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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...

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Founder & Publisher

LabCorp Loses A Hospital Lab Joint Venture

ONE OF THE NATION'S LONGEST-RUNNING LAB OUTREACH JOINT VENTURES involving a public lab company and a major hospital came to a quiet end on June 30. That's the day when **United/Dynacare Laboratories, LLC**, ceased to exist.

This was a joint venture in Milwaukee that was established in 1997 by 550-bed **Froedtert Hospital** and **Dynacare, Inc.**, then a public lab company. In 2004, Dynacare was acquired by **Laboratory Corporation of America.**, which then continued as a partner in the lab outreach joint venture. Neither party has commented publicly on the termination of the JV. It is not known whether any money was paid by one party to the other as part of the division of assets, including the lab facility, equipment, and client book of business.

Froedtert Hospital and a yet-to-be-named partner will continue to operate the existing laboratory outreach business. Since July 1, it has operated as **Wisconsin Medical Laboratories**. It is believed that LabCorp does not have a non-compete as part of the terms of the JV's dissolution. That could mean a competitive sales battle may be about to commence in the Milwaukee regional market between LabCorp and Wisconsin Medical Laboratories.

What is noteworthy about this development is that the two blood brothers have regularly told Wall Street analysts and investors that hospitals are looking to outsource their lab services. The termination of this lab joint venture would be a market example of the opposite happening—where a large regional hospital wants full control of its outreach lab program and is willing to go it alone without a public lab company partner.

Moreover, for those lab executives who have tracked the relatively small number of true lab JVs that came into existence since the mid-1980s, the dissolution of this JV is consistent with the pattern of the hospital partner eventually ending the joint venture so as to regain full control of its lab outreach program. Many lab outreach deals done in recent years have actually involved a public lab purchasing a health systems' lab outreach program to then be its sole owner and operator.

One interesting speculation about Froedtert Hospital's willingness to go it alone with its lab outreach program may be associated with how it is assembling an integrated healthcare delivery system. Administrators at Froedtert may recognize the value of having a single, unified lab test record that covers patient data from inpatient, outpatient, and outreach settings. TDR

Is New Cycle of Fraud Plaguing Lab Industry?

Sins of a few labs may cause unnecessary pain for all clinical labs and pathology groups

CEO SUMMARY: Taken collectively, the growing number of federal investigations of clinical lab companies and health insurer lawsuits against lab companies alleging fraudulent business practices signals a disturbing new trend for the lab industry. Although these allegations are leveled at just a handful of lab companies, the amount of money these labs took out of the system exceeds a billion dollars. Some experts expect payers will enact tough requirements to stop such abuses.

STARTING ABOUT TWO YEARS AGO, a stream of news stories about federal investigations of certain clinical laboratory companies for fraudulent practices have made regional and national headlines. During this same time, a number of health insurance companies have also made news after filing lawsuits against certain clinical lab companies that allege similar fraudulent practices.

Examples of recent federal criminal or civil cases against laboratories include:

- **BioDiagnostic Laboratory Services**, Parsippany, NJ, March 2013: federal convictions of 38 people, including 25 physicians, for offering bribes or accepting inducements to refer lab tests.
- **Health Diagnostic Laboratory, Inc.**, Richmond, VA, April, 2015: civil settlement of allegations that the lab paid inducements to physicians for referrals and billed Medicare and Medicaid for medically-unnecessary tests.
- **Singulex Laboratories**, Alameda, CA: April 2015: civil settlement of allegations that the lab paid inducements to physicians for referrals and billed Medicare and Medicaid for medically-unnecessary tests.
- **Bostwick Laboratories**, Nashville, TN, August, 2013 and October, 2014: two civil agreements with the federal DOJ to settle allegations of offering kickback incentives to physicians in exchange for referrals.
- **Millennium Health LLC**, San Diego, CA, case not settled: In June, *The Wall Street Journal* reported that Millennium, a large toxicology testing lab company, was in settlement talks

with the federal government to resolve allegations of billing Medicare and Medicaid for medically-unnecessary tests (and possible other violations). Settlement amount rumored to be in the range of $250 million.

Big-Dollar Fraud Cases

Several of these federal cases against lab companies involve large sums of money. Biodiagnostic Laboratory Services was said to have generated revenue of $200 million in the eight years of 2006 through 2013. Health Diagnostic Laboratories is reported to have produced revenue of $417 million in calendar 2012 and was projected to post revenue of $383 million in calendar 2013. That's a total of $800 million in revenue at this one lab company in just two years!

Pathologists and lab managers should not miss the point: this handful of bad actors in the lab industry accused of fraudulent business practices have taken more than $1 billion out of the healthcare system in just a couple of years! Keep in mind that the total spent on clinical laboratory testing is about $75 billion per year (per a recent **Cain Brothers** lab industry report).

Thus, if this small group of labs was able to pull $1 billion and more from their schemes to induce medically-unnecessary testing, what is the total amount of fraudulent lab test billing that Medicare, Medicaid, and private health insurance officials see?

Given the explosive growth over the past decade in the number of labs dedicated to toxicology and pain management testing, the dollar amount of lab claims paid based on fraudulent business practices in this industry sector may be a number that is too large for the payer establishment to ignore any longer.

But go beyond toxicology and pain management lab companies. Payers may also be seeing a substantial number of lab test claims from certain lab companies with proprietary molecular diagnostic assays and genetic tests that the payers consider suspect on grounds of: not clinically useful (or not supported by published studies in credible, peer-reviewed journals), medically-unnecessary, or test claims in which the test was ordered on the basis of suspected illegal inducements between the ordering physician and the lab.

Lab managers working in hospital and health system laboratories often see one aspect of unethical business practices from these molecular and genetic testing labs. There are labs that will tell the physician that the patient will never see a bill.

