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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

Florida Lab Story Has National Implications

PLEASE ALLOW ME TO THANK ALL OF YOU READERS who have contacted us with information, rumors, and useful intelligence about **UnitedHealthcare's** laboratory benefit management program in Florida that is administered by **BeaconLBS**, a division of **Laboratory Corporation of America**.

Your input, along with that from physicians in different specialties in Florida and their respective state and national medical associations, has helped THE DARK REPORT tell the remarkable story about how a huge national insurance company wants to cram a poorly-designed system for ordering lab tests down the throats of thousands of very unhappy doctors in the Sunshine State.

UnitedHealthcare has yet to provide data to physicians to justify why it believes that many well-established clinical lab tests must be pre-notified or pre-authorized. That failure rankles many of these clinicians. In addition, these physicians have legitimate concerns about the negative effect that the UHC program will have on patient care—particularly because it could disrupt an accurate and timely diagnosis what would otherwise occur when these physicians are ordering lab tests consistent with established evidence-based medicine guidelines.

For pathologists and laboratory administrators outside of Florida, this story is directly relevant. It is known that representatives from BeaconLBS are attempting to recruit labs in eight or 10 other states in order to replicate the laboratory benefit management program.

In fact, pathology groups should be particularly concerned about what happens to BeaconLBS in Florida. That's because the requirements for pre-notification and pre-authorization, if implemented in other states, would exclude about 40% of the pathology groups from providing services in their respective states! The clinical reasons to support these restrictive requirements have never been documented by UHC or BeaconLBS. Of course, it goes without saying that LabCorp, as owner of BeaconLBS, has the anatomic pathology resources to fully meet the requirements of UHC's laboratory benefit management program. Might some labs challenge this as anti-competitive business behavior?

These concerns show why the events unfolding in Florida with UnitedHealthcare and BeaconLBS have national implications—not just for pathologists and clinical lab managers—but for primary care and specialist physicians as well! TDR

Florida Docs Refuse to Use UHC's Lab Ordering System

Some specialist physicians are sending patients back to primary care doctors for lab test orders

CEO SUMMARY: It may not yet be open rebellion, but UnitedHealthcare faces strong opposition in Florida from physicians—and their medical societies—over the requirement that they obtain pre-notification and pre-authorization when ordering tests listed in UHC's laboratory benefit management program. Recent rumors say that UHC has exempted some medical groups from compliance with the program. If true, that could further complicate UHC's relationship with physicians in the Sunshine State who must continue to comply with this program.

In Florida, a significant number of physicians continue to resist efforts of **UnitedHealthcare** (UHC) to institute its laboratory benefit management program that is managed by **BeaconLBS**, a division of **Laboratory Corporation of America**.

Since October 1, 2014, UHC has required physicians to use this new decision support system when ordering lab tests for beneficiaries of UHC's commercial HMO patients. The program requires them to obtain pre-notification or pre-authorization for 82 lab tests.

If the physicians fail to do so, the laboratories performing the tests will not get paid. The physicians who ordered the tests may also face financial penalties assessed by UHC or even expulsion from UHC's provider network. UHC has suspended these parts of the laboratory benefit management program and has not stated when it will initiate what it calls "claims impact."

In the latest developments, physicians in Florida told The Dark Report that they and some colleagues continue to refuse to use the system when ordering clinical laboratory tests for UHC's commercial HMO patients. They say the system is cumbersome, time-consuming and interferes with patient care.

Further, these physicians report that some specialist physicians are sending patients back to their primary care physicians along with the lab test orders. In this way, PCPs can order the tests for patients and get the results back as well. By refusing to order the tests in their offices, these specialist physicians are hoping the PCPs will report the test results back to them.

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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).

Along with these objections about the excessive physician and staff time required to order lab tests through the BeaconLBS system, physicians and their medical specialty associations have told officials at UnitedHealthcare that the current design of the laboratory benefit management program infringes on their practice of medicine in unacceptable ways that could negatively affect patient care and patient outcomes. *(See TDRs, July 21, November 3, and October 13, 2014.)*

This is true of the **Florida Society of Pathologists** and the **College of American Pathologists**. Both medical associations have sent letters to UnitedHealthcare asking the health insurer to defer implementation of the program until serious issues affecting patient care can be addressed.

Specifically, in their letters, the FSP and CAP told UHC that the program: a) could affect patients' access to care and could delay some diagnoses; b) requires unnecessary certification by subspecialists for certain tests; c) has secondary review requirements that infringe on the practice of medicine; and, d) imposes an additional administrative burden on pathologists.

The **Florida Society of Pathologists** further stated that it "estimates that about 40% of all pathology practices will have trouble meeting the requirements as UHC specifies in this pilot program," despite the fact that these same pathology groups have been serving UHC's patients for decades in accordance with accepted medical practice. *(See TDR, January 5, 2015.)*

Excludes Most Florida Labs

There is another aspect of UHC's laboratory benefit management program that rankles Florida physicians and is a major issue of concern for clinical labs. Of the hundreds of clinical laboratories serving patients in Florida today, the BeaconLBS "laboratory of choice network" excludes all but 13 labs—and five of those lab companies are owned and operated by LabCorp (which is also the owner of BeaconLBS). Physicians are unhappy about this aspect of UHC's program, as it disrupts long-standing clinical relationships between physicians and their preferred labs. It also means that patients who have been served for years by their physicians' preferred labs must now visit one of the 13 labs in the BeaconLBS network.

When asked by THE DARK REPORT about these issues, UnitedHealthcare has provided specific statements. These can be found in the issues dated November 3, 2014, and January 5, 2015.

No Payment For Lab Claims

Initially, UHC intended to begin the "claims impact" portion of the laboratory benefit management program on October 1, 2014. The health insurer and its contracted manager of the program, BeaconLBS, were prepared to refuse payment to labs performing tests when the physician failed to properly obtain pre-notification or pre-authorization for those tests. Physicians not meeting the requirements of the program would be subject to enforcement as described earlier.

