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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

California Hospitals Become Health Insurers

WHAT CHANGES WHEN THE NATION'S HOSPITALS become health insurers? How do pathology practices and clinical laboratories contract to provide lab testing services when their parent hospital is also the insurer?

We are about to learn the answers to these questions by watching California. News outlets are reporting that **Sutter Health**, one of California's largest integrated healthcare systems, has filed papers with the **California Department of Managed Health Care** to notify the agency of its intention to market its own health insurance plan in Sonoma County, beginning in 2015.

This news comes on the heels of an announcement in September by **Anthem Blue Cross**, a division of **WellPoint**, about its new health insurance partnership with five California hospitals. The health plan is called **Vivity**.

Anthem's partners include such respected hospitals as **Cedars-Sinai**, **UCLA**, **Good Samaritan Hospital**, **Huntington Memorial Hospital**, **MemorialCare Health System**, **PIH Health**, and **Torrance Memorial Medical Center**. This unique partnership is designed to solve the problems of narrow networks (that often exclude higher-priced hospitals and academic centers) and high patient deductibles for inpatient care. For example, Vivity members will pay co-pays but not deductibles.

The venture will share profits among the partners and one goal is to keep premiums competitive with **Kaiser Permanente**. The credibility of this new health insurance consortium was affirmed with the news that the **California Public Employees' Retirement System** (CALPERS) will offer this health plan to its beneficiaries, effective on January 1, 2015.

All of these developments mean that pathology groups and clinical labs associated with Sutter Health and with the hospitals in Vivity will need to contract differently with their parent organizations. I am betting that it won't take long for the health plans owned by these hospitals to move their lab providers away from fee-for-service payment and onto other forms of reimbursement.

Moreover, the Sutter and Vivity health plan announcements are just the leading edge of this trend. You can expect to see a hospital/health system-owned health insurance plan coming soon to your own city or town. As that happens, your pathology group or clinical lab should be ready to negotiate reimbursement in arrangements other than fee-for-service. TDR

Labs Share Successes in Delivering More Value

Innovators gathered in New Orleans in October to present innovative outcomes that improve care

CEO SUMMARY: As the number of accountable care organizations and patient-centered medical homes grows monthly, a handful of innovative labs are seizing the opportunity to develop and deliver lab testing services that add more value to physicians and patients. These early-adopter labs recognize that fee-for-service reimbursement is on the way out. They want to get a head start on transforming their lab from a transaction-based culture to one that contributes value.

IN THE NEXT HEALTHCARE MARKET CYCLE, ample reimbursement will flow to those providers who deliver measurable value and contribute to improved patient outcomes.

This includes clinical laboratories and anatomic pathology groups. In recognition of this fact, a handful of innovative labs are already pushing forward with value-based initiatives designed to help physicians deliver better quality care.

One common strategy used by many of these labs today is to improve how physicians utilize lab tests. This most frequently involves working with physicians to reduce the ordering of lab tests that are inappropriate or medically unnecessary.

Another strategy is for the labs' pathologists and Ph.D.s to get outside the laboratory and consult with clinicians on how to interpret lab test data, then work as part of the care team to deliver more appropriate therapies to the patients. A high-payoff partner in this effort is often the pharmacy, since therapeutic drugs can cost tens of thousands of dollars for a single patient.

Both of these added-value strategies were part of the lab case studies presented at the eighth annual *Lab Quality Confab*, which took place in New Orleans, Louisiana, on October 21-22, 2014. A high-energy crowd of almost 300 attendees was on hand to hear the presentations, network, and share their lab's successes in intelligent cost-cutting and delivering value in ways that improve revenue margins for their clinical labs and pathology groups.

One example of how the lab can contribute more value occurred at **North Shore Long Island Jewish Health System**

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(NSLIJ) in Lake Success, New York. This is the nation's largest urban health system and the lab team took on the immense challenge of supporting a complete patient lab test record in the electronic health record system.

To achieve this, the lab team headed up a cross-discipline task force that set out to implement full-function validated interfaces. Their goal was to enable the accurate collection, in real-time, of core lab results, lab test data produced by point-of-care testing devices, and physician office lab instruments.

A complimentary goal was to establish and validate the interfaces needed to display this lab test data on the many types of mobile devices used by physicians and nurses affiliated with NSLIJ.

Reporting on this effort at *Lab Quality Confab* were Hannah Poczter, MPH, ASCP(DLM), Assistant Vice President Laboratory Services; Ed Giugliano, Ph.D., Six Sigma Black Belt, Project Manager; and, Carol J. Sien, MT, MS, ASCP, ASQ, Quality Management Manager, all from NSLIJ.

The team attacked this project in three waves. The first wave involved establishing and validating the interfaces between the labs of NSLIJ's 12 hospitals, along with associated institutions. Using Lean methods, the team was able to reduce the time required to validate the interface between each lab's IT hub from three months down to one month and the failure rate of test scripts during the validation process dropped from 35% to just 3%.

Validated EHR Interfaces

In the second wave, the team worked to validate the interfaces needed to deliver lab test data to the EHRs of hundreds of outreach clients and thousands of physicians served by NSLIJ. This required the engagement of the clients, their different EHR vendors, and the health system's LIS outreach team. Again, Lean methods and the experience from wave one enabled the team to establish validated interfaces in a timely basis.

