two Tally Yet

State officials have yet to tally how many labs had submitted data and how many had not under phase two of this reporting requirement. The Department of Health Care Services administers the state Medicaid program for low-income individuals, called **Medi-Cal**.

Michael Arnold, Legislative Advocate and Executive Director of the **California Clinical Laboratory Association**, said he did not know why more California labs did not submit data to DHCS except that some labs have said the process is difficult and expensive.

"We have suggested to CCLA members that more data would be better and have encouraged our labs to participate," stated Arnold. "For labs, it's probably a cost and time issue. They are all having a tough time these days, especially those who run tests for Medi-Cal beneficiaries.

"Keep in mind that DHCS plans to do this data collection annually," he added.

"We hope the compliance rate for reporting lab test prices will be better at the federal level, since the Medicare work is much more important to labs than the Medicaid work," observed Arnold. "But again, it's likely to be an issue of time and cost."

Difficult And Complicated

Commenting on California's experience collecting lab price data, Mark S. Birenbaum, PhD, Administrator, of the **National Independent Laboratory Association** (NILA), said, "We believe that the California data reporting clearly indicates that the PAMA reporting will be difficult and complicated.

"To date, no labs have reported private payer data to CMS because the agency has not published a final regulation," explained Birenbaum. "In March, a majority of the members of the U.S. House Ways and Means Health Subcommittee issued a letter to CMS that advised CMS not to rush the PAMA regulations."

It is reasonable to assume that the efforts to collect lab test rate-setting data in California would be of interest to federal officials tasked with the similar need to collect lab test price data in order to set Medicare Part B clinical lab payment rates as mandated under PAMA.

The experience in California with the state's market reporting requirement shows the challenges that CMS officials will face. Of the 742 California labs required to submit the data last year on what third-party payers paid them, only 66 unique labs submitted the requested data, DHCS figures show. DHCS also reported that those 66 labs represent most of the total claims for services.

Increase Data Submission

"Those 742 labs that were required to submit fee-schedule data were providers that had Medi-Cal utilization in 2014 reflecting paid claims totaling $100,000 or greater, and claim counts totaling 5,000 or greater," commented Anthony Cava, spokesman for DHCS, in an email response to questions from THE DARK REPORT. State officials are considering what methods they can use to increase data submission by the remaining 676 labs that did not provide the required data, noted Cava.

At this moment, the entire lab industry is waiting and watching to see what next steps CMS will take to implement market test price reporting. In recent months, legislators from both houses of Congress have signed letters asking CMS to reassess the draft regulation on market price reporting that it published last fall. To date, CMS has not made further comment about what it intends to do. TDR

California Lab Price Reporting Requirement Resulted In a Reduction of Medi-Cal Fees Paid for Lab Tests

OFFICIALS AT THE CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES hope that the latest round of reporting by labs on the prices they were paid for lab tests generates a better response than the first data collection effort.

"In addition to exploring methods to increase data submission by the labs, we will send reminders to these labs of the requirement to submit their data," stated Anthony Cava, spokesman for DHCS.

Under state regulations, specifically Welfare and Institutions Code 14105.22 (5)(F), Cava said, "Clinical laboratory providers that fail to submit data reports within 30 working days from the time requested by the department shall be subject to the suspension provisions of subdivisions (a) and (c) of Section 14123."

He added, however, that no penalties have been enforced to date. The data collection effort began last year and continued through March 18 of this year.

Asked to characterize what the data in the first round showed in terms of what labs are paid, Cava said new clinical laboratory fee schedule rates effective February 1, 2016, would result in savings of about $18.5 million compared with what DHCS paid in 2014.

DHCS achieved those savings by cutting what it paid for almost 400 clinical lab codes. "As a result of the new methodology, the Medi-Cal rates for a total of 370 codes decreased, effective July 1, 2015. Also, there were 35 codes that had no rate reduction," he said.

Of the 370 codes, payment for 229 of them was slashed by 16% to 20%, payment for 43 codes was cut by 21% to 25% and payment for 33 codes was cut by 26% to 50%, DHCS data show. Payment for 35 codes was unaffected.

"The labs that submitted the required fee schedule data were mid-sized to large labs, both hospital and independent," noted Cava. "Providers with 2014 Medi-Cal utilization that involved paid claims totaling $100,000 or greater, or claim counts totaling 5,000 or greater, were required to submit lab test fee schedule data."

The California Assembly approved the program under Assembly Bill 1494 in 2012. This law was in response to settlements made by the California Attorney General with **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. In 2011, Quest Diagnostics paid $241 million to settle charges under the state's False Claims Act that it overcharged Medi-Cal. Quest did not admit guilt.

Three months later, on August 30, 2011, Laboratory Corporation of America agreed to pay $49.5 million to settle similar charges and did not admit guilt.

Under California law at the time, reimbursement for clinical laboratory services provided under the Medi-Cal program could not exceed 80% of the lowest maximum allowed under the federal Medicare program.

But after the settlements involving Quest Diagnostics and LabCorp, the California Assembly drafted AB 1494 to develop a new rate-setting methodology for clinical laboratories and laboratory services based on the average of the lowest prices other third-party payers pay for similar services. The law also implemented a 10% payment reduction for clinical laboratory tests and lab services, excluding certain family planning services. That 10% reduction was effective July 1, 2012, and ended on June 30, 2015.