These labs price their proprietary tests at several hundreds to several thousands of dollars. They then submit claims—often as an out-of-network lab—to the patient's insurance company. They accept whatever the insurance company pays and some of these labs never bill the patient.

THE DARK REPORT is aware of a number of lab companies over the past 15 years that have followed this practice, which goes as far back as the late 1990s. One example was **Impath, Inc.**, the high-flying breast cancer testing company of that era. It typically priced its proprietary tests at double that of competing labs, billed most insurers as an out-of-network provider, and never aggressively collected money patients owed.

Financial Fraud At Impath

Impath turned out to be one of the lab industry's biggest financial frauds. When discovered in 2003, it was estimated that, in addition to the business practices described above, the company had reported $64 million in "phantom revenue" between 1999 and 2002. Eventually, CEO Anu Saad, M.D. and five other ex-Impath executives faced criminal charges for their roles in this case. *(See TDR, April 18, 2005.)*

In fact, private health insurers may be reaching a point where they will no longer tolerate any lab that fails to bill and collect the amounts that a patient owes for his or her lab tests. In the intelligence briefing which follows on pages 6-8, THE DARK REPORT is first to report on how **Cigna**, one of the nation's largest health insurance

companies, is sending audit letters to toxicology lab companies asking for documentation that the patient paid his/her deductible or copay before the insurer will issue payment to the lab that performed the test.

Attorney Richard S. Cooper, of **McDonald Hopkins**, was interviewed about the Cigna audit letters. As you will read on the following pages, he points out that payers will often start by auditing certain provider practices as a first step. The second step is to include language in provider agreements that addresses what the payer believes must change.

New Payer Requirements?

Effectively, Cooper is pointing out that Cigna may introduce language during the renewal of provider agreements that requires laboratories to document that they billed patients *and* patients paid their required deductibles. This would be a new burden for laboratories when submitting claims. Such contract language could also violate prompt-payment laws of some states.

On the other hand, it should not be overlooked that tens of millions of patients are now enrolled in high-deductible health plans (HDHPs). Thus, by design, HDHPs can only succeed when patients pay the full amount of their required deductible. Independent of any perceptions of lab fraud and abuse, HDHPs may be another reason why Cigna, **Aetna**, **UnitedHealth**, and other payers are becoming motivated to require all providers—including labs—to demonstrate that the patient has paid before reimbursing the claim.

The upside for the entire clinical laboratory industry from these developments is that the sooner payers take action against that class of labs considered to be engaged in fraudulent business practices, the sooner the competitive playing field will be leveled. The downside is that, should the federal Medicare and Medicaid programs enact onerous new requirements to stop these fraudulent schemes, this would add another expensive burden for those lab organizations that have always taken great care to fully comply with all laws and the terms of their provider contracts. TDR

Health Insurers Are Suing Labs Over Fraud in Billing for Tests

ONE OF THE FIRST LAWSUITS by a health insurer against a lab company alleging fraud in how lab claims were submitted was filed on October 15, 2014, in the U.S. District Court of Connecticut by Cigna Health and Life Insurance Co. against Health Diagnostic Laboratory, Inc., of Richmond, Virginia. Cigna accused HDL of "a fraudulent fee-forgiving scheme" and seeks $84 million in damages.

Aetna, Inc., was the next insurer to sue HDL. Its lawsuit was filed on April 10, 2015, in the U.S. District Court for the Eastern District of Pennsylvania. Aetna is seeking "tens of millions in monetary damages" because of the "fraudulent billing scheme" that was operated by HDL and **Blue Wave**, a contract sales entity that represented HDL.

In a separate lawsuit, Cigna targeted several lab companies that provide toxicology and pain management testing services. In court documents filed on July 17 in U.S. District Court for the Southern District of Florida in West Palm Beach, Cigna named **Sky Toxicology, Ltd.**, **Sky Toxicology Lab Management, LLC**, **Frontier Toxicology Ltd.**, and **Hill Country Toxicology, Ltd.**, as defendants. Court documents in this case show that, "Cigna has paid well over $20 million in claims that it was not obligated to pay under the terms of the relevant plans." *(See sidebar on page 7.)*

These court cases may be an early sign that private health insurers are prepared to launch court actions against labs they consider to be engaged in fraudulent business and billing practices. If true, this development will be welcomed by lab administrators in labs that take extra effort to comply with state and federal compliance laws.

Cigna Audits Tox Test Labs For Proof that Patients Paid

➤Health insurer wants proof that patients paid copayments before it will pay toxicology lab claims

➤➤CEO SUMMARY: In an unusually strong move, health insurer Cigna is auditing laboratories, including some labs that do toxicology testing. In these audits, the health insurer seeks documentation that the testing is medically necessary and that the laboratories are collecting copayments and deductibles from patients before Cigna pays the labs for the toxicology test claims. A lawyer working on these cases says that tactic may violate some state prompt-payment laws.

FINALLY, ONE MAJOR HEALTH INSURER is taking steps to crack down on the billing practices of certain labs, including toxicology lab companies. Lab professionals aware of these business practices consider them to be abusive and have waited for insurers to act.

Cigna, Inc., is taking a tough stand against toxicology lab companies, according to a lawyer familiar with the audits. For the claims being audited, Cigna requests documentation of medical necessity.

In a potentially ominous development for the lab industry, Cigna has begun to ask toxicology labs to submit proof of patient payment before it will reimburse those claims. Cigna has also filed a lawsuit against several toxicology lab companies alleging they submitted fraudulent and inflated claims. *(See sidebar on page 7.)*

Cigna did not respond to a request for comment.

These developments have come to the attention of Richard S. Cooper, an attorney with the national law firm of **McDonald Hopkins**. Several labs have contacted him about Cigna's latest moves.

