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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

Market Disruption Coming to Labs in Texas

IT WON'T BE WELCOME NEWS TO CLINICAL LABS AND PATHOLOGY GROUPS IN TEXAS that **UnitedHealthcare** will introduce its laboratory benefit management program in the Lone Star State. It will change the access many labs have to UHC patients and probably reduce the money these labs are paid if and when they do perform testing for UHC patients.

These were some of the outcomes many laboratories in Florida reported after UHC instituted the laboratory benefit management program (LBMP) there in March 2015. Because most labs in Florida considered the terms offered by **BeaconLBS**—which manages the program for UHC—as unfavorable, only 20 labs currently participate in UHC's laboratory of choice network in Florida and 25% to 30% of those are **Laboratory Corporation of America** or lab divisions of LabCorp (which owns BeaconLBS).

Another point of interest is that UHC announced the LBMP program in Texas just 18 weeks in advance of the March 1, 2017, start date. For that reason, the health insurer will have to scramble to educate physicians about the program and how to use the BeaconLBS system. Also, if UHC has not yet finalized agreements with Texas labs to participate in its laboratories of choice network, it will be pressed to accomplish that task.

I would be remiss in my assessment of this story if I didn't call attention to the fact that, last year, a significant number of physicians and state medical specialty societies in Florida went on the record with strong objections and opposition to the UHC laboratory benefit management program and the BeaconLBS system used in its implementation.

Since Texans have a justified reputation for protecting their rights, will UHC and BeaconLBS face tougher opposition from Texas physicians and their medical societies as they learn the details of the LBMP? Surely some Texas doctors will consider UnitedHealthcare to be just as unwelcome a dictator as their forebears did of Mexican President and General Antonio López de Santa Anna. The big question then, would be, might Texas doctors rebel against this scheme and cause UHC to stop implementation of the LBMP with the same success that General Sam Houston and the Texans did in the battle of San Jacinto on April 21, 1836? On that date, they routed the Mexican army and captured Santa Anna. Houston's victory ensured the independence of Texas. TDR

UnitedHealth to Bring BeaconLBS to Texas

Laboratory Benefits Management Program starts on January 1, 2017, becomes mandatory March 1

CEO SUMMARY: With a quiet announcement this month that it was bringing its laboratory benefit management program to Texas on March 1, 2017, UnitedHealthcare is taking on a big challenge. Enrollment in UHC's commercial plans in Texas is 4.3 million. That is twice the two million commercial plan members UHC has in Florida, where it introduced the LBMP in 2015. Moreover, UHC has just 18 weeks to educate physicians about the program and recruit Texas labs into the BeaconLBS lab network.

PHYSICIANS IN TEXAS ARE LEARNING that, effective March 1, 2017, they will be required to comply with **UnitedHealthcare's** laboratory benefit management program pilot when ordering certain clinical laboratory tests that require pre-notification or pre-authorization.

When implemented in Florida last year, this same program encountered significant opposition from physicians and clinical laboratories in the Sunshine State. Even today, more than one year later, many physicians remain unhappy with the requirement that they obtain pre-notification or pre-authorization before ordering lab tests as required with the BeaconLBS system.

In Texas, as in Florida, the pilot program will be managed by **Beacon Laboratory Benefit Solutions, Inc.**, a subsidiary of **Laboratory Corporation of America**. Again, similar to Florida, the program covers UnitedHealthcare members in Texas who are enrolled in the company's commercial plan.

The announcement was made using a low-key approach. UnitedHealthcare's Network Bulletin for October carried the news. *(See sidebar on page 5.)*

In the announcement, UHC says that physicians will be required to use the system as of March 1, 2017. That is when UHC will begin to enforce what it describes as "claim and service impacts." UHC also stated that physicians could begin using the BeaconLBS physician decision support tool on Jan. 1, 2017.

This is a more ambitious pilot program than what UHC undertook in Florida. Recent figures show that

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UnitedHealthcare has approximately 4.3 million beneficiaries in commercial plans in Texas. That is more than double the 2 million beneficiaries in UHC commercial plans in Florida.

Another interesting element to UHC's announcement that it would deploy this lab test pre-notification/pre-authorization program is that, as of this date, the list of UHC's "Laboratories of Choice" network on its website does not include any local Texas laboratories. It lists 20 laboratory companies that are currently in the LOC network for Florida.

A Surprise For Texas Labs?

If it is true that UHC and BeaconLBS representatives have not yet contacted clinical labs and pathology groups in Texas about becoming a laboratory of choice network lab, then the announcement of the March 1, 2017, start for the laboratory benefit management program may be a surprise for laboratories throughout the Lone Star State.

It will certainly be a surprise for those physicians who most frequently use the list of about 80 clinical lab tests for which pre-notification or pre-authorization must be obtained and put on the lab test requisition for labs in the UHC network to be paid.

THE DARK REPORT contacted several state medical specialty societies and the **Texas Medical Association**. Officials at each organization responded that they were unaware that UnitedHealthcare had announced that the laboratory benefit management program would become effective in Texas next year.

