Volume XXI, Number 13 Monday, September 22, 2014

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...

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To Be Paid More, Labs Must Deliver More Value

GETTING PAID FOR LAB TESTS IS BECOMING A MORE URGENT PRIORITY for both clinical laboratories and anatomic pathology groups this year. Multiple factors are responsible for lengthening the collection cycle and reducing overall reimbursement for lab testing.

Clients of THE DARK REPORT have followed our coverage of this development. On one hand, payers are getting tougher. In a change from past years, some payers are simply refusing to pay out-of-network claims—even as they narrow their networks by excluding local labs. On the other hand, both employers and the new health exchanges organized under the Affordable Care Act are enrolling more consumers in high-deductible health plans (HDHPs).

This is problematic for labs because patients covered by an HDHP must meet high annual deductibles, often as much as $5,000 for an individual and $10,000 for a family. Thus, more labs are faced with the need to collect the full cost of lab testing directly from the patient. This is a major reason why clinical labs and pathology groups are seeing substantial increases in patient bad debt.

These developments have raised the stakes for all lab administrators and pathologists. Labs must have the right response to this market shift in laboratory billing and collections in order to sustain themselves financially. What increases the difficulty of this challenge is that fee-for-service reimbursement is on its way out and most lab professionals don't have a clear idea of how labs will be reimbursed in the coming era of integrated healthcare that is delivered by ACOs, medical homes, and similar types of provider organizations.

This is one reason why THE DARK REPORT is introducing the "Laboratory Value Pyramid." *(See pages 10 through 15.)* In coming years, labs will be paid proportional to the value they deliver to physicians, payers, and patients. Such payments are likely to be part of a bundled payment for ambulatory services or in the form of a capitated monthly payment.

The laboratory value pyramid has been created to provide a useful roadmap for lab organizations to move from their current state to the ideal future state where their lab testing services contribute recognized value—and they are paid adequately for this value. In this issue, we explain level one of the four-level lab value pyramid. As the other levels are introduced in coming issues, I invite your feedback and suggestions for how to refine this useful concept. TDR

Wall Street Journal Raises Allegations of Lab Fraud

Some labs doing tests for cardiac biomarkers are subjects of investigation, newspaper says

CEO SUMMARY: Federal investigators are looking into possible violations of the antikickback law by a number of labs offering cardiology tests. The labs under investigation are alleged to have paid physicians processing fees of up to $20 per patient, the Journal reported in a front page story. The labs under scrutiny deny that they violated federal and state antikickback laws. Additionally, there is the potential for federal prosecutors to bring enforcement action against physicians who accepted the processing fees.

THERE'S ANOTHER FEDERAL INVESTIGATION of certain lab business practices and news of this probe generated front page headlines in *The Wall Street Journal*. In a story published on September 8, the newspaper said that at least five lab companies offering cardiac testing services are under investigation for possible violation of the federal antikickback law.

Federal investigators are looking for violations of the antikickback law specifically related to instances where the clinical lab companies were said to have paid physicians to refer patient's blood samples to the labs, reported the *The Wall Street Journal*. Lab companies named by the newspaper were:

- **Health Diagnostic Laboratory** in Richmond, Virginia.
- **Atherotech Diagnostics Inc.** in Birmingham, Alabama.
- **Berkeley HeartLab Inc.**, in Los Angeles, California.
- **Boston Heart Diagnostics Corp.** in Framingham, Massachusetts.
- **Singulex Inc.**, in Alameda, California.

Each of the labs denied the allegations and each said it was cooperating with the investigators, the *Journal* reported.

The issue in question was the payments labs made to physicians above the $3 that Medicare pays for venipuncture, the *WSJ* wrote. The newspaper noted that **Quest Diagnostics Incorporated**, which owns Berkeley HeartLab, said Berkeley ended such payments in 2011 when Quest bought the lab. Atherotech, Boston, HDL, and Singulex all said they stopped making

such payments after the federal Office of Inspector General issued a special fraud alert, "Laboratory Payments to Referring Physicians," on June 25, 2014.

HDL was paying $20 for blood specimens, a fee that included the $3 Medicare fee for venipuncture and $17 that HDL said was for processing and handling of specimens for shipment, the *Journal* reported, citing a memo from HDL CEO Tonya Mallory. The additional $17 covered the costs for storage and maintenance of blood collection supplies, maintaining patient logs, obtaining patient information, labeling vials, filling out shipping forms, cooling, and packaging specimens in biohazard shipping containers, according to an article in *TriCities Business News.*

Payment as Inducement?

Federal investigators could interpret payments such as HDL's $20 processing fee to a physician as an incentive to order unnecessary tests, the *WSJ* reported, citing a former federal prosecutor. In such a circumstance, the allegation of kickbacks turns on whether the money is intended as an inducement to get more patient referrals, the *Journal* explained, again citing the former prosecutor.

On the issue of intent, the fraud alert said: "OIG recognizes that the lawfulness of any particular arrangement under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by the arrangement's characteristics, including its legal structure, its operational safeguards, and the actual conduct of the parties to the arrangement."

A spokesman for HDL told the *Journal* that the $20 fee compensates physicians fairly for the cost of handling and preparing blood specimens for shipment. HDL and the other labs under investigation said the payments were done at fair market value as compensation for handling blood and that such payments are widespread among clinical labs, the *Journal* reported.

The labs also said the special fraud alert represents new guidance on the issue, the newspaper added. Quest Diagnostics said Berkeley stopped making payments to physicians of $7.50 to $11.50 per patient in 2011, when Quest Diagnostics acquired the lab company, the *WSJ* reported. Atherotech, Boston, HDL, and Singulex all said they stopped making such payments after the OIG issued the special fraud alert.

