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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Protecting a Lab's Access to Patients

TODAY I WANT TO CALL YOUR ATTENTION to a major issue in the lab testing industry that doesn't get the full attention it deserves at most clinical labs and pathology groups. It is the fact that labs of all types and sizes are losing access to patients.

Without access to adequate numbers of patients, a lab cannot generate the number of specimens it needs to sustain a high level of clinical services while remaining financially viable. Several healthcare trends are working collectively to make it tougher for local laboratories to protect their existing access to patients, along with their the ability to increase market share. One such factor is the narrowing of provider networks that deny local and regional labs access to patients.

As you will read on pages 14-16, **Humana** is the latest of the national health insurers to exclude regional laboratories from its network. Lab executives in Ohio and Texas report that, over the spring and summer, they learned that Humana had narrowed its lab networks in those states.

Another issue that has gone unremarked is that, as of 2014, almost one-third of Medicare beneficiaries are now enrolled in Medicare Advantage plans. I'll bet that most of you didn't know that fact. It's significant, since the private health insurers operating these plans tend to contract almost exclusively with national labs that offer the cheapest prices. Because of these developments, it can be argued that local labs across the nation have lost access to 15 million of the nation's 49 million Medicare beneficiaries.

What has also gone unremarked in this regard is that the nation's billion-dollar lab behemoths face their own challenges to protect and expand their access to patients. Yes, the two blood brothers hold exclusive contracts with most national and big regional health insurers. But the trend of doctors selling their medical practices to hospitals, health systems, and insurers puts the national labs at a disadvantage in situations where the new hospital or health system wants those office-based physicians to use the new owner's laboratory.

These trends and market dynamics continue to play out. For that reason, the clinical lab industry has not reached the end game that will be shaped by these forces. If there is good news in all of this, it is that community labs and regional labs still have time to develop strategies that improve their access to patients in their service regions. TDR

FL Docs Say: 'No Thanks' to UHC and BeaconLBS

UnitedHealthcare, BeaconLBS delay start for determining payment based on decision support

CEO SUMMARY: Some Florida physicians are declaring their intent to leave UnitedHealthcare's network because they find the insurer's new BeaconLBS laboratory benefit management system to be time consuming and onerous. The defections come as the program goes through a soft launch that began on October 1. Apparently in response to physician complaints, UHC announced a delay in the date when it will begin to use BeaconLBS to make coverage decisions on certain lab tests.

THERE IS VISIBLE PHYSICIAN RESISTANCE to the new laboratory benefit management program implemented by **UnitedHealthcare** (UHC) in Florida. On October 1, the health insurer began requiring physicians in Florida to use the **BeaconLBS** system to obtain pre-notification or pre-authorization for selected clinical laboratory tests.

Some physicians find the BeaconLBS system to be so time intensive and onerous that they are leaving the health plan's network, sources told THE DARK REPORT. Responding to those concerns, several Florida physician associations asked physicians to notify them about problems they experience when attempting to comply with UHC's new laboratory benefits program.

For its part, UnitedHealthcare recently notified providers in Florida that it would delay the date when it begins basing payment decisions for lab tests via the BeaconLBS. Payment determinations will be based on whether physicians properly followed the BeaconLBS decision support procedures when ordering any of the 81 clinical laboratory tests that UHC has designated on its website as needing advance notification or prior approval. UHC moved that date back to January 1, 2015.

In a letter to Florida providers, Catherine E. Palmier, M.D., UHC's Shared Services Chief Medical Officer in the East Region, wrote, "Although the laboratory benefit management program starts on October 1, 2014, *claims and service impacts will not go into effect until January 1, 2015. [Italics by TDR.]* This allows for additional time for physicians' offices to acclimate to the program. As a pilot we will closely monitor

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progress and will make refinements based on data, experience, and input."

In Florida, physicians and lab managers interpret the phrase, "claims and service impacts" to describe how UHC and BeaconLBS—its contractor for the laboratory benefits management program—will decide whether or not UHC will issue payment for lab test claims covered under the laboratory benefit management program.

Is There a Physician Revolt?

Meanwhile, UHC must deal with a physician revolt of some size. Jay Millson, the Executive Vice President of the **Florida Association of Family Physicians**, said that an unknown number of physicians are so upset about the hassles required to use the new laboratory benefit management system operated by BeaconLBS that they have said they will leave UnitedHealthcare.

"We have had at least a half dozen physicians simply indicate their intention to drop UHC from their practice," Millson said. "We have not provided, nor will we ever provide, any guidance to our members relating to participation in any insurance plan."

Florida physicians have asked UHC to pay them for the added time needed to use the BeaconLBS system. To date, no official at any Florida physician association reports receiving a response from UHC about physician requests for such payments. It is also believed that a hospital association in Florida has expressed its members' concerns about this program to UHC.

Physicians serving patients in UHC's commercial HMO can order most lab tests as they normally would. However, for 81 lab tests that UnitedHealthcare lists on its website, physicians are required to use BeaconLBS to notify Beacon when ordering one or more of these tests.

For two tests (BRCA1 and BRCA2), BeaconLBS and UHC require physicians to get prior approval. Without prior approval for these two tests, UHC has said it will not pay for these tests. BeaconLBS is a wholly-owned subsidiary of **Laboratory Corporation of America**.

For the 79 other tests—some of which are routine clinical tests—UHC requires physicians to use the BeaconLBS system to notify BeaconLBS that they are ordering these tests. In a letter UHC sent to providers in Florida, it said that, once Beacon receives such a notification, Beacon will issue clinical guidelines to the referring physician to help the doctor identify the best treatment options for his or her patient. On its website, UHC says it will not pay physicians who do not comply with the advance notification requirement.