As October 1 approached, UHC found itself confronted by a large number of physicians criticizing many aspects of the laboratory benefit management program. The large scale of this criticism is reflected in the letters and communications sent to UHC by such medical associations as **Florida Medical Association**, **American Congress of Obstetricians and Gynecologists** (ACOG) District XII (Florida), the **Florida Academy of Family Physicians**, the **Coalition of State Rheumatology Organizations, American College of Rheumatology**, and the Florida Society of Pathologists and College of American Pathologists mentioned earlier.

UnitedHealthcare decided to delay implementation of the claims impact until January 1, 2015. In December, it announced that the claims impact would be suspended until further notice, but that the laboratory

BeaconLBS Sending Letters to Florida Doctors That Tracks Their Non-Use of Lab Test Order System

From: Matt Parise <info@askbeaconlbs.com>
Date: Mon, Feb 9, 2015 at 2:20 PM
Subject: UnitedHealthcare® Laboratory Benefit Management Program
To: [redacted]

This message contains graphics. If you do not see the graphics, click here to view.

Re: Solicitation BeaconLBS Lab Benefit Management Program Dates and Reminders

BeaconLBS
Lab Benefit Solutions

Dear Provider,
The UnitedHealthcare Laboratory Benefit Management program requires that you provide advanced notification for these Decision Support Tests for your Florida commercial fully insured patients.
The report below identifies the test(s) that you did not provide advanced notification. In the future, when ordering these test(s) please provide advanced notification via the PDS portal at www.BeaconLBS.com, through one of our integrated laboratory ordering systems or EMR partners.
For more information on how to provide advanced notification for these test(s) please contact us at (800) 377-8809.
Regards,

Matt Parise
Director of Operations
BeaconLBS

Here is the text of a letter (left) that was sent this month to a Florida physician by a BeaconLBS official. It tells the physician that he/she has not used the BeaconLBS system, as required, to order lab tests that are included in the UnitedHealthcare laboratory benefit management program. It even attaches a report that identifies the specific tests where the physician failed to comply with the pre-notification requirement.

One issue that has been a major problem for UnitedHealthcare and BeaconLBS as they try to roll out their laboratory benefit management program is the lack of a smooth-functioning interface with the physicians' EMR systems. Without such an interface, physicians must go into two different systems to order a lab test. At right is a letter that UHC is sending to Florida physicians that shows which EMR vendors are "integrated or soon to be integrated." Of the top 10 outpatient EMR systems recently identified by *Beckers Hospital Review*, only **Allscripts** and **eClinical Works** appear on the UHC list.

UnitedHealthcare®

Laboratory Ordering System Options for the Laboratory Benefit Management Program

The UnitedHealthcare Laboratory Benefit Management Program was developed to help improve affordability and quality of care for our members. As part of this program, you must use a laboratory ordering system integrated with Physician Decision Support to order Decision Support Tests.

Physician Decision Support helps make it easier to choose tests and laboratories using evidence-based guidelines and industry best practices. It will automatically identify members who are part of the Laboratory Benefit Management Program, and it has advance notification for Decision Support Tests built in.

You can select from a variety of applications integrated or soon to be integrated with Physician Decision Support, including the following laboratory ordering systems and electronic medical records (EMR) applications.

Laboratory Ordering System Options	Product	Website
BeaconLBS Lab Benefit Solutions	Physician Decision Support	beaconlbs.com
LIAISON HEALTHCARE INFORMATICS	EMR-Link	liaisonhealthcare.com/solutions/emr-link
LabCorp Laboratory Corporation of America	LabCorp Ordering Applications	labcorp.com
MILLENNIUM LABORATORIES	Millennium MLIS	millenniumlabs.com
EMR Options	**Product**	**Website**
ADVANCED DATA SYSTEMS CORPORATION	MedicsDocAssistant	adsc.com/electronic-health-records
Allscripts	Professional EHR & TouchWorks EHR	allscripts.com
aprima EHR • PM • RCM	Aprima EHR	aprima.com
emdeon	emdeon Clinical Exchange EHR Lite	emdeon.com/ehrlite
eClinicalWorks	eClinicalWorks	eclinicalworks.com
hellohealth®	Hello Health®	hellohealth.com

Physician Decision Support was developed by Beacon Laboratory Benefit Solutions, Inc. (BeaconLBS®), a company that specializes in laboratory services management. UnitedHealthcare has chosen BeaconLBS to administer the Laboratory Benefit Management Program.

If you have any questions about the program, please contact your network account manager or Provider Advocate.

benefit management program remained in effect and physicians were expected to meet its requirements when ordering lab tests.

Neither UHC nor BeaconLBS announced a new date for making payment decisions with BeaconLBS. But UHC said it would give physicians 30 days' notice before implementing the system. The postponement of the BeaconLBS payment-decision start date is the fourth known postponement for the Beacon system and claims impact. Previously start dates were set for September 1, October 1, and January 1.

Two lab directors in Florida have heard that the new start date for making payment decisions is April 15. Elizabeth Calzadilla-Fiallo, Director, UHC's Public Relations for Florida and the Gulf States Region, denied that a new start date was set. Instead, she said, UHC will give physicians 30 days' notice before the program goes live.

Beacon Tracks Lab Orders

One new development is that BeaconLBS is tracking each physician's lab test ordering. As BeaconLBS learns that physicians have failed to use the BeaconLBS system to order the tests, Matt Parise, Director of Operations for BeaconLBS, has written "Dear Provider" letters that ask them to comply with UHC's requirements. *(See sidebar on page 5.)*

Another recent development that could be problematic for UHC is whether it is exempting certain physician groups or physicians from the program so that they do not have to participate. After hearing about this possibility from sources, THE DARK REPORT submitted the question to UHC but did not get an answer.

