Volume XXII, Number 7 Monday, May 11, 2015

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Labs Have High Interest in Theranos and BeaconLBS

WHAT ARE PATHOLOGISTS AND LAB EXECUTIVES TALKING ABOUT when they gather at lab industry conferences? If the hallway chats between sessions and dinner conversations that occurred last week at the 20th annual *Executive War College* are representative, then the clinical lab profession is closely tracking the **UnitedHealthcare** and **BeaconLBS** story on the East Coast (in Florida) and the **Theranos** story on the West Coast (California and Arizona).

I got plenty of feedback from folks who were in New Orleans for the conference last week and much of their commentary includes observations about the UnitedHealthcare/BeaconLBS lab test utilization program in Florida and the market expansion of Theranos in Arizona. Our editorial team was in attendance and confirms that, between formal sessions, many lab professionals were discussing these developments.

Both stories have been the subject of intelligence briefings by THE DARK REPORT over the past 24 months. Feedback from clients and regular readers has reflected their concerns that, if each of these developments gathered momentum and were deployed into more regions across the nation, each would be one more challenge to the financial sustainability of local clinical labs and anatomic pathology groups.

Recognizing the potential threats represented by each of these business initiatives, THE DARK REPORT was first to publish detailed assessments designed to help senior lab administrators and pathologists understand the respective issues involved in the UnitedHealthcare/BeaconLBS and Theranos stories. In fact, we've been ahead of established media on both stories.

In the case of the UnitedHealthcare and BeaconLBS lab test utilization program in Florida, only the *Naples Daily News* and *Modern Healthcare* have published stories about the unhappiness of thousands of physicians over the requirements for lab test ordering imposed by UnitedHealthcare for patients enrolled in its commercial health plan.

Similarly, I continue to be puzzled that major media news outlets have yet to conduct their own objective, detailed assessments of the lab testing services Theranos offers. On pages 16-18 in this issue, we provide information about our editor's most recent visit to have lab tests done by Theranos. His experience is both illuminating and informative. TDR

New Lab Industry Trends Require Responses by Labs

Speakers at Executive War College last week emphasized need for labs to deliver more value

CEO SUMMARY: One stark difference between the presentations delivered at last year's Executive War College and this year's presentations in New Orleans last week was near-unanimous recognition that the era of fee-for-service payment is soon to end! Speaker after speaker urged the audience to accept this marketplace reality. The common recommendation was for lab administrators and pathologists to take immediate steps to help their laboratories respond to this development in effective ways.

IF THERE WAS ONE UNIFYING THEME to most of the presentations delivered at this year's *Executive War College on Lab and Pathology Management*, it was the need for labs of all sizes and types to be more nimble and responsive to the changing needs of physicians, patients, and payers.

There was a specific reason why so many knowledgeable speakers advised labs to become more nimble and responsive. It is the recognition that the era of fee-for-service reimbursement is coming to an end—and fast! This was an important element in the keynote presentation delivered by Robert L. Michel, Editor-in-Chief of THE DARK REPORT and Founder of the *Executive War College* that opened the program on Tuesday, May 5.

In his remarks, Michel reminded the audience that the federal **Department of Health and Human Services** (HHS) was accelerating the Medicare program's transition away from fee-for-service and toward other forms of reimbursement. "In its press conference on January 26, HHS officials declared that the goal was to tie 30% of existing fee-for-service payments to 'quality or value' via such delivery models as ACOs and bundled payments," noted Michel.

"This will happen with unprecedented speed," he emphasized. "HHS says it wants to reach this 30% conversion by the end of 2016! That's just 19 months from now. It also wants to raise that 30% to 50% by the end of 2018.

"The story doesn't end here," continued Michel. "HHS officials further outlined a goal of tying 85% of all traditional Medicare payments to quality or value by 2016, then

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

moving that to 90% by 2018. This would be done within the Medicare Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.

Private Payers and Medicare

"Lab managers should keep in mind that, when Medicare changes coverage guidelines and reimbursement, private health insurers tend to incorporate similar changes into their policies," added Michel. "Therefore, if Medicare takes aggressive steps to reduce the proportion of pure fee-for-service reimbursement in favor of more value-based and bundled reimbursement, it can be expected that private payers will act with equal swiftness to adopt nearly identical payment models."

Michel's observations on the speed with which Medicare is poised to transition away from fee-for-service payments were affirmed by speakers who followed. For example, in his presentation, Sam Terese, CEO of **Alverno Clinical Laboratories** in Hammond, Indiana, pointed out that "ongoing budget cuts to Medicare will be the norm. Current projections are for Medicare cuts of $260 billion by 2022.

"Thus, going forward, there will be fewer Medicare dollars even as we see more bundled reimbursement from Medicare and private insurers," noted Terese. "The other trend for which labs must prepare is continued growth in the number of Medicare beneficiaries, accompanied by an increase in enrollment in Medicare Advantage plans."

Big Regional Lab Network

Alverno operates a central laboratory that provides lab outreach testing services. It also administers one of the nation's largest regional laboratory networks that includes 27 hospitals owned by its parent health systems, along with labs in four non-owned hospitals.

One key strategy at Alverno is to continue standardization of lab testing services across the organization. This has the benefit of supporting the full integration of lab test data, which, in turns, gives Alverno a rich data base of clinical information to mine as it works to deliver more value to clinicians and stakeholders.

"Another development with our parent healthcare organizations is their ongoing acquisitions of physician practices," explained Terese. "Alverno must then work to bring this 'captured outreach' into the system in ways that foster the ongoing integration of clinical care and clinical workflow."

Of course, cutting costs is another big goal. According to Therese, Alverno is committed to a 25% reduction in costs over the next five years, to be achieved through a succession of cost-cutting initiatives.