HDL paid some physician practices more than $4,000 per week in fees for blood samples, the *Journal* reported, citing a former HDL employee. In a review of 2010 data from Medicare, the *Journal* reported that HDL's client physicians were referring an average of 3.8 claims per patient. For 12 patients from one Mississippi physician, HDL submitted 140 claims to Medicare and was paid $14,780, the *Journal* wrote.

In addition to reporting on the fees paid for processing and handling specimens, the *WSJ* reported that HDL grew quickly after it was founded in 2008 and had $383 million in revenue last year. Of that amount, $157 million (or 41% of the total) came from Medicare, the *Journal* reported, adding that HDL collected $129 million from Medicare in 2012.

Bundled Cardiac Tests

When HDL performs tests for cardiac biomarkers, the lab may bundle 28 tests together and gets $1,000 or more for some bundles, the *Journal* reported.

When the *WSJ* reviewed Medicare spending for lab tests, it found that—for the nine lab processes that HDL runs—the company received 64% of what Medicare spent nationwide on those same lab processes, reported the newspaper.

For a process used to separate blood particles with an electric charge, HDL billed Medicare 262,308 times and collected $11.9 million in 2012, wrote the newspaper. That amount represented 93% of the total Medicare spent on that blood-separation process in 2012, the *Journal* wrote. By contrast, adding together what 35 other labs that use the same process

Ex-Berkeley HeartLab Executives Founded HDL, Upped Ante with More 'Processing Fees' to Docs

SINCE ITS FOUNDING IN 2008, Health Diagnostic Laboratory of Richmond, Virginia, has gotten plenty of attention because of its rapid growth. According to a recent story in *The Wall Street Journal*, the lab company had revenue of $383 million in 2013, just five years after its launch.

But the back story has gotten much less attention. As reported by the *WSJ* in its September 8 front-page story, some principals of HDL were former employees of Berkeley HeartLab, currently based in Los Angeles, California. The *Journal* wrote that Tonya Mallory, HDL's CEO, "was Berkeley's senior lab-operations manager in 2008 when she left to found HDL in Richmond, Va. Two Berkeley sales representatives, Cal Dent and Brad Johnson, later left to form **BlueWave Healthcare Consultants Inc.**, which became HDL's independent sales-and-marketing contractor."

Knowledgeable observers tell THE DARK REPORT that, while Berkeley HeartLab was paying referring physicians a processing fee of up to $11.50 per patient, Mallory and her executive team decided to up that amount and were paying referring physicians a processing fee of as much as $20.

Cal Dent and Brad Johnson are rumored to have played a key role in this arrangement. Also former employees of Berkeley HeartLab, they are believed to have formed BlueWave Healthcare Consultants as a way to circumvent any non-compete agreements they had with Berkeley Heartlab. This allowed them to immediately go to work on behalf of Mallory and HDL.

However, Berkeley HeartLab took action after the departure of its employees. The *WSJ* wrote that "Berkeley sued HDL, accusing it of stealing Berkeley's business after some doctors switched to ordering tests from HDL. In court filings, HDL denied the allegations. It settled the case for about $7 million, Celera said in 2010. Berkeley and HDL sued each other in 2011 and settled those suits under undisclosed terms. The companies declined to comment on the litigation."

charged Medicare, the *Journal* said these 35 labs billed Medicare for the process 19,621 times and collected $850,000.

Another element of the federal investigation could eventually ensnare physicians who accepted processing fees from the labs under scrutiny and may have ordered medically unnecessary tests. The *WSJ* wrote that "Some doctors stood out for heavy use of HDL's services in 2010 Medicare data. The data, which the *Journal* obtained for a fee, include reimbursement claims for a random 5% sample of Medicare patients and are the most recent the *Journal* could obtain showing individual patient billings."

The newspaper reported that "in that sampling, Charles 'Sam' Fillingane was the most prolific test prescriber among 296 doctors who referred patients to HDL. HDL submitted 140 Medicare claims in 2010 for the 12 patients in the sample referred by the Flowood, Mississippi, family practitioner—11.7 claims per patient. HDL collected $14,780 from Medicare for those 140 claims. Doctors in the HDL sampling averaged 3.8 claims per patient."

The *Journal* went on to report that Dr. Fillingane "sent HDL 1,179 blood samples in 2010's first half, which would have earned him $23,580 in [processing] fees."

Given the recent precedent of federal criminal prosecutions of physicians in the case of **Biodiagnostic Laboratories** of Parsippany, New Jersey, the potential exists for this federal investigation to result in prosecutions against some lab company executives and certain doctors who accepted the processing fees. **TDR**

—Joseph Burns

Did Labs Rip Off Medicare? Feds Are Investigating

➤News of federal investigation into practices of certain cardiology testing firms is an opportunity

➤➤CEO SUMMARY: One reason why there is not a level playing field in lab industry compliance with laws governing kickbacks and anti-business behavior is that government officials do not act quickly against the lab industry's worst offenders—if they take any action at all. News of a federal investigation into the payment of processing fees to physicians by a handful of laboratory companies offering cardiology testing is an opportunity for federal prosecutors to send the right message to the laboratory industry's bad players.

By Robert L. Michel

ONE OF THE GREAT DIVIDES in the laboratory medicine profession exists between hospital-based clinical laboratories and some independent lab companies.