Wave three is where things got interesting. The need was to develop an app that passed lab test data accurately to the mobile devices and in a secure fashion. The resulting app serves both iPhones and Androids. It allows users to open an account and validates the password. A user is logged-out at three minutes.

Delivering Value At H. Ford

A contrasting case study of value was presented by **Henry Ford Health System** in Detroit, Michigan. The presenters were Richard J. Zarbo, M.D., DMD, Senior Vice President and Chair, Pathology and Laboratory Medicine; and, Guarav Sharma, M.D., Director, Regional Medical Laboratory, Associate Medical Director, Core Laboratory, Quality Systems and Regulatory Affairs.

In recent years, Zarbo and Sharma have infused a Lean culture in the lab division and achieved ISO 15189 accreditation across 36 lab sites within the health system. These were steps that positioned the clinical laboratory and anatomic pathology lab to work more closely together to deliver an integrated lab medicine service.

Installation of a MALDI-TOF mass spec instrument—with associated changes in clinical work flow—allowed the lab to cut turnaround time for blood cultures by 33% while improving diagnostic accuracy. The resulting reduction in patient length-of-stay generated annual savings of $1.1 million.

Collaborating on cancer care is a source of substantial savings to Henry Ford Health. In working with clinicians to improve cancer test utilization management, Zarbo and Sharma gave the example of KRAS testing, a companion diagnostics for Cetuximab ($125,000 per patient). In 2013, the health system saved an estimated $4.8 million because of better utilization of the KRAS test while delivering better outcomes to cancer patients.

These examples demonstrate the progress lab innovators are making in their efforts to add value to clinicians. TDR

Lab Market Update

LipoScience Could Find No Other Interested Buyer than LabCorp

Specialty lab company was struggling to convince physicians and health insurers of its test's value

ONE EXAMPLE OF HOW TOUGH TIMES ARE for companies offering proprietary or patent-protected tests is the acquisition of **LipoScience** by **Laboratory Corporation of America** in a deal that was disclosed last September.

It was announced that LabCorp would pay $85 million, or $5.25 per share, for LipoScience, which analysts said valued the company at just $63 million. As recently as the winter of 2013, LipoScience had a value of as much as $170 million, based on its share price of $11 at that time.

The decline in LipoScience's stock price mirrored a decline in its annual revenue and specimen volume. In an analysis of the Raleigh, North Carolina-based lab company's problems, *The Triangle Business Journal* wrote that "In a broader context, the company's decline can be traced to two events, both boiling down to LipoScience's inability to convince enough physicians and insurers to favor the LipoScience test over others."

Founded In 1994 As LipoMed

Founded in 1994 as **LipoMed** by James D. Otvos, Ph.D., an adjunct professor of biochemistry at **North Carolina State University**, the company changed its name to LipoScience in 2002. Otvos currently serves as LipoScience's Executive Vice President and Chief Scientific Officer.

The flagship test was the LipoScience NMR LipoProfile, an FDA-cleared blood test that directly quantifies low density lipoprotein particles (LDL-P) circulating in the body. A study published in early 2014 in a peer-reviewed journal involving 15,000 patients over three years concluded that high LDL-P levels, which the LipoScience NMR LipoProfile measures, were associated with higher risk for heart attack or stroke.

Convincing Physicians

Despite the findings of this study, published in the journal *Atherosclerosis*, that LDL-P by NMR was a more clinically reliable measure of LDL and could be used to manage patients with increased CVD risk, the lab company could never leverage these findings in a useful way.

For example, such groups as the **American College of Cardiology** and the **American Heart Association** did not incorporate the LDL-P by NMR test into their recommended treatment protocols. That made it difficult to convince physicians to order the test. Similarly, the laboratory company struggled to negotiate favorable coverage determinations with many health insurers.

Health Diagnostic Laboratory (HDL) of Richmond, Virginia, also has a role in the LipoScience story. According to *The Triangle Business Journal*, HDL was the single biggest customer for LipoScience, representing about one-third of LipoScience's annual sales and about $12 million per year in revenue.

However, in March 2014, after HDL introduced its own proprietary test for LDL-P, LipoScience canceled its contract with Health Diagnostic Laboratory. As a result, LipoScience laid off 22 employees in its Raleigh laboratory facility.

LipoMed's Largest Customer

That left LabCorp, with its headquarters in Burlington, just down the road from Raleigh, as LipoScience's largest customer for its proprietary test.

Facing poor prospects for increasing specimen volume from its marketing efforts to physicians and given the resistance of health insurers to pay for the LDL-P test, LipoScience's board made the decision to sell the company.

The *Raleigh News-Observer* reported that, when LabCorp made its offer to LipoScience, the agreement included a provision that would let the Raleigh lab company solicit other acquisition offers until October 19. As part of the agreement, LipoScience agreed to pay $2.56 million to LabCorp if the deal didn't close or $1.7 million if LipoScience got a better offer before October 19.

While shopping for a buyer, LipoScience solicited bids from 14 companies and not one made an offer, according to *The Triangle Business Journal.* Of these 14 potential buyers, 11 of the 14 companies declined to make an offer and three didn't respond at all.

Directors Got No Offers

This was not the first time the company had solicited offers from potential buyers, the business journal reported. During the summer, members of the company's board of directors identified 40 companies that could be asked to make acquisition offers. Later, that number was reduced to eight companies that were most likely to make an offer, the business journal said. But again, the company got no offers. Five of the eight declined to make an offer and three did not respond, the business journal reported.