Better Use of Lab Test Data

The morning's next speaker reinforced the comments of Michel and Terese, while challenging the audience to think creatively in how to use lab test data to improve patient outcomes and help parent institutions contribute to bending the U.S. healthcare system's cost curve.

That speaker was Khosrow Shotorbani, CEO and President of **TriCore Reference Laboratories**, based in Albuquerque, New Mexico. Shotorbani stepped up to the podium and immediately cut to the chase, confronting the *Executive War College* audience with the three most significant questions facing every clinical lab and anatomic pathology practice today.

"First, if a lab will not be paid on a volume-based business model, how does it capitalize or monetize on value-based payments, particularly when it must deal with less volume as clinicians improve their utilization of lab tests?" asked Shotorbani. "Second, if your lab testing services are paid with bundled reimbursement arrangements, how does your lab make money?

"Third, during the time it takes to make the transition away from fee-for-service payment," he continued, "how does your lab team manage the dichotomy of operat-

IVD CEOs and Lab CEOs Identify Strategic Drivers Currently Confronting the Clinical Lab Industry

NOT IN MANY YEARS HAVE SO MANY CEOs of large lab industry vendors and clinical lab organizations come together at one time and in one place specifically to share strategic thinking and current developments in the lab testing marketplace.

On Wednesday morning last week at the *Executive War College*, the general session featured two special panel discussions. The first included CEOs from *in vitro* diagnostics (IVD) and lab informatics companies. The second panel was made up of clinical lab CEOs.

Because the IVD and informatics companies serve thousands of labs here and abroad, it was an opportunity to learn how they assess the current state of the clinical lab testing market, along with their predictions of the likely paths for healthcare's evolution.

Perspectives of Lab Vendors

On the first panel were: Matt Hawkins, President, **Sunquest Information Systems, Inc.**, Tucson, Arizona; John Kershaw, President and CEO, **Sysmex America, Inc.**, Lincolnshire, Illinois; and, Jennifer Zinn, Vice President, Strategic Affairs, **Roche Diagnostics Corporation**, Indianapolis, Indiana.

The three panelists all agreed that consolidation involving hospitals and health systems, as well as clinical labs and pathology groups, would be an ongoing and major trend. Zinn of Roche pointed out that "consolidation leads to standardization and, for labs, that contributes to the commoditization of diagnostics." Kershaw of Sysmex added that this consolidation, combined with more effective lab automation, is contributing to a de-skilling of the lab workforce—absolutely the wrong thing to happen to the lab testing industry at a time when personalized medicine is gaining momentum.

Hawkins of Sunquest noted that the consolidation of hospitals and labs among his company's client base is ongoing. As a consequence of this trend, and the accompanying regionalization of clinical services that follows, he said that improved interoperability becomes a critical success factor for labs serving these regional health organizations.

Panel of Lab CEOs

The following panel was made up of clinical lab CEOs: Richard Cotten, COO, **Boyce & Bynum Pathology Laboratories**, Columbia, Missouri; Stan Schofield, President, **NorDx**, Scarborough, Maine; and, Gregory N. Sossaman, M.D., Ph.D., Chairman, Pathology & Laboratory Medicine, **Ochsner Health System and Foundation**, New Orleans, Louisiana.

All three lab CEOs put improving capabilities with the lab's data analytics at the top of their strategic initiatives. Cotten of Boyce & Bynam and Sossaman of Ochsner both discussed how their respective labs were pursuing innovative collaborations and partnerships as a way to sustain their labs' abilities to contribute value in each of the regions that they serve.

Schofield of NorDx emphasized the need for all labs to do more with less and to develop ways to more smoothly integrate lab services as the parent healthcare system acquires hospitals or establishes new collaborations.

One of the interesting perspectives offered by Sossaman of Ochsner was about the relative value of expanding molecular test capabilities versus using data from routine tests to help physicians manage patient populations. He discussed the example of hemoglobin A1c testing and shared how his lab team was working to identify instances where diagnosed diabetics had not had their tests performed within the previous 12 months. By providing enriched lab test data to physicians, the Ochsner lab was contributing to improved patient outcomes across a large number of patients.

ing two opposing business models (volume versus value) at the same time?"

With these questions, Shotorbani had the full attention of the audience. He then laid out TriCore's vision for serving the changing needs of healthcare. "We all recognize how lab test data plays an essential role in the continuum of care," explained Shotorbani. "At TriCore, we want to leverage lab data in ways that allow us to be a partner and collaborator across the continuum of care. By supporting the improvement of patient outcomes and the reduction of healthcare costs, TriCore ensures that it will be paid appropriately for its contributions."

Diagnostic Info Exchange

Shotorbani next invited the audience to think of the concept of a diagnostic health information exchange. "In New Mexico, TriCore currently provides up to 70% of all lab test results throughout the state," he noted. "TriCore also has access to the full patient data held by its health system owners. This gives TriCore a unique position from which to help its parent hospitals, physicians, patients, and payers.

"We are engaged with specialized informatics companies to create such a diagnostic health information exchange," continued Shotorbani. "The goal is to deliver measurable value to all stakeholders in healthcare. This provides our lab with opportunities at three different levels.

"The first level is improving utilization of lab testing, such as with CPOE," he stated. "The second level is to use data analytics to help providers with prognosis, monitoring, and prevention. This is a more active collaboration involving TriCore, clinicians, integrated care organizations, and payers.

"The third level is the exciting one for lab professionals," noted Shotorbani. "This is where TriCore delivers predictive tools to stakeholders that enable diagnosis-based population health management, in return for a share of the bundled payment." TDR

Proposing Programs to Help Next Generation of Lab Leaders

FOR AT LEAST TWO DECADES, many in the lab industry have called attention to the looming retirements of baby boomer pathologists, med techs, and lab scientists. These individuals make up the largest proportion of supervisors, managers, and lab administrators working in labs today.