Consistently, the attorneys representing hospital-based laboratories will interpret federal and state laws and regulations in a conservative fashion. Consequently, the sales, marketing, and business development programs of hospital-based laboratories are rarely the targets of investigations by federal and state prosecutors.

Over on the independent lab company side of this schism, it needs to be said that there are indeed a substantial number of lab companies that take a similarly conservative position in their compliance with federal and state laws. Few of these lab companies ever find themselves investigated for possible violations of these laws because of their sales and marketing practices.

Unfortunately, the same cannot be said for a certain group of independent lab companies. In these lab firms, executives are ready to push their interpretation of federal and state laws governing inducements, kickbacks, and anti-business behavior. They justify these interpretations by paying law firms to provide opinions that support their aggressive reading of these laws and regulations.

➤Reluctance Of Investigators

This inclination of certain independent lab company executives to develop sales, marketing, and business development schemes that push right to the boundary—and often cross the line—of compliance is generally based on their confidence that federal and state prosecutors will be unwilling to investigate the case, file charges, and seek full recoupment.

These lab executives believe that, even when federal prosecutors take action against such a lab company, the final settlement will be a civil settlement where the government only recovers a portion of the profits generated by the offending laboratory. Further, with a civil settlement, they are confident that they won't be indicted and face the

expense and risk of a court trial for their actions. (Actions not taken by the overwhelming majority of lab professionals.)

It is important to recognize this schism that exists within the clinical laboratory industry. At any point in time, it is usually a new generation of miscreants who enter the lab testing business. Because they are willing to push and cross compliance boundaries, they gain immense competitive advantage. Often, the revenue growth and profits their illegal sales schemes generate is astonishing.

Latest Revelations

This is the reality of the clinical laboratory industry since the 1980s. Thus, the latest revelations of a sales scheme that was the subject of a front page exposé in *The Wall Street Journal* on September 8 demonstrate that there continue to be lab executives who want to push compliance boundaries in order to gain competitive advantage over other labs.

In its coverage, the *WSJ* reported that federal investigators are looking into the business practices of a handful of lab companies offering cardiology tests. These companies are alleged to have violated federal and state antikickback laws because they paid a processing fee each time a physician referred lab tests to them.

On pages 3-5, THE DARK REPORT provided details about the *Journal's* coverage of this development. What I would like to point out is how quickly such an alleged fraud can grow in the absence of appropriate regulation and enforcement action by federal and state authorities.

The *WSJ* reported that, in 2013, **Health Diagnostics Laboratory** of Richmond, Virginia, generated revenues of $383 million. Assume, for the moment, that three of the other four cardiology lab companies identified by the newspaper (**Atherotech Diagnostics Inc.**; **Boston Heart Diagnostics Corp.**; and **Singulex Inc.**) generated about $120 million in collective revenue in 2013.

Each of these companies is alleged to have paid processing fees to physicians to recompense them for handling lab specimens. This is one of the practices that the *WSJ* reported as under federal investigation (as well as the subject of an OIG Advisory Opinion issued in June 2014).

If you add up the $383 million and the $120 million, this totals more than $500 million in cardiology testing in one year for these four lab companies! It means these four lab companies took one-half billion dollars out of the healthcare system in just one year!

Federal prosecutors have good reason to believe that some proportion of these cardiology tests were medically unnecessary—ordered by physicians who might have been motivated to maximize the processing fees paid by these four labs.

Meanwhile, all of you reading this probably follow the classic adage that "if it walks like a duck, quacks like a duck, and looks like a duck, it probably is a duck."

Thus, why would only this handful of labs consider payment of a processing fee to referring physicians compliant with federal and state laws, when thousands of peer lab organizations in this nation do not? Moreover, these thousands of labs have lost physician clients and test referrals to this handful of labs that were willing, as described by the *WSJ*, to pay such processing fees to physicians in exchange for lab test referrals.

Opportunity For Feds

This is why federal prosecutors have the opportunity to send a message to the lab industry's bad players. As they review the evidence—and consider the huge dollars of this alleged multi-year fraud—they should hit offenders with all the remedies allowed by law, to the fullest extent. This should include all the physicians who were willing to accept processing fees and who ordered medically-unnecessary tests on their patients. Only when the lab companies, lab executives, and physicians are prosecuted with the full weight of federal law will we see a decline in the number of these schemes that plague the lab industry. TDR

Legal Update

Aetna Files Suit Against NJ Lab, Plans to Sue Two More Labs

By the end of October, insurer says it plans to file legal complaints alleging other labs committed fraud

FINALLY, A MAJOR HEALTH INSURER IS taking a hard line against clinical laboratories it suspects of committing fraud. **Aetna Health, Inc.**, and **Aetna Life Insurance Company**, of Hartford, Connecticut, have sued one lab company and included physicians as defendants in that case. Aetna officials indicate that other lawsuits against labs can be expected.

At a minimum, the filing of this case should put both clinical labs and physicians on notice that there are consequences from participating in schemes involving inducements and kickbacks that violate federal and state laws.

In July, Aetna filed a civil suit against **Biodiagnostic Laboratory Services, LLC**, of Parsippany, New Jersey, seeking $15 million in damages. In the suit filed in New Jersey Superior Court in Camden, Aetna listed Biodiagnostic Lab and at least 100 individual referring physicians and at least 100 companies as defendants. Aetna said they conspired to submit false and fraudulent insurance claims to Aetna.

Aetna's legal move follows the successful prosecution of BLS by the U.S attorney in New Jersey. In that case, more than 29 individuals, including 14 referring physicians, have already pled guilty in federal court in Newark to paying or accepting bribes to refer patients to BLS for unnecessary and inflated tests, the court records show.