"Cigna's effort to require documentation of patients' payments may be counter to prompt-payment laws," stated Cooper. "There is also a question as to whether Cigna's member contracts support such a procedure. If they do not, this could serve as the basis for an ERISA-based claim by a qualifying laboratory. Our firm is working with several toxicology laboratory companies that have received audit notices from Cigna since the beginning of the year."

➤Contract Language Next?

One important detail about Cigna's crackdown is that each lab that has contacted Cooper's office is *not* in Cigna's lab network. "As of this time, I am unaware of any in-network labs that have received audit letters or have been asked by Cigna to demonstrate medical necessity or that patients have paid their portions of their lab bills," explained Cooper. "Perhaps some participating labs have. But, if not, it calls into question why non-participating labs are being singled out for a different procedure.

(*continued on page 8*)

Cigna Sues Three Out-of-Network Tox Labs; Alleges that These Labs Overcharged for Tests

IN A LAWSUIT FILED LAST MONTH, Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company charged that three Florida toxicology lab companies conducted a pattern of wrongful actions, including a fraudulent scheme to overcharge the insurer.

The lawsuit was filed July 17 in U.S. District Court for the Southern District of Florida in West Palm Beach. Cigna named **Sky Toxicology, Ltd.**, **Sky Toxicology Lab Management, LLC**, **Frontier Toxicology Ltd.**, and **Hill Country Toxicology, Ltd.**, as defendants.

According to public records, the same group of executives operate the four companies named in Cigna's lawsuit. They are W. Wade White, M.D., CEO and Medical Director; Bradley West, Chief Operating Officer, and Lance Hupfeld, Chief Sales Officer.

Cigna requires its members to pay a higher percentage of the charges from out-of-network providers and the labs are all out of network, Cigna said. "Without this obligation, some out-of-network providers could submit charges to healthcare plans which have no relation either to the provider's actual costs or to the actual market for medical services, and members would have no incentive to avoid those providers," Cigna said in its lawsuit.

Failing To Bill Patients

Court documents alleged that Sky Labs is a group of related out-of-network diagnostic laboratories that attracted patients by misrepresenting patients' responsibilities for payment, failing to bill or actually obligate the patients for their required cost-share obligations, and by promising not to seek reimbursement from the patients for any portion of its bill that the plan does not cover.

These lab companies did not tell Cigna that they were forgiving patients' fees, the insurer said. "Put simply, the charges that Sky Labs submits to Cigna are inflated and fraudulent because they misrepresent the true amount billed to patients. In reliance on Sky Labs' misrepresentations, Cigna has paid well over $20 million in claims that it was not obligated to pay under the terms of the relevant plans," court documents showed.

Florida has declared such "fee forgiveness" schemes to be illegal and enacted a law criminalizing this conduct, Cigna said in its court filing. What's more, Cigna charged that the labs engaged in a patient-referral kickback scheme.

Physician Inducements

Cigna alleges that, to steer patients to its facilities, Sky Labs induces physicians and drug treatment centers to refer patients to their [Sky Labs] out-of-network labs by offering the referring providers ownership interests in the entities operating the laboratories, and then paying the referring providers kickbacks in the form of "dividends," which relate to the number of specimens referred to the laboratories, the court documents showed.

In court papers, Cigna said that Sky Toxicology, Ltd., Frontier Toxicology, Ltd., and Hill Country Toxicology, Ltd., are all limited partnerships in Florida. However, on the websites of these companies, addresses in San Antonio, Texas, are provided.

Cigna has agreements with in-network providers, but out-of-network providers—including labs—charge rates that they set on their own. "With few exceptions, the amounts out-of-network providers charge for their services are higher than the contractual rates agreed to between Cigna and in-network providers," Cigna commented. "Then the out-of-network providers 'balance bill' Cigna plan members."

The court documents showed that, from July 2011, Cigna issued payments to the entities as follows: $17.5 million to Sky Toxicology (40,000 processed claims), more than $3.4 million to Frontier Toxicology (5,900 claims), and more than $1.8 million to Hill Country Toxicology (3,400 claims).

(*continued from page 6*)

"Also, all of the audits we've seen that Cigna has conducted in the laboratory sector relate to toxicology testing," he said. Cigna also is conducting analogous audits of surgery centers and substance abuse treatment centers, Cooper added.

Audits Are First Step

"Usually the audit letter from Cigna is the first step," stated Cooper. In these audit letters, Cigna asks for documentation of medical necessity and for evidence of patient billing and of patient payment. This is where Cigna's efforts are more stringent than those of other health insurers. Most health plans want to see evidence that the clinical laboratory has made a good faith effort to collect by sending bills to patients.

"Labs know—or they should know—that they cannot routinely waive copayments, deductibles, or coinsurance," he added. "An exception can exist for true financial hardship cases. Labs need to do more than simply send a single bill to a patient.

"All providers, including labs, must make good faith efforts to collect," Cooper said. "The fact that a patient hasn't met his or her obligation does not preclude a payer from paying the lab's share of a bill.

"Frankly, collection rates in certain toxicology settings may not be particularly good, but that has nothing to do with the lab's effort to collect the deductible and coinsurance payments," he stated. "A lab needs a procedure to follow so that it can show that it has made a good-faith effort to collect patients' deductible and coinsurance payments.

Compliance Requirements

"The procedure should be specific, and the lab should instruct personnel and contractors about the compliance requirements for billing and collecting such amounts," continued Cooper. "Also, laboratories should instruct sales and marketing personnel that they cannot deviate from this policy.

"Labs need to follow those procedures before they waive or reduce any amounts patients owe, and any waiver or reduction must be compliant," noted Cooper. "Also, when health insurers audit a lab, the lab should know the prompt-payment laws in their state.

"Until now, we have not seen payers seeking proof of payment," he commented. "But that's just one part of the problem. The larger issue is the delay in payment until the laboratory submits evidence of patient payment. This delay can have a meaningful and harmful financial impact on a laboratory.