As they retire, every clinical lab and pathology group needs to have the next generation of leaders ready to step up and assume responsibilities. But, across the lab industry, there are limited opportunities for every lab's brightest up-and-comers to get the regular management development opportunities that are common among Fortune 500 companies.

That is why leadership was a major theme at this year's *Executive War College*. In his keynote presentation on Wednesday, May 6, Jeffrey McCausland, CEO of **Diamond6 Leadership** and a retired U.S. Army colonel, encouraged the audience to be more proactive at developing the next class of leaders within their laboratories. One way to accomplish this is to support mentoring activities.

Picking up this theme, Robert L. Michel, Founder of the *Executive War College*, asked the audience if a mentoring program at upcoming conferences would be a welcome addition to the program's offerings. The response was strong and enthusiastic.

Michel then asked if a reduced tuition program for young lab leaders would be of interest for the 2016 conference. Again, the audience was positive to the concept, particularly when McCausland suggested that such a program be organized so that a lab's mentor would attend with his/her mentoree.

He recommended that these two individuals could participate in special workshops designed to teach both mentor and mentoree how to interact to accelerate the mentoree's development and his or her ability to make significant contributions to the lab's clinical service excellence and operational success.

Fewer Blood Draws at UCSF Boost Patient Satisfaction

Initiated by residents, 'Think Twice, Stick Once' aims to change the culture of phlebotomy collections

CEO SUMMARY: Physician residents at the UCSF School of Medicine set a target of reducing unnecessary blood draws. By eliminating needless needle sticks, the residents are focusing on patient experience while also encouraging physicians to pay more attention to the need to decrease unnecessary clinical lab testing. The goal is a 5% reduction in phlebotomy procedures for the academic year 2014 to 2015, compared with the previous academic year. Early results show a decrease in phlebotomy procedures.

TREATING PHYSICIANS ARE SEIZING THE INITIATIVE to eliminate unnecessary clinical laboratory testing and the number of phlebotomy procedures performed on hospital inpatients.

This is the goal of a program developed by internal medicine residents at the **University of California San Francisco School of Medicine** (UCSF), a large tertiary-care academic medical center. During the 2014 to 2015 academic year, these physicians expect to reduce the number of phlebotomy draws per patient per day by at least 5%, as compared with draws done in 2013 to 2014.

"The program is in place within UCSF's internal medicine teaching service, which has a mean daily census of 88 patients," stated Daniel J. Wheeler, M.D., a Resident Physician in the Department of Medicine. "This effort to reduce inpatient testing is known as the 'Think Twice, Stick Once' campaign.

"From the beginning, our group sought a project that would achieve the **Institute for Healthcare Improvement's** Triple Aim of improving patient care, patient experience, and costs of care," explained Wheeler. "We thought phlebotomy reduction was the ideal project to meet those goals.

"Specifically, we targeted the reduction of unnecessary blood draws," he commented. "Overuse of testing is not a problem limited to phlebotomy; however, blood draws are a high frequency event in the hospital, which made this a good target for intervention.

Targeting Blood Draws

"It is our hope that changing the culture of phlebotomy will in turn affect how providers at UCSF think about other medical interventions, such as imaging studies and procedures," added Wheeler.

"Plus, by measuring phlebotomy frequency rather than the total number of tests, we are emphasizing the importance of patient experience while also providing high-value care and avoiding unnecessary patient harm," he said. "By eliminating needless needle sticks, we are improving the patient experience. Further, we expect the data on improved patient outcomes

will provide clinicians with a compelling reason to decrease unnecessary testing.

"Because the project began last summer, it's a bit early to say whether our intervention has moved the needle on patient satisfaction scores," stated Wheeler. "We also recognize that it will be difficult to prove a causative effect in retrospect.

Boosting Satisfaction Scores

"Anecdotal and qualitative evidence shows that frequent phlebotomy sticks are uncomfortable for patients," he said. "Thus, our efforts to quantify the effect of phlebotomy reduction on patient satisfaction are ongoing.

"We started the project on July 1," noted Wheeler. "It included the educational campaign, data collection, and performance feedback. From July to September we did not see much change in the number of blood draws per patient per day.

"However, we saw a clear decrease in blood draws from October onward," he continued. "That's when real downward changes in our phlebotomy numbers began to show up. This program is truly driven by residents and has led to changes in how residents order blood tests."*(See sidebar on page 9.)*

"Undoubtedly, there are multiple factors for this timing, but a big one is that the academic year begins in the summer," said Wheeler. "That's when members of the residency house staff are growing into new roles. We believe that is why there was some lag time before practice patterns of lab test ordering became visible."

Residents Created Program

Pathologists should take note about an interesting aspect of the "Think Twice, Stick Once" campaign. It was originated by internal medicine residents and led by them. In this sense, it shows how the thinking of clinicians is changing now that they are being asked to identify and implement programs that improve patient safety and contribute to better patient outcomes.

"Because we focused on the ordering of lab tests, we did not discuss our initial intervention with the Department of Pathology or the laboratory," recalled Wheeler. "In fact, our communication with the lab has been minimal—in part because the project has operated almost entirely at the direct clinical/provider level. This is due to the fact that our focus was on the act of ordering lab tests.

"Our primary role was to educate those who place orders for tests, namely, the internal medicine house staff," Wheeler said. "Also, we did not hear any concern from the lab about reduced testing. In fact, the project received positive feedback from lab leadership.

Unnecessary Blood Tests

"While we didn't hear concerns about reduced testing, we were, nonetheless, aware that running a project that aims to reduce unnecessary blood tests could unintentionally lead to a reduction in lab tests that actually affect medical management," he added. "Lab tests are essential to patient care, and we are sensitive to the concern that attempts to reduce even unnecessary phlebotomy could have a negative effect.