In an interview with THE DARK REPORT, Ed Neugebauer, the head of litigation for Aetna, Inc., said the health insurer would bring civil suits against at least two other clinical laboratories by the end of October. "There are several labs we're currently looking at," he said. "Probably before Halloween we're going to have a couple more cases against labs that we will bring to court."

One common type of fraud involves getting referrals for clinical laboratory testing by offering some form of payment to referring physicians. The case against Biodiagnostic Laboratory Services involved this type of fraud, noted Neugebauer. "We find that providers will pick an insurer and try to maximize their revenue from that payer. When the strategy is successful, they just keep doing it."

Cash for Referrals

According to Aetna's suit against BLS, the fraud started at least eight years ago. "Beginning at least as early as 2006, BLS bribed physicians and medical practices with illegal kickbacks in the form of cash payments and other remuneration in order to induce them to refer Aetna members to BLS," the court documents show. "BLS then misrepresented its actual charges for services, double-billed for the same services and violated the disclosure requirements of CLIA.

"BLS coupled its bribery with a policy of waiving patient financial responsibility to induce the physicians, medical practices, and patients to consent to the referrals in order to assure its access to the Aetna member base, said documents filed with the

court, also stating, "The financial inducements were concealed under the guise of facility use and services agreements that put money in the hands of physicians solely to reward them for directing patients to BLS."

For clinical laboratories, one important factor in this case is that Aetna not only filed the complaint against BLS and the lab's owners, David Nicoll, Susan Nicoll, and Robert Kerekes, but also against 14 named physicians and against 100 unnamed physicians, known as "Defendants John Does" in the court papers and 100 unnamed corporations known as "Defendants ABC Corporations."

Claims Against Defendants

The defendants offered, paid, and accepted referral fees and other remuneration through facility use agreements to induce referrals of patients who were Aetna members, the court documents show. In so doing, the defendants violated New Jersey's Commercial Bribery Statute, according to records.

Aetna paid the defendants more than $9 million for false and fraudulent claims submitted to Aetna. The defendants submitted multiple claims for some services, claims for unnecessary services, and double billed for some services. Defendants also waived more than $5.4 million in deductibles and coinsurance to induce members to use BLS services, the court records show.

Patient Billing Policy

An interesting aspect of Aetna's lawsuit against Biodiagnostic Laboratory services involves the lab's statements to physicians that it would not bill patients. In the federal investigation against **Health Diagnostic Laboratories** *(see pages 3-7)*, there is evidence that this lab company also told physicians that it would not bill patients. Such actions are not consistent with compliance requirements and payer contracts with doctors and labs. TDR

—Joseph Burns

Could Aetna's Lawsuit Encourage Similar Suits?

ONE REASON WHY ILLEGAL SCHEMES designed to transfer money to physicians in exchange for lab test referrals continue to be seen regularly in the marketplace is the lack of effective enforcement by government regulators and what has seemed to be a hands-off attitude by private payers.

Thus, it may be a significant development that Aetna has filed a lawsuit against the principals of Biodiagnostic Laboratory Services and certain physicians who accepted money from BLS in arrangements that the U.S. Attorney from New Jersey determined to have violated federal antikickback laws.

Aetna does have a legal road map it can follow because of the federal prosecutions of BLS and certain physicians who participated in these inducement schemes. As well, substantial money is at stake.

It was reported that, in its short business life of seven years (2006-2013,) Biodiagnostics pulled in revenue of more than $200 million and its president personally took $33 million in cash distributions out of the lab company during that time. This shows the magnitude of the fraud, because private insurers were billed, along with the Medicare and Medicaid programs.

How is it possible for scamster lab companies to grow into multi-hundred-million-dollar businesses in just a few short years? The simple reason is that private health insurers and the government Medicare and Medicaid programs are not good at watching incoming claims and identifying patterns consistent with fraud and abuse in real time.

Further, once such fraud is uncovered, the culprits often face few legal consequences for their actions. Thus, Aetna's legal action against BLS and certain physicians—on the heels of the federal criminal prosecutions—should encourage law-abiding pathologists and lab leaders everywhere.

CEO SUMMARY: With the American healthcare system undergoing a major transformation, it is essential that all clinical laboratories and pathology groups recognize this transformation and effect the right strategies to meet the needs of physicians, patients, and payers. A group of lab collaborators proposes a four-level laboratory value pyramid as an effective roadmap to guide labs from their current state to a future state that delivers the right value to stakeholders.

Introducing the concept of a universal 'Laboratory Value Pyramid'

Defining a Path to Clinical Lab Best-in-Class via Benchmarks

Part One of a Series

ACCEPT THE PREMISE that healthcare in America is at a significant, once-in-a-lifetime crossroads, then it is logical to assert that the clinical laboratory profession is at an equally significant once-in-a-lifetime crossroads of its own.

After all, clinical laboratories serve every type of provider, such as hospitals, physicians, and nursing homes, to name a few. Given the transformation now happening to the health system, it is necessary for clinical labs to shift their operations and clinical service orientation so as to meet the changing diagnostic needs of providers.