—Joseph Burns

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Market Update

Mayo Medical Laboratories Will Close Massachusetts Lab

Decision to close this lab facility after 20 years is a response to ongoing changes in healthcare

IN AN ANNOUNCEMENT MADE LAST MONTH, **Mayo Medical Laboratories** said that it would close the lab facility it operates in Andover, Massachusetts, by the end of the year.

As a result of this move, Mayo will eliminate 105 jobs in this leafy suburb north of Boston. For 20 years, MML has operated the lab in Andover, its only facility in New England.

News outlets reported that the lease on the property was soon to end. The leaseholder of the property asked Mayo to make a long-term commitment to the facility and Mayo declined.

No Physicians to Serve

The fact that no Mayo physicians were in the region was a another factor in the decision. "This [laboratory] testing facility is a highly successful operation in terms of quality, safety, productivity, and cost efficiency," stated William Morice, II, MD, PhD, Chair of **Mayo Clinic**'s Department of Laboratory Medicine and Pathology in Rochester, Minn. "However, the facility is not near a Mayo Clinic medical practice. Our decision is based upon the long-term future for this facility, not the great work that is performed there every day.

"This was not an easy decision—in fact, it was an incredibly difficult decision," added Morice, who is also CEO of Mayo Medical Laboratories. "Our primary concern is helping the affected staff at this location in every way possible.

"As we transition the testing from New England to Mayo Clinic in Rochester throughout 2016, it is my hope that some of the staff in Andover will be interested in open positions at other Mayo locations," emphasized Morice.

MML runs approximately 23 million tests each year in support of the clinic's 4.5 million patients worldwide. In its clinical laboratory in Rochester, it has 165 physicians and clinical laboratory scientists working in more than 90 subspecialty areas of pathology.

Mayo Medical Laboratory entered this region in the mid-1990s by acquiring a medical laboratory company in the Boston area. This was a time when competition for hospital reference laboratory testing was increasing. For instance, at this same time, **Specialty Laboratories, Inc.**, was establishing a processing center in Worcester and making a big sales push to win more hospital reference testing business from hospitals in the area.

However, the competitive dynamics in the hospital reference and esoteric testing sector are much different today. Hospital ownership is being concentrated by integrated health systems as they acquire community hospitals or enter into joint ventures with independent hospitals. ACOs are another way that providers are coming together in a business model that allows them to bundle their lab test volume in order to negotiate more favorable prices for reference and esoteric testing. TDR

How to Cover Genetic Tests Confounds Health Insurers

UnitedHealthcare announced requirement for genetic test pre-authorization later this year

CEO SUMMARY: Managed care experts say health insurers are being overwhelmed by the number of new genetic tests and that many labs find it tough to get paid for these tests. UnitedHealthcare just announced it will require pre-authorization of molecular and genetic tests during 2016. Meanwhile, Cigna, which already has pre-authorization in place for certain genetic tests, said it intends to cover exome sequencing tests for selected patients, but it will not cover whole-genome sequencing.

HEALTH PLANS ARE STRUGGLING to find the best way to manage the rising tide of new genetic and molecular tests entering the market every week. Coverage policies vary by payer.

For example, on March 1, 2016 **UnitedHealthcare** announced that it would introduce prior authorization for molecular and genetic tests in the third quarter of this year. Between now and then it would release details on how the "mother-may-I" approach would work.

UnitedHealthcare actually has been behind the curve in adopting prior authorization for genetic testing, stated Paul von Ebers, former President and CEO of **BlueCross and BlueShield of North Dakota**. "Most Blue Plans, **Aetna**, and **Cigna** have had prior authorization for these tests for a while," he added.

NextGxDx, a health IT company, estimates that clinical labs introduce eight to 10 new genetic and molecular tests each week. This is why a payer's review and approval for every test is a significant undertaking, requiring an army of geneticists, genetic counselors, pathologists, and PhD-clinicians to meet the demand.

Health plans seeking to manage these tests are using a wide variety of methods to contain utilization. No one method seems to work for all. "It's all over the map," said Rina Wolf, Vice President of Commercialization Strategies, Consulting, and Industry Affairs for **Xifin, Inc.**, a revenue cycle management company for labs.

Pre-Authorization Policy

In response to a question from THE DARK REPORT, UnitedHealthcare spokesman Daryl Richard said, "Prior authorization is already required for certain genetic tests, such as BRCA testing. We also request genetic counseling visits in advance of testing with an independent counselor to remove potential conflicts of interest that could arise if a genetic testing lab was providing the counseling on services it performs. We also encourage our members to contact **InformedDNA** as an additional resource. This company maintains a database of genetic specialists who provide independent reviews."

"Here at Xifin, we track the policies for different payers and we find these policies changing almost on a daily basis,"

explained Wolf. "That is just one problem for labs. Another problem is that most labs do not have a direct encounter with the patient. Therefore, it's difficult for a laboratory to know when prior authorization is required and when it's not."

Von Ebers, former President and CEO for Blue Cross of North Dakota, agreed, saying insurers have recently stepped up their vigilance on new expensive molecular and genetic lab tests. In addition, genetic testing labs often are left out of exclusive contracts between insurers and the leading national lab companies.