"However, it is also possible that a reduction in unnecessary phlebotomy could have a positive impact on patient outcomes. As we move forward, it will be important to look at balancing measures that link phlebotomy usage with clinical outcomes," he added.

"To reinforce that important point, our educational campaign emphasized that the focus is to help physicians reduce unnecessary clinical laboratory tests," commented Wheeler. "We explained that the primary goal was to reduce the number of blood draws as opposed to the number of lab tests ordered.

"By calling attention to the number of blood draws, the emphasis is thus placed on the patient experience," he noted. "Of

At USCF Medical Center, Residents Use Education to Reduce Number of Phlebotomy Procedures

RESIDENTS IN THE INTERNAL MEDICINE SERVICE at the University of California San Francisco School of Medicine implemented an interprofessional educational campaign to reduce unnecessary clinical laboratory testing focused on phlebotomy.

The residents produced timely feedback of team-specific phlebotomy data and used financial incentives to change practices related to inpatient laboratory testing, according to an abstract the **Society of Hospital Medicine** published for its annual meeting March 29 to April 1 in Baltimore, Maryland. In the medical center's "QI Incentive Program," each resident physician was eligible for an annual $400 reward for meeting a specific performance goal.

To create awareness and change the behavior of clinicians, the residents publicized the project to house staff, nurses, and faculty by using the slogan "Think Twice. Stick Once." The educational campaign utilized the following activities:

- An introduction of strategies for phlebotomy reduction during monthly house staff orientation sessions;
- Posters and pens featuring the slogan "Think Twice. Stick Once;"
- A "Facilitator's Guide" for all attending physicians that includes suggestions for discussing appropriate use of lab tests with trainees;
- Discussions at monthly didactic sessions regarding best practices for appropriate lab test ordering.

To track progress, each of eight internal medicine teams reports team-specific phlebotomy data twice monthly. All members of the teams can view the data and thus can compare one team against others.

During the academic year prior to project implementation (2013 to 2014), the average phlebotomy usage across all medicine teams was 2.09 draws per patient per day.

In the current academic year (2014 to 2015), after the first three months of the project, there was no change in average phlebotomy use. However, during the fourth and fifth months, the average dropped to 1.93 draws per patient per day, suggesting possible improvement. The "Think Twice, Stick Once" program has the goal of reducing the overall number of phlebotomy procedures per patient by 5%, when compared with the prior year.

course, our program also asks residents to consider not only if a test should be ordered, but also when.

"For example, non-urgent lab tests can sometimes wait until the next morning rather than being drawn immediately," he observed. "This avoids causing an extra, unnecessary, uncomfortable poke. ICU patients were excluded from our data collection because they often need more frequent monitoring and testing."

One visible reward for improving the patient experience is that the program is expanding within UCSF. "The Division of Hospital Medicine started tracking phlebotomy usage just when we started our project and now follows phlebotomy usage as a performance metric for its non-resident services," he said. "The division's decision to track this data was not a direct response to our early successes, but it is evidence of a growing acknowledgement of the importance of the initiative.

Phlebotomy Usage Metric

"All of these efforts show that the project has been well received within the residency program and in our Division of Hospital Medicine," noted Wheeler.

Recognizing that it is important to share the positive outcomes for this initiative, Wheeler and his colleagues have taken the

opportunity to present the program in other settings. "Multiple groups have heard our presentation," he said. "For example, we submitted the project to the UCSF Medical Center's Resident and Fellow QI Incentive Program, which works with resident groups to promote quality improvement.

"Our project was accepted into the program, which provides all participating house staff with a financial award of approximately $400 per person for meeting a stated performance goal," stated Wheeler. "Within our department, the goal is to reduce the number of phlebotomy draws per patient per day by 5% compared with draws done in the prior academic year.

"We also discussed the project with the Division of Hospital Medicine, and DHM has been very supportive of the project," he continued. "DHM currently reports the same phlebotomy data to its hospitalist service. Also, along the way we received wonderful mentorship from within the Division of Hospital Medicine."

What's Next At UCSF?

What's next for the UCSF Internal Medicine teaching service? "Now that we have early success in reducing the number of phlebotomy procedures, we are considering how to move the project forward," noted Wheeler. "One idea is to collaborate with the hospital lab staff to identify specific tests that are typically needed only once during a patient's hospitalization.

"Our hope is to use the electronic medical record to call attention to such lab tests and remind providers that they need not be ordered more than once during a patient's hospital stay," he explained. "We are considering other cultural changes to lab test ordering, such as the utility of ordering lab panels versus single tests. These are ideas that we hope to discuss with the lab staff in the future." TDR

—Joseph Burns

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Opportunities for Lab to Help Improve Care

ONE EXPERT IN HEALTH POLICY URGES pathologists and laboratory professionals to engage clinicians more actively to improve utilization of clinical lab tests.

"The 'Think Twice, Stick Once' initiative here at UCSF shows the potential that exists for clinical laboratory directors to have an important role in helping to develop such programs in hospitals," stated R. Adams Dudley, M.D., Professor of Medicine and Health Policy and Director of the UCSF Center for Healthcare Value.

"Healthcare's emphasis on improved patient outcomes and a better patient experience in hospitals makes the time ripe for lab directors to take the initiative with these types of programs," continued Dudley. "Lab directors have big advantages over other clinicians in terms of access to data, and they know—or at least could calculate—how many tests are done per patient per day. Other clinicians have only a vague sense about this issue and don't have the data to check.

"Lab directors also know which tests are more expensive and which ones have higher false positive rates," he said. "False positives are particularly problematic in terms of waste, because they lead to unnecessary additional testing or, even worse, unnecessary treatment. Pathologists also understand which lab test numbers change slowly over time for a hospital inpatient, meaning that there is no reason for physicians to check them frequently.