It may be that such arrangements include a non-disclosure clause, meaning neither party could comment on such a carve-out. However, if UHC is exempting some physicians from this program, that would not be well-accepted by physicians under pressure from UHC and BeaconLBS to comply. TDR

—Joseph Burns

Florida Medical Associations Object to UHC, BeaconLBS

IN RECENT MONTHS, physician associations in Florida have sent letters to UnitedHealthcare to express their vigorous opposition to the health insurer's laboratory benefit management system that is administered by BeaconLBS.

For example, the Coalition of State Rheumatology Organizations said it could not support the implementation of UHC's Beacon Laboratory Benefit Solutions system "without data supporting the inappropriate use of laboratory testing by rheumatologists." The coalition also said it "will do all that is necessary to controvert this policy."

In a letter dated September 11, to UHC's National Medical Director, Richard Justman, M.D., CSRO President Michael C. Schweitz, M.D., wrote, "We are going to suggest to our members that they investigate all ethical and legal means to resist this policy and we will pursue the reversal of this policy with our state and national societies through every regulatory, legislative, and public means possible." *(See TDR, January 5, 2015.)*

Members of the American Congress of Obstetricians and Gynecologists in Florida are just as concerned. In a letter sent September 11 to Linda Stewart, Vice President of UHC's national lab program, Robert W. Yelverton, M.D., Chair of ACOG's District XII (Florida), described how ACOG members have expressed those concerns to UHC, he said, but the health insurer has failed to address their concerns.

"...those [issues] highlighted here compel us to request that UHC suspend this test program as a requirement for Florida providers immediately and indefinitely," Yelverton wrote. "ACOG District XII values its relationship with UHC and recognizes our shared responsibility in improving the quality and efficiency of patient care. However, we view the implementation of the BeaconLBS program, in its current form, as a giant step backward." *(See TDR, November 3, 2014.)*

Market Price Report Rules Must Address All Issues

Lab industry awaits release of rules by CMS and whether such rules will favor some types of labs

CEO SUMMARY: Under the Protecting Access to Medicare Act, CMS must collect market price and volume data from certain labs beginning January 1, 2016. CMS will use this data to establish Part B clinical laboratory fees beginning in 2017. One lab association representing community and regional laboratories points out that CMS has complex issues that must be appropriately addressed if the resulting rules are to avoid favoring some types of labs over others, whether intentional or not.

THERE IS MUCH ANTICIPATION about how the federal **Centers for Medicare & Medicaid Services** intends to write the rules that specify which labs must report market data on test prices and what data must be collected and reported.

The Protecting Access to Medicare Act of 2014 (PAMA) that became law on April 1, 2014, calls for labs to report such data and the test volumes associated with that data, beginning on January 1, 2016.

Then, on January 1, 2017, CMS will use the market data to set prices for the Part B Clinical Laboratory Fee Schedule. As currently written, PAMA specifies that CMS cannot cut the price of a specific lab test by more than 10% in each of 2017, 2018, and 2019, nor by more than 15% in each of 2020, 2021, and 2022. There is no limit on price reductions outlined in the law for years following 2022.

For community and regional labs, market price reporting based on lab volume has the potential to cause such serious erosion to their finances that they may be forced out of business. This is due to several reasons. First, the largest national laboratories have significantly higher test volumes for the most commonly performed tests and offer deep discounts in pricing, and as a result, their data may dominate the pricing analysis outlined by the law.

More Medicare Patients

Second, community lab companies typically serve a much higher proportion of Medicare patients than do the nation's biggest lab companies and they also serve more costly Medicare populations such as those in skilled nursing facilities. For example, Medicare makes up about 15% of the revenue of the two biggest national lab companies. By contrast, it is common for community labs to have between 30% and 65% of their revenue come from Medicare Part B payments.

Three, community labs tend to have a much narrower testing menu and could see far greater reductions in overall Medicare reimbursement in comparison to national competitors with broader testing menus that can buffer reductions.

This is why the current round of educational and lobbying efforts happening inside the Beltway will have a significant effect on the financial stability of a large number of the nation's clinical lab organizations. PAMA requires CMS to issue the rules for market data reporting by clinical laboratories, and how the rules are structured will greatly affect the quality, relevance, accuracy, and usefulness of the data that labs transmit to CMS.

Will Rules Favor Some Labs?

Further, how the rules are written could favor one group of labs over another group of labs. This is precisely the concern of community labs that make up the membership of the **National Independent Laboratory Association** (NILA). According to Julie Scott Allen, NILA members see the potential that the market reporting rules that CMS eventually issues could favor larger national labs over independent labs. Allen is a government relations director for **Drinker Biddle & Reath** and Senior Vice President with the firm's **District Policy Group**, representing NILA.

"NILA disagrees with the premise that PAMA presents an opportunity for a fair market analysis," stated Allen. "First, it is unclear whether CMS will collect data from the whole laboratory market in terms of all entities that perform laboratory testing and their prices and volumes, or whether the regulations will be skewed in a way that will harm smaller independent labs by comparing only their prices and volumes to those of the largest national independent labs.

"Second, the laboratory market is derived of different players that compete for contract business in different ways. PAMA's approach is focused on price and volume only," she continued. "It does nothing to look at the markets being served and to fairly evaluate issues of access to services or the cost of services in different markets. It assumes all laboratory contracts are uniform, which is not true.

"NILA is also seriously concerned about the burden labs will face when they have to report to CMS on test volume and the prices they get paid by different payers for the tests they run," noted Allen. "There are many questions about what data CMS will collect and whether data collection can and will be uniform across all labs.

"For example, will the data allow true apples-to-apples comparisons when there is such diversity in the way private contracts for lab testing are negotiated and finalized?" she asked. "Forget how complicated it is to compare between different commercial payers; there is significant variance in each individual contract for any single commercial payer.