"In many cases, insurance companies have consolidated their lab deals into exclusive or semi-exclusive contracts with major national or regional labs to get the best prices across their whole lab spend," said von Ebers, currently President of **Prospective Health LLC** in Fargo, N.D.

Start-Up Labs Struggle

"Many start-up genetic testing labs have had trouble getting contracts with the largest insurers, such as UnitedHealth, Aetna, Cigna, and **Anthem**, because of these exclusive deals," he added. "To get around this problem, some labs have tried waiving the fees patients have to pay because genetic testing is so expensive.

"But the issue goes beyond the expense of these tests," observed Von Ebers. "That's because insurers cannot effectively negotiate prices if they must accept all providers or if there are no disincentives for plan members to go to non-contracting providers."

"When prior authorization is required, the lab, the patient, and the ordering physician may wait weeks and still not get an approval," stated Wolf. "Then, if a lab tries to force the issue, it might get a flat denial with no explanation. Labs have told us that, when they attempt to get prior authorization, payers sometimes call the lab's physician client and pressure him or her either to not order the test or to order it from an in-network lab.

"Even when a plan requires prior authorization, it can be extremely difficult for labs to get that approval," continued Wolf. "The ordering physician has to call the plan to get approval, but that can be a challenge, particularly if that patient's plan or specific circumstances don't allow such tests or if the patient is out of network.

Third Coverage Problem

"There is also the third problem of which specific plan from Aetna, United, or Cigna, requires prior authorization," she added. "Aetna could put this policy in place, but it doesn't apply to every Aetna product or it doesn't apply to a self-funded plan because the employer may not require it. Or an employer may require it but the payer doesn't require it in general.

"Sometimes, clinical labs will skip the prior approval phase, run the test, and then ask the health plan to pay for it," said Wolf. "In essence, the labs are asking for forgiveness rather than getting permission first. They do this because a lab does not have a direct encounter with the patient. Thus, this lab won't know the clinical circumstances. Only the ordering physicians know those details."

Some health plans, such as Cigna, require genetic counseling for certain tests, particularly for the BRCA1 and BRCA2 tests for breast cancer. "But again, the lab may not know that genetic counseling was provided. Only the physician can state that this was provided for the patient,' she said. "We recommend that our clients who perform these tests capture information about genetic counseling on their requisitions.

"Right now, Cigna seems to be the most forward-thinking health plan when it comes to whole exome testing," Wolf added. "They do require that certain criteria be met and are requiring genetic sequencing for those tests."

In November, Carol Hall, Xifin's Payer Relations Manager, said Cigna issued a policy saying it would cover whole exome sequencing (WES) for some patients. When

it did so, it was the first time a national health plan explained its coverage criteria for WES, Hall reported. *(See sidebar at right.)*

Before approving any test—especially expensive genetic or molecular tests—most health insurers will ensure that the test actually will result in improving a patient's care, von Ebers said.

"Precision medicine is a wonderful idea and eventually it will probably allow the medical system to focus treatments on what works at the individual patient level," he noted. "The problem is that many labs offering genetic and bio-marker tests will recommend broad criteria for screening and they often package multiple genetic tests into a single panel.

Results To Guide Treatment

"Insurers would love to pay only for treatments that will work on an individual patient, because the savings of effective precision medicine are theoretically huge," said von Ebers. "But many times the genetic tests do not produce results that can actually affect treatment. In general, insurers will pay when the genetic testing is clearly indicated for this patient due to his or her ethnic background, disease state, or other factors and when the results of the test have a meaningful chance of changing the treatment.

"Over time, insurers will get better at managing molecular and genetic tests," he concluded. "The controversy over this issue will calm down for two reasons.

"First, some labs do a better job of selling the value of their tests to payers and are learning to work within the health plan's rules," he observed. "Second, more genetic tests will be approved for payment over the next few years, and the prior authorization will be relaxed when some clear standards are set as to which patients benefit from these tests and which don't." TDR

—Joseph Burns

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Cigna Corp. Now Covers Whole Exome Sequencing

FOUR YEARS AGO, JUST A HANDFUL OF LABS offered whole exome sequencing (WES). At the time, THE DARK REPORT wrote that, for diagnostics, WES was not yet routine, but genetic testing labs, such as **Ambry Genetics**, were getting close. Also quoted was one researcher who characterized WES as promising but 'not quite ready for prime time." *(See TDR, April 2, 2012.)* Now, that assessment may be changing.

In November, **Cigna** announced that it would cover WES under certain criteria. It is the first national health insurer to make this decision. Most health plans consider WES and whole genome sequencing (WGS) to be investigational or experimental. When it announced its coverage decision on WES, Cigna decided not to cover WGS, saying such tests were experimental, investigational, and as yet unproven.

For its coverage policy on WES, Cigna worked with **InformedDNA**, a company in St. Petersburg, Florida, that uses genetic counselors to advise health plans, providers, hospitals, and patients on genetic testing. *(See TDR, August 19, 2013.)*

Cigna and InformedDNA determined that coverage for whole exome sequencing would be appropriate if: a) a geneticist or specialist physician decided the testing would affect the patient's outcome; b) that the patient's condition had a genetic component; and, c) that tests for a single gene or with a panel of genes would likely fail to identify a cause.