In its letter to providers, UHC said: "UnitedHealthcare is implementing the laboratory benefit management program as a pilot to help enhance quality and affordability, while supporting appropriate use of outpatient laboratory services. The program includes multiple components designed to work together to achieve these goals. One of the components, physician decision support, is an interactive tool to help physician offices to: select laboratory tests using evidence-based guidelines and industry best practices; select in-network laboratories that have the expertise to perform these tests; and support program requirements such as advance notification and/or prior authorization."

Routine Test Orders

But physicians who have seen the BeaconLBS system are confused about why they need to use it when ordering routine tests. "I don't understand the purpose of this program other than to try to get out of paying for lab tests," one physician wrote in an email to FAFP. "As a physician, I have completed four years of medical school, three years of residency, and 11 years of practice.

"I don't need 'decision support' to know when my patients need a Pap smear or a TSH level," continued this physician. "If they were requiring authorization for expensive or less commonly ordered tests it might make some sense, but a TSH

UnitedHealth Tells Florida Patients They May Need to Pay If Tests Don't Meet Evidence-Based Guidelines

PATIENTS IN UNITEDHEALTHCARE'S HMOs in Florida may be required to pay for their own clinical lab tests under the payer's laboratory benefits program.

UHC is introducing Beacon Laboratory Benefit Solutions (BeaconLBS) and requiring physicians treating patients in UHC's Florida HMOs to use the system to get prior approval for two tests (BRCA1 and BRCA2) and notify BeaconLBS in advance when ordering any of 79 other tests. *(See TDRs, July 22, 2014, and September 2, 2014.)*

UHC members in Florida were sent a letter dated September 15 from Linda Stewart, Vice President, National Lab Program. She explained what will happen after physicians notify BeaconLBS of their intention to order one of these lab tests.

"At the time of notification, UnitedHealthcare will give the doctor evidence-based guidelines (medical treatments that have been shown to have the best results that will help them choose the best test(s) for you) and identify laboratories that are best qualified to perform the test(s) based on quality criteria and industry best practices," she wrote. "The select network laboratories are called 'Laboratories of Choice.'"

In essence, the advance notification is similar to a prior approval because if BeaconLBS or UHC denies the physician's request to run the planned tests, the patient would need to pay for the test, the letter says. "Certain laboratory services may not be covered by your benefit plan based on evidence-based guidelines. If your doctor orders a laboratory service that is not covered, he or she may ask you to sign a form confirming that you are aware of the potential cost to you."

About advance notification, a UHC spokesperson said, "Advance notification applies to decision support tests (it's not all lab tests) and provides UnitedHealthcare a heads up when a test has been ordered for one of our members. It does not require clinical review and the notification must be completed within 10 days from the date of service."

costs about $3 for me, and I'm sure United pays even less. Given the cost in lost time spent on this, it would be cheaper for me to just pay the lab out of pocket and avoid the hassle. And this is truly a ridiculous alternative."

Another complaint voiced by Florida physicians is the lack of functional interfaces between their EHRs and BeaconLBS. This requires them to leave their EHR and log into the BeaconLBS system before they can enter the information required to obtain pre-notification or pre-authorization for the lab tests that they want to order for their patients.

In her letter to a Florida physician, Palmier wrote, "While we understand physicians and their office staff may have concerns regarding the program, it is designed to offer multiple options. Physician decision support is already an integrated component of LabCorp's online order entry system and is integrated with two electronic health record (EHR) systems, **Emdeon** and **Liaison Technologies**. Two additional EHRs, **Aprima** and **eClinicalWorks**, are in the plans to be integrated as well."

Integration With Other EHRs

BeaconLBS is also working with other EHR vendors. "BeaconLBS … continues to work with additional EHR companies to expand the list of applications integrated with physician decision support," Palmier added.

It was not known how many Florida physicians in UHC's HMO network use

these two EHR systems, but there are hundreds of EHRs that are not integrated with the BeaconLBS. To ensure that the lab test order is part of the patient's EHR, physicians using an EHR not integrated with the BeaconLBS would need to enter lab orders twice: once online via the BeaconLBS website and once in their EHR.

Some Predictions Of Chaos

Across the clinical laboratory industry, those who knew the details of the UHC–BeaconLBS scheme have generally predicted that its implementation would cause chaos for all the reasons identified by those Florida physicians irate enough to publicly complain.

That seems to be the case, based on events during during the first two weeks of that UnitedHealthcare has required physicians to use the BeaconLBS system as part of its laboratory benefit management program. On the one hand, there are indications that several Florida physician associations and possibly one hospital association in the state are communicating the dissatisfaction of their members about the BeaconLBS system to UHC.

On the other hand, the letters sent by UHC to providers and UHC beneficiaries in Florida in recent weeks indicate that the health insurer knows it has a tough fight to gain acceptance for this lab test utilization management scheme.

Claims Adjudication Delayed

The best evidence of substantial physician resistance is the fact that UHC has backtracked on its plans—beginning on October 1—to use BeaconLBS pre-authorization and pre-notification procedures to determine which lab claims to pay and which lab claims to deny. UHC has notified providers that it won't implement that aspect of the laboratory benefits management program until January, 1, 2015. Because of the national implications of this lab test utilization scheme, lab executives across the nation are watching developments in Florida. TDR

—Joseph Burns

Physicians Complaining To Their State Associations

PHYSICIANS IN FLORIDA ARE VOICING their concerns about the Unitedhealthcare laboratory benefit management program. One example comes from the Florida Association of Family Practitioners (FAFP).

A solo physician in Miami said he was concerned about the time and expense required to use the BeaconLBS in his practice. "In order to keep my practice financially viable, I keep my overhead low by performing all patient care services myself," he wrote in an email to FAFP. "I have only one employee, my office manager, who has plenty to do on the administrative side."