"We also want to understand what rate information CMS will collect," she said. "Will those rates represent all that goes into final pricing for an individual test code, including such things as patient co-pays? Since many commercial payers have entered into arrangements with large national laboratories, effectively shutting community laboratories out of their networks, will CMS seek to collect out-of-network payment rates? Comprehensive rates and out-of-network rates certainly represent market-based rates."

Approach Questioned

CMS must write regulations to implement the laboratory requirements under PAMA. As of early February, the laboratory industry has seen no proposed rule or economic impact analysis. The federal **Office of Management and Budget** must review the rule, and there was no sign as of February that it had done so.

"How can laboratories comply with requirements on January 1, 2016, when these requirements might not be finalized until late in 2015?" asked Allen. "NILA seeks to understand what the agency might do to minimize this process, and whether, for example, the agency proposes a limited review of a portion of the fee schedule and what tests are included in such a review.

Many Factors Involved in Lab Market Data Reporting

IN THE PROTECTING ACCESS TO MEDICARE ACT (PAMA), CMS is directed to collect market price data and use the data to establish prices for the Part B Clinical Laboratory Fee Schedule, starting on January 1, 2017.

"As part of its reporting of rates, PAMA requires laboratories to outline all discounts and rebates," stated Julie Scott Allen, Senior Vice President with the District Policy Group, representing the National Independent Laboratory Association (NILA). "However, the law excludes some of the biggest forms of discounting, including capitated rate arrangements.

"Organizations such as NILA have questioned how discounting will be applied to the final rate calculations CMS conducts, given the complexity of those arrangements," she noted. "There are numerous forms of discounting, including by test, by overall contract, and by volume. Sometimes discounts to lab tests are not applied until the end of a specified contract term to ensure a metric is met.

"How such discounts are ultimately considered and applied to CMS' rate calculations are of concern," Allen said. "Most community independent labs do not typically compete on volume or offer discounts. Instead, they compete on quality and an ability to provide services to communities otherwise not served by the nation's largest lab companies. CMS needs to consider these issues.

"PAMA does not clearly define what types of laboratories are required to report test prices and volumes," continued Allen. "The law outlines that 'an applicable lab' is one in which the majority of its Medicare payment comes from either the Physician Fee Schedule or the Clinical Laboratory Fee Schedule.

"Thus, we must ask, 'Who was this intended to exclude?" she said. "Hospital inpatient laboratory services are paid under DRGs but not under either fee schedule. Hospital outpatient laboratory services have largely—though not entirely—been paid as a bundled payment for overall services provided to these patients.

"That leaves hospital outreach laboratories that can be significant competitors to small and mid-size community and regional laboratories," concluded Allen. "However, which labs are required to report market data will ultimately be determined by CMS. "

"Any such review must include a diverse array of tests, including high dollar, high utilization, esoteric, and routine tests, in order to not have an adverse effect on market competition," she added.

"NILA wants these issues considered as part of any proposed so-called market-based regulatory assessment," she said. "NILA members have long argued that any regulatory process and subsequent adjustments to Medicare rates must be considered for how they affect laboratory competition and access to laboratory services. In particular, this process must consider the impact in communities primarily served by community and regional laboratories, including rural communities, inner cities, and specific sites such as skilled nursing facilities.

"This kind of process and assessment simply cannot be an after-thought," Allen explained. "It can't wait for a GAO evaluation years later," she explained. "By then, the small- and mid-size market will likely be depleted. Congress and CMS must understand this.

"These regulations and their outcome must not favor large labs over small or mid-size labs or favor publicly-traded national labs over privately-held local labs," added Allen. "Writing the regulations so that they favor one over the other would be a gross government manipulation of the market and destroy competition."

Lab administrators and pathologists interested in this issue should contact their respective lab associations for more information. CMS is expected to issue the market data reporting regulations soon. TDR

—Joseph Burns

Contact the National Independent Laboratory Association at 314-241-1445.

Level Three of Laboratory Value Pyramid

Gearing Up the Lab To Exceed Expectations Of External Customers

CEO SUMMARY: This is the third installment of THE DARK REPORT's description of the Laboratory Value Pyramid. It describes "Level Three: Deliver Value that Exceeds Expectations." This is the level where the laboratory organization now shifts its emphasis from internal operation of the lab to external; to how it contributes added value to its parent hospital and the healthcare community it serves. Level three is where the lab organization can position itself as a recognized contributor to improved patient outcomes that also lower the cost of healthcare.

Part Three of a Series

THIS INSTALLMENT OF OUR ONGOING SERIES about the Laboratory Value Pyramid describes the third level of the pyramid. This is the level where the lab organization shifts its emphasis away from internal operations and focuses its efforts externally to deliver value to different stakeholders outside the laboratory.

The Laboratory Value Pyramid is comprised of four levels. Level one and level two were introduced by THE DARK REPORT in the issues dated September 22, 2014 and November 24, 2104, respectively. 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.

It is generally accepted today that the American healthcare system is undergoing a major transformation. The delivery of healthcare is changing in fundamental ways. The cornerstones going forward will be proactive care to keep people out of hospitals, precision care to deliver customized health services tailored to the needs of individual patients, and a fully-integrated healthcare delivery system. **Kaiser Permanente** is organized around many of these attributes.

An equally important element of healthcare's transformation will be radical changes in how hospitals, physicians, clinical laboratories, and other types of providers will be paid. Since money is the necessary element for financial stability, lab administrators and pathologists must pay attention to how payers alter the ways that they pay providers.

For decades, not-for-profit hospitals, particularly those organized by religious orders and faith-based groups, have stated a basic truth to their physicians and staffs: "No margin, no mission." Stated another way, if the hospital cannot deliver its health services in such a manner so that there is a positive margin once costs are subtracted against revenue, then that hospital will be forced to close and will no longer be able to serve the community.