"For all these reasons, experts in laboratory medicine and pathology can use their knowledge to bring together different services and help them figure out how to implement programs like 'Think Twice, Stick Once,'" observed Dudley. "Clinical laboratory directors are uniquely positioned to stimulate interdisciplinary conversations about how to make care better in terms of cost and patient experience through improved utilization of lab tests."

What Labs Need to Do as Payers Audit More Claims

Both government and private health plans are aggressively auditing labs for multiple issues

CEO SUMMARY: Attorneys who advise pathologists and clinical laboratories on compliance issues say the number of audits from the government and third-party payers has increased sharply in recent years. In those audits, payers are looking for recoupment of overpayments. A lab's failure to provide proper documentation during these audits can result in the need to pay six- and seven-figure amounts. Payers also are auditing out-of-network billing and patient balance billing.

CLINICAL LABS AND PATHOLOGY GROUPS are facing an unprecedented level of audits from healthcare payers, according to lawyers who represent medical labs and pathologists.

"In addition to a substantial increase in audits, more health insurers are scrutinizing how pathologists and labs handle out-of-network billing, including how they balance-bill patients," stated attorney Jane Pine Wood, of the national firm of **McDonald Hopkins**.

"Payers are also conducting more audits of pathology and lab claims to assess medical necessity," she continued. "Much of this audit activity is associated with payer concerns about specific fraud and abuse issues triggered when a pathologist or laboratory offers benefits or payments to providers. Some of these issues were identified in an OIG advisory opinion issued on June 25, 2014.

"In this advisory opinion, the OIG described two specific trends it identified and described as 'involving transfers of value from laboratories to physicians that it believes present a substantial risk of fraud and abuse under the anti-kickback statute,'" noted Wood. "One of these activities is the payment by laboratories to physicians for collection and handling services.

"Payments by laboratories to physicians for participation in studies or registries was the other activity discussed in the OIG advisory opinion," stated Wood. She made these comments during a recent webinar produced by THE DARK REPORT.

Many More Audits Of Labs

"Probably the most significant development, however, is that both government and private payers are doing many more audits of labs' and pathology groups' billing practices than they have done in the past," emphasized Wood. "In addition, federal investigators are looking closely at the need for documentation of special stains and test panels for toxicology, molecular, and genetic testing.

"In our law practice we see a tremendous uptick in the number of audits of our pathology and clinical laboratory clients by both government and third-party pay-

ers," commented Wood. "Not only has the number of audits increased, but, compared with past years, a much greater number of third-party payers are conducting audits and seeking to recoup money from our pathology and laboratory clients."

Wood identified areas of audit risk and discussed how labs should be prepared to handle such audits.

"It is important to respond appropriately to audit requests," observed Wood. "Often, auditors will check only a few billing records. Then, if errors are found, they will extrapolate and hit pathologists and labs with bills for hundreds of thousands of dollars or more.

"If your practice or lab gets an audit request, look carefully at everything the auditor requests and supply everything that you can," advised Wood. "If it's not possible to assemble everything needed in time to meet the auditor's deadline, request an extension and document in writing that the extension was granted. Next, do everything you can to send in all the requested information at one time.

Auditors Becoming Stricter

"This is important because increasingly we find that auditors are very strict," she noted. "If your lab is missing any bit of information, the case gets denied.

"Keep in mind that these audits are part of an extrapolation process," Wood stated. "If the auditors find an error rate of 50% in 20 to 30 charts and should any medical information be missing, then the auditors look back at all the CPT codes involved over the previous two years. Auditors then extrapolate that into an overpayment made to the pathology practice or lab.

"The next communication the pathology practice or lab will receive will be the extrapolated amount—which can be a six- or seven-figure dollar total," she noted. "Your practice or lab does not get additional time to resubmit any information that was not included earlier. Thus, your lab is now in a defensive position. So the more information collected and submitted up front, the better."

Having explained the need to respond quickly and completely to any audit request, Wood next outlined how payers are asking for more documentation from labs, particularly additional documentation for claims involving special stains or test panels.

Asking For More Documents

"The common theme among these audits is the requirement for documentation of medical necessity," explained Wood. "But third-party payers have a challenge in defining and determining medical necessity, particularly when dealing with physicians or ordering clinicians. Providers often question what role third-party payers have in determining medical necessity.

"In any discussion of payment policies and audits, it's important for pathologists and lab managers to think of 'medical necessity' as code for what the payer considers to be a covered service," continued Wood. "Therefore, defining 'medically necessary' is like 'beauty' in that it is determined somewhat in the eyes of the beholder.

"The criteria to establish medical necessity can be different from one setting to another because it depends on the payer's view," she said.

Defining Medical Necessity

"In fact for pathologists and labs that participate in health plans that serve as clearing houses for multiple payers, the individual plan or payers typically define medical necessity," Wood explained. "As a result, even when a pathologist or lab bills one common payer, that payer could have multiple interpretations of medical necessity.

"Generally, government and private payers have three basic criteria for determining medical necessity," she added. "To explain these criteria, it's best to think about medical necessity as a payer would consider the need for an MRI scan. When any payer

Health Insurers Now Want Documentation When Pathologists Order Special Stains

WHEN A PATHOLOGIST ORDERS a special stain, currently he or she does not usually include a signed order for this additional service. That may be changing, due to new polices by health insurers.

Jane Pine Wood, an attorney at McDonald Hopkins who advises clinical laboratories and pathology groups, says that government and private payers are beginning to request documentation from physicians when special stains are needed.

"When a pathologist orders a special stain, nothing excuses the pathologist from the same requirements that would apply to any other physician or any other service," she stated. "This means the insurer needs to have a signed order from the pathologist for that additional service.

"The pathologist's order could be a signed requisition," she continued. "It could be something signed on a chart within the laboratory. Because of that lack of a signed order, we've seen payers rule against client pathology practices and pathology labs during these types of audits.