The physician went on to write, "I struggle to keep up with charting, drawing and processing lab [tests], and dealing with crises throughout the day when I see my patients. I have no idea how I am going to have time to do prior authorizations for labs that should be routine. This is a real burden on me, because almost one third of my patient population right now is on United."

THE DARK REPORT published a more detailed critique of the BeaconLBS system that was provided by Dennis Saver, M.D., a family physician, geriatrician, and founder of **Primary Care of the Treasure Coast**, in Vero Beach, Florida. His staff determined that a single test order requires five to seven extra minutes to process through BeaconLBS. Staff also estimated that between 20 and 30 mouse clicks and multiple computer screen changes will be needed to enter the information for each patient requiring lab testing through the BeaconLBS portal.

Saver's conclusion was direct and to the point: "As a contracted physician for UnitedHealth, I find this whole idea that we need to do more work for no additional pay to be extraordinarily objectionable!" he declared. "And, frankly, I find UnitedHealthcare's argument that this will create better medicine to be unsupported. This simply means that UnitedHealth will pay less in lab fees." *(See TDR, September 2, 2014.)*

Physicians and Labs Wary of United's Lab Test Program

UHC says goal is improved quality, but physicians, labs see program as cost control

CEO SUMMARY: Providers seem to have a natural distrust of health insurers, particularly when payers introduce new programs with the stated purpose of improving quality and ensuring that physicians deliver evidence-based medicine. Doctors serving members of UHC's HMO plans in Florida are told by UHC that it wants to improve the quality of lab test ordering and help them practice within guidelines. However, physicians and labs in Florida believe the BeaconLBS arrangement is about cost control.

NOW THAT THE LABORATORY BENEFIT MANAGEMENT PROGRAM created by **UnitedHealthcare** has launched in Florida, it is time for clinical lab managers and pathologists everywhere to pay attention to this development.

That's because UnitedHealthcare (UHC), as the nation's largest health insurance company when measured by enrollment (with 36.5 million beneficiaries in 2012), is attempting to create a new approach to contain the cost of laboratory testing. If it succeeds in Florida, the company has already announced that it will implement this program in other states.

Thus, UHC's laboratory benefits program has the potential to soon show up in your neighborhood. And, as currently designed and implemented, one consequence of the UHC laboratory benefit program is that it will be used as a tool to exclude many local labs as providers of lab testing services to UHC members.

That has proven true in Florida. In one of the nation's most populous states, with 212 hospitals (only Texas and California, with 376 and 348 hospitals, have more), the BeaconLBS laboratory of choice panel includes just 13 lab organizations on the UnitedHealthcare website. Of these 13 labs, five are owned and operated by **Laboratory Corporation of America**. Of the others, two are toxicology labs, four are pathology labs, and two are clinical labs (not including LabCorp).

Questions About Goals

Legitimate questions have been raised about the goals of UHC's laboratory benefit management program, not to mention its design. Within the physician and clinical lab communities, questions to UHC about the actual proportion of laboratory testing that is considered to be inappropriate or outside of clinical guidelines have gone unanswered.

Physicians and labs in Florida want to know why a health insurer like UHC believes the problem of inappropriate lab test orders is so great as to require a new and complex bureaucracy to monitor physicians at the time they order a test.

Equally significant, given the 81 lab tests on the decision support test list, does UHC

have statistics about inappropriate utilization that justify including each test on this list? Physicians point out that tests with well-established guidelines and which are included in HEDIS reporting are on the decision support test list. They ask why they should be required to go through the time and expense of pre-notification each time they must order such common and high-volume assays as Pap tests, HCV tests, and HIV tests, to name a few.

Evidence Of Benefits

What benefit does UHC believe it will produce for patients by requiring each physician to obtain pre-notification for each of these tests each time they are ordered? To date, it is believed that UHC has not responded to these legitimate concerns with a public statement and evidence to support the need for this bureaucratic procedure and the inclusion of those 81 tests on its decision support list.

It is not a surprise to anyone who has looked into the details of this scheme that some physicians are speaking out vociferously against the design of the laboratory benefit management program. There is plenty of evidence to support their complaints about the substantial amount of time required to go into the BeaconLBS system, enter the necessary information and receive a pre-notification or pre-authorization code.

Could Docs File Lawsuits?

Another question that may be soon answered is whether physicians and their state associations will consider UHC and BeaconLBS to have overreached to such an extent that they feel it necessary to file lawsuits to address this matter. In such an event, the plaintiff would likely ask the court for an immediate injunction to cease implementation of the laboratory benefit management program until both parties can present evidence to the court in a formal hearing.

That might make for an interesting time in the courtroom. To date, UnitedHealthcare has not offered much data to support its claims that pre-notification of clinical lab tests is needed to control inappropriate utilization and improve patient outcomes.

Moreover, there are some healthcare experts who believe that, were some type of legal action to commence over this matter, UnitedHealthcare would have some thorny conflict of interest issues to address. That's because BeaconLBS—the gatekeeper that determines which labs participate—is owned by a laboratory that competes with all the laboratories in Florida that are candidates to be on the laboratory benefit management program's "laboratories of choice" list.

Moreover, Laboratory Corporation of America, the owner of BeaconLBS, has an exclusive national lab testing contract with UnitedHealthcare. It doesn't take much imagination to picture UHC having to respond to assertions that the two companies have colluded to create a scheme that denies competing labs access to UHC patients—access that some labs in Florida already have. (These labs hold contracts with UHC, but have not registered with BeaconLBS and do not appear on the list of laboratories of choice.)

Asking For Comments

Of course, these are all speculations as to how physicians and their state associations may respond to BeaconLBS and the UHC laboratory benefits management program. What is true is that a number of physicians have spoken publicly about their questions and concerns and Florida physician associations are asking their members for comments about the program.