Healthcare's transformative forces are powerful and they continue to gather momentum. As more clinical laboratories and anatomic pathology groups find themselves dealing with the trends described earlier in their communities and regional markets, it will become clear to the laboratory medicine industry at large that any lab organization that attempts to maintain the status quo will be relying on a losing strategy.

Some Labs Will Disappear

Simply said, with each passing year, the labs that remain static with their operations, their provider relationships, and their business plans will be the ones to disappear. Some labs will simply close their doors and file bankruptcy. But most will be absorbed by a financially-stronger organization.

For these reasons, the senior administrators, executives, and pathologist business leaders of every lab must begin to act with urgency and with foresight. It is their leadership that will guide their respective clinical labs and pathology groups through the tough challenges that lie ahead.

That is why the laboratory value pyramid is a timely concept. It is designed to provide the leaders of clinical labs and pathology groups with a conceptual framework that they can use to move their laboratory from its current state to an ideal future state.

Favorable Comments

Response to the laboratory value pyramid has been consistently positive. It has been shown at lab conferences in both North America and Europe and earned favorable comments from lab managers, industry vendors, and lab consultants.

Much the same reaction was recorded after the publication in THE DARK REPORT of part one and part two of this series. Readers

saw how it would help their labs and have expressed interest in learning more.

Before describing the specific attributes of level three of the laboratory value pyramid, it will be helpful to present a quick review of level one and level two.

Review of Level One

By design, a lab that meets the criteria of *Level One: Achieve Normalcy and Predictability* is moving away from traditional management and organizational models that have predominated in the laboratory medicine profession for decades.

In level one, the focus is internal and the laboratory must shift from the system of detection/failure to a system of prevention. To do this requires use of real time, visible lab process improvement metrics that are presented alongside traditional QC data.

A culture of continuous improvement must be infused throughout the entire lab and team members at all levels must be empowered to identify and eliminate the sources of recurring and systemic errors.

Another important characteristic of the level one lab is that it now openly engages outside experts to help bring in the knowledge and expertise needed for the lab to succeed with the system of improvement and deliver more value. *(See TDR, September 22, 2014.)*

Review of Level Two

With the foundation of level one in place, the lab can pursue *Level Two: Establish and Meet Standards of Value*. The focus of this level is also internal and has the final stages a lab must pass through to be prepared to go external to deliver more value to its customers.

Benchmarking is now well-established and used to establish criteria for value. The lab staff has moved past the "volume mentality" (an accurate lab test result delivered on time) to a "value mentality" (where lab test data is converted into actionable intelligence that improves outcomes and reduces costs).

Quality parameters are infused throughout all lab activities and include measurements of physician, patient, and payer satisfaction, for example. Best practices are pursued in all activities, including production, supply chain, and finance.

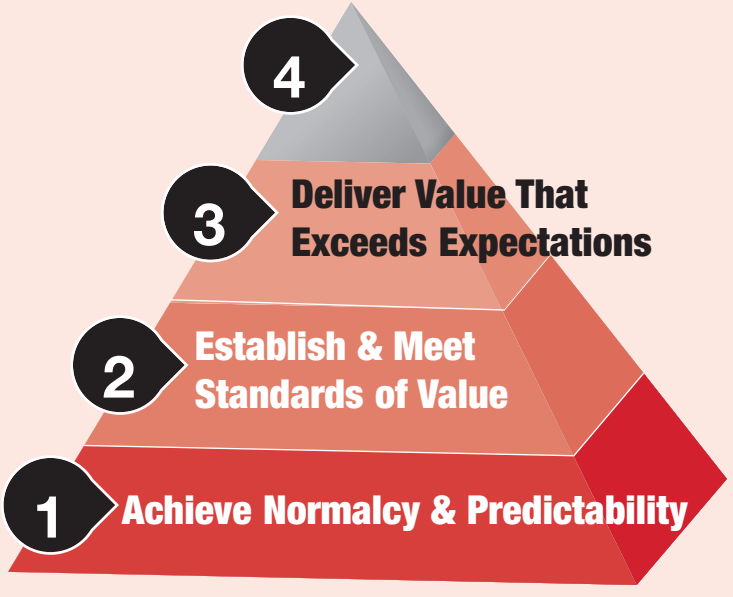
The level two lab will think and act like a business, with accountability visible at all levels of the organization. The lab team is trained to produce detailed business case analyses to justify major lab investments by senior administration. Staff is trained in identifying opportunities to add value and the culture supports assessing activities with a value-added perspective. Continuous improvement is now a permanent aspect of the lab's working culture.

Probably the biggest challenge for a lab to achieve level two involves information technology. As part of level two, labs must adopt IT systems that generate real-time data in support of two activities. One is associated with lab operations and work processes. The other is involved in combining lab test data with other types of clinical data in ways that help the lab deliver more value to the parent organization, physicians, patients, and health insurers. *(See TDR, November 24, 2014.)*

Both level one and level two have the lab focused on its internal functions. It is necessary for the lab to not only put its own house in order before going outside its walls to deliver value, but the lab must also put the right informatics capabilities in place and be comfortable with using outside experts before it can venture outside its own four walls to identify and deliver services that add value to its customers and other stakeholders.

With these accomplishments behind it, the lab is ready to tackle *Level Three: Deliver Value that Exceeds Expectations*. This is the level of the laboratory value pyramid where the lab can confidently shift its sights outside the lab to identify ways that it can deliver more value. The attributes of level three are described on the pages that follow.