"Typically, the medical necessity to support the pathologist's order for special stains will be in the report itself," stated Wood. "This is why I urge pathologists to write down why they are ordering an IHC stain, for example. In addition, I've seen audits where private payers denied payment for FISH and flow cytometry tests due to lack of documentation. In particular, **UnitedHealthcare** is denying these payments.

"Should the health insurer not see documentation in the pathologist's report about why he or she ordered these additional services, then payment could be denied," commented Wood. "For pathologists currently not including such information in the reports, my suggestion is to prepare standard language that can be included in the report, as appropriate, to ensure payment.

"On this point, **Palmetto GBA**, the Medicare Administrative Contractor (MAC), has made an issue of the need for documentation for special stains," she noted. "Other MACS and private health insurers sometimes follow Palmetto's lead.

"Recently, there was a local coverage determination (LCD) from Palmetto about special stains that has been controversial," explained Wood. "Despite complaints from the **College of American Pathologists**, among others, against the presumptive guidelines in the LCD, pathologists still need to comply with the LCD.

"In response to Palmetto's policy, we see evidence that the other MACs are adopting this same policy," concluded Wood. "There is also evidence that one private payer is in the process of adopting that policy."

considers a payment for an MRI, the first criteria is typically to see evidence of documentation. If it's not documented, the payer will assume it didn't occur.

"So, the first step is to ensure your practice or lab has a physician's signed order," she explained. "In the pathology and clinical laboratory context, Medicare does not require signed orders for clinical lab tests and does not require a signed requisition. But still there is a requirement for documentation that a physician ordered a clinical laboratory test. Even in anatomic pathology which, according to Medicare, is different from the clinical lab world, there is still a requirement for a written order.

Physician Order Needed

"Again, it's not necessary to have a signed requisition for clinical laboratory tests, but clinical labs and pathologists need some documentation signed by the physician showing that he or she ordered the test," emphasized Wood. "It could be a signed requisition or an electronic signature sent through an EMR. Alternatively, the physi-

cian might document and sign in the patient chart that he or she ordered the particular service or lab test.

"In a worst-case audit scenario, it may be necessary to go back to the ordering physician and request a signed attestation stating that he or she ordered the tests in question," she stated. "Such an attestation is not ideal, but would be better than not having any documentation.

"The second element that payers require is medical necessity documentation," continued Wood. "This has gotten to be very difficult for a number of clients, particularly when test panels are involved.

"We now see payers asking many questions about test panels in toxicology and in genetic and molecular testing," she noted. "It's not such a problem in anatomic pathology at this point.

"Payers want to see something in the patient's medical record where the attending physician documented why that test would be necessary for the patient," stated Wood. "For example, if a genetic test was ordered, the payer wants to know what factors in the patient's medical condition led the physician to order that test.

Test Panels Draw Scrutiny

"Pain management is a good example because these physicians often have a panel of tests that they order for certain classifications of patients," she said. "Payers now ask for documentation that every test in that panel is necessary. And if these tests are ordered frequently for a particular patient or group of patients, payers want documentation that such frequency of testing is required.

"The same is true for genetic testing, particularly in pharmacogenetics," she continued. "If the test is ordered as a comprehensive genetic panel, payers want to see documentation in the patient chart that there is medical necessity for each test being ordered.

"One aspect that labs need to consider is the design of the lab requisition," warned Wood. "Back in the 1990s and early 2000s, there were large Medicare settlements for labs that offered panel testing without the ability of physicians to select individual tests. In such cases, federal healthcare officials view automatic prepackaged bundling as fraud and abuse.

"I have seen significant recoupments from some of our lab clients recently," she added. "That's because the design of their requisitions did not give physicians the ability to order individual tests and the physician's medical records didn't adequately document the medical necessity for every test in the panel.

New Document Requirement

"The third element about medical documentation is a new requirement from payers that we've seen in several audits," noted Wood. "Payers want to see documentation in the patient record of the use or review of the information by the referring physician.

"This happens often, for example, when a neurosurgeon orders an MRI," she continued. "Almost invariably, there will be mention in the medical record that the neurosurgeon reviewed the MRI and discussed results with the patient. If nothing else, that's standard documentation from a liability standpoint. This is something payers want in the document, but we have yet to see that happen with clinical lab testing."

In closing, Wood explained that clinical lab directors and pathologists need to address the need for documentation. "As the laboratory or pathology provider, you're the ones who got the money. So if a repayment is needed, it will not come from the ordering physicians. That repayment comes from your laboratory," she emphasized. "So it is prudent to do everything you can to educate physicians about proper ordering and documentation for lab tests and pathology services." TDR

—Joseph Burns

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Lab Market Update

LabCorp Prepares to Expand Direct-to-Consumer Test Program

RECENT DEVELOPMENTS MAKE IT SEEM as if lab test orders signed by physicians might soon go out of style. Last month in Arizona, **Theranos** played a role in changing a state law that now lets consumers order their own clinical laboratory tests without a physician's order. Then, before the end of last month, **Laboratory Corporation of America** said it would expand its direct-to-consumer testing program nationwide.

On April 24, *Bloomberg News* disclosed the new LabCorp DTC program, writing that LabCorp will let consumers order cholesterol, thyroid, and other tests online, bypassing their doctors. The nation's largest laboratory company did not identify which tests it will offer or how much it will charge, *Bloomberg* said.

Consumers can pay for tests online and then visit a LabCorp service center to get their blood drawn, the news organization said. When their test results are available, they can view those results online, *Bloomberg's* Cynthia Koons reported.

Serving Internet Lab Firms

"The company has already been doing back-office lab work for a number of Internet firms that let people order up tests without a doctor," she added. In addition, Koons wrote that all clinical laboratories are facing competition from companies that make and market at-home diagnostics tests, as well as from labs that cater to patients who pay cash so that neither insurers nor their health plans know about the test results.