Further, Cigna decided that WES would be appropriate if it meant the patient and clinician could avoid repeat invasive workups, also known as a diagnostic odyssey.

Cigna stated that, for the general population, WES was not necessary and it would not cover WES for prenatal diagnosis or preimplantation testing of an embryo.

CEO SUMMARY: Before a redesign of phlebotomy workflow at Marshfield Clinic, patients might wait as long as an hour, particularly before noon when phlebotomists would see 75% of each day's patients. After the redesign, the number of draw sites was reduced from five to two while handling an increase in daily patient volume from 700 to 855. Patient wait times fell to a range of two to 10 minutes. Prior to the Lean project, the department corrected four to five clerical errors each week before transportation and testing. After the Lean project, clerical errors dropped to zero and the clinic has sustained that level over time.

Dramatic reduction in wait times, lower costs, more patient satisfaction

Marshfield Clinic Lab Tackles Phlebotomy Workflow Redesign

EVERY CLINICAL LABORATORY faces the identical challenge with its patient service centers and phlebotomy services: how to keep wait times at a patient-friendly level while dealing with the morning surge of patients that drops off during the day.

What can further aggravate patients is a disjointed workflow at the PSC and phlebotomists who struggle to meet the expectations of patients because the venipuncture does not go well or causes unnecessary discomfort and even pain.

At **Marshfield Clinic** in Marshfield, Wisconsin, a process improvement team in the clinical laboratory was challenged with tackling all of these problems. Armed with the tools of Lean, Six Sigma, and process improvement, the team set out to improve the patient experience at the outpatient PSCs, while also reducing wait times, cutting unnecessary costs, and balancing the phlebotomy workload throughout the day.

The need to tackle phlebotomy workflow was obvious. "Prior to this improvement project, phlebotomists were located throughout the clinic's sprawling main campus and the workflow was both highly inefficient and confusing to patients," stated Pam Carter, the clinic's Director of System Laboratories. Carter was speaking at the *Lab Quality Confab* in New Orleans in November.

"After eliminating waste by redesigning phlebotomy operations, our lab team at the Marshfield Clinic achieved remarkable results," stated Eileen Seidel, Manager of Phlebotomy Services. "Before the redesign, patients sometimes waited to see a phlebotomist for more than 40 minutes.

"After our Lean redesign project, we were able to reduce the number of draw sites from five to two and yet increased collections from 700 to 855 per day!" noted Seidel.

"Through the redesign and process improvement project we decreased the needed staffing resources to operate the PSCs. This was an important outcome because phlebotomy resources are limited and difficult to find at times.

"The patient experience improved as well because wait time was reduced," she commented. "Another benefit of this Lean project was a reduction in the volume of clerical errors that needed to be corrected prior to specimens being sent to the main laboratory for testing." *(See chart, page 13.)*

These are impressive results and contributed to a measurable increase in patient satisfaction with phlebotomy and the lab's specimen collection process. To achieve these results, the laboratory team engaged professional expertise outside of the Phlebotomy Department to reinforce the culture of Lean and process improvement, to accelerate implementation of improvements to phlebotomy workflow, and to improve PSC design and layout. Leslie Sprick, CEO of **Sprick Group LLC** in Mooresville, North Carolina, contributed to the success of this project.

"We took a comprehensive approach to solving the problems associated with phlebotomy and the operation of PSCs," stated Carter. "Supply management was fine-tuned and workflow was standardized. But, because we wanted to achieve a paradigm shift in the performance of our patient service centers, we dove deeper.

"We did that by questioning the existing design and layout of our PSCs," added Carter. "The laboratory team studied the existing floor plan and applied Lean design principles to the physical layout of each PSC. We engaged Marshfield's Performance Improvement Department to validate and test the redesign plan. We then sought ideas from outside of the lab industry and innovated by applying current tools differently."

The project was substantial because Marshfield Clinic is a big healthcare system. "We are the largest private multispecialty medical practice in Wisconsin and will have our 100-year anniversary next year," observed Carter. "We are a physician-led, private, nonprofit organization.

"Marshfield Clinic has 7,000 employees and 780 physicians," she noted. "It primarly operates outpatient-focused clinics. We don't do a lot of hospital work. In our laboratory, we do some hospital inpatient testing for our large multispecialty hospital on the main campus, but currently there are not many hospitals in our system.

Serving a Large Rural Area

"Marshfield's service area includes the entire northern half of Wisconsin and there are some patients from the Upper Peninsula of Michigan who travel to our clinic for specialty services," explained Carter. "As an outpatient-focused organization, we have 60 locations, including dental clinics and four ambulatory surgery centers. We also do veterinary pathology.

"In addition to providing routine lab services for the clinic at our main campus, we also provide regional and reference lab services as well," she said. "The reference lab allows us to do about 98% of all the tests that our providers order. Last year, the lab did approximately 3.8 million tests with about 425 full-time equivalent employees spread across those 60 locations. We have 18 physician FTEs and 10 veterinary pathologists.

"We aim to offer affordable and personalized care, and same day lab-test results for our patients, whenever possible," she said. "Because we serve such a large geographic area, our couriers travel about 10,000 miles a day, which shows the rural nature of our business. All of these factors make it a challenge to manage our costs.