That sets the stage for the next round in what is shaping up to be a battle of the wills. Might UHC risk further ill-will by continuing to push physicians with the BeaconLBS program? Or, might it decide to back off? Stay tuned, because the next chapter will soon play out. TDR

—Joseph Burns

Theranos Pursues Different Business Plan in Arizona

Company is building CLIA lab in Scottsdale, now has sales reps canvassing docs in the area

CEO SUMMARY: Since its big public debut in late 2013, Theranos has been the subject of keen interest and much skepticism among pathologists and clinical laboratory professionals. Theranos is expanding its presence in Phoenix, Arizona. However, as it does, it looks more like a conventional clinical laboratory—with all the associated costs—than a disruptive lab testing innovator with proprietary technology that can shift the paradigm in the lab testing market.

PROBABLY NO COMPANY has a higher profile in the clinical lab industry at the moment than **Theranos** of Palo Alto, California. The company has repeatedly told the national press that its technology will allow it to revolutionize lab testing by offering benefits that range from a more patient-friendly method of collecting specimens and shorter turnaround times to cheap lab test prices.

However, just one year into its actual operation as a laboratory company providing clinical testing services to the public, the reality is that the company looks more like a conventional lab testing company than an innovative disrupter poised to transform a clinical service anchored in practices unchanged in decades.

New CLIA Lab In Scottsdale

The evidence supports that argument, particularly given the company's activities in Arizona. Theranos has leased a 20,000 square foot facility in Scottsdale and is proceeding to build a laboratory there which will be CLIA-licensed. Newspaper accounts state that Theranos plans to hire 500 workers to staff that facility.

Currently, Theranos offers lab testing services in approximately 40 **Walgreens** pharmacies throughout the Phoenix metropolitan area. By contrast, in Palo Alto, where its CLIA-licensed lab facility is located, Theranos offers testing through only one Walgreens pharmacy in that city. *(See TDRs, September 30, 2013 and August 11, 2014.)*

Another piece of evidence supporting the development of a conventional lab operation is the fact that Theranos is building a lab sales force. Lab managers in Arizona tell THE DARK REPORT that Theranos is sending sales representatives into physicians' offices to solicit lab test referrals. Because Theranos prices its lab tests at 50% of Medicare Part B clinical laboratory test fees, some physicians are referring their uninsured patients to the company for their lab tests, sources say.

If the comments from competing labs about how Theranos is conducting business in Phoenix are accurate, then at the present time the company is using the same business model that it said it intended to disrupt. It appears to be on the path to building a central regional laboratory that

will test specimens coming in from its company-owned collection sites (such as Walgreens' pharmacies) and any physicians' offices that are collecting specimens and referring those tests to Theranos.

It also means that Theranos must invest in courier and logistics capabilities to transport specimens. It will need to invest in information technology to interface its laboratory information system to the hundreds of different EHR systems that referring physicians use.

Each of these infrastructure items and operational costs at Theranos would give it a cost structure comparable to existing clinical lab operations. Yet, the company says it will price its tests at just 50¢ on the Medicare dollar for all patients.

Same Cost Structure

It is precisely this point that puzzles experienced clinical lab executives. How can any company, including Theranos, be profitable if it must sustain the same cost structure required for specimen collection, logistics, testing, information systems, billing/collections, and the like—and will only charge half of Medicare lab test fees?

Another question being asked is why Theranos is expanding in Arizona and not Northern California, where its corporate office and 400,000 square foot manufacturing facility is located. Experienced lab professionals believe the reason is that California is a state where medical laboratory testing is under tight regulation by the **California Department of Health**.

Unlike California, Arizona has few state laws that are tougher than federal laws governing the operation of clinical laboratories. For example, California has laws governing the licensure of clinical laboratory scientists and phlebotomists. That is not the case in Arizona.

Having told its story of disruptive innovation to prominent media outlets over the past year, Theranos now faces the tough task of delivering on its claims. It appears that the company believes Arizona will be the best regional market to execute its business plan.

At the same time, those pathologists and clinical laboratory professionals closely watching Theranos continue to be puzzled about the nature of its diagnostic technology. With their deep knowledge of *in vitro* diagnostics, these professionals still wait for more detailed evidence from Theranos that its proprietary technology does live up to the company's claims. TDR

Is Theranos Learning Tough Lessons in AZ?

COMPETING LABS IN PHOENIX are keeping a close watch on Theranos. Because their sales reps go into the same physicians' offices as the Theranos sales reps, they uncover much business intelligence.

By the nature of the stories that are circulating, Theranos executives may be getting some hard lessons in the rough-and-tumble market for clinical lab testing. It's a reality far removed from the strategy sessions that probably have taken place in the company's executive suites in the Silicon Valley.

Multiple sources told THE DARK REPORT that Theranos sales reps have been telling some physicians that their lab company is in-network for all insurance plans. In response, competing lab reps are taking letters from payers into those doctors' offices to demonstrate how their laboratory is in-network and Theranos is not. Of course, this is a common sales tactic in the lab industry and not unique to the sales reps at Theranos.

At a minimum, however, this sales gossip indicates that executives at Theranos are undergoing their baptism by fire in what has always been a tough environment for selling lab testing services to office-based physicians. As outsiders just coming into the clinical lab industry, observers will be watching to see if they understand federal and state antikickback laws that deal with inducement.

Doctors at Johns Hopkins Improve Lab Test Utilization

Improved utilization of cardiac testing helped health system to save $1.3 million over 12 months

CEO SUMMARY: Efforts to help physicians improve their utilization of clinical lab tests paid big dividends at the Johns Hopkins Bayview Medical Center in Baltimore, Maryland. Working collaboratively, physicians and the clinical lab team identified overused or needless cardiac biomarker tests, then designed interventions to improve how physicians used these tests. The result was a 66% drop in the volume of cardiac biomarker tests and a $1.3 million yearly reduction in patient charges.