What these developments show is many prospective buyers were given the opportunity to look at LipoScience. After studying its finances and its prospects for expanding its specimen volume and market share, these parties declined to make an offer to buy the lab company.

That left LabCorp as the one interested buyer. It can be assumed that LabCorp was able to acquire LipoScience at a bargain basement price. With no other bidders for the troubled lab company, the LipoScience board had few other options but to sell to LabCorp.

The sale is pending and has cleared one regulatory hurdle. It was announced on October 15 that the **Federal Trade Commission** granted early termination of the waiting period required before LabCorp can complete its purchase of LipoScience. Both parties expect the sale to close by year's end.

LipoScience's Track Record

What should interest pathologists and lab executives about the financial woes of LipoScience is the fact that this company had operated for 20 years, had an FDA-cleared lab test, and had a credible clinical study that concluded the test had value in assessing an individual's risk for heart attack and stroke. Yet, despite these facts, the headwinds in today's healthcare marketplace were too great to overcome.

Could it be that the toughest marketing challenge facing LipoScience was increased resistance by health insurers to pay for proprietary diagnostic tests? Given the news about the abuses in the cardiovascular testing market published this fall by *The Wall Street Journal* naming Health Diagnostic Laboratories and several others, it is reasonable to conclude that more health insurers are wary of covering any proprietary cardiology tests. TDR

—By Joseph Burns

Medicare Special Stain LCD May Hinder Path Workflow

Medicare contractor's crackdown on abuse raises concerns about wider consequences

CEO SUMMARY: Under a proposed rule for Medicare region J-11, a pathologist will no longer be able to use "reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine H&E." While the proposed LCD is designed to target a relatively small number of pathologists who regularly overutilize special stains, if implemented as written, the LCD is expected to change the workflow for every pathologist ordering special stains. It also creates a new motive for RAC auditors to visit pathology labs.

PATHOLOGISTS USING SPECIAL STAINS in their daily practice have reason to be concerned about a local coverage determination (LCD) recently proposed by one Medicare administrative contractor (MAC).

Last month, **Palmetto GBA**, the MAC for the J-11 region of North Carolina, South Carolina, Virginia, and West Virginia, proposed the LCD titled, "MolDx: Special Histochemical Stains and Immunohistochemical Stains (DL35693)," to address what Palmetto called "aberrant local utilization."

This proposal affects providers in Medicare region J-11. Pathologists and lab directors can comment on the proposal until December 25. After that, it may be revised or become effective as currently written. The effective date could be as early as this January.

The primary impact of the proposed LCD is to end a procedure common to many pathology laboratories. In the proposed LCD, Palmetto writes that use of "reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist are not reasonable and necessary."

To comply, the proposed LCD states that "a pathologist must first review the H&E stain prior to ordering special stains or IHC. The medical necessity for the special stain or IHC studies, the results of the stain or IHC, and review of the control must be documented in the surgical pathology report."

Should this LCD take effect as written, it will create a new workflow task for every pathologist. As noted on a *Pathology Blawg* post of October 30, 2014, "the LCD will have an impact on all pathologists in that they will be required to fully explain the medical necessity for each ancillary stain they order in their report if they want to be reimbursed for it."

Pathology Blawg was careful to observe that only a small number of overutilizing pathologists will be negatively affected by the proposed reimbursement restrictions, writing that "the reimbursement restrictions Palmetto is proposing will not impact the vast majority of pathologists who

already order ancillary stains appropriately. Rather, they will for the most part only impact those pathologists who are ordering ancillary stains inappropriately."

Unnecessary Utilization

Palmetto's proposed LCD is intended to address overutilization of immunohistochemical (IHC) and special stains by pathologists for breast, gastrointestinal, prostate, lung, gynecologic, genitourinary, skin, soft tissue, central and peripheral nervous systems, bone marrow, and tumor chemosensitivity specimens.

The publication of the proposed LCD is a case of "be careful, you may get what you wish for!" That's because, earlier this year, the **College of American Pathologists** (CAP), sent a complaint to CMS in response to an educational letter the MAC had posted on its website about ancillary stain overutilization by pathologists on gastric biopsies.

In that letter, dated June 25, 2014, among other things, CAP wrote that, "to the extent that Palmetto believes that any additional all-encompassing guidance is needed in the gastric biopsy area, it should establish such a coverage policy through the existing LCD process to ensure stakeholders the ability both to provide input during policy development and to appeal those policies with which they disagree."

Educational Letter Removed

Palmetto did remove the offending educational letter from its website. That action was followed by the posting of the proposed LCD addressing appropriate utilization of special stains and IHC studies.

One lab industry executive watching these developments believes that, if approved as currently written, the proposal will make it more complicated for any pathologist to order a special stain. But that is only part of the story, observed Joe Plandowski, the founder of **In-Office Pathology** in Lake Forest, Illinois. "Should this LCD be implemented as written, pathologists in those states will face interesting workflow problems and have added risk from additional audits. For example, implementation of this LCD may also motivate Recovery Audit Contractors (RACs) and Zone Program Integrity Contractors (ZPICs) to visit local pathology groups to audit for improper utilization of special stains and IHC studies."

What adds complexity to this issue for the pathology profession is that, each time a pathologist orders a special stain, it is a self-referral. It is this aspect of special stains which motivates the relative handful of less-ethical pathologists to overutilize special stains and IHC studies.