"I can understand a payer asking for evidence that the laboratory has billed patients for what they owe," explained Cooper. "But for a health insurer to require evidence of patient payment seems to go beyond what is appropriate.

Prompt-payment Laws

"I also see the potential for delays in payment to laboratories to be violations of state prompt-payment laws," he said. "Prompt-payment laws exist in most states. These laws vary in terms of the prerequisites, exceptions, and time periods for payment.

"It would be interesting if Cigna could point to prompt pay statutes in which proof of patient payment is a recognized prerequisite to its prompt payment obligation," he added.

Cigna's actions may signal a change in payer policy that could eventually become part of the managed care contracts insurers ask clinical laboratories and pathology groups to sign, warned Cooper. "However, to date, I've seen nothing like that in Cigna contracts. Any such requirement would have to be consistent with applicable prompt pay statutes and underlying member contracts," he concluded. TDR

—Joseph Burns

Contact Rick Cooper at 216-348-5438 or rcooper@mcdonaldhopkins.com.

Lab Briefs

QUEST SETTLES TEST-PRICING CASE WITH FOUR CALIFORNIA LABS

LAST WEEK, A CALIFORNIA JUDGE APPROVED the settlement of a lawsuit that claimed **Quest Diagnostics Incorporated** had violated a state law that forbids selling services (in this case, lab testing) below cost.

In a decision last week, U.S. District Court Judge William H. Orrick approved an agreement between Quest and four California clinical laboratories that stemmed from a suit filed in 2012. In the suit, the plaintiff labs were **Hunter Laboratories LLC, Rheumatology Diagnostics, Pacific Breast Pathology Medical Corp.,** and **Surgical Pathology Associates.**

The plaintiffs charged that Quest and its codefendants **Aetna Inc.** and **Blue Cross Blue Shield Association** prevented the labs from competing for the insurers' business. They also charged that the insurers aided Quest's plan to drive the labs out of business, *Law360* reported.

In the case, the labs alleged that Quest Diagnostics violated antitrust law by selling lab tests below costs to physician groups. By contracting for testing below cost, Quest sought to drive testing away from the plaintiff labs and to get the physicians to refer their Medicare and Medicaid patients to Quest for lab testing, *Law360* wrote.

By settling, the parties avoided a trial, which was scheduled to begin in the U.S. District Court for the Northern District of California on August 17. Unfortunately for lab executives in California watching this case, no details of the settlement were released.

Attorneys for the plaintiff labs said the parties agreed not to comment on the settlement. The agreement not to comment deprives other lab executives of the details about the strength of each parties' case in this lawsuit involving lab test pricing under California law.

MORE TROUBLE FOR MILLENNIUM HEALTH OVER TOXICOLOGY TESTING

IT'S ANOTHER EXAMPLE OF PRIVATE INSURERS cracking down on the billing practices of lab companies that do toxicology and pain management tests. The nation's largest drug-testing lab, **Millennium Health LLC** of San Diego, is in a legal dispute with **Humana Inc.** of Lexington, Kentucky. *(See intelligence briefings on pages 3 through 8 about how **Cigna** is auditing labs that bill for toxicology tests.)*

Humana seeks monetary damages from Millennium. *Bloomberg News* reported that Millennium allegedly filed unlawful insurance claims and Humana sought damages along with an injunction while seeking to arbitrate the matter.

The Wall Street Journal reported in June that Millennium was talking with investigators for the U.S. Department of Justice over allegations that the drug testing company overbilled federal health care programs for lab tests. Federal officials threatened to rescind Millennium's ability to bill Medicare and Medicaid because of billing irregularities, including urine tests the lab never performed and tests for dead people, *Bloomberg* said. Under a settlement proposal, Millennium may pay a $250 million fine in four installments, Bloomberg reported.

Lab administrators and pathologists working in hospital and health system laboratories should take notice of these developments. If it is true that there has been significant fraud and abuse in toxicology and pain management testing, then both the Medicare program and private payers may implement tougher billing requirements for these tests. TDR

Lab team innovates to help physician

Detroit Hospita Develops 10 W To Add More Va

➤➤ **CEO SUMMARY: Clinical labs are beginning to make based financial model to a model based on value-based p sition, labs must find ways to create value. The lab at H identified 10 ways that it can contribute more value to ph system. One way is to help eliminate needless tests an involve improving supplier processes, helping to reduce p a lab test formulary, and demonstrating the financial effi**

First of Two Parts

BY NOW, MOST PATHOLOGISTS AND CLINICAL LAB ADMINISTRATORS recognize that the era of fee-for-service reimbursement will soon end. To stay ahead of this critical financial trend, innovative clinical laboratories are taking steps to add value to lab testing services.

Such an effort is underway within the clinical laboratory and anatomic pathology departments at **Henry Ford Health System** in Detroit, Michigan. Early efforts are generating encouraging results and pathologist Gaurav Sharma, M.D., has identified 10 ways that labs can create value, along with the five most common barriers that laboratories face when implementing these value-creation steps.

Sharma is the Director of the Regional Medical Laboratory and Associate Medical Director of Core Laboratory, Quality Systems and Regulatory Affairs at HFHS. He explained how labs can demonstrate value at the *Executive War College* in New Orleans in May.

"The first step in the value-creation process is to recognize that this is a new model—a new paradigm—for lab testing services," recommended Sharma. "All labs will need to leave behind the long-standing model of the laboratory as a stand-alone cost center in which increased specimen

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Henry Ford Health System has
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cacy of all lab interventions.

volume generates more fee-for-service revenue. Today, increasingly, a lab will be reimbursed and judged on how it delivers value during the entire patient encounter, particularly in ways that lab test results contribute to improved patient outcomes.

"The great challenge now is to figure out how to transition to the future model, a model where labs may no longer be independent silos within hospital systems," he said. "Instead, within our health system, our lab's value will be judged on its overall clinical and financial outcomes.