ON THE SUBJECT OF LABORATORY TEST UTILIZATION, physicians and pathologists in many cities around the nation find themselves united in a common goal of eliminating unnecessary test orders.

This is a welcome development for pathologists and clinical lab administrators who daily see the waste and potential patient harm that can occur when physicians order unnecessary or inappropriate tests for their patients.

Two primary factors motivate physicians today to become proactive about improving their utilization of lab tests. One is acceptance of integrated care (such as ACOs and medical homes) and the other is reimbursement in the form of bundled payment or capitated rates.

The benefits of collaboration between physicians and clinical laboratory professionals to improve the utilization of lab tests can be significant. At the 545-bed **Johns Hopkins Bayview Medical Center** in Baltimore, Maryland, such a collaboration tackled cardiac biomarker tests. The objective was to identify overused and needless cardiac biomarker tests. Interventions were implemented to ensure appropriate utilization of these tests.

The results were phenomenal. The clinic saw a 66% drop in the volume of cardiac biomarker tests, along with a reduction in patient charges of $1.3 million in one year. The physicians published their results June 28 in the *Journal of General Internal Medicine.*

Broad Implications

"This study has broader implications for the healthcare system, as most hospitals continue to use this redundant way of testing patients with chest pain," said Jeffrey C. Trost, M.D., Assistant Professor of Medicine and Director of the Cardiac Catheterization Laboratory and Co-Director of Interventional Cardiology at Johns Hopkins Bayview Medical Center. "Implementing these interventions could potentially save patients a significant amount of money," he noted.

The intervention was the result of an effort Trost started in 2010 with Marc R. Larochelle, M.D., an internal medicine resident at Johns Hopkins Bayview

Medical Center and others. Trost, Larochelle, and colleagues founded a group called **Physicians for Responsible Ordering** to identify wasteful inpatient diagnostic testing at the medical center.

"At the time, we believed that cardiac enzymes were ordered in far higher quantity and frequency than what the professional guidelines suggested," recalled Trost. "After reviewing data on our test ordering, we recognized the opportunity to reduce inappropriate cardiac enzyme ordering."

For years, cardiologists used the troponin test as an accurate way to determine if a patient with chest pain has had a heart attack or is about to have a heart attack. "Yet medical center physicians continued to order troponin testing as well as tests for creatine kinase and creatine kinase-MB (CK-MB)," observed Trost.

Trost knew about the work of Allan S. Jaffe, M.D., Chair of the Division of Clinical Core Laboratory Services in the Department of Laboratory Medicine and Pathology at **Mayo Clinic**. "Jaffe investigated the use of biomarkers to characterize the pathobiology of acute cardiovascular disease," stated Trost. "He is the co-author of a special report published in 2008 in the journal *Circulation* that suggested that troponin testing should replace the CK and CK-MB tests."

Seeking Guidance From Labs

"When we began this initiative, we sought advice from our lab director, Stefan Riedel, M.D., Ph.D.," Trost said. Riedel is an Assistant Professor in the Department of Pathology, Division of Microbiology, and Director, Clinical Laboratories, at Johns Hopkins Bayview Medical Center.

"As clinicians, our perspective is patient care," he stated. "Having the lab director's perspective was helpful. He helped us understand the actual costs in the lab, how cardiac tests are run, throughput of such tests, and useful insights about the sensitivity and applicability of the different cardiac tests. As clinicians, we know little about these aspects of lab testing.

"In his paper, Jaffe gave compelling arguments why the troponin is a far superior test to the CK-MB," he explained. "Jaffe recommended that hospitals should stop ordering it. In fact, Jaffe and his co-authors concluded the *Circulation* article by saying, 'We've stopped ordering it and we think others should too.'

New CK-MB Guidlines

"That hit a nerve for me because patients here get *both* tests ordered every day!" noted Trost. "This was an opportunity for our institution to take a lead role in this area of clinical care. Thus, we crafted an intervention that could reduce—if not eliminate—cardiac testing with CK-MB.

"We also spotted another opportunity," recalled Trost. "As we studied lab test utilization data, we noticed that physicians ordered the troponin test far more than the two to three times that are necessary to make the diagnosis.

"Our estimate was that, in a given setting, about 25% of our patients got many more troponin tests," he stated. "Our physicians recognized that there was no clinical justification for this. Riedel concurred and advised us about the specific interventions the lab could offer our physicians.

"Ultimately, we decided to eliminate the CK-MB test from the default order sets," comment Trost. "As part of this change, a soft stop was created in the CPOE for any physician who tried to order troponin more than three times in 24 hours."

From August to October 2011, Trost and Larochelle introduced new guidelines into the computerized physician order entry (CPOE) system that is part of the hospital's **Meditech** EHR. Education sessions with the internists and ER physicians took place to explain the change.

For patients suspected of having acute coronary syndrome, the guidelines suggest troponin testing alone and that the test be done no more than three times in 24 hours. "The CK and CK-MB tests were removed from the medical center's stan-

Today's Financial Incentives in Healthcare Do Not Support Efforts to Eliminate Needless Lab Tests

MANY MORE PHYSICIANS would seek to eliminate redundancies in their utilization of clinical laboratory tests if the proper financial incentives were in place, stated Jeffrey C. Trost, M.D., an assistant professor of medicine at Johns Hopkins Bayview Medical Center in Baltimore, Maryland.

"Were you to ask why this protocol for improved utilization of troponin testing has not been more widely implemented, my answer would be that perverse financial disincentives discourage more appropriate use of these tests," noted Trost. "A similar problem affects the Choosing Wisely campaign despite the fact that those recommendations were issued through the specialty societies.