Public Comment Period

Thus, as pathologists and interested parties submit comments to Palmetto about the proposed local coverage determination, any argument that pathologists should be allowed to exercise their professional discretion as to when a special stain is medically necessary (and how the language of the LCD impinges on the standard of care) is likely to ring hollow with administrators at Palmetto. After all, the LCD is a response to the alleged overutilization of special stains that originally caused Palmetto to take this action.

The good news is that pathologists, pathology practice administrators, pathology consultants, and industry vendors have until December 25 to submit comments about the proposed LCD. It provides one opportunity for pathology professionals to give Palmetto additional perspectives about the downstream consequences of the LCD that they overlooked or failed to consider.

However, for the reasons noted above, the LCD's language is not likely to undergo much change. That makes it likely that the LCD will be implemented pretty much as written and as early as January. TDR

—Joseph Burns

Contact Joe Plandowski at 847-840-3077 or jwpmail@gmail.com.

What Motivated Palmetto GBA to Issue this LCD Requiring Prior Approval for Special & IHC Stains?

ONE REASON PALMETTO GBA issued its proposed rule to require additional documentation for special stains and IHC stains is that some pathologists complained that certain of their colleagues were ordering stains inappropriately, said Joe Plandowski, founder of In-Office Pathology.

"For several years, pathologists have complained about overutilization of special stains and IHC stains by certain pathologists, including those pathologists working in physician's office labs and bad pathologists in general," he said. "In fact the College of American Pathologists has pushed for something to be done about this problem involving overutilization of IHC and special stains.

"However, taking action against offenders means that such agencies as the federal Centers for **Medicare & Medicaid Services** (CMS) or its authorized contractor, Palmetto GBA, will issue rules that affect all pathologists—not just the overutilizers," explained Plandowski. "Thus, by complaining about just one segment of pathologists, CAP and its allies seem to have convinced Palmetto to crack down on all pathologists. So now those rules will be onerous and it will be very difficult to get them revised."

CAP Complained to CMS

In May, CAP complained to CMS about an effort by Palmetto to reduce the number of inappropriate stains for gastric biopsies, Plandowski said. Palmetto had cited recent articles in the medical literature that reported that ancillary stains should be done on no more than 20% of all gastric biopsies and they should be done before the pathologist examines the H&E, Plandowski said.

"But that's not how it works when a pathologist needs stains for a gastric biopsy," explained Plandowski. "Often, what the pathologist is looking for in a gastric biopsy is *H. pylori*. Anytime *H. pylori* is present, established protocols direct the pathologist to automatically do an IHC stain and an 88313. In these gastric biopsies, they are not looking at the H&E stain first and then ordering the special stains based on the H&E stain findings.

"But what happened was, following CAP's complaints last May about one effort by Palmetto to raise a question about special stains, Palmetto has responded with a proposed LCD that is onerous for all pathologists," he said.

Problem Was Perpetuated

In a post on the *Digital Pathology Blog* this summer, pathologist Keith J. Kaplan, M.D., wrote about this issue, saying, "It puts the College of American Pathologists in a difficult spot, because many of its members and their accredited laboratories... regardless of where they practice—be it pathologist, hospital or urologist/gastroenterologist-owned laboratory—have perpetuated the problem. No doubt with some help from some self-referring clinicians but also likely from themselves and their administrators."

"Another issue of concern about Palmetto's proposed LCD is the potential for it to be adopted by other MACs," speculated Plandowski. "Should this happen, pathologists in other regions of the country will need to comply with this LCD when they order special stains and IHC studies. It is an example of one MAC cracking down on a small number of overutilizing pathologists, but in the process, that MAC's new policy changes the workflow for every pathologist who orders special stains as other MACs across the United States decide to adopt the same policy."

THE DARK REPORT observes that Palmetto's attention to the problem of overutilization of pathology services is not an isolated episode. Federal healthcare fraud investigators are actively pursuing overutilization such as in the **Biodiagnostic Laboratory Services** case.

➤➤ ***CEO SUMMARY**: In this second installment of our series on the laboratory value pyramid, we introduce "Level Two: Establish and Meet Standards of Value." This second level continues the lab's focus on its internal operations and activities. The goal is for the lab to develop the working culture and staff training required to identify relevant internal standards of value. It will then benchmark its progress against these standards of value as preparation to pursue Level Three and Level Four.*

Defining the 'Laboratory Value Pyramid' as a Way To Deliver More Value

Level Two of Value Pyramid Defines Internal Benchmarks

Part Two of a Series

IN THIS SECOND INSTALLMENT about the laboratory value pyramid, we provide the details about the second level of this four-level concept.

Wherever it has been shown to experienced lab administrators, pathologists, and lab professionals, there has been positive feedback about the laboratory value pyramid. This early feedback from knowledgeable audiences is useful evidence that the concept of a laboratory value pyramid is relevant—particularly at a time when healthcare is undergoing a major transformation that includes new ways to reimburse providers, including labs.

The laboratory value pyramid was introduced in part one of this series. *(See TDR, September 22, 2014.)* This four-level pyramid is designed specifically to give the strategic leaders of lab organizations a vision and an ideal that can be attained by their lab team.

At the same time, the design and function of the laboratory value pyramid will complement the future state of the providers that are served by the lab. This is essential because labs undergoing their own transformation need the full support of the parent hospital or organization.

Clinical laboratories and pathology groups must be closely-tuned to needs of its users. As hospitals and physicians adapt to the new realities of healthcare in the United States, successful labs will be those who have transformed themselves ahead of their referring physicians and can thus deliver lab testing services that add value and improve patient outcomes.