"Today, clinical laboratories are a service specialty," he explained. "Yet, under the Affordable Care Act, hospitals and health systems are charged with three basic tasks and none of them applies to ensuring the continuation of any service specialty. To survive in an ACA-driven environment, labs must be able to:

1) "Improve patient care outcomes because quality metrics and new payment models are tied to those quality metrics;
2) "Improve financial outcomes by cutting costs while continuing to deliver the same or higher levels of care; and,
3) "Decrease waste.

"Among these three tasks, there is a concern about what will happen to the lab in its current role as a service specialty, given that there is also no way to increase payment for our lab testing services," Sharma stated. "If a lab can't increase or sustain revenue, the only option is to spend less.

"While there are very few ways for labs to spend less, one thing we can do is target things that don't need to be done in the first place or have to be done more than once, such as speciman redraws, for example," he added. "Also, we could work to eliminate anything in the lab that has to be done manually. Manual processes require staff time, and salaries are one of any lab's highest costs. If better technology is available, and if automation can solve the problem, then our lab should get it.

Need To Find Cost Savings

"We can control what happens in the labs. That's why we have Lean and process improvement tools," he noted. "Because the need to find cost savings is so acute, we should look both within and outside the laboratory.

"Unfortunately, when we look outside the lab, we find that's where many of our costs and waste originate," Sharma said. "What percentage of defects occur outside the lab? It's more than 80%.

"That means, all but 20% of the defects your staff encounters and wastes time fixing are not caused by your staff!" he said. "This is why controlling the overall cost of lab testing is a challenge.

"Outside the lab we find collection and order defects, or we find something that went wrong with the specimen in transport," stated Sharma. "So why do we typically fixate on continual analysis and tweaking of our in-lab processes when over 80% of the defects in lab testing are not in our direct control?"

Changes To Lab Operations

"The answer is that we need to create value from those elements that our lab can control or influence," he answered. "Our lab team at HFHS has identified 10 opportunities for labs to create value. As you understand each, you will see that most of the 10 opportunities involve making changes inside the lab and collaborating with partners outside the lab. They are as follows:

1) Choose the right technology to reduce length of stay.
2) Question the need for expensive tests.
3) Create an institutional test formulary.
4) Demonstrate the financial efficacy of the formulary's interventions.
5) Understand the downstream implications of lab decisions.
6) Monitor and reduce defects.
7) Improve supplier processes.
8) Reduce unintended operating room testing.
9) Reduce unintended inpatient testing.
10) Reduce unintended testing in specialty clinics.

1) Choose the right technology to reduce length of stay

"The first strategy is to choose the right technology," noted Sharma. "This requires evaluating how much use of a new technology can save in dollars versus current technology.

"One good example comes from using mass spectrometry, specifically mass spec with matrix-assisted laser desorption/ionization–time of flight (MALDI-TOF) in microbiology labs," he advised. "This technology typically costs over $110,000. If you were in the finance department, you would ask the lab to justify that expense. Traditionally, this would be limited to savings in FTEs or a similar lab-based metric.

"Our microbiologists demonstrated that MALDI-TOF reduced our turnaround time for reporting a positive result for *Candida* from 4.5 to 2 days," Sharma said. "That's a reduction of 2.5 days for each patient with *Candida* sepsis, almost all of whom are in the intensive care unit.

"Next, we determined the effect of this early reporting on the length of stay of each of these patients," Sharma noted. "Before MALKDI-TOF, it was over 14 days. After the introduction of MALDI-TOF, length of stay fell to under 10 days. That is a reduction in average length of stay of more than four days!

"One day of stay in the ICU costs $4,100," he added. "That means the system would save $19,000 for each *Candida* patient who can go home 4.8 days sooner.

"Based on the number of patients we have with *Candida,* use of MALDI-TOF and our ability to render an earlier diagnosis from our microbiology lab saved $1.1 million the first year for Henry Ford Health System," he said.

"Using the right technology basically means using the right tool for the job," Sharma added. "As we did so, the technology paid for itself in the first month. We got this result despite the fact that working though those calculations took us a week or more of manual chart review.

"Now, here's the best part: We use MALDI-TOF when diagnosing 100 other pathogens," Sharma explained. "Without MALDI-TOF, we lacked the capability to quickly identify these organisms and enable a more focused treatment plan.

2) Question the need for expensive tests

"Strategy number two is to question the relevance of and need for expensive tests," stated Sharma. "Most labs start with send-out tests and historically doing so has been a success. In fact, our success in this

How One Lab Contributed $50 Million of Annual Cost Avoidance with Companion Diagnostics

Lab Test	Cancer	Therapeutic Drug	Treatment Cost	2012 Patient Care Savings	2013 Patient Care Savings
EGFR	Lung	Gefitinib	$72,000	$14,184,000	$14,832,000
ALK FISH	Lung	Crizotinib	$72,000	$12,600,000	$13,248,000
BRAF	Melanoma	Ipilimumab	$120,000	$1,560,000	$2,880,000
Her2 FISH	Breast	Herceptin	$70,000	$12,180,000	$14,560,000
KRAS	Colon	Cetuximab	$125,000	$5,750,000	$4,750,000
Total Savings				**$46,274,000**	**$50,270,000**
Lab Test Cost				$253,994	$243,551
Lab Reimbursement				$173,881	$176,796

Source: Dept. of Pathology and Clinical Laboratory, Henry Ford Health System

As the lab team at Henry Ford Health System in Detroit worked to demonstrate more value, one of the most effective approaches was to implement a lab test formulary, which is the third of 10 ways to deliver more value that are in use at HFHS. The fourth way to deliver more value is by demonstrating the downstream savings derived from physicians using in-house molecular test results for selection of appropriate pharmacological regimens for cancer patients. Presented about is a summary that the molecular lab developed in collaboration with the pharmacy department to show the cost avoidance associated with just five companion diagnostic tests.

domain has prompted us to use the same strategy to reduce spending on inappropriate inpatient testing.