"Particularly over the past 18 months, the focus on cutting costs is what led the clinic to suggest consolidating our multiple phlebotomy stations," recalled Carter. "Our lab was asked about what we could do.

"That led us to a series of questions," she continued. "Can we improve throughput? Can we streamline the draw process? Should we revise the layout? But all of these issues paled in comparison to the biggest concern I had about doing any work on phlebotomy," she warned.

"As soon as you walk in the front door of the clinic, our phlebotomy station is right there on the ground floor," Carter stated. "That means everyone—physicians, administrators, staff, and patients—will see a problem if there's any backup whatsoever. Being highly visible made the project much more of a challenge because it meant we had to succeed in improving efficiency enough to boost throughput."

In her role as the clinic's Manager of Phlebotomy Services, Siedel knew the details of the project. "As mentioned earlier, we started with five drawing stations and they were all in one place: right next to the lab," she said.

"That's what you do: When you need blood collection in one area of your facility, you put in a drawing station," she stated. "Over 20 years, one drawing station grew to be five drawing stations and we needed staff for those five stations and the number of staff varies by station.

"In the clinic, we have limited resources for specialized blood collections, which means patients have been directed to numerous locations, which can be confusing," observed Seidel. "For example, previously, a patient might see a provider on the fourth floor and be sent to the second floor for a phlebotomy draw. But the next month, they might be sent to the third floor. So, putting all phlebotomy in one place was a priority.

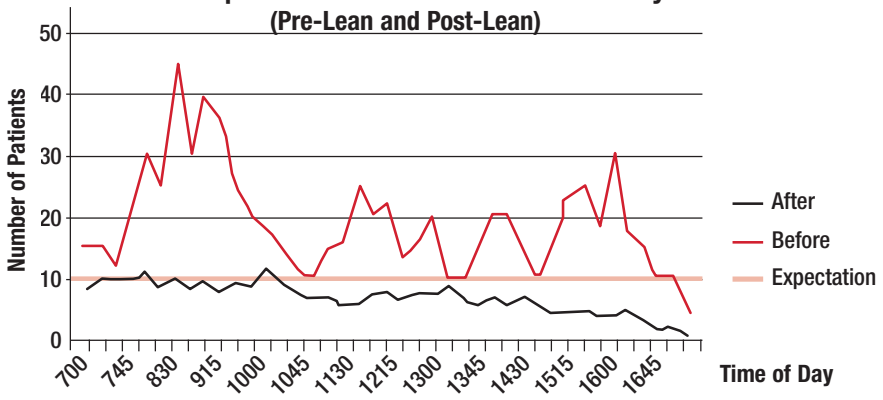
Complicated Scheduling

"But scheduling complicates this issue because some patients require a different phlebotomy skill level," emphasized Seidel. "If I staff one drawing station with two phlebotomists—but neither one can draw a pediatric patient—what happens when a pediatric patient arrives?

"We must also accommodate handicapped patients or anyone needing a wheelchair," she said. "Yet in our older facility, the doors are too narrow to accommodate most wheelchairs today because they are wider than they once were. Plus, special draws can

Serving More and Happier Patients in Fewer PSCs and in Less Time with Greater Satisfaction

A. Outpatient Wait Times for Phlebotomy (Pre-Lean and Post-Lean)



THESE TWO TABLES DEMONSTRATE the impressive improvements that resulted from a Lean process improvement project by the laboratory team to redesign phlebotomy workflow at the Marshfield Clinic.

Table A shows how patient wait times were improved to meet patient expectations at any time of the day.

Table B provides the key metrics that the lab's Lean team tracked to show the effectiveness of its improvement project.

B. Phlebotomy Redesign Outcomes

Measure	Before	After	% Improve
# of draw sites	5	2	60% decrease
# of collections	700/day	855/day	22% increase
# of Phlebotomists	13 full time 11 part time total: 24	9 full time 12 part time total: 21	40% increase in productivity
Wait time (mins)	20-60	2-10	80% decrease
Total square footage (sq ft)	3150	2200	30% less space
Errors per Week	4-5	0	Sustained over 7 years

show up at any time. So, our patient service centers had to be ready for anything.

"For these reasons, we engaged the lab staff to help with assessing the floor plan and physical layout of the PSCs. This step is one most labs don't think about," stated Seidel. "We also engaged with the Process Improvement Department because we didn't want to introduce anything in the new setting that wouldn't work. The PI Department helped us analyze and standardize our workflow to make it as efficient as possible.

"Then, we looked outside of our industry to the restaurant business to see how to improve the waiting process," she continued. "Most times laboratorians look within for solutions. But many industries face similar challenges and have great process improvement ideas.

"When we looked at how our patients come into phlebotomy, we did so by tracking each patient and recording the time of day," she recalled. "The process improvement team used software that looked at all of our patient workload data

and identified our throughput capabilities. "It matched that data with the time each patient checked in and the length of time each patient spent in phlebotomy. That told us how fast patients moved through the PSC and what staffing level we needed to maintain the level of service we wanted.

"The metrics told us that we do more than 75% of our workload by noon each day," said Seidel. "When we draw about 800 patients a day, that means 600 of them arrive in the first five hours. Those are key statistics because we needed to have enough space for each patient and we needed enough phlebotomists to do the work.