As we noted in part one of this series, lab administrators and pathologists who understand these once-in-lifetime changes in the paradigms of healthcare and laboratory medicine are faced with their own unique challenge: What is the next paradigm in laboratory medicine? What should change in how laboratories are organized and how they deliver clinical lab testing services?

It was to answer these questions and give lab professionals a useful roadmap that several collaborators, including THE DARK REPORT, a veteran lab industry executive and a team within a major *in vitro* diagnostics company, came together and developed the laboratory value pyramid.

As a reminder, in this series, THE DARK REPORT will present each level of the value pyramid as a separate intelligence briefing. This is intentional. The collaborators involved in creating the concept of a Laboratory Value Pyramid want each level to be fully understood before introducing the next level in this four-step progression.

➤'Best In Class' Laboratories

In its current configuration, the Laboratory Value Pyramid puts an internal emphasis on level one and level two. An external emphasis is put on level three and level four. By way of explanation, every clinical laboratory must first put its own house in order. Only then can it begin the journey to deliver greater value to physicians, patients, and payers while, as part of this effort, achieving "best in class" in its operations and service delivery.

As discussed in part one of this series, the first step in this journey is for the laboratory to establish normalcy and stability in its daily operations. The goal is to eliminate the daily chaos that has traditionally been accepted as a normal part of clinical laboratory operations.

The chaos is due to the variety of ways that individual work processes fail at inconvenient moments. One source of chaos is caused when specimens are lost in transport from phlebotomy sites to the lab, or when specimens "disappear" in accessioning or at the bench. In response, med techs and lab staff begin to search to find the specimens (which are often misplaced).

Batched testing can often cause chaos if the incoming flow of specimens unexpectedly exceeds the capacity of the lab analyzers or assigned staffing. What is important is to understand that a lab that reaches level one has eliminated this type of chaos because it has adopted a system of prevention mindset and culture. It can thus regularly attack the systemic source of errors in each work process and create predictability and normalcy.

It is this state of normalcy and predictability that is necessary for a laboratory

to prepare to attain level two. With systemic sources of errors and chaos eliminated because of level one activities, the lab can now focus on the competencies of its staff in all the necessary management skills required to sustain normalcy while learning how to deliver more value to all of its customers, as defined in the characteristics of a level two laboratory.

Becoming A Level Two Lab

As you will read on pages 14 and 15, the challenge of achieving the laboratory value pyramid's level two is to create a staff culture that is rooted in the system of prevention and where all the contributors understand: a) the management techniques and tools of continuous improvement; b) how to add value as defined by the customer; and c) how to use real-time metrics to guide decisions.

As one of the collaborators points out, the key to level two is to put people, process, and products together so as to achieve a best practice organization. The secret to a best practice organization is that it has more value than just the sum of the individual parts.

People: When considering people, three distinct groups must be recognized, and must be treated as customers. The first group is the lab's staff. The second group is made up of all employees working within the parent institution and outside the walls of the laboratory. The third group is comprised of all the lab's customers who are not employees of the institution.

How People Contribute Value

The level two lab will understand how each of these groups of people impact the organization of the laboratory and how it delivers its services. This understanding is used to optimize the lab's interactions with each group in ways that complement the lab's efforts to achieve its goals of delivering more value.

Process: Think of this in three dimensions. The first dimension is the front-end order and supply side of the lab operation. The second dimension is the lab operation itself, metaphorically, the lab factory that produces products.

The third dimension is the activities downstream from the actual testing (analytical stage) performed by the laboratory. This downstream activity deals with the lab's factory output, including data, information, knowledge, physical tube, and waste. Each of these three dimensions requires focused effort for the lab to move to its eventual goal of a "best in class" organization. Outside subject matter experts (SMEs) are the best way to gain the needed knowledge and apply such knowledge to achieve world-class performance in the lab.

Products: Yes, products exist as the third dimension of Process described above. But products also deserve a special call-out because of their importance to creating value for the lab, especially in the evolving U.S. healthcare environment.

Differentiating With Value

Here is where the lab must be creative to establish value that differentiates its products from that of other labs. The wrong paradigm is to think of the product as a lab test result. Labs that retain this paradigm will disappear.

Two elements can help the lab identify opportunities to add value to its products. One is to regularly survey customers to understand their definition of quality and their unmet needs. The second is to have a seat at the table in the parent organization to gain the insights needed to determine what is most important to the institution.

THE DARK REPORT invites your comments as each level of this four-level laboratory value pyramid is described. The challenge of mapping what labs should look like in the future is great, but the rewards for getting it right are worthwhile.

(See pages 14-15 for description of level two.)

Laboratory Value Pyramid

Understanding Level 2:
Establish & Meet Standards of Value

One primary purpose of the laboratory value pyramid is to provide a step-by-step process to allow any laboratory to assess its current state, then work to evolve via the four levels into a "best practices" organization. Level two attributes include:

- Uses benchmarking of its internal activities to establish criteria for value.
- Lab staff culture centered upon lab performance mentality (and not a lab-result-only mentality).
- Quality parameters incorporated across all functional areas of lab, such as patient results, customer/employee satisfaction, best practices in production, supply chain, financial, and similar.
- Lab managed as well-run business with same accountability of management and staff found in top-performing businesses. Outside subject-matter experts (SMEs) engaged regularly to help establish best practices in clinical, operational, and financial areas.
- Laboratory staff recognizes value-added work processes from non-value-added. Staff uses Lean, Six Sigma, and performance improvement methods to continually increase value in measurable ways.
- Lab's information technology, including LIS, can deliver real-time data about work processes and lab operations and has capability to generate lab test data and combine it with other clinical data in ways that deliver more value to the parent organization, physicians, patients, and payers.

