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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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Why It Matters That Your Lab Has Low Test Prices

TODAY, THE LAB INDUSTRY FACES A CONTRADICTION when setting prices for individual lab tests. At one extreme, a certain sector of labs seeking to win exclusive managed care contracts sets high-volume routine test prices at or below the fully-loaded cost to perform those tests. At another extreme, laboratory companies with specialty molecular and genetic tests price their tests at multiple thousands of dollars.

Both types of pricing strategies are destructive to the financial health of the clinical laboratory industry. As these pages have chronicled over the past 22 years, loss-leader pricing by a handful of large lab companies to win exclusive network status and exclude competing labs from access to those networks accelerates the ability of private payers to cut prices for all labs. This decades-long process will culminate on January 1, 2018, when the federal **Centers for Medicare and Medicaid Services** will reduce Medicare Part B clinical lab test fees substantially using the market price data under the Protecting Access to Medicare Act (PAMA). That data consists mainly of deeply-discounted prices private health insurers pay to the largest labs.

At the other extreme are the high prices many specialty lab companies charge. Sometimes the motive of specialty labs is to charge high prices with the knowledge that private insurers will not reimburse for all claims. Other times, the high prices are part of abusive marketing schemes where such lab companies may be inducing physicians for lab referrals and want high prices. This latter strategy maximizes whatever reimbursement the labs may get from health insurers while allowing these labs to pursue unlucky patients for the balance of the amount owed, or the full amount if the claim was denied.

Sitting in the middle of these two lab test pricing extremes is a handful of lab companies whose executives understand the classic economics of price and quality versus supply and demand. Seeing that health insurers resist issuing favorable coverage and payment decisions for proprietary molecular and genetic tests, these companies are pricing their tests at levels that can be described as patient- and payer-friendly.

You will read about one of these companies on pages 3-5. **Color**, of Burlingame, Calif., set the price of its 30-gene test panel at $249 for cash-paying customers. That attractive price is one reason the lab company is now an in-network lab provider for more than 100 million Americans. TDR

Lab's Low Gene Test Price Gets Insurers' Attention

California lab firm contracts with insurers, gains in-network access to 100 million members

CEO SUMMARY: At a time when most molecular and genetic testing companies are struggling to gain coverage for their tests, this Silicon Valley-based lab company has become an in-network lab provider for a number of health insurers—including three of the nation's largest payers. It did this by establishing a patient-friendly price of $249 for its 30-gene test panel and building a physician-friendly portal that makes it quick and easy for doctors to meet pre-authorization requirements when ordering the test.

Do Silicon Valley executives schooled in the intensely competitive web marketplace understand the market forces driving genetic testing better than pathologists and clinical laboratory directors and the private equity firms that fund their lab companies?

The answer to that question may be yes, based on the impressive managed care contracts that **Color** (formerly **Color Genomics**) announced last month. The two-year-old company snared multiple managed care contracts to provide testing for more than 100 million lives for its 30-gene cancer test. Color operates a CAP-accredited, CLIA-certified laboratory in Burlingame, Calif.,

Priced at just $249 for cash-paying consumers, the test is convincing evidence that some of the nation's largest health insurers appreciate Color's strategy of setting a patient-friendly price for its genetic test.

On June 15, Color will become an in-network lab provider for three of the nation's large health insurers: **UnitedHealthcare, Blue Shield of California**, and one other unidentified insurer. These payers will reimburse Color when in-network physicians order its 30-gene test for hereditary cancer risk for patients who meet the insurers' medical criteria, Color said.

Color's in-network status gives it immediate access to more than 100 million Americans. For any insurers not under contract, Color will accept out-of-network payment.

In 2015, Color launched a 19-gene test for $249 for women who wanted to know their risk for breast and ovarian cancer. Then, in April 2016, Color expanded the

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test to 30 genes and marketed the new panel to men and women seeking to assess their risk for developing eight common hereditary cancers. Although it had expanded the genetic markers in the test panel, Color retained the $249 price.

A Simple, Direct-Pay Model

Last year, Color's co-founder and CEO Othman Laraki told THE DARK REPORT, "From day one, we have adopted a simple, direct-pay model. We did not put a lot of effort into pursuing insurance payment because our focus has always been on improving patient access to these genetic tests." *(See TDR, July 5, 2016.)*

Low prices helped to improve patients' access to those tests and generated a lot of buzz, with publications such as *Forbes*, *Fortune*, *The New York Times*, *TechCrunch*, and *BuzzFeed* writing stories about Color's low price.

Being savvy shoppers, health insurers noticed and soon came calling. "This is the only time in my career that insurance companies actually started to reach out to us," stated Darrin Crisitello, Color's VP of Global Sales, Marketing, and Operations. Because of the complexity of billing inherent in any insurance contract, health insurers will pay more than $249 for the test, but Crisitello would not reveal contracted rates.

"Our $249 price point resonated with insurers, and so we were able to contract with them at rates that are much less than they currently pay to other labs," he said. "Not only did we get a lot of traction with UHC and Blue Shield, but we'll have more payers within the next quarter.

"Many lab companies are trying to determine what's the most amount they can charge for a genetic test or service," commented Crisitello. "But we have the opposite view about price.

"We want to know what's the least amount we can charge to promote more widespread access to our genetic test panel and truly be a disrupter," he explained. "Our foray into managed care contracting shows that same thinking."

Color is particularly gratified about its contract with Blue Shield of California, Crisitello said. "The interesting thing about Blue Shield is we became one of their preferred laboratory vendors for BRCA testing," he noted. "That's exciting for us because our cost is dramatically lower than what our competitors charge. That helps us negotiate favorable terms with payers.

"We don't share our list price or our contracted rates with the payers, but you can assume that there are some additional fees because there are added steps involved in billing insurers compared with billing a cash-paying or self-pay individual," he said. "Those rates are higher than our cash rates." Like most labs taking insurance payment, Color needed to hire a billing team, for example.