No Response To Inquiries

As of this date, UnitedHealthcare and BeaconLBS had not responded to inquiries from THE DARK REPORT. The only public information seems to be the announcement in the UHC Network Bulletin for October and certain pages on the UHC website which have been updated to include information about implementation of the program in Texas starting next year.

There will be much interest in which laboratories in Texas decide to enter into agreements with BeaconLBS to be a member of the laboratory of choice network. Not only do these agreements have pricing and restrictive terms that many Florida labs rejected, but signing such an agreement means that the lab is then subject to terms created by a company owned by LabCorp, a major competitor.

It is be expected that the entire clinical laboratory industry will watch the launch of the laboratory benefit management pilot program in Texas. Throughout the United States, lab administrators are aware that implementation of this lab test program in Florida triggered much opposition by physicians, clinical laboratories, and pathology groups.

Florida Docs Frustrated

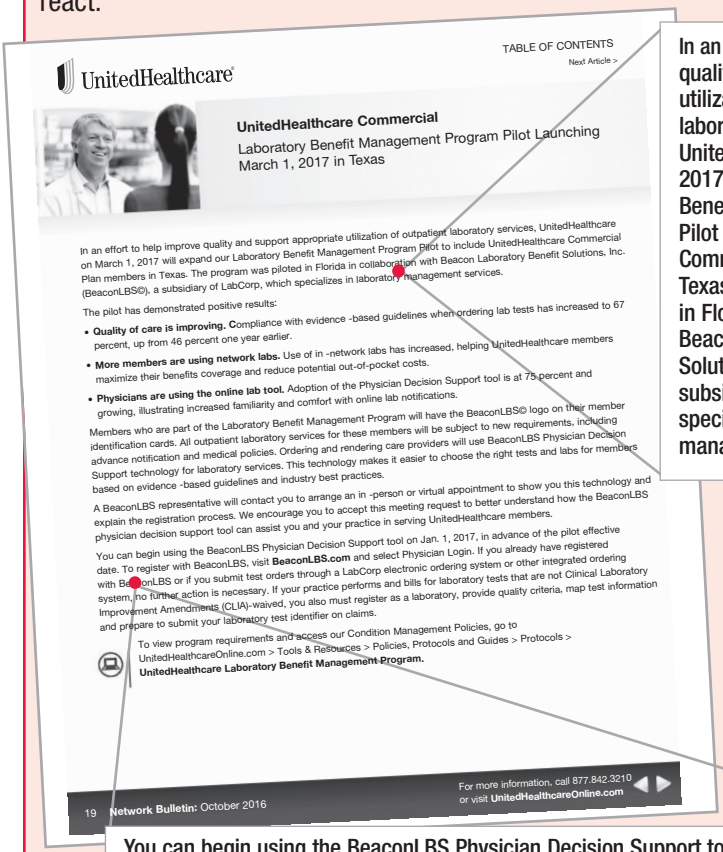
In the Sunshine State, some physicians and labs were frustrated about various aspects of the program, difficulties in using the BeaconLBS system to obtain pre-notification and pre-authorization, and the algorithms used to determine whether a lab test order was medically necessary or not.

Because UnitedHealthcare has twice the number of lives in its commercial plans in Texas, compared with Florida—4.3 million and 2 million respectively—it faces an even bigger challenge to implement the laboratory benefit management pilot program. Thus, it is odd that its first official announcement that the LBMP was coming to Texas was published just 18 weeks before the scheduled implementation date of March 1, 2017.

Another factor may add interest to this story as it unfolds. Texans are legendary for valuing their independence and are willing to fight hard to maintain it. Might it turn out that UnitedHealthcare finds itself facing better-organized resistance by Texas physicians than it did from Florida physicians? TDR

UnitedHealthcare's Network Bulletin for October Announces Start of Laboratory Benefit Management Program in Texas

IT REMAINS TO BE SEEN HOW PHYSICIANS, CLINICAL LABORATORIES, AND ANATOMIC PATHOLOGY GROUP PRACTICES IN TEXAS respond to the news that UnitedHealthcare will require use of its laboratory benefit management program, effective March 1, 2017. (Although physicians can begin ordering tests through the BeaconLBS system starting on January 1, 2017.) When this program was announced for Florida in 2014, for implementation on October 1, 2014, resistance from physicians was immediate and intense. UHC moved the start date back to March 15, 2015, and still faced plenty of pushback from physicians and labs. Since the news of this development is less than two weeks old, it is too soon to gauge how physicians in Texas will react.



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UnitedHealthcare

UnitedHealthcare Commercial
Laboratory Benefit Management Program Pilot Launching March 1, 2017 in Texas

In an effort to help improve quality and support appropriate utilization of outpatient laboratory services, UnitedHealthcare on March 1, 2017 will expand our Laboratory Benefit Management Program Pilot to include UnitedHealthcare Commercial Plan members in Texas. The program was piloted in Florida in collaboration with Beacon Laboratory Benefit Solutions, Inc. (BeaconLBS©), a subsidiary of LabCorp, which specializes in laboratory management services.