"Once-in-a-lifetime" certainly describes three major paradigm changes happening in healthcare and medicine:

- Healthcare is transforming from a reactive medical service to a proactive medical service. *(Keep patients well and keep patients out of hospitals.)*
- Healthcare is transitioning from primarily fee-for-service reimbursement to primarily value-based and budgeted payment. *(Change how an organization is paid and you change how it organizes to deliver its services.)*
- Healthcare is moving away from medicine based on the average (as determined in clinical studies) to "personalized medicine" and "precision medicine" as new knowledge in the fields of genetics, proteomics, metabolomics, and microbiomics are swiftly incorporated into daily medical practice. *(Labs will perform tests that allow physicians to identify and understand the elements of health and disease that are unique to their individual patients.)*

With the healthcare world as we know it now undergoing these fundamental changes to long-standing paradigms, it is no surprise that hospitals and physicians are responding in a variety of ways. For example, physicians are selling their medical practices to hospitals, health systems, and insurers and becoming employees. Similarly, hospitals and health systems are consolidating in cities across the United States by creating ever larger and more deeply-integrated health delivery organizations.

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?

Although forecasting the future is an imprecise science, it is relatively simple to assess current developments in the healthcare and lab testing marketplaces. These insights can then guide the strategic direction of clinical labs and pathology groups.

On this point, THE DARK REPORT is working at a strategic level to identify what attributes of a lab organization will make it successful going forward. Collaborators in this effort include a veteran lab industry executive and a team within a major *in vitro* diagnostics company.

Working At A Strategic Level

Since the lab industry lacks a true think tank like the **Rand Institute** or the **Battelle Memorial Institute**, innovative thinking in laboratory medicine will spring from guerilla initiatives like the collaboration described above.

What is emerging from this work is a framework for how labs should organize themselves to be responsive to medicine's new paradigms in patient care, reimbursement, precision medicine, and genetic/molecular medicine. This framework is grounded in the common attributes seen today by best-of-class labs, particularly those labs owned and operated by the nation's most progressive hospitals and health systems.

What THE DARK REPORT will present in this series is the concept of a value pyramid for laboratory organizations. It has four levels and is intended to guide the administrative team and the lab staff in moving their lab organization from its existing current state (today's healthcare reality) to an ideal

future state offering laboratory testing services that deliver the added value expected by providers in the transformed healthcare system.

Defining A Vision For Labs

The goal of this four-level pyramid is to give the strategic leaders of lab organizations a vision and an ideal that can be attained by their lab team. Of equal importance, this vision and ideal will complement the future state of the providers served by the lab. This is essential because labs undergoing their transformation need the full support of the parent hospital or organization.

One challenge is to give this lab performance pyramid a name that accurately communicates what it represents. Given the fact that this is a guerilla effort and that input will be forthcoming from many different collaborators in coming months, THE DARK REPORT will suggest this as a preliminary working name: "Laboratory Value Pyramid."

Yes, we agree it is not imaginative, but it does call attention to the core element of tomorrow's healthcare system: success for any provider will require it to deliver recognizable value to clinicians, to patients, and to payers. This will be as true for clinical labs and pathology groups as it will be for office-based physicians and hospitals.

Moving Past Cost Basis

This philosophy is different from the cost-based laboratory mindset that dominates in many lab organizations today. Remember the insight of W. Edwards Deming, a seminal thinker in modern quality management. He said that only the customer can define quality (and value). Thus, it is necessary for an organization to regularly ask its customers to define quality, then use that information to develop services that add value and meet (and exceed) the expectations of its customers.

Our proposed Laboratory Value Pyramid is intended to be consistent with Deming's concept of quality and value. The pyramid provides lab managers with a framework to move from a traditional model of lab management and operations that is in common use today to the desired future state.

In this series, THE DARK REPORT will present each level of the 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.

Universal Concepts

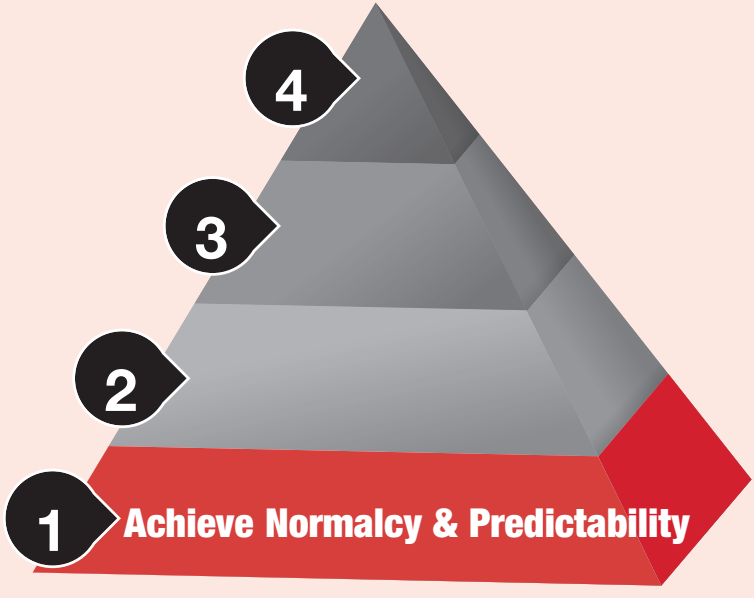
Keep in mind that the Laboratory Value Pyramid represents abstract concepts that we believe to be universal. The collaborators on this project recognize the difficulty in describing these abstract concepts so that everyone "gets the picture" and shares a common understanding of the characteristics and attributes that would be true of each laboratory that progresses from level one of the pyramid to level four.

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 externally to physicians, patients, and payers while, as part of this journey, achieving "best in class" in its operations and service delivery.

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

(See page 14 for description of level one.)