Physicians Prefer One Lab

The reason to pursue insurance contracts is simple: Physicians who order tests from Color wanted to offer the same lab test to their insured patients. "Physicians want a way to offer genetic tests to their patients that will be covered by the patients' health insurance plan," explained Crisitello. "Physicians use other commercial laboratories that take insurance but would rather use one lab for all their needs—if possible."

Crisitello then added the twist that appears to be making his company's pricing strategy a double-winner. "It's easier for physicians to use a single laboratory for two types of their patients," he said. "One type are folks who meet insurance criteria. The second type are patients who may have high-deductible health coverage or are self-pay for the full cost of the genetic test."

Recognizing the value of being physician-friendly, Color built a physician portal to ease the prior-authorization process to make it easier for doctors to order its test. Often, obtaining preapproval for a genetic test can be troublesome for physicians and their office staff.

Genomics Lab Company Focuses on Patient Experience To Attract Patients, Physicians

COMPANIES IN THE SILICON VALLEY are known for focusing on the users' experience. Some of today's biggest tech companies in the San Francisco area grew by meeting and exceeding users' expectations.

In 2015, tech entrepreneurs founded Color to offer affordable genetic testing. Two of the founders had worked at **Google** and **Twitter**. Their work in consumer platforms is visible in Color's user-friendly approach toward patients and toward physicians.

For patients, the attraction was low price. For physicians, it was ease of use, noted Darrin Crisitello, Color's VP of Global Sales, Marketing, and Operations.

"We want to make it easier for physicians to order tests so they can spend their time with their patients," he explained. "Our design, product, and engineering teams aim to offer providers a simple user-friendly experience.

"On our platform, a physician enters patient information," continued Crisitello. "The system then identifies the insurer's criteria and the patient's potential out-of-pocket costs, including the deductible and co-pay.

"This tool streamlines the ordering and approval process for our genetic test because it gives the physician the information he or she needs to decide whether to choose the self-pay or insurance-submission process," he explained. "Therefore, physicians can be more efficient when ordering a genetic test from Color.

"In this industry, the payer system for adjudicating claims is challenging," added Crisitello. "It shouldn't take 12 people to review and process a lab test claim. It seems to have reached this point because a significant number of labs are billing exorbitant amounts and payers have installed various restrictions and denials to ensure that they're properly managing costs.

"We hope that the best way turns out to be the simplest way," he added. "We'd like to see payers tell our lab what the criteria is for their patients. Then our lab will submit only those patients who meet that test criteria. When we submit the claim, the health plans will pay us. In that way, we make the process as simple and efficient as possible."

"Our goal was to give physicians the same type of user experience that we provide to consumers," noted Crisitello. "Each specific payer has requirements that individuals must meet, including personal and family history, for instance.

"That's why we designed our physician portal to make it simple for doctors to identify which patients meet insurance criteria and which do not," he said. "It also helps physicians understand what their patients' out-of-pocket costs may be.

"With the online tool, the physician can make the best choice for the patient on what the lowest cost would be, whether through insurance that includes an out-of-pocket portion or whether the patient is to use the self-pay option of $249," he explained.

Given the low price and simplified ordering, does Color expect volume to increase overnight beginning June 15?

"Simply getting insurance contracts doesn't mean that our lab automatically gets that volume," observed Crisitello. "But the lab has been scaled for significant volume from day one in part because we are participating with the **University of California's** WISDOM trial. Under an exclusive contract, we're assessing 100,000 women for their hereditary cancer risk.

"So, from a scale and a volume standpoint, we're comfortable we'll be able to handle whatever volume comes from payers and providers," he said. **TDR**

—Joseph Burns

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Mississippi Blue Cross Sues Hospital, Tox Labs

➤In just 120 days, 29-bed rural hospital submits laboratory test claims totaling almost $34 million

➤➤CEO SUMMARY: Last month's lawsuit filed by Blue Cross Blue Shield of Mississippi against a small rural hospital in Mississippi and multiple defendant lab companies in Texas is the latest attempt by health insurers to rein the widespread fraud that threatens to overwhelm the pain management and toxicology sectors of healthcare. Increasingly, the nation's community and rural hospitals are being approached and asked to provide lab testing and billing in dubious schemes.

FIRST IN A SERIES

Editor's Note: Ongoing fraud and abuse involving lab testing is now a national problem that continues to grow. The different types of schemes, the new forms of inducements, and the involvement of different types of providers seen today are much more sophisticated than any seen in past years.

THE DARK REPORT is starting a series of intelligence briefings to help pathologists and clinical lab managers understand the complexity of these illegal arrangements. In recent months, many hospital lab administrators have told **THE DARK REPORT** that their CEOs are being approached to recruit their hospitals into these arrangements.

AMID ONGOING REPORTS OF RAMPANT FRAUD in the pain management and toxicology sectors of clinical lab testing, a recent lawsuit filed in Mississippi could mark a turning point in payers' willingness to take legal action against entities that are submitting claims that are based on potentially fraudulent and abusive business arrangements.

What is notable about this lawsuit is that it names, as one defendant, a community hospital, along with other defendants that provide toxicology testing services. Another notable fact is the claim in this lawsuit that a 29-bed rural hospital submitted almost $34 million in lab test claims to a single payer in just 120 days!

➤Scheme Targets Hospitals

In recent years, operators of toxicology and pain management testing lab companies have developed a scheme in which they convince a community hospital or a rural hospital to enter into a business agreement whereby the hospital agrees to provide certain lab testing services and to bill—as an in-network provider—for all lab tests performed by the labs or providers who are part of this agreement.

If lab managers are aware that their hospital's administration has been approached with offers to enter into similar-sounding lab testing arrangements, then they may want to learn more about this unusual lawsuit that was filed last month.