"Controlling sendout tests can be challenging, not the least because reference labs send sales representatives to market their proprietary tests directly to HFHS physicians, usually neurologists or oncologists," observed Sharma. "Based on the marketing material, physicians or patients may ask that these tests be sent out. Our challenge was that only a very small minority of these send-out tests would come to a pathologist's desk for a formal review.

"Further, when we determined a test was irrelevant and contacted the provider, a disagreement often ensued about who should be making these decisions," he continued. "That means a majority of esoteric and expensive send-out tests went to reference labs, and we lacked a mechanism to manage these orders.

"While figures may vary, large academic institutions like ours can easily spend about $3.5 million a year on send-out tests," recalled Sharma. "In particular, the novel molecular and genetic tests are an area of challenge for laboratories and providers and so our team kept track of such requests.

"There was also a lack of standardization," he said. "Some physicians wanted to send out additional tests for liver cancers. Some wanted to send out the same test only for head and neck cancers. We realized that we needed to reduce this variation and bring in standardization by our third value-creation strategy, which was drafting a framework for a multidisciplinary and institutionwide formulary for lab tests.

3) Create an institutional test formulary

"An institutional formulary solved this problem because it is based on one of the leading principles we found in creating value: Before you reduce waste in a particular area, it is best to first standardize lab processes," he said.

"That's what a formulary does: it standardizes your processes for test ordering," explained Sharma. "For a lab test formu-

lary to be successful, a committee is needed that represents all parties involved, such as clinical providers and financial representatives.

"Our committee included a chief medical officer, chief financial officers, the chief operating officer, all their designees, two pathologists, an oncologist, and two surgeons," he noted. "The formulary committee meets every quarter and our lab has a departmental review committee that meets every month.

"Whenever the lab gets a request for a send-out test now, it is not automatically sent to the reference lab," stated Sharma. "Rather, the order goes to a pathologist review or a department review, where a decision is rendered. If the clinician disagrees, we take it to the formulary committee, and the formulary committee decides whether to agree or disagree with the order.

"To date, of 38 decisions the committee has rendered, we had zero occasions when the formulary committee disagreed with the recommendation of the lab," commented Sharma. "Following that decision, our laboratory can decide whether we should run the test internally or refer it out. We can set the utilization protocols for that test as well.

"When we studied the efficacy of using a formulary, we were surprised by the results, and this finding led us to our fourth value-creation strategy," he stated.

4) Demonstrate the financial efficacy of the formulary's interventions

"To demonstrate the efficacy of our interventions at HFHS, we listed costly assays and then analyzed the clinical benefit of each one," noted Sharma. "On receiving a request for a next-generation sequencing test, we consulted with an oncologist on the intended use of results.

"The oncologists responded that the test was new, and patients demanded it," recalled Sharma. "The cost of the test was $5,800 for solid tissue tumors and $7,500 when used for hemato-lymphoid malignancies. We found that most payers did not cover this test.

"We found no FDA approval; there was no mention of this specific assay in the NCCN guidelines at that point in time; and the assay was not part of a clinical trial at HFHS.

"For all these reasons, our formulary made this test unavailable as a service accessed through the HFHS formulary mechanism. But it was still accessible through the off-formulary mechanism, which I'll explain below," he said.

"At HFHS, when we send out tests that are on our formulary, we support the cost," he explained. "Also, we are Michigan's largest cancer center. Therefore, a lack of standardization in how we managed send-out tests meant that this one test was being requested for a range of malignancies.

"For another assay, there was a claimed use in management of patients with ER+ node-negative breast cancer," said Sharma. "At the time of our analysis, there was no FDA approval nor a specific mention of this test in NCCN guidelines," he said.

"The economics were similar to that of the earlier assay," Sharma added. "The cost was $3,500 and the reimbursement was $150, meaning a cost of $3,350. Based on the cohort of cases that would qualify for these assays, the cumulative costs could be millions of dollars for HFHS.

"Here is the crux of the issue: One of the complexities with cancer care is the fact that the laboratory must factor in and try to address the psychological burden of a terminal diagnosis," he said. "Once diagnosed with cancer, the patient is worried and looking for all possible help," he stated. "We feel the laboratory must play a positive and proactive role in assisting the patient.

"Every lab has the challenge of balancing the responsibility of the health system to do everything humanly possible to support these patients versus the stark reality of these costs," noted Sharma. "Previously, because our lab had no system to resolve

this issue, the lab was often seen as being an obstacle to care rather than facilitators of cancer care.

Protocol Proves Its Value

"Now, the formulary and cost analysis tools are in place," he explained. "Our lab has a policy, a procedure, and a protocol for each of these tests. Thus, if the lab formulary does not endorse a test and the patient still wants to go forward, we will assist by releasing the tissue to the patient or the patient's provider.

"From that point on, that test is off-formulary," emphasized Sharma. "This may sound unconventional, but this process is routine for pharmaceuticals, where hospital formularies have been in place for years. Many times an institutional pharmacy formulary will allow off-formulary use on humanitarian grounds or when the patient assumes financial responsibility.

"You might think clinicians don't like this, but the reality is they endorse it because they are no longer in the uncomfortable position of having to justify pathology's position to cancer patients," he stated. "They give the patient all the documentation, which includes the lab formulary's recommendation. This transparent system provides our patients with all the information they need to make informed decisions.

5) Understand the downstream implications of lab decisions

"Value-creation strategy number five resulted directly from strategy number four," Sharma continued. "As part of our investigation into the relevance of our in-house molecular tests, such as EGFR, KRAS, and BRAF, we asked the pharmacy department about the cost of the drug targets associated with these tests.