"That's why we created a group called Physicians for Responsible Ordering," he continued. "At our institution, we are evaluating other lab tests and clinical procedures where we might intervene to ensure that lab test usage is more appropriate."

Another organization concerned about the rising financial burden on patients is **Costs of Care**, a group of physicians, nurses, and other caregivers who seek to protect patients from financial harm. A recent article on the Costs of Care website addressed the issue of lab testing costs. Michael J. Misialek, M.D., a pathologist at **Newton-Wellesley Hospital**, which is part of **Partners Healthcare** in Boston, wrote about the role pathologists can and should play in protecting patients from financial harm.

"Each test ordered could result in harm and unnecessary expense to the patient," explained Misialek. "We must do everything possible to minimize these occurrences and be more proactive to drive down the underused and overused tests, which leads to cost savings in medicine as a whole. Enormous challenges lie ahead to reduce costs and improve overall treatment; however, changing the way we order lab tests is a great place to start."

dard order sets," explained Trost. "If a physician attempts to order a troponin test within six hours of a previous troponin test, the system issues a warning."

Over 12 months, physician use of the new guidelines increased from 57.1% to 95.5%. As this happened, there was a 66% drop in the number of tests ordered.

"Obviously there was the question of whether patients were harmed by this intervention," he added. "That's difficult to determine directly. We knew that the intervention did not have much of a risk of underuse because we continued to use the troponin test.

"We assessed this by looking at the diagnostic rate of patients with heart attacks or about to have a heart attack (that's what the troponin test tells you)," Trost explained. "These patient diagnoses were listed under the umbrella of acute coronary syndrome.

"The diagnostic rate before the change in the cardiac laboratory test guidelines was compared to the rate during the intervention," commented Trost. "There was no appreciable difference in patient outcomes. Had there been underuse of cardiac marker testing, the diagnostic rate would have gone down because our physicians were not utilizing cardiac biomarker testing as aggressively as they had in the past.

"Enormous challenges lie ahead to reduce costs and improve overall treatment. Changing the way we order lab tests is a great place to start," concluded Trost. "For us, it boils down to the incentives for choosing wisely and the incentives for not choosing wisely." **TDR**

—Joseph Burns

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Humana Reduces Number Of Labs in Its Networks

➤Lab directors also report that some payers require copays from Medicare Advantage patients

➤➤CEO SUMMARY: In Ohio, a lab director said his lab was not informed directly about its exclusion from the Humana lab network. Lab officials got the word from their client physicians. In Texas, another lab director said Humana cut 35 lab contracts, reportedly because the insurer wanted to steer more test volume to its preferred national labs. In a related development, some payers are requiring their Medicare Advantage patients to pay copays for lab testing, a move that financially benefits the health insurers.

ANOTHER NATIONAL HEALTH INSURER has taken steps to narrow its network of laboratory providers. Physicians in Ohio report getting letters this summer from **Humana, Inc.**, informing them that they could use only two national companies for clinical laboratory testing. Those two labs were **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

Lab executives told THE DARK REPORT that Humana has taken steps to eliminate labs in other states from its lab provider network. "Humana terminated 35 contracts across the nation—not because they weren't providing valued service or good patient care—but because Humana was trying to steer the volume to the national labs in order to keep spending at a certain level," said one lab director in Texas who declined to be identified.

"This is what we heard from our own sales staff and others in the industry," he added. "Even though our rates are as low as those of the national labs, Humana still terminated us from their network because they wanted to steer a larger volume of business to their national labs to keep their rates from increasing with LabCorp or Quest Diagnostics."

A lab director in Ohio, who also asked not to be named, said no other labs besides Quest and LabCorp were allowed to serve Humana members in that state. "The letter Humana sent to physicians was dated June 30 and effective immediately," the lab director said. "And we got no letter or any form of notice from the insurer. Humana sent it only to our physicians. We had to hear about it from them."

➤Goal Is To Spend Less

The lab directors said they asked Humana's lab contracting officials about why the labs were eliminated. They were told the decisions were made strictly to steer volume to the large national labs.

"We even asked whether our propriety tests might be included as a payable benefit and the Humana officials told us the decision had nothing to do with proprietary tests," the Ohio lab director reported

For the Ohio lab director, the termination came with no notification and no transition.

"I called Humana to ask about it and didn't get very far," the lab director said. "Humana simply sent a letter to physicians and said the change was effective immediately. Any lab director will tell you a transition period is needed. And, our contract calls for at least 30 days' notice before the end date. But Humana did not do this.

"Plus, we wanted to know if our lab was being eliminated from all Humana plans or just some of the plans," he continued. "These issues were never addressed. That left patients and their physicians to figure out how they could get lab testing done."

In Ohio, Humana has a significant presence, particularly in Medicare Advantage plans, the lab director said. "Losing this Humana contract is a big deal for our lab," he noted. "I estimate that it's about 10% of our overall revenue, which is a lot.

Making Co-Pays Work

"And, about 7% to 8% of that 10% is in the nursing home business," he continued. "We know Quest and LabCorp don't want to do that nursing home work.

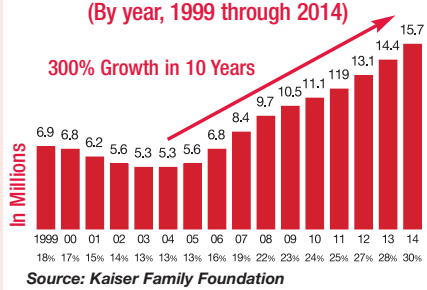
"So, now what do we tell our client nursing homes, given the changes Humana made?" he asked. "We must now explain to patients that our lab cannot do their lab work and that they may need to get other labs to do their lab work and possibly wait several days to get their lab test results. Or, the nursing home operators may have to take their patients to the nearest hospital."