Presentations about these new lab testing arrangements that are given to hospital

administrators, describe the agreement with a new acronym—HOPD. It stands for "hospital outpatient diagnostics."

On May 4, 2017, **Blue Cross & Blue Shield of Mississippi** filed a lawsuit in the U.S. District Court for the Southern District of Mississippi against a small community hospital and several lab companies. Named as defendants were:

- **Sharkey-Issaquena Community Hospital**
- **Sun Clinical Laboratory, LLC**
- **Mission Toxicology Management Company, LLC**
- **Mission Toxicology, LLC**
- **Mission Toxicology II, LLC**
- 10 unnamed "John Does"

The 29-bed hospital is located in Rolling Fork, Miss. (population 2,500). The other defendants are based in Texas.

Multiple Claims In Lawsuit

In the court documents, Blue Cross lists the following claims: breach of contract, fraud, civil conspiracy, negligent misrepresentation, and unjust enrichment. The lawsuit says that, "between February and May, 2017, the hospital submitted to the insurer claims totaling in excess of $33.8 million. Of that, Blue Cross has paid out more than $9.8 million. Claims submitted, but which the plaintiff contends are misrepresented, thus not covered, amount to over $24 million."

The suit alleged that, "since February, 2017, claims are being submitted to Blue Cross for payment for laboratory services that: 1) purported to have been performed at and by the hospital; 2) were not ordered by a licensed health professional with appropriate staff privileges at the hospital; and, 3) were not performed at the hospital in Rolling Fork, Miss."

According to court documents, in January, 1995, Blue Cross contracted with the hospital to provide "hospital services which are medically necessary when such services are ordered by a licensed physician or other licensed health professional who has appropriate staff privileges at [the] hospital." Blue Cross further stated that its contract with the hospital excluded "services performed by an organization or facility not itself licensed by the state as a general acute hospital."

Billing With Hospital's Name

Further, Blue Cross alleged that the hospital entered into a contract with one or more of the defendants to allow them to use the hospital's name and billing information to submit claims, even though the laboratory services were not to be performed at or by the hospital.

By subsequently submitting what it calls misrepresented claims, Blue Cross asserted the hospital breached its contract with the insurer. Blue Cross further asserted that the hospital attempted to obscure its breach by "leasing" an employee and space at one or more of the defendants' facilities in an attempt to conceal the breach. The hospital's attempt to conceal, Blue Cross claimed, was a further breach of contract. The insurer additionally stated that it believes that one or more of the defendants is reimbursing the hospital for this "arrangement."

"The contract provides for a percentage of charge reimbursement rate…because of [the hospital's] small rural nature," Blue Cross stated in the complaint, also writing that, "Blue Cross contracted at this rate with the hospital as a hospital, and not as a laboratory for non-hospital patients; and, certainly not to allow third parties to take advantage of the percentage of charge rate."

'Misrepresented' Claims

Blue Cross has asked the court that it not be required to pay misrepresented claims that are pending and to bar the hospital and defendant laboratories from submitting misrepresented claims going forward. The insurer asked for actual and consequential damages, prejudgment and post-judgment interest, and costs from the hospital.

Against the laboratory defendants and their affiliates, Blue Cross seeks actual and

consequential damages, as well as punitive and exemplary damages, attorneys' fees and costs, and prejudgment and post-judgment interest.

Are Payers Quicker To Act?

The fact that Blue Cross took legal action only three months after it began receiving claims submitted by the defendants could suggest that payers are becoming more attuned and vigilant to the various "red flags" that would signal lab companies using fraudulent and abusive business practices.

In the lawsuit, Blue Cross described an important characteristic of the HOPD scam model. The lab companies and other providers participating in the agreement need the hospital's in-network provider status in order to submit the lab test claims and have them be reimbursed. That is why the hospital lab is asked to use its provider number and NPI for the test claims that will be submitted to different health insurers.

This seems to be the case in the Mississippi lawsuit. In the court documents, Blue Cross described how its initial investigation revealed that, under the "arrangement" between the hospital and Sun and the Mission Companies, orders for laboratory services were submitted to Sun Clinical Laboratory, **Hermann Drive Surgical Hospital**, Houston, TX, CLIA #45D2027576 and Mission Toxicology, 2145 NW Military Hwy #102, San Antonio, TX, CLIA #45D2071649.

Hospital's CLIA Number

The court documents further stated that the lab test results were submitted to the providers who ordered the tests on forms with Mission Toxicology or Sun Clinical Laboratory logos—but with the hospital's CLIA number and Mississippi address and with a Texas phone number.

Blue Cross pointed out in its complaint that the hospital's CLIA number "is for laboratory work performed in the hospital laboratory" and that the "laboratory work related to the misrepresented claims was not performed in the hospital in Rolling Fork."

Blue Cross further asserted that the misrepresented claims did not meet the medical necessity provisions of benefit plans as required under its contract with the hospital, and that defendants failed to submit the claims in the proper venue, that is "in the state in which the specimen is drawn."

There is another most important insight to be gleaned from the lawsuit filed by Blue Cross against the rural hospital and the other defendants. Blue Cross alleges that this 29-bed rural hospital submitted almost $34 million in outreach lab test claims in only 120 days.

Billing For Big Dollars!

However, this is just one health insurer. What is the dollar total of lab test claims that Sharkey-Issaquena Community Hospital submitted to all other health insurers, Medicare, and Medicaid during that same 120 days?

It is reasonable to assume that this hospital—in its role as part of this lab testing scheme—submitted a substantially greater amount of claims to all other payers. Collectively, could this mean that Sharkey-Issaquena submitted lab test claims totalling from $68 million to $100 million during this same four-month period?

If true, two numbers can be extrapolated. First, these assumptions indicate that Sharkey-Issaquena is billing Blue Cross in Mississippi at a rate of $108 million per year. Second, its billings to all payers could be anywhere from $180 million to $300 million on an annualized basis.