Laboratory Value Pyramid



Understanding Level 3:
Deliver Value That Exceeds Expectations

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 three attributes include:

- Apply knowledge of your core competencies that were created in level one and level two to other areas outside the walls of the lab.
- Shift from a state of being held hostage by IT, LIS, HIS, and middleware to a state where the lab is proactive and is driving improvements in its informatics capabilities that are designed to create more value from lab data and the lab's consulting services.
- Justify the cost of IT projects that integrate essential lab patient info into algorithms that diagnose more accurately and sooner, thus contributing to shorter hospital stays, reduced diagnostic workups, and less chance of readmission within 30 days.
- Shift from service provider of lab results to a vital contributor in generating clinical value. This is the transition often described as "from volume to value."

Level Three: (Lab Focus Is External)
Deliver Value that Exceeds Expectations

TWO KEY ELEMENTS DISTINGUISH *Level Three: Deliver Value that Exceed Expectations* from the two previous levels of the laboratory value pyramid. First, the emphasis switches to external. Second, by design, level three activities deliver increased value to the lab's customers and end users and can be the source of expanded lab budgets and increased revenue.

Level three is also the step in the laboratory value pyramid where the lab organization completes its evolution from a simple provider of lab results (accurate results delivered on time) to an essential member of the integrated clinical care team (contributing measurable clinical value).

It must also be emphasized that this evolution from level one and level two to level three is based on effective use of modern quality management methods. That includes appropriate introduction of a quality management system (QMS), such as ISO 15189 and daily use of continuous improvement methods that utilize the techniques of Lean and Six Sigma, for example.

RECOGNIZING LEVEL THREE

Your lab is competent at level three:

- **When your reputation and outcomes are recognized outside of your hospital and institution by your peer groups.**
- **Regular requests for speaking engagements, requests for publications, citations in publications and similar outside recognition start to happen.**

The end state for level three of the value pyramid is achieved when the lab organization can show these characteristics:

- Is now a vital contributor in the flow of patients with the hospital, health system, physician office, skilled nursing facility, or other care setting, including handling, processing, and patient well-being. This is the application of the knowledge and core competencies that the lab created in levels one and two and is now being applied to healthcare settings outside the walls of the lab.
- Lab is now solidly in control of its information technology (IT) systems and is using the LIS, HIS, middleware and other informatics solutions to access the data and metrics needed to create value for end users of lab testing, along with ongoing support for continuous improvement of the lab's internal and external operations.
- Lab is using its ability to access other sources of patient data to combine with its lab test data to develop algorithms that diagnose more accurately and sooner, thus contributing to shorter hospital stays, reduced diagnostic workups, and less chance of readmission within 30 days.
- Lab administration and lab staff fully understand the goals of the parent hospital and the healthcare community it serves. Similarly, the entire lab team understands how value is defined and measured. The lab then uses this knowledge to creatively identify projects where lab data and analysis are a vital component of improving value for the hospital and the health system. Examples are reduction in MRSA outbreaks/cases annually within the hospital or reducing TAT for Troponin from receipt of test order by emergency department staff to delivery of test results to the ER physician.
- Lab has gained recognition as a core competency of its parent hospital

At Level Three, Labs Can 'Go External' to Share Methods, CTQs with Other Hospital Departments

WHEN THE LABS OF A MULTI-HOSPITAL HEALTH SYSTEM are ready to move up the Laboratory Value Pyramid and go from level two to level three, the skills and systems established in the first two levels will form the essential foundation for this effort.

Among the different lab sites within the integrated health system, it is likely that the central lab is farthest along in establishing standards of value. Thus, one of the best ways to contribute added value outside that lab—and grab low-hanging fruit—is to look at all the other labs in the network for opportunities to consolidate, standardize, remove costs, and create value.

By applying what has been learned by the lab team at the central lab facility as it moved through the first two levels of the laboratory value pyramid, that team can easily teach and apply the same principles at the other lab sites in the network.

Remember that, in level one and level two, outside resources were engaged to assist in identifying Critical to Quality parameters (CTQ's) appropriate to that primary lab. Now this same approach can be used to identify the CTQ's for the other lab sites.

This effort should apply today's automated technology, the proper use of integrated middleware, and the true scalability of today's testing platforms with identical reagents across all platform sizes to achieve full and tight integration across all the laboratory sites within the network.

At the same time, it is appropriate to use the knowledge gained in level one and level two to build a business case and plan for the lab network that would include justification of costs and capital investment. Present this business case and an implementation plan to the C suite or senior administration. As these best practice methods and the CTQs are deployed across all the lab sites within the health system, the entire lab network will be on its way to displaying true level three characteristics—while also delivering added value outside the labs themselves.

This is also a good time to consider another way to contribute value. It may be appropriate to suggest to senior administration that the laboratory team be allowed to take the same methodology that enabled the lab network to advance through level one and level two of the value pyramid and to now work with other clinical departments to introduce those same methods into their service offerings.

The justification would be to achieve outcomes similar to what was achieved in the lab network that allowed the labs to establish and meet Standards of Value.

There is an example of an integrated health network in the Mid-Atlantic region, where over three years, this exact scenario played out. After the lab had essentially went through the steps of level one and level two, it then took the outcomes and the learnings from within the lab and worked to share those across multiple hospitals and departments within the health system.

As this happened, the lab became the "incubator and breeder" of process improvement expertise and replicated their methodologies across the enterprise. The cost benefits to the enterprise were over a $1 million per year with the added benefits of improved patient care, improved employee satisfaction and retention, decreased waste, and increased productivity.

or health system specifically because of continuing and numerous examples of where the laboratory has contributed to value creation as defined and measured by the hospital and health system. **TDR**

Achieving CLIA, ISO 15189 at Same Time with A2LA

➤Physicians Choice Laboratory Services is seeking ISO 15189 and CLIA from one source

➤➤CEO SUMMARY: An interesting milestone for the clinical lab industry is on the horizon. Physicians Choice Laboratory Services in South Carolina will soon become one of the first lab organizations in the United States to earn joint CLIA and ISO 15189 accreditations with the American Association of Laboratory Accreditation (A2LA). While it was undergoing ISO 15189 accreditation, the organization began to prepare for CLIA accreditation through A2LA, both for a single price.