Introducing the Laboratory Value Pyramid



Understanding Level 1:
Achieve Normalcy & Predictability

One primary purpose of the laboratory value pyramid is to provide a step-by-step process by which any laboratory can assess its current state, then, in a deliberate manner, work to evolve into a "best practices" organization that is justified because the lab's metrics can be benchmarked favorably against world class labs. Level one represents the foundation for the lab's journey to excellence. Level one emphasizes bringing work processes under control, establishing the needed real-time metrics, and establishing the culture of change and continuous improvement with the lab staff that is necessary for the lab to move to the higher levels of the lab-

- Shift the lab organization away from system of inspection and adopt the system of prevention.
- Shift to a system that incorporates real-time, visible performance metrics of lab processes alongside traditional QC data.
- Shift to the mindset of continuous improvement.
- Shift to a culture that regularly engages outside experts to help lab staff understand key issues and develop appropriate solutions for further improvement throughout the lab.

Level One: (Lab Focus Is Internal)
Achieve Normalcy & Predictability

IN THE LAB VALUE PYRAMID, no laboratory can deliver exceptional value to external customers and users until it has its internal house in order. That is why level one and level two of the four-level pyramid concentrate on the internal performance of the lab organization.

What will be true of the lab value pyramid at all four levels is that it incorporates the concepts of quality management as found in the world's top-performing corporations and organizations. Lab leaders should familiarize themselves with these concepts in preparation for guiding their lab through the four progressive levels of the lab performance pyramid.

➤Planning The Transition

This is a necessary step to prepare a laboratory to meet healthcare's once-in-a-lifetime transition into new paradigms of medicine and care delivery. Senior administrators must be prepared to help lab staff understand and accept the fact that continuing to operate a lab with the management models of the 1970s, 1980s, and 1990s is to handicap that lab from achieving its full potential—while putting it at high risk of failure, meaning bankruptcy or merger into a stronger lab organization somewhere down the road.

The point here is every laboratory organization is at a true crossroads. Success is dependent on choosing the correct road. The path of the laboratory value pyramid is one choice that offers the highest potential for clinical success and financial stability going forward.

With this introduction, we can move forward with the description of level one. To achieve success in meeting the characteristics of a level-one lab, the organization must achieve a constant state of normalcy and predictability.

The end state for level one of the value pyramid is achieved when the lab organization can show its:

- shift from system of detection/failure to system of prevention.
- shift to a system that incorporates real-time, visible lab process performance metrics alongside traditional QC data.
- shift from a state of "don't fix it till it breaks" mindset by both employees and administration to the mindset of continuous improvement.
- shift to a culture that is open to engaging outside subject matter experts to help understand how lab test data is used by clinicians and healthcare stakeholders, then contribute to using this knowledge to improve the value of this lab information to end users.

These four attributes or characteristics are a starting point for describing a laboratory organization that has achieved level one of the laboratory value pyramid.

As one collaborator on this project said, "You will know when you are competent at this level when your lab: a) performs according to your panel of specifications 95% of the time or greater; b) when you have a growing list of identified improvement projects that happen regularly; and, c) when you know how and where your data is being stored and how it can be accessed and analyzed."

➤Recognizing Level One

Keep in mind that the goal here is to describe, in a clear objective manner, the attributes of a lab that has achieved normalcy and predictability. By meeting that goal, it becomes easy for anyone—inside the lab or outside the lab—to recognize normalcy and predicability as they observe the lab's daily performance of its operational requirements and clinical services.

More Detailed Descriptions about the Attributes of a Laboratory Working to Achieve Level One

TO PROVIDE FURTHER INSIGHT into the recognizable attributes of a level one laboratory, the collaborators offer the following general points.

One example of a system of prevention mindset involves the lab consciously aligning itself with instrument suppliers that have remote monitoring of critical performance parameters. These suppliers can predict when an instrument will go down or will need adjustment. This capability allows them to dispatch a service tech to fix or adjust the instrument before failure occurs, consistent with a system of prevention.

Next, the lab's transition to a system that incorporates real-time, visible process performance metrics alongside traditional QC data requires several elements. First, the lab's process performance metrics are accessible in real time, as are the traditional QC data.

Second, the lab regularly engages subject matter experts (SME's) in lab process control and has these experts work with lab staff to identify and establish a core group of performance metrics unique to that lab's successful operation. These metrics establish baseline performance and set expectations.

Third, the lab fully characterizes each metric and develops a real-time visible tracking process. Such tracking could include dashboards on mobile device apps, digital display boards throughout the lab, red/yellow/green lights on specific instrument modules, and other methods.

During its transition away from an employee/management mindset of "don't fix it till it breaks" to the continuous improvement mindset, the lab will be seen to involve employees in daily huddles to review performance metrics from the last 24 hours. These same employees are empowered to make the improvements required to keep things running to specifications.

Another element of continuous improvement is that lab managers at all levels engage employees in Lean and Kaizen events that produce immediate improvement. This activity is always visible and is rewarded in positive ways.

The fourth attribute is regular and open access to subject matter experts to directly support the lab staff in achieving and surpassing goals. In preparation for the lab's move to higher levels in the laboratory value pyramid, one particularly important use of SMEs is in how the lab's end product—lab test results—is stored, managed, retrieved, and utilized in support of improved patient outcomes and cost-efficient clinical care.

Self-assessment of the lab's performance is based on multiple factors: a) achievement of the key metrics 95% of the time; b) a growing list of improvement projects within the laboratory that are successfully implemented; and, c) the lab team knows how and where lab test data is stored and, of equal importance, how it can be accessed and analyzed in support of the lab's creation of more value for all its stakeholders.