"One interesting fact about the design of waiting rooms in healthcare is that, many times you count only patients. But, in reality, you need enough chairs for almost every patient's mom, dad, child, or friend. The data we gathered showed that our PSCs needed room and chairs for one more person for every patient.

Balancing Supply, Demand

"Now, we had to establish goals to balance supply and demand every hour while also minimizing waiting room times to 15 minutes or less," said Seidel. "Another goal was to limit the waiting room size to 30 people during peak hours.

"That was a challenging goal we set for ourselves: How do we draw 800 patients before noon and make sure that no more than 30 people are in the waiting room at one time and no patient waits more than 15 minutes?" she asked.

"To do that required optimizing staff utilization and load leveling," Seidel said. "Most phlebotomy departments use the first-come-first-serve method. But if there's no set lab appointment time, phlebotomists don't know who's coming or when.

"Thus, as a process improvement, we set up lab appointments, which required educating our patients so they would come at their assigned time," she explained. "Lab appointment times offer several benefits: You can staff appropriately and the patient gets the best patient experience without having to wait.

Paging Patient Next

"Plus, our service would be consistent, which is what patients want," she added. "They feel less apprehensive. And, you control the environment and how much supply you'll need each day, all of which standardizes workflow.

"Two other changes helped to improve the waiting process itself," noted Seidel. "One was to establish a separate waiting room for children. Often, adults get agitated when children are crawling around, crying, or being disruptive. Thus, having that space for children allowed the main waiting room to be as calm and soothing as possible.

"The other change came from the restaurant industry," stated Seidel. "We now give each patient a pager so that when the phlebotomist is ready, he or she pages that patient. That also eliminates the need to call out the patient's name or use numbers. Part of our streamlined workflow includes cleaning each pager after every patient's use.

"Now the last change I'll mention is one that is important to any Lean project and that is visual management," offered Seidel. "As each patient checks in, a screen located in the phlebotomists' work area populates the name and the lab appointment time.

"Then we color coordinate to make sure the phlebotomists can maintain an appropriate workflow and identify the next patient," she added. "This board will change the color for a specific patient every five minutes from green to yellow to red. Once a patient has waited 20 minutes, it goes to red. That means we need to take some action This visual is updated every three minutes or when a patient checks into the lab drawing station.

"So, what did all of these changes accomplish?" concluded Seidel. "As mentioned earlier, we now have 60% fewer drawing stations. That freed up valuable

Sustaining Lean Improvements in the Lab Requires a Cultural Change in Staff Thinking

ONE CHALLENGING aspect of introducing Lean methods and Lean thinking in a clinical laboratory is sustaining the improvements over time.

"In order to sustain Lean in your lab organization, you have to grow a Lean culture, which requires a Lean management system," observed Leslie Sprick, Owner and CEO of **Sprick Group LLC** in Morresville, N.C. Sprick consulted with the Marshfield Clinic on a Lean project last year. "To do that your lab must start with organizational alignment around a true culture of continuous improvement. If the lab doesn't have a robust Lean management system, what it accomplishes fades over time, before disappearing.

"There are four key elements in a Lean management system," she said. "They are:

1. Leader standard work;
2. Visual controls;
3. Daily accountability; and,
4. Leadership discipline.

"As the management expert W. Edwards Deming said, 'You have to manage the system; the system doesn't manage itself.' Truer words were never spoken," emphasized Sprick.

"All these elements need to work together," she added. "For example, with leader standard work, lab managers need to have regular gemba walks and do these daily whenever possible because it creates daily accountability. It is also essential to conduct frequent meetings to discuss problems, identify solutions, and to recognize successes. These can be standup meetings, or informal huddles. It does not matter what they are called.

"Particular attention must be paid to handoffs, reviews, and to the continuous improvement projects," advised Sprick. "These are all components of leader standard work—which means all managers need to do them throughout the lab organization. Otherwise, a Lean culture will not take root.

"Next is the process for daily accountability," she continued. "Huddles come to mind or any meeting in which lab managers review the cycle of plan-do-check-act (PDCA). This cycle must be repeated over and over again. Also needed is the discipline to review it daily or weekly.

"Visual controls are essential to Lean and the culture of continuous improvement," stated Sprick. "Labs can have huddle boards in every department, along with huddle process standards among departments. It is essential that all huddle boards have a consistent format and look. The process of conducting huddle meetings must be the same in all lab departments.

"A key component of visual controls are metrics," she concluded. "When a lab team hits its goals, show it in green. If not, show it in red. Then post it where everyone can see it. That provides immediate feedback and staff at the bench level can see it each day. One good technique is to conduct kaizen events, which is an effective way to engage staff and produce fast improvements throughout the lab."

space in those facilities. We also have fewer phlebotomists and yet we're doing more draws. For patients, the wait time was reduced by 80% and we've sustained that performance. Labeling errors have been reduced to zero and sustained over seven years since these process improvements were implemented."