FOR THE FIRST TIME, A LAB IN THE UNITED STATES is working toward accreditation to CLIA and ISO 15189 during the same time frame and through the same accrediting body.

This accomplishment is happening at Physicians Choice Laboratory Services (PCLS) of Rock Hill, South Carolina. In December 2014, it was accredited to ISO 15189:2012 and soon, PCLS will receive its additional CLIA accreditation.

PCLS' CLIA accreditation will also be a milestone event for the **American Association for Laboratory Accreditation** (A2LA). That's because it will be one of the first CLIA accreditations issued by A2LA since CMS granted deeming authority to A2LA last year. *(See TDR, April 7, 2014.)*

"PCLS is now the seventh clinical lab and the first toxicology lab in the United States to be accredited to ISO 15189:2012 by A2LA," stated Dinah Myers, PCLS Chief Compliance and Quality Officer. "Achieving the ISO 15189 accreditation is a visible symbol of the quality foundation of this lab.

"PCLS achieved the accreditation after a review of its quality management system and after demonstrating its competence in clinical laboratory testing," she said. "Accreditation to ISO 15189 through A2LA demonstrates our competence to manage and perform the activities defined by A2LA's Scope of Accreditation (A2LA Certificate 3556.01). These activities include clinical testing in chemistry, cytogenetics, and cytology."

➤ISO Brings Many Benefits

According to Myers, multiple benefits resulted from undertaking the ISO accreditation and CLIA certification at almost the same time. "As the quality management system (QMS) of ISO 15189 took root in our lab, it improved communication across all areas and functions of our lab," she noted. "Next, we gained a sharper focus on meeting the needs and requirements of our customers, which is a fundamental goal of the ISO 15189 accreditation. Another big win for us was reduced variation in work processes which reduced variation in analytical results."

PCLS is an esoteric laboratory focusing on customized treatment information for clinicians nationwide. The lab's services improve physician awareness of patient conformance with drug therapy, identify and reduce narcotic diversion, minimize adverse drug reactions, improve women's healthcare, and facilitate personalized patient care through innovative molecular diagnostics and analytical services.

When the lab was founded in 2009, Myers joined the staff after working for more than 20 years under ISO quality standards in consumer labs, testing labs, and calibration labs. PCLS is the first clinical laboratory in her career. Recognizing that all labs produce results as an end product of running processes repeatedly, it was not difficult to transfer what she knew from other labs into the clinical laboratory operations of PCLS, she said.

Standards Compared

"It doesn't matter what field is served by a lab," observed Myers. "What is essential is to identify the processes and the measurable parameters of quality metrics used by the lab team," she explained. "Every lab must meet certain statutory and regulatory requirements, regardless of whether the lab is in the medical industry or other industries. The ISO family of standards requires that the lab meets those compliance and regulatory standards.

"Currently PCLS is CLIA certified by the **College of American Pathologists**," continued Myers. "However, because PCLS was going to be accredited to ISO 15189:2012, it made sense to have A2LA accredit the lab to the CLIA standards as well. Although the requirements are similar, the ISO standard goes much further in terms of its requirements for a quality management system and for the document management system."

In the fall of 2012, the lab began the ISO accreditation process, which took just over one year to complete. "Adopting ISO 15189 introduced its quality management system (QMS) into our lab," she noted. "Also, unlike other accreditations for clinical labs in the United States, only A2LA ISO 15189:2012 is recognized worldwide. PCLS serves physician clients nationwide, but now we can compete internationally because most companies in Europe require ISO accreditation to do business."

PCLS benefited from its adoption of the QMS of ISO 15189 because the QMS allows lab directors and managers to now gain a deeper understanding of their lab's strengths and weaknesses. "For example, the 15189 accreditation process usually uncov-

Earning ISO 15189 while Also Certifying to CLIA

CLINICAL LABORATORIES NOW HAVE a choice when seeking to be accredited to CLIA that includes the ability to simultaneously accredit to ISO 15189:2012.

Last year, the federal Centers for Medicare & Medicaid Services (CMS) approved A2LA to accredit laboratories to the CLIA waived testing requirements. A2LA adopted the guidelines published by the CDC (CS242576-A) related to waived testing. Although A2LA does not accredit laboratories that perform waived testing exclusively, those laboratories that perform non-waived testing in addition to waived testing are eligible for A2LA accreditation, A2LA said.

The decision by CMS meant that A2LA is the only accreditation body in the United States with the following dual recognitions in clinical laboratory testing. It can accredit laboratories under the International Laboratory Accreditation Cooperation (ILAC) accreditation to ISO 15189:2012, and it can accredit labs to the requirements of the Clinical Laboratory Improvement Amendments.

Clinical labs can apply for accreditation to ISO 15189:2012 or CLIA or both. For labs seeking to be accredited to both standards, A2LA offers a service called Platinum Choice, and it has a single price for the dual accreditation and certification to the two standards.

ers two common weaknesses: communication and documentation," noted Myers.

"Throughout the process of becoming accredited to ISO 15189:2012, it became clear that—even though the communication throughout the PCLS laboratory was excellent—we still had room for improvement," she said. "To accomplish this, our lab started at the lowest level of the organization and went right to the top of the organization. At each level, it is important to explain that information must flow both ways. Each individual must understand his or her role in the quality management system and the importance of fully meeting the needs of our lab's customers.

Meeting Customers' Needs

"Understanding your customers' requirements is another lesson learned from the accreditation process," she continued. "One key ISO standard specifies that your lab must meet the requirements of its customers. If your lab can't meet those requirements, then the QMS standard requires you to notify your customers about that inability to meet their needs.

"Most labs have set processes," she stated. "But if those processes don't help the lab to meet customers' requirements, then those processes are inadequate to the job. Many labs, when asked for something by a customer, might typically answer with 'This is the way we do it, and if your request doesn't fit into our processes, then we can't help you.'