This lawsuit is a road map that lab administrators and pathologists can use to understand one type of illegal lab test scheme, along with the huge magnitude of dollars that are involved. TDR

—Pamela Scherer McLeod

Developments in UnitedHealthcare's Lawsuit in Florida against Tox Labs, Other Providers

LAST YEAR, UnitedHealthcare Group, Inc., the nation's largest health insurer, filed a $50 million lawsuit in Florida against five urine-drug testing labs, three lab management companies, a physician, other individuals, and several recovery centers.

The lab defendants included **Sky Toxicology**, **Frontier Toxicology**, **Hill Country Toxicology**, **Eclipse Toxicology**, and **Axis Diagnostics.** All of the labs have the same address in San Antonio.

In the 57-page complaint, UHC alleged that the defendants perpetrated a scheme to defraud UHC and other payers through deceptive and unfair trade practices related to claims for urinalysis (UA) tests. In the complaint, UHC also charged that the defendants offered kickbacks to those who refer patients for large quantities of UA for testing. In addition, UHC alleged negligent misrepresentation, unjust enrichment and interference with the contract UHC had with the labs.

Seven months later, the court dismissed the case, saying UHC did not have standing to bring the case against Sky Toxicology and other defendants under the federal Employee Retirement Income Security Act of 1974 (ERISA). That dismissal came on Nov. 1.

The next day, Sky Toxicology and the other defendants countersued UHC, saying that in 2015 UHC alleged that the San Antonio labs committed fraud against the insurer and stopped processing the labs' claims. This lawsuit was filed in the federal Texas Western District Court.

ERISA Preemption Question

In the countersuit, Sky Toxicology and other defendants charged that UHC did not pay them under the assignment of benefits provisions of the UHC contract and that the nonpayment totaled millions of dollars in claims. "Plaintiffs have exhausted all administrative remedies and extensively tried to settle its issues with United without success," the plaintiffs said in the countersuit.

The defendants also charged in the countersuit that UHC had breached its contract with its health plan members by failing to pay for UA testing while the labs performed the duties as outlined in their contracts with UHC.

At the same time, court documents say UHC denied the labs' access to UHC's administrative procedures and so the labs claimed that they had sustained damages totaling the amount of claims denied, a figure that would be determined at trial. The labs also had damages for all attorneys' fees and costs.

In their countersuit, the labs claimed that ERISA applies to their case and so UHC would need to respond to the lab companies' demands. The case has been on hold since the end of March when it was stayed for 45 days. Then it was stayed twice more, the most recent time on May 10. That stay expires on July 1.

Cigna Sued Same Lab Firms

The UHC case was not the first one that a health insurance company brought against these defendants. On July 17, 2015, **Cigna** filed a lawsuit in the federal Southern District of Florida's West Palm Beach Division, listing as defendants: Sky Toxicology, Sky Toxicology Lab Management, Frontier Toxicology, and Hill Country Toxicology. Cigna alleged fraudulent claims of $20 million. The lawsuit noted that the defendants were entities organized in Florida and with the same registered agent at the same street address in Delray Beach.

Unlike in the UHC case, however, the parties in the Cigna case settled. In May 2016, the plaintiff and the defendants reached an agreement to resolve all claims. Under the agreement, the parties asked the court to dismiss the action, and each party said it would be responsible for its own attorneys' fees and expenses.

Time to drop lab 1.0, achieve Clinical Lab 2.0

Message to Labs: Improve Outcomes, Get Paid More Money!

CEO SUMMARY: By now, there is widespread recognition among pathologists and clinical lab managers that the era of fee-for-service reimbursement is giving way to new forms of payment that reward value. First-mover lab leaders are in the earliest stages of developing enhanced lab testing services that contribute to improved patient outcomes while reducing costs. These innovators use the term "Clinical Lab 2.0" to describe the attributes of enriched diagnostic services that will make labs successful in clinical settings where adding value means greater reimbursement.

For pathologist James Crawford, MD, PhD, the fundamental question most clinical laboratory directors should address today is simple. "How can we get beyond just running our labs and begin—as experts in laboratory medicine—to influence the totality of healthcare?" he asked as he introduced a day-long session last month at the *Executive War College* on Clinical Lab 2.0. *(See TDR, May 24.)*

Speaking of the need for labs to migrate toward this new business model, Crawford, who is the Senior Vice President and Executive Director of Laboratory Services for **Northwell Health** in Lake Success, N.Y., stated, "Moving to Clinical Lab 2.0 is about delivering more value. But getting paid for delivering that additional value is the issue with which all of us in the clinical lab industry must wrestle."

The focus of the concept of Clinical Lab 2.0 is for the lab to engage with physicians and other healthcare stakeholders in new ways. "Going forward, the labs that succeed will be those that provide diagnostic services that improve patient outcomes while simultaneously lowering the overall cost of care," he said.

"Labs can do this in two ways," continued Crawford. "First, they can support precision medicine by increasing their collaboration with providers and patients. Second, they can support population management by leveraging the information from lab test data with other clinical, demographic, and financial data."

Clinical labs are just beginning to discuss how to transition their operations away from Clinical Lab 1.0, which is about taking lab test orders from physicians and then delivering lab test results back to them, said Crawford.

Representing one of five of the nation's more progressive clinical lab organizations involved in developing a program called **Project Sante Fe,** Crawford explained that the project's member labs are developing enriched diagnostic testing services that contribute to improved patient outcomes and significant reductions in cost. Their goal is to publish the findings from these efforts in peer-reviewed journals.

By publishing these outcomes from well-designed studies, the Project Santa Fe labs hope to accomplish two goals. First, the studies will serve as roadmaps that other labs can follow to achieve similar improvements in patient outcomes.

Second, healthcare policymakers and hospital and health system administrators will have clinical evidence of how they can use clinical lab testing services to improve the precision medicine and population health management services they deliver.