Level Two: (Lab Focus Is Internal)
Establish & Meet Standards of Value

ONCE A LAB ORGANIZATION MEETS the criteria of *Level One: Achieve Normalcy and Predictability*, it has the necessary foundation to tackle *Level Two: Establish and Meet Standards of Value.*

Level two is an internal focus, just like level one. That's because the lab is still putting its own house in order before shifting full concentration to its external customers, as defined in level three and level four of the laboratory value pyramid.

Stated in another way, once a laboratory has achieved level two, it has achieved alignment of these factors: 1) lab staff is trained and using system-of-prevention mindset; 2) all operational processes are undergoing continuous improvement; and, 3) the lab's information technologies are capable of supporting big data applications that use lab test results to deliver more value to the lab's customers. These include the lab's partner organization (such as a hospital or health system), physicians, payers, and patients.

The level two lab can be described as having these attributes:

- Uses benchmarking of its internal activities to establish criteria for value.
- Mentality of lab staff and culture is centered upon lab performance mentality (and not a lab-result-only mentality).
- Quality parameters are incorporated across all functional areas of the lab, such as patient results, customer and employee satisfaction, production best practices, supply chain best practices, financial best practices, and similar.
- Lab is managed as a well-run business that includes the accountability of management and staff found in top-performing businesses. Lab regularly creates a complete business case analysis including financial justification for major lab investment requests and submits it to the "C suite" for consideration. Outside subject-matter experts (SMEs) are regularly engaged to help establish best practices in clinical, operational, and financial areas.
- Lab staff can recognize value-added work processes from those that are non-value-added. Staff uses Lean, Six Sigma, and performance improvement methods to continually increase value in measurable ways.
- Lab's information technology, including the laboratory information system, is capable of delivering real-time data in two dimensions. One dimension is data about work processes and lab operations. The other dimension involves the lab test data and the ability to combine it with other clinical data in order to deliver more value to the parent organization, physicians, patients, and payers.

When performing at level two, a clinical laboratory has moved beyond a traditional mindset of the clinical service that delivers accurate lab test results on time. The level two lab now has a razor-sharp focus on delivering value to its parent organization and customers.

➤ High-Performance Laboratory

The level two lab has used its level one accomplishments as the springboard to create a high-performance organization that fully engages lab staff at all levels in the pursuit of excellence. All the people within the lab are fully trained in the principles of the system of prevention and are competent in applying these principles to further the performance of their laboratory.

Evidence of this operating state and level two achievement is when the lab staff is highly interactive in working with other departments within the hospital and health system on optimizing shared practices.

The level two lab regularly conducts customer satisfaction surveys with all of the

More Detailed Descriptions about the Attributes of a Lab Working to Achieve Level Two

UPON ACHIEVING LEVEL TWO of the laboratory value pyramid, the lab has demonstrated its mastery of core management, business, and financial essentials. In particular, the level two lab is passionate about using a handful of key metrics to maintain its focus of delivering highest quality services at the most competitive cost.

Collaborators in the development of the laboratory value pyramid note that Key Performance Metrics, or CTQs (critical-to-quality) are the cornerstones to sustaining level one and two achievement. Moreover, they note that just a handful of CTQs—about 10 or so—are needed to guide and direct lab staff in the core process of producing valued patient diagnostic information (lab test results and information that is actionable by clinicians).

A level two lab is open and alert to "borrowing from the best." Lab staff is always watching, learning, and "stealing" from best-in-class manufacturing and distribution leaders, including such companies as **Toyota**, **Federal Express**, **General Electric**, and **Johnson & Johnson.** The level two lab regularly engages outside subject matter experts (SMEs) to help its lab team learn useful management techniques and successfully deploy them across the lab.

Part of the activity to achieve level two is to identify the most useful CTQs and determine "in control" limits for each CTQ. Next, a process is set up to measure them, ideally in real-time, but no less than over a 24-hour "production cycle or turn."

Keep in mind this is *not* Levy Jennings or Westgard QC charts for control values! Rather, these CTQs are separate and measure the true heartbeat of the lab's daily operation. They need to be continuously monitored as well. One of the collaborators in the development of the laboratory value pyramid says, "Think of it this way, CTQ's are to Value as Westgard Rules are to QC."

As a level two laboratory, the resources of people, processes, and products have been developed to a high-level of internal performance. This positions the laboratory to begin its progress toward achieving level three in the laboratory value pyramid.

lab's users and customers and uses the findings to drive the next round of continuous improvement projects that add more value to the lab's end users.

When Your Boss Is Watching

You will know your lab is competent at level two when the owners, directors, and C-suite executives outside the lab want to know about the core competencies established by your lab, along with how your team nurtured the staff culture of continuous improvement and delivering more value to customers.

Another sign of the level two lab is when your boss and his/her boss both ask you and your lab team to help other areas of the parent organization achieve the same level of performance.

When done right, leaders of the level two lab will have earned themselves a "seat at the table" within the institution to participate when resources are allocated, budgets are set, strategies are formulated, business decisions are made, and capital equipment funds are allocated. Inclusion in these strategic management activities of the parent organization is another sign of level two achievement.