"Our lab team learned from this accreditation process that if our processes don't allow us to meet our customers' requirements then it was time to adjust the processes until they support us in meeting our customers' requirements," she said.

"Another lesson we learned was that we have three shifts running every day and every person who performs the same job should perform that job in the same manner," she stated. "We brought the people together who work on alternate shifts so that we could develop best practices and spread them across all shifts.

Factors in Lab's Decision to Accredit to ISO 15189

BASED ON HER EXPERIENCE with testing laboratories in other industries, Dina Myers said that one factor influenced the decision by PCLS to opt for A2LA as its ISO 15189 accrediting body.

"When our team studied the ISO offerings of CAP and A2LA, it believed that there is a significant difference between what A2LA offers and what CAP offers," explained Myers, who is Chief Compliance and Quality Officer at Physicians Choice Laboratory Services. "CAP certifies to its own version of 15189, called CAP 15189.

"By contrast, A2LA accredits to ISO 15189:2012," she continued. "Moreover, A2LA is a signatory of the **International Laboratory Accreditation Cooperation** (ILAC) and A2LA is itself accredited to the requirements of ISO/IEC 17011:2004 Conformity assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. This means that A2LA itself is itself audited and thus must meet this international standard for accrediting bodies.

"There was another factor that influenced this decision," said Myers. "The PCLS team studied CAP's version of 15189 and found that it does not require clients to perform a determination of measurement uncertainty. That is a very important element of ISO 15189:2012, whether you're testing in a calibration lab or in a clinical lab. ISO 15189 states that clinical labs must perform a determination of measurement uncertainty for every analyte."

"In so doing, we eliminated variation in processes, and that allowed us to eliminate variation in our results," added Myers. "This is essential because consistency of work performed is one of the strong points of having a quality management system." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

GeneCentric is a new lab testing company in Durham, North Carolina that was started by former executives of **Laboratory Corporation of America**. It intends to raise $20 million in a Series B capital offering. GeneCentric's business model is to license molecular diagnostic tests, then develop the clinical trial data required to obtain coverage guidelines and reimbursement from payers. Involved in this company are CEO Myla Lai-Goldman, M.D. (formerly Chief Medical officer of LabCorp); Dr. Hawazin Faruki, DrPH, Vice President for Clinical Development (formerly Vice President of Operations at LabCorp); and Christy Marshuetz Ferguson, Ph.D., Vice President of Business Development (formerly Associate Vice President of Corporate Development at LabCorp). LabCorp invested $5 million in GeneCentric as part of its Series A funding.

ADD TO: *Genetic Tests*

There must be strong demand for services to validate the clinical utility of proprietary molecular diagnostic assays. On February 10, **TriCore Reference Laboratories** of Albuquerque, New Mexico, announced formation of the **TriCore Research Institute**. This new business starts with 25 employees and will offer services in clinical trials, biobanking, and development of new assays, including gathering data to support clinical utility of these tests.

SPENDING GROWS FOR COMPANION DIAGNOSTICS

According to analysts at **Kalorama Information** of New York City, the global market for companion diagnostics reached an estimated $1.14 billion in 2013. This was an increase of 25% compared to the estimated total of $910 million for the previous year.

TRANSITIONS

• **The Joint Commission** announced the appointment of John D. Cochran, M.D., FCAP, to the position of Clinical Director of its Laboratory Services Accreditation Program. This is a newly-created position. Cochran will continue to serve at his current position as Laboratory Director for **Pathology Lab of Georgia, LLC**, in Decatur, Georgia.

• Don Larson is now the new CEO for **Incyte Diagnostics** of Spokane, Washington. This is a new position. Larson has held executive positions with **Ameripath** and **Hospital Corporation of America**.

STATEMENT:

In response to a story in the January 5, 2015 edition of THE DARK REPORT entitled, "Phlebotomist Describes Questionable Lab Practices," **Boston Heart Diagnostics** issued the following response:

"We have conducted an internal review of all claims submitted by Boston Heart to third party payers since October 4, 2010. There is not a single instance where we applied 10 ICD-9 codes. We do not partner our services with other laboratories, in particular, HDL and Singulex. We have standard operating procedures in place to educate clients about the high risk and secondary prevention factors appropriate for Boston Heart testing and the corresponding diagnosis codes."

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 9, 2015.

SPECIAL SESSION!

Transforming a System of 28 Hospital Laboratories to Meet Evolving Needs of Integrated, Proactive, and Personalized Healthcare

Sam Terese
President and CEO, Alverno Clinical Laboratories

Learn how a multi-year journey of regionalization and standardization now positions lab to add value!

In healthcare, big is quickly becoming better! One sign of this trend is community hospitals coming together to form health systems and the nation's biggest health systems merging to form mega-systems.

In every case, hospital labs involved in these mergers and ACOs find themselves under pressure to deliver cost savings through regionalization, and standardization. At the same time, such mergers create the opportunities for the labs to deliver more value.

That makes the experience of Alverno Clinical Laboratories all the more useful. It serves 28 hospitals in three states and, in recent years, has effectively regionalized lab services while standardizing test menus, instrumentation, and staff training. Now it is using real-time management dashboards to drive forward with new value-added services that contribute to improved patient outcomes and lower costs. Register now to guarantee your place for this information-packed session!

20 YEARS

It's our 20th Anniversary!

Executive War College

Conference On Laboratory & Pathology Management

UPCOMING...

- ***New Developments in Out-of-Network Billing as More Health Insurers Get Tougher on Labs.***
- ***Billion-dollar Lab Vendor Opens CLIA Lab in China to Tap Demand for Esoteric Testing.***
- ***More Private Practice Pathology Groups Closing, Selling, or Merging Due to Reimbursement Cuts.***