Evidence of Clinical Utility

"Whether it is Medicare or private insurers, payers are asking labs to provide evidence of the clinical accuracy and clinical utility of their tests," observed Crawford. "The Project Santa Fe labs are now engaged in collecting and publishing that evidence. This evidence is essential as the healthcare system shifts away from volume-based payment and adopts value-based reimbursement strategies.

The five labs participating in Project Santa Fe are:

- **Geisinger Health**, Danville, Pa.
- **Henry Ford Health**, Detroit
- **Kaiser Permanente-Northern California**, Berkeley
- **Northwell Health**
- **TriCore Reference Laboratories**, Albuquerque, N.M.

"We know our labs already deliver a lot more value beyond the 3 cents on the dollar that lab testing represents in the health system," Crawford said. "But getting recognized for that value and getting paid for it are two different things.

"At Northwell Health, we will have that discussion during the upcoming budget negotiations that begin later this year with our adminstration," he said.

Crawford, who is also the Chair of Pathology and Laboratory Medicine at **Hofstra Northwell School of Medicine**, outlined the steps laboratories need to take as they move from Clinical Lab 1.0 to Clinical Lab 2.0.

Transactions to Integration

"We need to focus on how clinical labs can integrate information—which is our primary product—by using our expertise to proactively bring that knowledge forward to our stakeholders," he observed. "Right now, lab test results are a commodity. Providing leadership in extracting the value of our information enables us to justify our existence as we move to Clinical Lab 2.0.

"To do that, labs must compete. But how do we compete within the hospital and in the outreach market on the basis of price for payers and other stakeholders?" asked Crawford. "We need to make our decision makers—meaning the CEO, COO, CFO, and other administrators one level down from the C-suite—recognize how and why the lab is an essential system asset."

Crawford is referring to the efforts by several national labs to approach hospitals and health systems with offers to manage or purchase the inpatient lab and outreach lab business.

"These decision makers need to understand that they would be crazy to separate their clinical lab from their health system simply because they view lab tests as commodities!" he explained. "How to bring that message forward is one of the goals of Project Santa Fe.

"One way to demonstrate to the C-suite that clinical labs are not a commodity is to show that we are, in fact, incredible experts who deliver high quality and accurate analyte results," said Crawford. "For example, as much as we may feel that our anatomic pathology and molecular diagnostic acumen is world class, we need to recognize that, as soon as our data goes over the electronic transom, what we produce is just another piece of data.

"Even those who are consumers of anatomic pathology data may have no idea about how hard it is to practice anatomic pathology at a high-quality level," he added.

"That's why our labs—in the Clinical Lab 2.0 business model—need to demonstrate that we are, in fact, subject matter experts in the practice of medicine," he said. "When we do that, we will be welcomed more broadly.

"Why do I say that? Because our pathologists and lab scientists are the first ones to know when someone has cancer," continued Crawford. "Similarly, we are the first to know the cause of a patient's inflammatory disease. We are the first to know just about everything about a patient's condition.

Serving all Stakeholders

"By looking at our data as subject matter experts, we can explain what that data means in ways that others cannot," he emphasized. "We know that our lab test data makes it possible for us to identify risk.

"We can use lab test data to close gaps in care, and so on," added Crawford. "We also know that we can use our lab data to drive innovation in patient care and to improve the financial health of our hospitals and health systems."

At this point, Crawford explained that lab directors need to identify and serve their stakeholders. "In other words, who is paying for our information?" he asked.

"Stakeholders are health insurers, health systems, employers, and increasingly they are consumers," he noted. "In Clinical Lab 1.0, consumers were often not part of the equation. But today, so much of the cost of care is being shifted to

consumers. This forces them to assume a bigger role as healthcare decision makers. A lab operating as Clinical Lab 2.0 recognizes this fact and provides services that a consumer recognizes as value.

For Consumers, Price Is Right

"For consumers, price is such an important issue that it doesn't take much for them to feel that they should go to a lower-priced product even if there are problems with that product," added Crawford. "For all these reasons, we must acknowledge that consumers are an important stakeholder for clinical labs.

"As with any group of stakeholders, they want value. By definition, value is what someone is willing to pay regardless of whether we're talking about lab test results or other products and services," he said.

"To serve our stakeholders well, we need to determine if we are meeting their needs," he said. "A key part of Clinical Lab 2.0—and a major goal of the Project Santa Fe labs—is to generate and publish the evidence demonstrating how our labs meet their needs.

"Proving you are the lab that stakeholders should use is harder to do than you might think," he warned. "It takes leadership from the lab to drive programs for the total delivery of care, not simply the generation of lab test results. Clinical Lab 2.0 is about leadership, not followship. Our job is to provide leadership.

Communication Is Key

"However, as pathologists and clinical lab directors know, the problem is that serving our stakeholders has never been easy," stated Crawford. "That's because the stakeholders our labs serve—starting with the C suite—don't appreciate us fully and don't appreciate the expertise required for our practice."

He offered an example of how clinical lab expertise is unappreciated. "The State of the New York remains the only state in the union that prohibits pathologists from talking to patients about their test results," he noted. "In hearings, I have testified along with others that we talk to patients about their results. I haven't gone to jail for it, but I have had members of hearing committees ask me, 'How you can do that? You are not knowledgeable about the meaning of your test results.'

"I argue to the contrary—that we are precisely the individuals who bring insight and understanding to the clinical information we produce," he said.

"Think about that for a minute. State legislators believe that, as a board-certified pathologist, I don't know the meaning of my data," he said. "We have had some modest success in correcting that problem. However, it illustrates what the profession of laboratory medicine is up against.