To help better describe the attributes of a laboratory that has achieved normalcy and predicability, one collaborator included the following:

- Staff in the lab have an unmistakable positive attitude toward change.
- Lab staff are aligned with the vision and with a set of measurable objectives defining quality and performance.
- Entire lab operates with full accountability for individual and collective achievement in meeting or exceeding the metrics that validate normalcy.

The next three levels of the lab value pyramid will be presented in future issues. All comments are welcome! **TDR**

Contact Robert L. Michel at 512-264-7103 or rmichel@darkreport.com.

Letter to the Editor

Pathologist Raises Questions about Theranos' Business Model

Dear Editor:

I read your two articles on **Theranos** in the August 11 issue of THE DARK REPORT, and concur in large part with your thoughtful conclusions.

For several years, I have closely followed Theranos and have been quoted in trade publications speaking favorably on Theranos and its relationship with **Walgreens**. Originally, I was attracted to the potentially disruptive model based on knowledge of the industry and the following representations of the two companies:

1) Theranos manufactures an analyzer which can rapidly measure the common analytes ordered by physicians for outpatient visits.
2) The analysis can occur on a small amount of blood, between 25 to 50 microliters.
3) The analysis could be done in up to 8,200 existing retail locations (Walgreens) almost in real time
4) The company can be profitable charging and collecting a price equal to half that of Medicare.

Unique Business Model

Under this business plan, I envisioned that a physician would order lab tests for patients and the lab orders could be electronically sent to a nearby Walgreens (as prescriptions are now). The patients could walk into the Walgreens pharmacy, identify themselves and display the lab test order with a mobile app (like at **Starbucks**). After Theranos collected the specimen, the patient and the doctor could get the lab results quickly.

For tests like INR, glucose, HgbA1c, and cholesterol, the cash cost of the test might be comparable to a copay. (Examples are: Prothrombin time with INR=$2.70, fasting glucose=$2.70, cholesterol=$2.99, HgA1c=$6.67). The convenience to the consumer—as with flu shots—is a value that empowered consumers would find desirable and for which they would pay.

Major Threat To Labs?

Such a model would be obviously disruptive to commercial outpatient laboratories. That's because these labs have less favorable business hours, higher personnel costs for collections, higher space costs, and slower services. Depending on the scope of the menu, the degree of disruption could be sufficiently large to be a major threat to the routine outpatient services of commercial laboratories.

Unfortunately, the business model I described above—emphasizing routine lab tests—does not appear to match the Theranos/Walgreens service as described by Editor Robert Michel when he visited a Walgreens in Palo Alto to have Theranos perform some clinical laboratory tests. *(See TDR, August 11, 2014.)*

Rather, Theranos appears to have moved from its stated goal of being a rapid provider of routine tests to something that already exists today: a centralized lab provider of a couple of hundred tests for outpatient care, acute care, and specialized care.

Originally, it was implied that the samples would be analyzed onsite at Walgreens. Theranos recently stated on its website, and I quote: "Our proprietary infrastructure allows us to perform our test analyses with unprecedented speed. So we can have results to you and your doctor in a matter of

hours, not days. Which means a fast diagnosis to support better, more informed treatment."

But, in reality, today Theranos does not provide a faster service because Theranos centers at Walgreens are just draw stations, not laboratories. At the current time, all samples are sent to its central CLIA lab in Palo Alto. Turnaround time, (I called two Walgreens in Phoenix and Theranos itself this past July) is at least 24 hours. Theranos plans a second CLIA laboratory site in Arizona, but that doesn't substantially change the service it delivers.

In other words, the lab is not providing a better service than, say, **Enzo** (where I used to work), **BioReference**, with whom we competed, or many other laboratories, which endeavor to get all results to the doctor by 8 A.M. the next morning. Additionally, unless it has the same in-network insurance contracts in Arizona as **Sonora Quest Laboratories**, it would seem Theranos is unlikely to be competitive for insured patients in that state.

Regulatory Issues

As best as I can determine at the moment (and assuming that its instruments measure what they are supposed to measure), Theranos seems to have realized that it faces significant regulatory issues were it to put its instruments into 8,200 Walgreens pharmacies—although the company claims a point-of-care instrument is in development.

I see no way it could skirt the FDA and run those sites as independent CLIA labs with LDTs, as it now does in Palo Alto. It would have to get FDA approval, either as IVD assays to be used in CLIA labs, or as waived tests done in sites with CLIA waivers. Moreover, Theranos would need site directors and appropriately-trained lab personnel at each of those 8,200 sites. Either approach would be time-consuming and costly.

Further complicating the issue, the entire menu of tests Theranos wishes to offer to patients would need to be approved at launch in order to implement the rapid on-site lab testing model described above.

Hub-And-Spoke Lab Model

As it operates today, it appears that Theranos has moved to a typical hub-and-spoke model with minimal advantages and several disadvantages compared with competing labs. The use of drug stores for draw locations is uncommon, not the least because the space devoted to phlebotomy does not generate revenue comparable to other retail uses for that square footage.

Next, the use of finger sticks instead of venipuncture is not a benefit if many patients require venipuncture anyway (as was the experience of editor Robert Michel). As well, Theranos currently does not provide the full menu of tests that commercial labs offer.

Nor does Theranos apparently take on the burden of drawing and sending out lab tests that they don't perform in-house. In the New York area, no lab would survive if it had patients go to second laboratory for a second draw in order to complete a routine order, as was required in editor Michel's example.

There are two communities following Theranos. One is the traditional lab testing community. The other is made up of professional investors and financial analysts. Both communities have several outstanding questions.