In conclusion, Sprick said, "The beauty of this work is that if a lab sustains a Lean culture over time, it increases the employees' knowledge, skills, experience, and expertise. Self-esteem and engagement in the lab organization goes up, along with rising productivity and a renewed commitment. Isn't that what we all want in our work?" she asked. **TDR**

—Joseph Burns

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Accumen Acquires Chi To Beef Up Lab Consulting

Lab management partnerships with hospitals and health systems is Accumen's business goal

CEO SUMMARY: Two different business models of clinical laboratory consulting have now been brought together. Chi consultants have long focused on analytics and improving outreach performance, among other areas of lab performance. By contrast, Accumen's business model is nontraditional and centers upon a shared-savings partnership with a hospital or health system. Executives at Accumen are betting that a combination of both types of lab performance solutions will be of interest to hospitals.

LAST WEEK, IT WAS ANNOUNCED THAT **Chi Solutions, Inc.**, of Ann Arbor, Michigan, had been acquired by **Accumen, Inc.**, of San Diego, California. The combination creates a company that has a unique mix of clinical laboratory services.

While Chi Solutions has built a reputation over 33 years as one of the best-recognized lab consulting companies, Accumen is less well known, having been in the clinical laboratory performance improvement business for the last five years. Because both companies are private, terms of this acquisition were not announced.

Accumen is the current name of the company that was launched in 2010 by **Accretive LLC**, and, under the name **aLabs**, entered into laboratory partnerships with two major health systems the following year. These partnerships are with **ACL** (the combined lab business of **Aurora Health Care**, in Milwaukee, Wisconsin, and **Advocate Health Care** in Chicago) and **Sharp HealthCare** in San Diego.

Accumen President and CEO Jeff Osborne viewed the purchase of Chi Solutions as a perfect complement to Accumen. In an interview with THE DARK REPORT, Osborne explained that the consulting work Chi Solutions does for hospitals and health systems across the country could be the first step in a multi-step process that begins with lab consulting and proceeds to a risk-share/gain-share partnership with hospitals and health systems designed to transform their labs' performance.

Evolving Process

"We view the work that Chi Solutions does as the beginning of a partnership that is likely to evolve over a number of years," explained Osborne. "Some hospitals that Accumen believes may be potential partners for a lab transformation opportunity are not always ready for the full commitment required to enter into a risk-gain share model."

Obsorne stated that an Accumen partnership designed to transform and improve all dimensions of the hospital lab or health system client is a shared-risk-

and-reward arrangement. This typically involves the 'cohabitation' of Accumen performance team members within the hospital lab environment, he said.

As it approaches hospitals and health systems to initiate discussions about a lab partnership that involves the shared-risk-and-reward arrangement, Accumen now has an additional service to offer. "Having Chi Solutions available to consult with any potential Accumen client provides an excellent entry point to accommodate those hospitals with targeted needs or opportunities that will eventually lead to a longer term transformation partnership," observed Osborne.

Kathleen A. Murphy, PhD, CEO of Chi Solutions, agreed. "Accumen's acquisition of Chi represents the classic story of 'the whole is greater than the sum of its parts,'" she said. "Over my 22 years with Chi, the company has transformed through several iterations. At no time in our history has a partnership been as complementary or as potentially transformative, as the combination of Accumen and Chi."

Lab Transformation

For Osborne, the acquisition is an opportunity to offer a wider array of services to its hospital clients. "We realized that, as we approached some potential clients to discuss what we call lab transformation, they were not always ready for the full execution commitment of our transformation strategy," he explained.

"This is why it makes sense to create a lab consultancy within Accumen," continued Osborne. "This is particularly true because many of us come from a consulting background. We are familiar with how consultants work. The Chairman of our Board of Directors, Bill Green, was the CEO of **Accenture**, one of the nation's largest consulting firms. What we love about the consultancy model is how it can help clients at their point of need and build the trust required to create opportunities for future business.

Chi Solutions' Long History Of Lab Consulting Services

IT IS A LAB CONSULTING COMPANY with roots that stretch back almost four full decades. The company currently known as Chi Solutions (and now a business division of Accumen, Inc.), was originally founded by two individuals.

It was in the late 1980s when James Root, MBA, and Jan W. Steiner, MD, FCAP, FRCP(C), brought their individual lab consulting activities together to form **Chi Laboratory Services**. At this time, it was a division of **Chi Systems, Inc.**, of Ann Arbor, Michigan.

Chi Systems, itself founded in 1969, had a significant healthcare consulting business and Steiner had joined that company in 1985 as a partner. Previously, he had been the medical director of the U.S lab operations of **MDS Healthcare**, based in Toronto, Canada.

Root had worked at several lab companies in Portland, Oregon, then, as a result of a lab acquisition, had worked in several executive positions at **MetPath, Inc.**

Within a few years, Steiner and Root had established Chi Laboratory Services, Inc., as a separate company from Chi Systems. During the 1990s, Chi Laboratory Services grew steadily and established strong relationships throughout the clinical laboratory industry.

In 1999, **Park City Solutions** acquired Chi Laboratory Services. It would own Chi for just six years. **Carilion Clinic** purchased the Laboratory Solutions Group of Park City Solutions in 2005. The consultancy was renamed Chi Solutions. At this time, Earl Buck and Kathy Murphy, PhD, were the principal consultants.

Carilion would itself sell Chi Solutions in 2010. This time, it was Murphy and Buck who acquired the company. It continued to operate as Chi Solutions and Buck retired in 2012, leaving Murphy as the principal.