Companies such as **WellnessFX Inc.** and **Direct Laboratory Services LLC** offer these DTC services, Koons reported. Consumers using these labs prefer to monitor their own health outside of the traditional doctor's office.

"We need to retake that territory for ourselves," stated LabCorp CEO David King in the *Bloomberg* story. "It's a growth opportunity for us. It's something consumers increasingly want to have access to, and it's something we're doing already and our capabilities are being utilized without us getting the benefit from a branding perspective."

Cutting Out the Middleman

Why this timing for LabCorp to announce its expansion of its DTC testing program? Some observers think that LabCorp is acting now to strengthen its direct-to-consumer testing services in anticipation of Theranos entering more regional markets.

THE DARK REPORT has another theory. For the past 15 years, LabCorp has been one of the major "wholesalers" of clinical lab tests to many internet-based lab companies. Typically these companies pay LabCorp a price significantly below the Medicare rate for the test and use of the patient service center. The lab then charges the consumer a price that is typically the amount of the Medicare Part B test price.

Because of this wholesale relationship, LabCorp is able to see the rates of growth in specimen volume for these Internet-based lab firms. Should it be true that LabCorp is seeing these lab companies enjoy substantial rates of growth, then that may be the reason why LabCorp wants to expand its DTC testing program to get a larger share of the market for consumer self-testing. TDR

—Joseph Burns

Our Editor Describes Visit To Theranos Test Center

To collect specimens for four tests, Theranos said it required one venipuncture, two finger sticks

CEO SUMMARY: Theranos now operates wellness centers in Walgreens in Palo Alto, California, and Phoenix, Arizona. It continues to claim it is transforming the lab testing experience for patients and physicians. It says it can perform hundreds of lab tests, using a finger stick collection and a micro-specimen vial, and return results in four hours. Last month, our editor visited a Theranos wellness center in a Walgreens pharmacy with a test requisition for four lab tests. He reports here on the experience.

IN THE ONGOING CASCADE of media stories about **Theranos** and the public speeches of its young CEO, the company continues to describe its proprietary clinical lab testing service as something that consumers will recognize as being friendlier, faster, and cheaper than the lab test services offered by conventional medical laboratories.

Such statements have been met with skepticism by many pathologists and lab administrators. They understand the complexity of diagnostic testing and have questions about many aspects of what Theranos has stated in its media stories and public speeches by its CEO. To date, the secretive company has offered few details about how and why it claims it has the capability to "revolutionize blood testing," as noted by *Phoenix Magazine* earlier this month.

For example, in various media stories, Theranos has said there is no need for a venipuncture because a simple finger stick will suffice. There is no need for three to four vacutainers of specimen because a micro-sample will do. Using its proprietary test technology, Theranos says it will provide test results within four hours. And Theranos will charge about 50% of the Medicare Part B lab test fees.

Last year, another member of THE DARK REPORT'S editorial team visited three Theranos wellness centers (two in Phoenix and one in Palo Alto) and reported on one of those visits. *(See TDR, August 11, 2014.)* To our knowledge, this was the first news report of an independent visit to Theranos/Walgreens to purchase lab testing services.

Assessing Theranos Today

To provide our clients and regular readers with an assessment of the clinical lab testing services Theranos currently delivers to consumers, this editor used a glorious sunny Sunday last month to visit the one Walgreens pharmacy in Palo Alto, California, that offers the Theranos medical laboratory testing service. Here is my report of what transpired.

In the Walgreens at 300 University Avenue, the Theranos sign is clearly visible from the front door. I walked up to the

"Theranos Check-in" counter adjacent to two pharmacy counters.

I tell the clerk at the pharmacy counter that I want lab tests done and she asks, "Do you have an order?" Yes, I have printed my order off the Theranos web site by searching for "Theranos requisition." On the form, I have already written my name, address, birth date, and other personal information and my doctor's name, address, phone, and fax number.

I leave blank the space for my doctor's NPI and signature because my doctor has no idea I'm ordering blood tests 3,000 miles from home. I check the non-fasting box and then choose "Microsample" (because that's one of the keys to Theranos' technology). I could have selected "Patient's choice" or "Traditional Phlebotomy."

When I give her the form, the clerk asks if I will use my insurance or self pay. I'll pay cash. When she asks for identification, I hand over my Massachusetts driver's license. To the question, "Do you have a local address?" I say, no, I'm visiting.

Prices For Lab Tests

On my requisition, I've ordered a basic metabolic panel (CPT 80048) for $5.38, a complete blood count with differential (85025) for $5.35, a lipid panel (80061) for $9.21, and vitamin D 25 OH (82306 for $20.35).

She transmits my completed requisition by fax and tells me I need to wait for a few minutes. I'm guessing that means someone at Theranos HQ will review my order. Gladys Knight and the Pips are singing over the intercom, "You're the best thing that ever happened."

A few minutes later, the pharmacy tech calls me back to explain that my total will be $40.73 and that the vitamin D can't be done with the microtainer and must be done by venipuncture. "They need more blood for that one," she says.

So we eliminate the vitamin D test, dropping my total payment to $20.38. I pay with my credit card and she sends me

Comparing Patient Visit With Advertised Benefits

HOW DID AN ACTUAL LAB TEST EXPERIENCE match the features described by Theranos in its media stories and on its web site?

Last month, our editor visited the Theranos wellness center in the Walgreens pharmacy in Palo Alto, California. Here is a comparison of his consumer experience with the features that Theranos promotes.