Questions About Technology

For example, how much lab testing from its current menu of 219 assays is being done with technology that is unique and proprietary to Theranos? Alternatively, how much existing testing is done using standard diagnostic technologies for which Theranos has no specific advantage? How many of these tests does it currently perform in-house?

Such tests as ABO/RHD blood typing, CBC with reflex, ESR, Occult Blood, Platelet Count, Prothrombin Time, Stool

Culture, and Urinalysis would most likely use standard and established techniques. It would be hard to imagine validating non-FDA approved procedures for these tests.

Collecting Lab Specimens

Theranos does not have an obvious collection mechanism for collecting specimens for *Chlamydia* and *Gonorrhea*, or for urine and stool collections. Does it really have a unique respiratory virus panel, or is it offering the panels developed by such companies as **Biofire**, **Luminex**, or **Genmark**?

Does Theranos have its own LDTs in place of molecular tests for HIV, HCV, and HBV? Or does Theranos use **Roche** or **Abbott** test kits, like most every other lab? Does Theranos actually run its extensive menu of endocrinology, tumor markers, serology, rheumatology, and toxicology on proprietary platforms? Or, like most every other lab, does it use a complex and cumbersome cluster of analyzers and instrument systems that are needed to provide reliable results for clinical purposes?

I estimate that the current Theranos test menu includes about 95% of the tests, by value, of a typical regional laboratory (i.e, not including genetics, cancer diagnostics, anatomic pathology, and cytology with associated molecular tests). I would be very skeptical, until proven otherwise, that Theranos currently has a significant competitive advantage for the majority of these types of lab tests.

Small Device For Lab Testing

It was initially plausible that Theranos might design a platform to do say, 40 routine analytes using small sample volumes on a simple device. In this case, such a proprietary device might supercede the Piccolo Express (the chemistry analyzer sold by **Abaxis, Inc.**) or the i-Stat (the hand-held point-of-care device sold by **Abbott Laboratories**) on ease of use, test menu, and price. However, keep in mind that such a business model would face the same types of regulatory and reimbursement challenges faced by the manufacturers and users of those devices.

It would be a remarkable *tour de force* if Theranos has technologies that could simplify clinical laboratory testing and reduce costs for the majority of the tests it now offers. Many trained laboratory scientists and pathologists with whom I speak are skeptical that Theranos, as of today, is doing such testing on their proprietary platform, as it claims.

Given these observations, Theranos does have one factor that works in its favor: This is the general belief by many smart people that Theranos "can't be making it up." Obviously, I have no better idea about this as any other outsider. Having said that, it is always useful to remind oneself that "if it sounds too good to be true," it probably is!

Prices Less Than Medicare

My only disagreement with the information presented by THE DARK REPORT is your skepticism that Theranos can be profitable charging just 50% of Medicare Part B clinical laboratory test prices. This is not a problem that is unique to Theranos. My understanding is that commercial laboratories are being presented with payment schedules from health insurers at rates less than that.

In fact, some capitated contracts may pay as little as 10% to 20% of Medicare Part B Prices for certain high-volume tests. Given the potential for Congress and CMS to enact deep cuts to lab test fees over the next seven years, we may end up considering a cash price that is 50% of today's Medicare rates to be quite desirable.

Yours truly,

Robert J. Boorstein, M.D., Ph.D.

Editor: *Robert J. Boorstein M.D., Ph.D., is the founder of the* ***ClasGroup Company****, a pathology consultancy, and provides molecular pathology services for regional laboratories in the New York metropolitan area. Contact him at rjboorstein@yahoo.com.* TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Did you know that the world's longest automation track in a clinical laboratory has just become operational in India? At 93.5 meters (307 feet), it is longer than a football field, according to a press release issued by **Siemens Diagnostics**. The automation was installed at the central lab of **Thyrocare Technologies** in Mumbai, India. The lab company says it handles more than 30,000 specimens daily and that the capacity of this automated line is 200,000 tests per day.

MORE ON: *Thyrocare*

Thyrocare purchased the Siemens Aptos lab automation system. The press release stated that "it has 31 instruments (24 Advia Centaur XP Immunoassay systems and 7 Advia 2400 Chemistry systems) docked to the track, [along with] 10 rack loading–unloading robots and 5 decappers." The scale of this lab automation project is one sign of robust growth in the clinical laboratory testing market in this populous nation of 1.3 billion people.

PARTNERS HEALTH, SUNQUEST CREATE JOINT VENTURE

In response to the fast-moving advances in gene-sequencing and genetic medicine, **Partners Healthcare** and **Sunquest Information Systems** announced a strategic alliance. The two organizations will collaborate to develop "a next generation genomic information system and knowledge base that will speed the advent of precision medicine." In the press release, Jeff Golden, M.D., Chairman, Department of Pathology, **Brigham and Women's Hospital**, noted that "There is a need for a single, complete and seamless laboratory information system that combines both a strong genomic IT platform with an anatomic pathology and clinical pathology platform."

TRANSITIONS

• Todd G. Johnson was appointed as President and CEO by **LABS, Inc.**, of Centennial, Colorado. Previously, Johnson held executive positions at **Pathway Genomics**, **Biocept**, **Insight Health**, **Laboratory Corporation of America**, **Ventana Medical Systems**, and **Abbott Diagnostics**.

• Charles A. Parkos, M.D., Ph.D., was appointed Chair of Pathology at the **University of Michigan Medical School**, effective September 15. Parkos came to Michigan from **Emory University**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 13, 2014.