"The pharmacy team worked with us over two months to determine the costs" he stated. "Once we had those numbers, we could determine the manner in which our results affected the costs to HFHS and to our patients' health insurers.

"Based on the number of cases we for lung cancer, for example, we generated pharma cost savings of over $14 million in 2012 and a similar figure in 2013," Sharma noted. "So, yes, all labs run these tests every day. But seldom did we leave the lab to ask the customer, 'Did you like it? Does it make any difference to you and the way you manage the patient?'

"We found that the pharmacists and providers use this diagnostic information because it gives them actionable data for decision making when selecting the right drug for each patient," he stated. "It results in substantial savings in therapeutic drug costs. Unfortunately, the lab normally doesn't capture how much money it saved because of more appropriate test orders and chemotherapy.

"However, we did add up each cancer type and learned that there was over $50 million annually in cost avoidance!" stated Sharma. "This is a big contribution by the laboratory. We realize, however, that cost-avoidance is not cost-reduction that can come out of a specific financial silo. But still, cost avoidance results in great savings for the system overall.

"Think about the value of the lab's work in better use of lab tests: Without the tests that we did, $50 million more per year would have been spent on drugs. And without the time and effort of analysis with the pharmacy department, our downstream value creation would not have been captured," Sharma concluded. "Therefore, we feel that these numbers demonstrate the value of the work our lab contributes to our parent health system, our physicians, and our patients." TDR

—Joseph Burns

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PART TWO

In the second part of this series, we will review the next five value-creation strategies, along with the barriers labs encounter when creating value.

More AP Consolidation: Aurora Buys Two Groups

Brazos Valley pathologists find a new owner that will support independent pathology services

CEO SUMMARY: Seeing the changes overtaking pathology practices, Brazos Valley Pathology decided to sell two of its group practices to Aurora Diagnostics. Last month's transaction was not designed to fix financial problems nor was it because of retiring pathologists. Rather, it was done proactively to ensure that BVP's 11 pathologists had access to the resources of a larger pathology organization so that they could expand or add technology as needed in the future, while practicing independently.

PRIVATE ANATOMIC PATHOLOGY practices continue to face the dual pressures of lower reimbursement for key anatomic pathology CPT codes and exclusion from the narrow networks of managed care plans.

This double-whammy means pathologists are paid less per test and are losing access to patients. As a consequence, smaller pathology groups are opting to put themselves up for sale, looking to merge with larger groups, or negotiating to become employees of hospitals and health systems.

Consolidation In Pathology

As the consolidation of private pathology groups gained momentum over the past five years, THE DARK REPORT has written about these transactions. When small pathology groups lose their independence, it's seldom publicized, making the scale of such consolidation difficult to gauge. *(See TDR, May 19, 2014.)*

One recent acquisition of community hospital-based pathologists in Texas provided an opportunity to talk with the selling pathologists and learn the reasons behind their decision to sell to a larger pathology company.

On July 15, **Aurora Diagnostics, Inc.**, of Palm Beach Gardens, Florida, announced that it acquired two divisions of **Brazos Valley Pathology, PLLC**. This Texas company has an affiliated pathology billing business and two community hospital-based pathology practices. One is **Brazos Valley Pathology**, based in Bryan/College Station. The other is **Trinity Pathology Associates** of Tyler, Texas. A total of 11 pathologists work in the two pathology groups.

This transaction is part of a trend of regional pathology consolidation. That's because Aurora Diagnostics will operate the two newly-acquired pathology groups from its business division in Austin, Texas, known as **Austin Pathology Associates**.

"We saw several benefits in this transaction," stated Michael K. Cohen, M.D., the President and Partner Pathologist of Brazos Pathology Associates and Trinity Pathology Associates. "For example, the

11 pathologists in BVP gained a large partner with expertise and resources that can help us going forward. Our pathologists saw this as providing more security as we move into the future.

Two Pathology Groups

"Brazos Valley Pathology was founded in 1996 and our pathologists have worked independently in the two groups since then," he noted. "We saw that Aurora Diagnostics had a similar model of practice and was already operating in Austin, Texas, and both of those were important considerations."

Aurora Diagnostics describes itself as an "independent specialized laboratory company focused on anatomic pathology at 25 locations in the United States. Employing over 130 licensed physicians, Aurora Diagnostics provides high-quality diagnostics and testing information" to referring physicians and to "more than 60 community hospitals."

In addition to acquiring the two practices and its 11 pathologists, Aurora also acquired **ProMedX Billing Solutions**, an entity majority owned by **Pathology Resource Consultants, LP**, that focuses on billing services, Cohen said. "Aurora did not acquire **Pathology Resource Consultants**, a pathology practice management firm," added Cohen. "PRC's consultants will continue to consult with pathologists in other group practices."

After years of deep budget cuts, pathologists are struggling financially. In addition, many older pathologists have retired, closing their practices or selling to larger pathology groups.

Pathology Group's Sale

However, according to Cohen, neither of those scenarios drove BVP to sell the two practices to Aurora. "The transaction was not designed to fix problems that our pathologists faced in the current market for pathology services," noted Cohen. "Rather, we wanted to ensure that the 11 BVP physicians had access to the resources of a larger pathology organization so that they could expand or add technology as needed in the future.

"The market for pathology services in Texas is still robust," he continued. "Our hospital contracts are solid and the independent practice of medicine may be stronger in Texas than it is in other parts of the country.

"Our agreements with payers are good right now, but the future is less certain. That's true everywhere," observed Cohen. "What is happening among health plans is a concern for anyone who contracts with insurers. For example, **Anthem** has announced plans to acquire **Cigna** and **Aetna** has said it wants to merge with **Humana**. Those deals could disrupt the market here in Texas.