Remember that the level two lab also has a robust information technology capability that allows real-time assessment of clinical data. This is necessary for the lab to begin its pursuit of level three. TDR

Attorneys Outline Issues In FDA's LDT Guidance

➤Labs have opportunity to provide comments; FDA wants to be notified of all LDTs a lab performs

➤➤CEO SUMMARY:- Officials at the FDA believe that CLIA does not go far enough because it does not address the issues of whether laboratory-developed tests (LDTs) have been designed correctly or have been manufactured in accordance with sound standards. Also, CLIA does not include a process to verify if LDTs are safe, accurate, or efficacious, said a legal advisor to labs. This may be why FDA views enforcement of new regulations as filling in gaps in CLIA or at least supplementing it.

Some experts say the FDA's plan to regulate laboratory-developed tests (LDTs) has the potential to be one of the biggest changes to the practice of clinical laboratory medicine since the passage of CLIA in 1988.

On October 3, the FDA published proposed draft guidance in *The Federal Register* for the new LDT framework and notification requirements. This draft guidance started the 120-day comment period, after which the FDA will issue final guidance. Pathologists and laboratory directors wishing to submit comments that might affect the final regulations the FDA will issue, will need to submit those comments by February 2, 2015.

Given the lab industry's high interest in the FDA's proposed regulation of LDTs, The Dark Report sponsored a recent webinar where attorneys Rick Cooper and Jane Pine Wood of **McDonald Hopkins** explained the steps that clinical laboratories need to take to prepare for the day when these new rules become effective.

"The FDA proposed these rules because it believes that, although CLIA regulates labs, CLIA does not go far enough," commented Cooper. "The FDA is of the opinion that CLIA is not adequate to regulate LDTs because CLIA does not address such issues as whether LDTs have been designed correctly or have been manufactured in accordance with sound standards. Additionally, the FDA believes there is a need for a test-specific process that a lab must use to verify that its LDTs are safe, accurate, or efficacious.

➤Assessing Safety Of LDTs

"FDA officials are also concerned that CLIA does not account for post-marketing safety monitoring and data gathering in support of that type of assessment," continued Cooper. "Seen from this perspective, the FDA views its enforcement of LDTs as filling in gaps or supplementing CLIA in a useful way.

"Another source of concern at the FDA is the probability that some labs are marketing unnecessary tests to clinicians and even selling these tests directly to consumers," he stated. "Another potential issue is that some LDTs currently marketed to clinicians may

be less efficacious and cost more than other tests already available in the marketplace."

After explaining why the FDA believes regulation of LDTs is necessary, Cooper offered three considerations for labs. First, the fact that the FDA delivered a detailed description of how it will regulate LDTs is significant, he said.

"The LDT draft guidance is detailed and, for that reason, it gives us insight into how the FDA wants to see enforcement roll out," he noted. "Quite often, these proposals are not this detailed. It shows that the FDA has given considerable thought into how it will pursue enforcement.

"Second, the FDA's proposed guidance calls for putting the various elements for the proposal in place over time," he stated. "Because the various enforcement components will not be implemented immediately, labs will have time to comply.

"Many labs, particularly those performing LDTs that will be subject to the most stringent compliance requirements, will need to make meaningful changes in the way they operate," noted Cooper. "That is why the FDA's proposed extended timeline will be critical as labs take the needed steps to comply with these new regulations.

"Third, some lab directors and pathologists believe that specific LDTs they currently perform in their labs will not be subject to the new rules," emphasized Cooper. "This belief is incorrect.

"There will be no grandfathered LDTs," he said. "Therefore, labs rushing to introduce new LDTs into the market before these rules take effect will gain no significant advantage, at least given the draft language issued by the FDA."

With the release of the draft guidance on the LDT framework and notification process, the FDA is expected to take progressive steps to develop implementing regulations. "After the public comment period, the FDA's next step will be to announce the language of the guidance, which will disclose the date when the guidance takes effect," stated Wood. "The FDA is proposing a nine-year process to phase-in these regulations. But that doesn't means labs can do nothing. To the contrary, within six months of the issue date of the final regulations, most labs performing LDTs will need to take steps to comply.

"The first step to comply with the LDT rule (as contemplated in the proposed guidelines, which are subject to change from the draft as currently written) involves the notification requirement," stated Wood. "Every lab will need to notify the FDA of the LDTs they are performing.

"Labs also will need to do some medical device and adverse event reporting associated with their LDTs," she commented. "Adverse event reporting is needed to address a concern at the FDA regarding patient safety. The FDA believes it is not getting enough information regarding adverse events."

Gather Data in Advance

"But the bigger issue involves notification. Within six months of the publication of the final guidance, labs will need to notify the FDA about each LDT," emphasized Wood. "To get a head start on this process, labs should start thinking about which of their tests meet the definition of an LDT.

"Should a laboratory fail to comply with this notification requirement, the penalty would be to go through the FDA's pre-market review process," she said. "Complying with notification is important because most labs would be hoping to avoid the time and expense of a pre-market review.

"What concerns some lab directors who have studied the notification requirements is whether their existing LDTs will fall into the category of tests that will require pre-market review," noted Wood. "The FDA will make decisions about the need for pre-market review based on the risk classification scheme described in the proposed LDT rule."