Another lab director explained that, in many communities, physicians serving nursing homes order lab tests on patients early in the day and often need to get results later the same day. Fast turnaround time allows them to adjust their patients' medications if needed. Having same-day lab test results allows them to diagnose medical conditions or identify other patient needs.

"If a large lab must assume nursing home contracts, the turnaround time for lab test results often goes from one day to two to three days," she said.

Local Labs Losing Access To Medicare Advantage

Total Medicare Private Health Plan Enrollment (By year, 1999 through 2014)



Source: Kaiser Family Foundation

NOT ONLY ARE LOCAL LABORATORIES being eliminated from the networks of many national and regional payers, but they are losing access to a growing proportion of Medicare patients because of the increase in the number of Medicare beneficiaries choosing to enroll in Medicare Advantage.

Health insurers offering Medicare Advantage plans are contracting almost exclusively with national laboratories in order to obtain rock bottom prices for lab tests. This excludes local labs as providers.

At the same time, seniors are enrolling in Medicare Advantage plans at a remarkable pace. **Kaiser Family Foundation** reports that Medicare Advantage enrollment topped 15.7 million people in 2014. This is 30% of all Medicare beneficiaries and represents three-fold growth in just 10 years! (Enrollment in 2004 was 5.3 million people).

These two factors, when combined, mean that community laboratories do not have access to one-third of Medicare beneficiaries. If existing trends continue into future years, an even larger proportion of Medicare beneficiaries will be enrolled in Medicare Advantage plans—and local labs are not guaranteed access to service these beneficiaries.

Local and regional laboratories and pathology groups will want to recognize these trends in their strategic business planning. In particular, they should develop high value-added lab testing services that much larger lab companies cannot match.

"Other service issues develop that negatively affect patient care," he commented. "For example, in our region, we don't see Quest Diagnostics and LabCorp sending out phlebotomists at 3:00 AM to collect blood and urine specimens from nursing home patients. That's the only way we know that makes it possible for a lab to get the test results back to the nursing homes later the same day."

Making Co-Pays Work

Lab executives and clinical lab directors identified another strategy health plans are using this year. This strategy is designed to take advantage of the rapid growth in enrollment in Medicare Advantage plans and creates a financial opportunity that some payers seek to exploit. *(See sidebar on enrollment growth in Medicare Advantage plans on page 15.)*

A managed care contracting executive for a regional laboratory told THE DARK REPORT that some health insurers are requiring patients enrolled in Medicare Advantage plans to pay copayments for laboratory tests as a way to increase profit.

"Under traditional Medicare, lab services are covered at 100%," said the executive, who asked not to be named. "Under Medicare Part B, there is no copayment or out-of-pocket costs for clinical lab tests.

"Traditionally, labs must accept what the government pays for these lab tests, and no balance billing is allowed," the lab executive noted. "Plus, Medicare pays electronically within 14 days and no bill goes to the patient. There's no follow-up needed by the lab unless something goes wrong. Up until January, when it came to lab testing, most Medicare Advantage plans were operated in much the same way and any copays were very low. At least, that was the case here in Ohio.

"**UnitedHealthcare** was the first payer to require a lab test copayment for patients enrolled in its Medicare Advantage plans," stated the lab executive. "This copayment is between $10 to $25.

"Requiring a Medicare Advantage patient to make a copayment for lab tests can generate substantial revenue to the health insurer," he continued. "For example, many Medicare Advantage patients need to have their prothrombin time (PT) tested to see how long it takes their blood to clot.

"These patients are on a blood thinner, usually warfarin, and this year these tests cost $5.37 for our lab to run," the lab executive explained. "Now some—but not all—Medicare Advantage patients must meet a deductible or may have to pay copayments to the lab of $10 to $25. And by law, we cannot waive that copayment.

"When the Medicare patients heard they had to pay this copayment for their lab tests, they were upset," he said. "They complained to us because, as Medicare patients, they were not previously required to pay anything out of pocket for a lab test. Now they're paying $25!

"The health insurer directly benefits from this arrangement," the lab executive added. "Each time the Medicare Advantage patient's copayment is above the cost of the lab test, the health plan does not need to pay the lab for the test because the patient is paying for the entire cost. Therefore, the health plan saves money on these low-cost and high-volume tests."

Looking Ahead

Despite the challenges of being excluded from the Humana contract, another Ohio lab director was optimistic about the future. "For 20 years, private payers have tried to put us out of business. It hasn't worked yet and it isn't going to work now because of the value we deliver to physicians in our community.

"Exclusionary deals are not new from health plans," she concluded. "But Humana's action to exclude our lab from its network is new. Going forward, we must be more diligent with innovation so we can deliver lab test services that make a difference for physicians and patients." TDR

—Joseph Burns

Labs Working to Release Test Results to Patients

One lab IT director wants to know: will patient requests come in a trickle or a flood?

CEO SUMMARY: A new federal requirement requires labs to make test results available to patients beginning this month. What is unknown is how patients will respond to the opportunity to see their lab test results. The effective date for this new requirement was October 6. It is expected that patients with chronic conditions will have the greatest motivation to regularly access and retain their lab test results. However, at this point, labs don't know what proportion of patients will request access to their lab test results.

THIS MONTH, a new federal law became effective that requires clinical labs and pathology groups to give patients access to their lab test results just five days after their physicians have seen them. Mandated by the federal Health Insurance Portability and Accountability Act (HIPAA), this requirement took effect on October 6.

One big question mark is how many patients may want to see their laboratory test results. "Will labs see a tidal wave of patient interest or will only a handful of patients want access to their lab results?" asked Greg Kennedy, Director of Information Technology for **ClearPath Diagnostics** in Syracuse, New York.

"That's the question every clinical lab is asking today," noted Patricia Brown, Marketing Director for **Lifepoint Informatics**, a healthcare IT company in Glen Rock, New Jersey. "Patient engagement always has been a challenge for physicians and all providers.