Time to Buck Tradition

"The business model of Clinical Lab 2.0 is about ceasing to be the traditional transactional laboratory and instead, becoming an integrated part of our hospitals and health systems," he asserted. "If we remain in the first category—as a transactional laboratory—we are at risk of not controlling our destiny. But if we are an integrated laboratory and we provide leadership in our hospitals and health systems, then our labs can begin to influence the decisions that are made that affect the financial and clinical existence of all our labs.

"Fortunately, the healthcare system is ready for clinical labs to assume a more integrated role," Crawford said. "Thanks to the rapid changes occurring in healthcare, there has never been a better opportunity for labs to provide leadership in programs and projects that provide better care.

"This is true of our lab at Northwell," he added. "On a daily basis—and sometimes on an hourly basis—we identify opportunities to support better clinical and financial outcomes for our health system." TDR

—Joseph Burns

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Clinical Lab 2.0 Project Shows Off Value of Lab Test Data

Use of Creatinine to Improve Diagnosis, Treatment of AKI

INNOVATIVE CLINICAL LABS are making significant changes to accommodate the shift from volume to value. In one change, they are collaborating with clinicians to use lab test data to improve patient outcomes.

In another, they are collecting the clinical data from these efforts to publish the outcomes in peer-reviewed medical journals to spread the word about their efforts.

The clinical laboratory at Northwell Health in Lake Success, N.Y., is such an innovator. At the *Executive War College* last month, Tarush Kothari, MD, MPH, Physician Informaticist at **Northwell Health Laboratories**, explained how collaboration between the lab and clinicians can improve the diagnosis and treatment of patients with acute kidney injury (AKI).

Now in its third year, this clinical collaboration has helped physicians, nurses, and other caregivers diagnose AKI earlier. In turn, patients are getting the right therapy sooner. This effort has improved patient outcomes and reduced healthcare costs.

At the center of these impressive outcomes is a lab test that is ubiquitous, easy to run, and inexpensive: serum creatinine.

In his presentation, Kothari explained the evidence-based criteria for diagnosis and staging of AKI and how laboratories are positioned to drive quality improvement efforts for patients outside the lab.

The findings from the three-year project show that the lab's efforts resulted in a significantly higher rate of detection of AKI from the baseline year of 2014 through 2016. Clinical data collected during this project showed that using lab test data—including creatinine results—while following the Kidney Disease Improving Global Outcomes (KDIGO) guidelines allowed clinicians to identify more AKI cases than what the hospitals had previously identified using DRG data.

Value of Collaboration

"The result was earlier detection of AKI leading to better patient care, more accurate diagnoses and coding, and reduced costs," said Kothari, who has submitted the data for publication in a peer-reviewed journal.

"Today, it's not enough for clinical lab scientists to just sit in our silo and think that we're doing a great job," observed Kothari, an Assistant Professor in Pathology and Laboratory Medicine at the Hofstra Northwell School of Medicine. "What this project taught us is that we need to step out of our lab and collaborate with our peers who are doing quality improvement work in clinical settings.

"For this project, we set out to standardize early detection of AKI and reduce variability in diagnosis and management by embedding clinical decision support systems into patient care workflows," he explained. "We were not just embedding clinical decision support in the laboratory information systems.

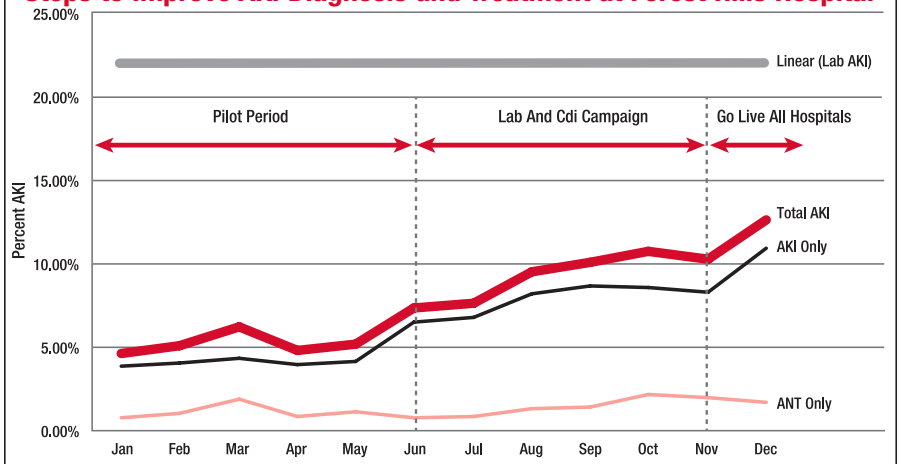
"As we built up the Clinical Lab 2.0 team with the goal of improving diagnosis and treatment of AKI, we asked ourselves this question," added Kothari. "How could we improve clinical and financial outcomes while showing value to all stakeholders, meaning our patients, providers, health systems, and obviously payers?"

Kothari was in the first week of his job at Northwell Health Laboratories on Long

How Northwell's Lab Team Helped Improve Care of Patient's with Acute Kidney Injury

TO IMPROVE THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ACUTE KIDNEY INJURY **(AKI)** at Northwell Health, the clinical lab team worked with physicians and nurses to agree on care protocols and put new alerts into the **Cerner** LIS and **Epic** EHR to support closer interaction. Creatinine results for individual patients were used to indicate the need for clinical teams to provide appropriate care. The project produced faster diagnosis of early stage AKI and improved outcomes.

Steps to Improve AKI Diagnosis and Treatment at Forest Hills Hospital



In the project to improve diagnosis and treatment of patients with acute kidney injury (AKI), it was determined that incidence was just 5% to 6% using the DRG data. But, with the use of creatinine, the laboratory data showed an actual incidence of AKI of more than 20%.