Wood and Cooper pointed out that the FDA is proposing to use its existing classification scheme. Thus, lab tests deemed to be

Class I devices will have the lowest risk. Class II tests will have moderate risk and Class III tests will have the highest risk.

"We know the FDA will require pre-market approval for Class III devices, per the language of the proposed rule," observed Wood. "Class III will be the highest hurdle for any laboratory seeking to get LDTs to market."

"This is what makes the notification process important—both to labs and the FDA," noted Cooper. "The FDA will gather information on LDTs through the initial notifications. It will then classify each LDT and notify laboratories about that classification."

"It is expected that the notification process itself likely will be electronic," said Wood. "The FDA will look for information on every LDT, including monthly test volume, intended use, testing method, sample type, analytes that are used or the organisms that are detected, the clinical use of the test, and the patient population.

➤FDA To Use Expert Panel

"Based on this information, the FDA will determine a risk classification," stated Wood. "The FDA will involve consideration of such factors as the risk level of the disease involved, the type of clinical decision involved, if the test is screening or diagnostic, if the LDT is the sole information upon which a clinician would make a decision to treat the patient, and whether there are any other testing options available. Expert panels will advise the FDA concerning how it should classify LDTs."

Given that the FDA's proposed new guidance represents such a significant change in how LDTs are regulated, it is important for pathologists and lab managers to stay informed about the new guidance and dates for its implementation. TDR

—Joseph Burns

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FDA's 9-Year LDT Review Could Start Next Year

CLINICAL LABORATORY DIRECTORS AND PATHOLOGISTS have until February 2, 2015, to comment on the two documents issued by the FDA issued on October 3. The documents provide draft guidance on how to implement a new regulatory oversight framework for laboratory-developed tests (LDTs).

In a presentation for THE DARK REPORT, Jane Pine Wood of McDonald Hopkins explained that the FDA could take as much as nine years to implement this regulatory oversight. The first step in the implementation has already begun, That is the 120-day comment period which began October 3 and ends on February 2, 2015.

The next step will begin six months after the final guidance is published. This next step is the process when labs need to notify the FDA about the LDTs they provide. It is possible that the FDA will issue final regulations by the summer of 2015 at the earliest, Wood estimated. At the same time, labs would need to notify the FDA about the LDTs they offer and any adverse events resulting from the use of these LDTs, Wood said.

"Following the six-month review, the FDA will begin enforcing the premarket review requirements, about 12 months after the final guidance is published," Wood said. "The FDA's review will begin with the highest-risk LDTs. This review will be phased in over four years because the FDA will commence reviewing the highest-risk LDTs before proceeding to review those LDTs it designates as lower risk.

"After the FDA completes its review of high-risk LDTs, it will next review moderate-risk LDTs. That will begin five years after the guidance is finalized, and the phase-in will be over an additional four years. That's how we get to nine years altogether for a phase-in period," she said.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Interesting things are unfolding in San Diego with **Pathway Genomics**, a company with a CLIA lab that offers genetic testing to physicians. On November 12, it was announced that the **IBM Watson Group** had invested in Pathway Genomics. The two companies said that they are teaming up to deliver "the first-ever cognitive consumer-facing app, based on genetics from a user's personal makeup." Called Panorama, the app will interact with Watson's cognitive computing capabilities to allow "consumers to ask health related questions, in their own words and receive personalized and relevant responses," stated Stephen Gold, Vice President, IBM Watson Group.

MORE ON: *Pathway*

The Panorama app is designed to allow the consumer to upload medical records and connect tracking devices like Fitbit. It will also accept genetic information, regardless of which lab performed the genetic test. Pathway Genomics is one of the fastest-growing start-ups in the genetic testing space. Earlier this year, it was ranked 33rd on *Inc. Magazine's* annual list of the fastest-growing 500 private companies, based on a three-year growth rate of 2,415.5%.

DIGITAL PATHOLOGY TRAINING IN THE UK

Digital pathology is making steady inroads in clinical settings. Earlier this month, the **University of Bradford** in England announced a collaboration with **Phillips Digital Pathology Solutions**. The university will offer the United Kingdom's first formal academic training program in digital pathology for both undergraduate and graduate students. The goal is to train the students in how to use new digital tools to support diagnostics.

TRICORE TO TACKLE BIG DATA

TriCore Reference Laboratories of Albuquerque, New Mexico, is embarking on an ambitious project to harness big data, including lab test results, to bring more value to patient care. TriCore is working with **Wave**, the **Salesforce Analytics Cloud**. The lab wants to provide physicians with a medical platform "that can display chronological health data in order to optimize clinical processes." Because it serves 70% of the New Mexico lab testing market, TriCore believes it is positioned to help physicians with population health management.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...how a team at **Stanford University** used nanotechnology to develop a diagnostic test for type-1 diabetes that can be performed in a physician's office and does not require a specimen collected by venipuncture.

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

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 15, 2014.

It's our 20th Anniversary!

20 YEARS

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Details Coming Soon!

- Latest market developments
- Roundtables for Lab CFOs, CIOs, Sales/Marketing VPs
- Powerful lab case studies
- Top keynote speakers

Suggestions for Topics or Speakers?
Contact us at: kat@darkreport.com

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- ***The Dark Report's List of 2014's Ten Biggest Lab Industry Stories.***
- ***DNV Certifies Two Hospitals as Infection Control Centers of Excellence: How Their Labs Contributed.***
- ***Consolidation and Mergers Continue to Thin Ranks of Private Pathology Groups.***

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