- Relative to the finger stick collection; consumer arrives at Walgreens and presents a lab test requisition for four tests (metabolic panel, CBC with auto diff, lipid panel, and vitamin D 25(OH)D). Theranos rep at Walgreens tells him that a venipuncture is required for the vitamin D test. The other three tests can be performed from a microspecimen collected by fingerstick.
- Consumer declines the venipuncture, which means he would be "stuck" at least twice for Theranos to collect the specimens it requires.
- At collection, consumer learns Theranos requires that two different fingers get needle sticks in order to collect the specimen volume required for the three lab tests. This was not disclosed to him during the transaction at the pharmacy window. He assents. He reports that the two different finger sticks were minimally painful.
- Cost of the three tests performed was, as advertised, about 50% of the Medicare Part B lab test fee schedule. The total price was $20.38.
- Lab results were reported to the consumer's physician the next day. It took 10 days for the consumer to get Theranos to send him a copy of his lab test results after obtaining permission from his physician to release those results.

around the corner back to an individual named Sal. The entire interaction with the pharmacy tech—including the time it takes Theranos HQ to review my requisition, discuss my options, and pay—takes less than nine minutes.

In the Theranos drawing station, a large flat screen on the wall shows moving images of a tropical fish tank. It's mesmerizing. Personable and friendly, Sal asks my name and date of birth and if I'm taking any blood thinners or aspirin? No, I say.

Sal explains that he can take blood from any finger and that he will need to stick two different fingers and he gives me the choice. I select my middle finger and ring finger. He wraps this first finger in a warmer to improve circulation.

Two Finger Sticks

After removing the finger warmer, he sticks the tip of my middle finger and yet I can hardly feel it. "Does this hurt?" he asks. Not at all, I say. He fills two microtainers from my middle finger, then has me place the bleeding tip of my finger onto a gauze pad. He wraps it in a self-adhesive bandage. Next, he gets out a second finger warmer to prepare my ring finger.

Again, I feel no pain when he sticks this finger. My results will take 24 to 48 hours, he explains, and if I want them by email, I need to call client services. Or, if I download the Theranos app and register on the Theranos site, I can get my results in my phone. "We're on all the devices. Android, Windows, and iPhone," he says.

I ask why I couldn't get the vitamin D test with a finger stick. "If you have a test that requires more blood, then we'll stick you in the arm and not the finger. Or, if you want it both ways, that's fine. We give you the option," he explains.

Then he places my ring finger onto a second piece of gauze and then wraps it in a bandage. "You are all set," he adds.

Once outside, I check my watch. The entire process from walking in off the street to back out on the sidewalk took less than 19 minutes.

Five days later, my lab test results are not available on my phone and so I call client services at Theranos. I'm told they will look into it and get back to me.

Judging Actual Performance

So, how did Theranos measure up to its own standards? The service was fast and painless and the staff behind the counter and the individual who collected my specimens were friendly.

I consider it significant that Theranos would require two finger sticks and a venipuncture to perform the four lab tests that were on my test requisition. On its website, there is no mention of the fact that a patient or consumer may need to be "stuck" multiple times for Theranos to get all the blood specimens it requires for its proprietary lab test technology.

Also, although the staff at the Walgreens told me that my lab test results would be reported in 24 to 48 hours (and that is much longer than the four-hour reporting benefit that Theranos discusses in media interviews), that did not happen. Instead, five days later, having heard nothing from Theranos, I had to call the lab firm and wait while their representatives investigated why my lab results had not been reported to me. So Theranos has no advantage there. Overall, I would rate the experience pleasant but inconclusive.

Lab Test Requisition

There is another issue that alert pathologists probably picked up. I visited Walgreens with a lab test requisition that was unsigned by my physician and did not include my physician' national provider number. Yet, Theranos collected my money and performed the tests. As a resident of Massachusetts, I am unaware of how this fulfills California state law, which I understand requires a physician to directly order medical laboratory tests on behalf of the patient. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last month, **TriCore Reference Laboratories** of Albuquerque, New Mexico, announced that it had purchased the **Rhodes Group**, of Vernon, Connecticut. Rhodes Group provides data integration services for labs and other healthcare providers. TriCore had long been a customer of Rhodes Group. TriCore is pursuing a strategy of leveraging lab test data with other clinical and healthcare data. This would allow TriCore to help providers and other stakeholders improve patient outcomes and better manage the cost of care. In the press release announcing the transaction, TriCore noted that Rhodes Group will continue to operate from its current offices, develop its data integration products, and serve its existing and new customers without interruption.

MORE ON: *Lab Data*

Rhodes Group is known for its expertise in developing effective middleware solutions that improve workflow in labs and other providers. Its acquisition by TriCore caught many lab executives by surprise. However, companies offering lab middleware solutions seem to be a hot commodity these days. It was in February when **Sunquest Information Systems** acquired **Data Innovations**, one of the longest-established sources of lab middleware solutions. Since it was acquired, Data Innovations continues to operate as an independent business unit of Sunquest. That is similar to TriCore's plans for the Rhodes Group.

MED TECH SUPPLY AN ISSUE IN CANADA

On April 28, the **Canadian Society for Medical Laboratory Science** (CSMLS) visited Parliament in Ottawa. The goal was to educate lawmakers about the looming shortage of medical laboratory technologists in Canada. CSMLS officials called for more funding for education and incentives to recruit MLTs into rural and remote communities.

TRANSITIONS

• Evans Calas retired on May 1. He was formerly an owner and the CEO of **Sterling Reference Laboratories**, based in Tacoma, Washington. During his career, Calas held executive positions with **Laboratory Corporation of America**, **National Health Laboratories**, and **International Clinical Laboratories**.

• In Phoenix, Arizona, Chris Young, owner of **Laboratory Management Support Services**, retired on April 22. Young founded his lab consulting company in 1997. His 40-year career in clinical laboratories included time at **Sonora Laboratory Services**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 1, 2015.

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UPCOMING...

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- ***Anticipating the Impact of Coming CMS Guidelines for Market Reporting of Clinical Lab Test Prices.***
- ***New Breakthroughs in Improved LIS Interfaces with EHR Systems Used by Office-Based Docs.***

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