Conclusions: AKI vs. DRG Data

- Significant gap in 2014 between "lab detected AKI episodes" and "coded DRG AKI episodes"
- This gap narrowed in 2015 and continued to improve in 2016
- Better capture of data on disease severity
- Significant increase in financial results
- Lab played leading role but was not the only factor in improved clinical, financial results
- Physician education and buy-in were critical for success
- Increase in capture of DRG diagnosis because of better provider recognition and documentation

Demonstrate Value of the Laboratory

Value to Providers

- Provide clinical decision support based on evidence-based criteria
- Reduce variability in diagnosis
- Reduce diagnostic latency
- Reduce severe AKI episodes

Value to Health System

- Improve clinical documentation of disease severity
- Increase in revenue

Value to Payers

- Understand AKI disease burden
- Reducted inpatient dialysis costs
- Lower incidence of chronic kidney disease after episode of AKI and lower long term costs

Island when he got an email from the chief medical officer at 250-bed **Forest Hills Hospital**, in Queens, N.Y., one of 22 hospitals in the Northwell system. "The CMO was seeing three patients with radio-contrast-induced AKI every day," commented Kothari.

"Three cases per day equals about 1,100 cases per year," he calculated. "If you attribute two excess length-of-stay days to an episode of AKI, the math works out like this: 2,200 excess days per year at about $500 per day in variable costs, or about $1 million in additional cost annually just for this one hospital. And, in severe AKI cases—where the length of stay goes up by three to seven days—means that total costs of care rise by about $4,000 to $10,000 per patient encounter.

"That amount of excess spending on AKI patients represented potentially huge savings—not just at this hospital, but across our entire health system," recalled Kothari. "That was the impetus that got me started.

"What we knew about AKI is that—when serum creatinine increases by even minute amounts in a short time—mortality rates rise and healthcare costs rise too," he noted. "We also know that about 20% of medical and surgical patients suffer from AKI in general hospital settings.

"The incidence in critical care settings is actually much higher, about 20% to 30%," continued Kothari. "Also, AKI encompasses a variety of disease states.

Who Makes The Diagnosis?

"It is important to note that, although this is a condition nephrologists treat, the doctors who make most of the diagnoses of AKI include general internists, surgeons, and ER physicians," he said.

"To pick up this diagnosis can be challenging because AKI is usually secondary to a primary diagnosis, such as sepsis, pneumonia, or trauma," commented Kothari. "It's easy for doctors to forget about this diagnosis. Yet, AKI is a broad problem in all hospital settings for all subspecialties.

"The literature shows that AKI represents about 5% of total hospital costs and annual healthcare costs attributable to hospital-acquired AKI exceed about $10 billion in the United States," he said. "When AKI progresses in severity from Stage 1 to Stage 2 to Stage 3, the mortality, length of stay, and costs all worsen," he added.

"The diagnosis of AKI relies on the incremental rise in inpatient serum creatinine compared with a minimum baseline value within a fixed time period," noted Kothari. "According to the KDIGO standard, the diagnosis of AKI requires one of these two criteria: 0.3 mg/dl rise above baseline within 48 hours or 1.5 to 1.9 times baseline within seven days.

A Challenging Diagnosis

"The staging of AKI also depends on the relative rise of creatinine," he said. "So if the creatinine rises by 0.3 mg/dl from baseline or by 1.5 to 1.9 times baseline, that is Stage 1. Greater than 2.0 to 2.9 times is Stage 2, and greater than 3.0 times baseline is Stage 3.

"Making this diagnosis is challenging and is often missed because of two key factors," Kothari said. "One is the definition of baseline. In cases where the patient's baseline value was not known, we decided to use the minimum inpatient value as the baseline, as per KDIGO criteria.

"The second important factor for diagnosis is the time frame," he stated. "The rise has to happen by a certain amount in a set duration. So a rise of 0.3 mg/dl can happen only within 48 hours. A rise of greater than 1.5 times baseline should happen within seven days.

One problem the lab faced when seeking to identify patients with AKI was how to reconcile the creatinine data collected at the point of care with the hospital's DRG data. "When we compared the lab data showing the incidence of AKI with the data the hospital had for AKI incidence based on DRGs, we observed a significant increase in the documented rate of AKI from about 5% in 2014 to more than 12% in 2016," Kothari explained.

"When we looked at the absolute numbers of cases from our baseline of 2014, we captured 8,000 more episodes of AKI in 2015 and about 10,000 more episodes of AKI in 2016," he added.

"Then, even rough math will show that if the hospital gets paid about several hundred more dollars for a secondary diagnosis of AKI, then our clinical collaboration could increase reimbursement significantly in 2015 and in 2016.

"One conclusion we can draw from this project is there was a significant difference between the lab-detected AKI episodes and coded DRG AKI episodes," emphasized Kothari. "This gap narrowed in 2015 and in 2016 because of the attention we gave to this condition. Plus, we captured disease severity more accurately.

"One factor that was essential to our success was collaborating with our clinical documentation team and with our physician colleagues," he said.

"At this stage, our work is not done," he added. "We are now linking our lab data sets to other data sources—such as pharmacy and hospital cost data—to refine our intervention so that we can measure reductions in the cost of care for patients with AKI objectively. There is much more value that can be realized by doing so." TDR

—Joseph Burns

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Northwell's Laboratory Had Role in Developing Decision Support to Help Physicians with AKI

IN ANY HOSPITAL, GETTING PHYSICIANS to understand the value of lab data at the point of care can be challenging. Identifying patients with acute kidney injury (AKI) is one example because guidelines show that the diagnosis depends on the increase in serum creatinine over a certain time.

"This is where clinical decision support comes in because this is a busy hospital," stated Tarush Kothari, MD, MPH, Physician Informaticist at Northwell Health Laboratories. "Busy clinicians do not have time to apply the Kidney Disease Improving Global Outcomes (KDIGO) criteria consistently and prospectively in real time. Plus, there is a lack of effective clinical decision support tools for AKI within our EHR. Even if you build alerts in the EHR, they may not be integrated appropriately into the clinical workflow."