"Another development was the recent announcement by **Blue Cross Blue Shield of Texas** that it was pulling out of the PPO market in Texas" he stated. "Who knows what that will do to pathology services—if anything? We also suspect that payers may require at-risk contracts in the future. There are signs that health plans are making such changes now as they prepare to accommodate the Affordable Care Act.

Preparing For The Future

"All these changes show that we can't be certain about what will happen in the future," said Cohen. "We would like to continue to practice independently and this is what I believe will be the best practice model for pathologists going forward. So it makes sense for us to join a larger organization that will allow us to do so.

"Since we founded PRC, our two constituent groups have operated under that umbrella and practice independently," emphasized Cohen. "In addition, our consulting business has managed other groups over the years, providing services so that pathologists can practice independently.

"BVP was structured so that Pathology Resource Consultants did the accounting and all the backroom functions to support the two practices," he explained. "That allowed the five pathologists and two pathology assistants at BVP and the six pathologists and two pathology assistants at Trinity Pathology to concentrate on providing pathology services full time. That's what they went to school for and that's what they wanted to do.

Pathology Best When Local

"When you look at what's happening across the country, pathology is like most specialties in medicine in that it's best practiced locally," he said. "Therefore, to succeed, specialists like us need to continue to practice locally. There are models of pathology practice that haven't allowed pathology groups to function independently, and I believe those systems don't allow pathologists the appropriate level of freedom for them to practice most effectively.

"We thought that the system Aurora developed seems to respect the traditional practice of pathology with enough support so that our pathologists can be professionally satisfied and successful," explained Cohen. "This benefits the pathologists, the medical communities they serve, and Aurora Diagnostics.

Pursuing Independence

"I'm biased, of course, but I believe the best model for pathologists is for them to develop relationships with the physicians in their communities and with their local hospitals," declared Cohen. "After all, we're in the business of reporting results and that work is still very personal and important. It's why pathology at the point of care works best. In our conversations with Aurora, we saw that same philosophy.

"Equally important was our view of pathology's future," he continued. "We realized that we pathologists will need to have a larger organization behind us. In the coming years, it will become more difficult, if not impossible, to practice in smaller groups that have just four, five, or six pathologists.

"Aurora is a larger organization that has the technical expertise to continue to deliver pathology services into the future," added Cohen. "Aurora Diagnostics also has the administrative support we might need in the coming years. That includes such resources as enhanced information systems and digital pathology equipment that we may soon require to be competitive and offer more sophisticated diagnostic services.

"It had all of these capabilities that we didn't have," he noted. "Because of these reasons, Aurora looked like the right way to go for us. And now we're all employees of Aurora and we believe that's the best arrangement for us going forward.

Contracting With ACOs

"One last factor that made Aurora a good fit was that we know we will need to contract more with accountable care organizations in the coming years," emphasized Cohen. "ACOs do not have a very big presence here where we operate, but that is likely to change soon. We felt that we would be able to find out how to work with ACOs by discussing contracting strategies with pathologists in any of the other Aurora locations.

"For all these reasons, we think that our merger with Aurora Diagnostics positions us well for whatever happens in the near future and in the long term as well," he concluded.

Pathologists and their practice administrators should take note of one important element in the reasons for the decision to sell Brazos Valley Pathology and the timing of this sale. The 11 pathologists decided to restructure their business in advance of any negative market changes. As a consequence, they had a wider range of sale options than if their practice was under financial pressure. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

California is always in the forefront of states doing innovative things. It announced a public-private effort to develop a clinical laboratory assay that "will enable detection of all known pathogens with a single DNA sequencing test, to diagnose acute infections in hospitalized patients." Funding is provided by the **California Initiative to Advance Precision Medicine**. Leading the development team will be the **University of California San Francisco**. Collaborators will include other UC campuses and academic medical centers in California. UCSF pathologist Charles Chiu, M.D., Ph.D., led the team that submitted the proposal. It is hoped that this diagnostic test development project will deliver an assay that is available for clinical use within two to three years.

DRONES TO DELIVER BLOOD SPECIMENS?

In a proof-of-concept exercise, researchers at **Johns Hopkins University School of Medicine** used a drone to transport blood specimens for as long as 40 minutes. The specimens were then tested in the medical laboratory to determine if transport by drone affected lab test results. The study was published in the journal **PLoS One**. Lead author and pathologist Timothy Kien Amukele, M.D., stated in a press release that "Such movements could have destroyed blood cells or prompted blood to coagulate and I thought all kinds of blood tests might be affected, but our study shows they weren't, so that was cool."

MORE ON: *Drone transport*

In the study, six blood samples were collected from each of 56 healthy adult volunteers at **Johns Hopkins Hospital**. Half of these specimens were transported in a drone for between six and 38 minutes. All specimens were then tested for "33 of the most common laboratory tests that together account for around 80% of all such tests done." Researchers determined that transport by drone had no discernable effect on the lab test results, compared to the control specimens.

TRANSITIONS

• Gregory F. Solak, 62, died of cancer on July 15 in East Amherst, New York. He was Vice President of Laboratory Services at **Kaleida Health** in Buffalo, New York. Solak previously held lab administration positions at several health systems in Michigan.

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DARK DAILY UPDATE

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

...a new company that wants to disrupt how labs provide phlebotomy services. **IGGBO** of Richmond, Virginia, is emulating **Uber** and **Lyft** with a service that enables on-demand phlebotomy services. Launched in January, IGGBO claims to now operate in 19 states with a roster of 4,500 phlebotomists.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, September 14, 2015.

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UPCOMING...

- ***Direct Access Testing in Phoenix: First-hand Report on Theranos and Competing Labs.***
- ***Part Two on 10 Ways that Labs Can Add Value: How to Reduce Unintended Inpatient, OR Testing.***
- ***Three Disruptive Diagnostic Technologies Deliver Remarkable Outcomes for Innovative Labs.***

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