"Thus, when pursuing clinical lab consulting opportunities, who better to partner with than a consulting firm like Chi Solutions?" he asked. "We see them as equally passionate about the opportunities in the lab industry and Chi brings talented expertise that complements the Accumen team and their mission to profoundly impact healthcare.

Strategic Partners

"We start by finding out what potential clients want to do with their labs. What do they need to achieve excellence in their labs? Should they sell their lab or retain it, optimize it, and grow it?" he asked. "As the potential client answers these questions, it gives us the opportunity to customize our offering to meet these hospitals at their point of need and help them clarify their aspirations for their lab.

"This approach allows us to address a large variety of lab needs and offer hospital administrators solutions to fit the needs of many different labs, whether they are small, mid-sized, or located anywhere across the country," stated Osborne.

"In addition, Chi Solutions has a number of capabilities that allow us to compare the results of our client labs with other labs around the nation," he noted. "For example, along with its consulting and outreach businesses, Chi Solutions has its Chi IQ, a web-based benchmarking solution. This service allows one lab to compare its results with those of peer labs based on key indices, including volume and test complexity.

Benchmarking Performance

"The Chi IQ Benchmark Database is comprised of the data from nearly 1,000 labs," added Osborne. "In many ways, that is a standard for comparison because it provides the supporting data that allows labs to understand how close or how far from excellence they might be. Without comprehensive tools, it's difficult for labs to benchmark themselves against the best labs because performance information on the lab industry is kept close to the vest.

"We've been looking at our capability to bring an end-to-end solution that is 'all things lab'," he said. "We envision that what we will offer is a one-stop shop for clinical labs.

Strategic Partners

"Before we acquired Chi Solutions, there were several areas in which we were interested in adding to our portfolio," continued Osborne. "Those areas included consulting, data analytics and personalized medicine. The addition of Chi helps fill some of these capabilities and we will continue to look for opportunities to work with other strategic partners to continue to add additional value to the clinical laboratory industry."

In addition to watching for such announcements, lab directors and pathologists will want to keep an eye on any word from Accumen about whether its earliest partnerships will be renewed. Announced in 2011, the initial laboratory partnerships with ACL and Sharp Healthcare have a five-year term that comes due this year. TDR

—Joseph Burns

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In 5 Years, Accumen Has Gained Partners

SINCE 2011, ACCUMEN has partnered with the following clinical labs to transform their operations and improve results, sometimes including patient blood management, while sharing in any savings that result:

- Sharp HealthCare, San Diego
- ACL Laboratories, Chicago
- Advocate Health Care, Chicago
- Aurora Health Care, Milwaukee
- St. Joseph's/Candler, Savannah, Ga.
- HonorHealth, Scottsdale, Ariz.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Tonya Mallory is back in the news and this time she is teaming up with the former CEO of **Bon Secours Virginia** to launch a new healthcare company. Mallory was formerly CEO of **Health Diagnostic Laboratory** of Richmond, Virginia. This is the lab company that settled a major whistleblower case with the federal government, without admitting guilt. In court filings, federal prosecutors claim that HDL was paid $500 million by the Medicare and Tricare health programs between 2010 and 2014 for false claims. Now Mallory is a partner with Peter Bernard, formerly of Bon Secours Virgina. The two ex-CEOs have founded **Creo Wellness, Inc.**, a company that news reports describe as offering blood testing and health coaching services designed to reduce the long-term healthcare costs of employers.

MORE ON: *Mallory*

Mallory, along with other individuals associated with Health Diagnostics Laboratory and **BlueWave Health Consultants**, was sued by federal prosecutors in a case filed in August 2015. In court papers, federal prosecutors say the defendants "knowingly and willfully offered and/or paid kickbacks, primarily in the form of $80 million dollars in improper process and handling fees to induce physicians to refer blood samples," to specialty laboratories for large panels of tests. Federal prosecutors are seeking to recover $80 million from the defendants.

TRANSITIONS

• Paul R. Labbe retired last week from **CompuNet Clinical Laboratories** of Moraine, Ohio. He was Interim Chief Operating Officer. It was 1980 when Labbe started at **Miami Valley Hospital**, an owner of CompuNet. He joined CompuNet in 1986, at its formation, and completed 30 years of service there last week.

• James A. Santucci was named the new Chief Operating Officer of **Desert Regional Medical Center** in Palm Springs, California. He has held administrative and executive positions at **Swedish Medical Center**, **Allina Medical Laboratories**, **Laboratory Corporation of America**, **Dynacare Laboratories**, **Scripps Health**, and **Quest Diagnostics Incorporated**.

• In January, Ken Botta retired as President of the Western Division for **Sonic Healthcare USA**. During his career, he held positions with **Cleveland HeartLab**, **SED Laboratories**, **AmeriPath**, **Laboratory Corporation of America**, **Unilab**, and **National Health Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 2, 2016.

UPCOMING...

- *Theranos Testing Is Subject of a Clinical Study; Lab Firm Names Noted Lab Experts as Advisors.*
- *First Report of Lab Innovations and Successes Discussed at this Year's Executive War College.*
- *Legal Expert Weighs in on 'Waiver of Charges' Tactic Used by Some Labs to Offer Free Testing.*