The solution Northwell implemented was to apply the KDIGO guidelines into the laboratory information system to flag patients who meet the AKI criteria. "The goal was not to miss a single AKI patient," explained Kothari.

"We let the physicians decide how they wanted to act on the lab AKI alert because ultimately this is a clinico-pathologic diagnosis," he explained.

"When we implemented this alert at Forest Hills Hospital, our expectation was that we would see about 10 to 15 alerts per day," Kothari said. "But we actually saw about 40 AKI alerts per day in a 250-bed hospital. This corresponded to roughly 20 patients, or a 10% to 12% incidence rate in a busy community hospital.

"Next, before we rolled out this alert across seven other hospitals in the Northwell Health system, we validated the algorithm," he continued. "Then we educated physicians and nurses about how it worked and why it's important to identify AKI early.

"These alerts are meaningless unless we supplement them with physician education and awareness," noted Kothari. "That is why our CMO carried out a major awareness and physician-education campaign to ensure that all the key physician champions and everyone on staff were educated about implementation of this alert.

"In essence, this was a multifactorial informatics intervention guided by lab data," Kothari concluded.

Lab Fraud Update

31st Physician Pleads Guilty In Federal Lab Fraud Case

Latest conviction in Biodiagnostic Lab Services case, U.S. Attorney continues to pursue docs who took bribes

AN INTERNAL MEDICINE PHYSICIAN who practiced in Yonkers, N.Y., is the latest physician to admit to taking bribes in connection with a laboratory test referral scheme that **Biodiagnostic Laboratory Services LLC** (BLS), of Parsippany, N.J., operated for years.

The physician, Ricky J. Sayegh, MD, 44, of Scarsdale, N.Y., pleaded guilty before U.S. District Judge Stanley R. Chesler in Newark federal court, according to Acting U.S. Attorney William E. Fitzpatrick.

To date, the investigation into BLS has resulted in 45 convictions, including 31 physicians. The DOJ said that number of physicians convicted in the BLS case is believed to be the largest number of medical professionals ever prosecuted in a bribery scheme.

Sayegh was charged with accepting cash bribes in return for referring blood specimens to BLS. For more than three years beginning in February 2010, Sayegh collected approximately $400,000 in bribes from BLS, the DOJ reported. In exchange, BLS used Sayegh's referrals to generate more than $1.4 million in lab business, the DOJ said.

BLS executives have admitted that the scheme involved millions of dollars in bribes and resulted in Medicare and private health insurers paying more than $100 million to BLS.

In the investigation, the DOJ has recovered more than $12 million through forfeiture from physicians, BLS executives, and others involved in the scheme. Last year, executives from BLS pleaded guilty and the company was required to forfeit all assets. The lab company no longer operates.

Facing 5 Years in Prison

Sayegh is scheduled to be sentenced on Sept. 6. He could serve a maximum potential penalty of five years in prison and be required to pay a fine of $250,000.

In April, the DOJ reported, that a physician who practiced in the New York City borough of Staten Island pleaded guilty to accepting bribes in exchange for sending patient's blood samples to BLS. That physician, Ahmed El Soury, MD, 44, of Monmouth Junction, N.J., practiced internal medicine, Fitzpatrick announced.

El Soury faces a maximum penalty of five years in prison and a $250,000 fine when he is sentenced on July 19.

Among the 31 physicians convicted in the case, only one, Brett Ostrager, MD, has been sentenced. He was sentenced to 37 months in prison. He had a practice in Nassau County, N.Y.

In 2015, a federal grand jury indicted Ostrager. He was charged with one count of conspiring to violate the Anti-Kickback Statute and the Federal Travel Act, three substantive violations of the Anti-Kickback Statute, and four substantive violations of the Federal Travel Act. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Have you ever wondered how many consumers have ordered genetic tests from **23andMe**? According to the *MIT Technology Review*, more than 2 million consumers have ordered genetic tests from the Silicon Valley company. Moreover, 85% of these consumers have consented to have their data used for research, noted 23andMe. By the way, these tests are priced at $99 to $199. Thus, an average of $150 per test times 2 million would generate revenue of about $300 million for 23andMe since its inception.

MORE ON: *23andMe*

True to its Silicon Valley roots, 23andMe is currently engaging 20,000 customers in an at-home experiment to have participants report their response to pain stimuli and match that to their genetic profiles.

OPKO'S BRLI UNDER FED. INVESTIGATION

On May 10, *Reuters* reported that **Bio-Reference Laboratories, Inc.**, a business unit of **Opko Health**, is the subject of a federal investigation. This information was disclosed by Opko in a securities filing. *Reuters* described the probe as an "investigation for improperly billing the federal government for services for patients at certain hospitals." For many years, lab industry insiders have speculated that the lab company was under investigation for various billing practices. This is the first public disclosure that the lab company is being investigated by federal regulators.

TRANSITIONS

• **Theranos** of Palo Alto, Calif., named Cass Grandone as its Senior Vice President of Product Development. Grandone came to Theranos from **Pfizer**. Prior to that, he had served in various executive positions with **Abbott Laboratories** for almost 30 years.

• Pat Noland is the new President of **Boston Heart Diagnostics** of Framingham, Mass. Formerly, Noland was with **Genetic Signatures Limited**, **Strata Pathology Services Inc.**, and **Laboratory Corporation of America.**

• Don Hardison was appointed CEO of **Biotheranostics, Inc.**, of San Diego. He has been a director for the company since 2016. Previously, Hardison held executive positions with **Good Start Genetics**, Laboratory Corporation of America, **Exact Sciences Corp.**, **Quest Diagnostics**, and **SmithKline Beecham Clinical Laboratories**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

... how **Aetna**, **UnitedHealth Group**, and **Anthem** are reporting that currently 50% of their reimbursements are now linked to value-based arrangements. It is a reminder that the era of fee-for-service payments is coming to an end. *You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.*

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 26, 2017.