"Labs will now begin to see which patients are accessing their test results," she said. "Typically, a patient must enroll with the lab as a necessary step to gain access to their lab results. How many patients will do so is an open question at the moment.

"It is believed that patients with chronic diseases will have the greatest motivation to view and save their lab test results," continued Brown. "How to best encourage patients to become more engaged in their own well-being is an issue that frustrates physicians. In fact, this issue is linked to the issue of how the healthcare system can motivate patients to take ownership of their health."

Watching Patient Response

Kennedy agreed, adding, "Here at ClearPath, we don't know if we're going to get two requests a week or two thousand requests a week from patients wanting to view their lab test results. In either case, we have to be compliant."

ClearPath is a pathology group that serves the Northeast. To comply with the new requirement, it installed a patient access portal from Lifepoint. "By the deadline of October 6, we were delivering lab test results to patients who requested

them," stated Kennedy. "Under existing New York State law, labs are not allowed to give patients access to their test results. So, conforming to this new federal requirement is a big change for us.

Patient Portal Strategy

"The decision to implement a patient portal to meet the new federal requirement simplifies the process any clinical lab or pathology lab would follow to make test results available to patients," explained Kennedy. "Mailing results would be time consuming and expensive. Thus, our ability to post results online within our portal is a positive step for ClearPath."

A patient wishing to see his or her lab test results must first make that request to ClearPath, he commented. "If the patient has Internet access, our team directs the patient to our website for access to the Lifepoint-powered portal. There, the patient can create the account needed to gain access to lab test results.

"If the patient does not have Internet access, we have a manual process to authenticate the request and deliver hardcopy results," he added. "The online process is similar to that of a number of other experiences that people have online. For example, just as with online banking, our patient visits the portal, answers a few questions, and creates an account. It's fast and simple.

Manual Process Available

"Not only do we want to comply with the regulations, but we need the patient to have safety and security," he added. "Thus the patient's answers to several questions are used to confirm identify. Next, the patient is sent an authentication number by email that he or she uses to visit the portal, to log in, and to view results."

Federal regulations dictate the timing of release. Physicians see the lab results first. Following a delay that could be as much as 30 days, the lab test results are then available to patients, according to the *Federal Register*, which published the regulations on February 6.

HHS Says New Rule Boosts Patients' Rights

In February, the federal **Department of Health and Human Services** issued rules to allow patients (or an individual designated by a patient) to have direct access to the patient's complete laboratory test reports.

At the time, former HHS Secretary Kathleen Sebelius stated, "Information like lab results can empower patients to track their health progress, make decisions with their healthcare professionals, and adhere to important treatment plans."

The rule amends the Clinical Laboratory Improvement Amendments of 1988 to allow laboratories to give a patient, or a person designated by the patient, his or her "personal representative," access to the patient's completed test reports on the patient's or patient's personal representative's request, HHS said.

Technically, three agencies within HHS issued the rule: the **Centers for Medicare & Medicaid Services** (CMS), the **Centers for Disease Control and Prevention** (CDC), and the **Office for Civil Rights** (OCR), which enforces the HIPAA privacy rules. The final rule is available for review at the *Federal Register site (http://www.federalregister.gov).*

The title of the rule is "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; A Rule by the Health and Human Services Department and the Centers for Medicare & Medicaid Services on 02/06/2014."

ClearPath Diagnostics will make the results available to the patient after the ordering provider has had time to review them, Kennedy said. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Quality management systems (QMS) have made inroads in some of the organizations that accredit clinical laboratories in the United States to the requirements of CLIA. Last month, **COLA** of Columbia, Maryland, acknowledged that it had recertified to the standards of ISO 9001: 2008. The recertification was obtained through the **British Standards Institute**. COLA earned its first certification to ISO:9001 in 2012.

MORE ON: *QMS*

In the United States, the newest organization to have deeming authority to accredit clinical labs to CLIA is the **American Association for Laboratory Accreditation** (A2LA), of Rockville, Maryland. The **Centers for Medicare and Medicaid Services** granted that status to A2LA in 2013. A2LA is itself accredited to ISO/IEC: 17011 *Conformity Assessment—General Requirements for bodies providing assessment and accreditation of conformity assessment bodies.* It is also a signatory to the **International Laboratory Accreditation Cooperation** (ILAC) Mutual Recognition Arrangement (MRA) and the **International Accreditation Forum** (IAF) Multilateral Recognition Arrangement (MLA). Because of its ILAC recognition, when A2LA accredits a lab in the United States to ISO 15189, other countries that are ILAC signatories will accept that lab's test data and its ISO accreditation.

TRANSITIONS

- Franklin R. Cockerill III, M.D., was appointed Vice President and Chief Laboratory Officer by **Quest Diagnostics Incorporated** of Madison, New Jersey. Most recently, Cockerill was Chair of Laboratory Medicine and Pathology at **Mayo Clinic** and President and CEO of **Mayo Medical Laboratories**.

- **Neogenomics, Inc.,** of Ft. Myers, Florida, named Robert Shovlin as COO. He has held executive positions at **Bostwick Laboratories**, **Aureon Biosciences**, **Quest Diagnostics, Incorporated**, and **Dianon Systems**.

- Robert Pettit is the new Vice President of Revenue Cycle Management at **Aurora Diagnostics** of Palm Beach Gardens, Florida. Previously, Pettit served at Quest Diagnostics Incorporated.

- **RainDance Technologies, Inc.,** of Billerica, Massachusetts, announced the appointment of Fritz Eibel as Senior Vice President of Strategic Marketing. Eibel was formerly at **Agena Bioscience**, **Sequenom**, **Gen-Probe**, **Life Technologies**, and **Roche Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 3, 2014.