The pilot has demonstrated positive results:

- **Quality of care is improving.** Compliance with evidence -based guidelines when ordering lab tests has increased to 67 percent, up from 46 percent one year earlier.
- **More members are using network labs.** Use of in -network labs has increased, helping UnitedHealthcare members maximize their benefits coverage and reduce potential out-of-pocket costs.
- **Physicians are using the online lab tool.** Adoption of the Physician Decision Support tool is at 75 percent and growing, illustrating increased familiarity and comfort with online lab notifications.

Members who are part of the Laboratory Benefit Management Program will have the BeaconLBS© logo on their member identification cards. All outpatient laboratory services for these members will be subject to new requirements, including advance notification and medical policies. Ordering and rendering care providers will use BeaconLBS Physician Decision Support technology for laboratory services. This technology makes it easier to choose the right tests and labs for members based on evidence -based guidelines and industry best practices.

A BeaconLBS representative will contact you to arrange an in -person or virtual appointment to show you this technology and explain the registration process. We encourage you to accept this meeting request to better understand how the BeaconLBS physician decision support tool can assist you and your practice in serving UnitedHealthcare members.

You can begin using the BeaconLBS Physician Decision Support tool on Jan. 1, 2017, in advance of the pilot effective date. To register with BeaconLBS, visit **BeaconLBS.com** and select Physician Login. If you already have registered with BeaconLBS or if you submit test orders through a LabCorp electronic ordering system or other integrated ordering system, no further action is necessary. If your practice performs and bills for laboratory tests that are not Clinical Laboratory Improvement Amendments (CLIA)-waived, you also must register as a laboratory, provide quality criteria, map test information and prepare to submit your laboratory test identifier on claims.

To view program requirements and access our Condition Management Policies, go to UnitedHealthcareOnline.com > Tools & Resources > Policies, Protocols and Guides > Protocols > **UnitedHealthcare Laboratory Benefit Management Program.**

19 **Network Bulletin:** October 2016

For more information, call 877.842.3210 or visit **UnitedHealthcareOnline.com**

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You can begin using the BeaconLBS Physician Decision Support tool on Jan. 1, 2017, in advance of the pilot effective date. To register with BeaconLBS, visit BeaconLBS.com and select Physician Login. If you already have registered with BeaconLBS or if you submit test orders through a LabCorp electronic ordering system or other integrated ordering system, no further action is necessary.

LDT Regulation Update

FDA Official Outlines Need for Federal Regulation of LDTs

Harvard Medical School pathologist questions the idea that all LDTs put patients at risk of harm

AT A CONGRESSIONAL BRIEFING LAST WEEK, a federal official charged with regulating laboratory-developed tests made the case that LDTs are inconsistently reliable and thus put patients at risk, according to *MedPage Today*.

"If you take the same patient sample and you send it to different labs, you can get different results," stated Jeff Shuren, MD. He is Director of the **FDA's Center for Devices and Radiological Health**. In a report last year, Shuren's office listed 20 LDTs that the FDA said produced invalid and clinically erroneous results. The report, *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies*, was designed to bolster the FDA's case to regulate LDTs.

Framework for Regulation

In October 2014, FDA released its *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*. Since then, it has not moved to adopt the recommendations in the framework.

Shannon Firth, a Washington correspondent for *MedPage Today*, reported that, at the briefing, representatives of the clinical lab industry disputed the need for the FDA's recommendations in its regulatory framework. She cited the comments of one pathologist in particular, Anthony John Iafrate, MD, an Associate in Pathology at **Massachusetts General Hospital**; Medical Director for the Center for Integrated Diagnostics; and a Professor of Pathology at **Harvard Medical School**.

He questioned the idea that all LDTs are dangerous and that all FDA-approved tests are good, Firth reported. Many FDA-approved tests are not performed in a way that conforms to the package insert for those tests, making them essentially no different from LDTs, Iafrate argued.

Requiring laboratories to prove clinical utility for every analyte each time the lab prepares to introduce a new test is impractical, Firth wrote. If a test has clinical utility then it has proven to be useful to the clinicians using that test, she added.

Iafrate cited the example of tests used to identify EGFR mutations. "We know that EGFR mutations predict an EGFR inhibitor response. Why would I need to perform a very expensive large clinical trial to show that my test predicts that?" he said, adding that some changes to the CLIA regulations would allow oversight of LDTs with minimal disruption and no FDA approval.

What's more, clinical labs are already subject to oversight since all labs must do proficiency testing (PT). While such testing does not review the actual validity of LDTs, PT is one way that labs must prove their processes meet certain minimal standards. "All the labs that do this type of testing have to subscribe to and pass PT, and if they don't pass there are real repercussions," stated Iafrate.

Shuren responded that the FDA is not proposing to regulate all 60,000 LDTs in use. Instead, the agency's proposed framework would exempt low-risk tests that do not need clinical-validation studies. TDR

PSCs in Safeway Stores Popular with Consumers

Lab company adds patient service centers to seven additional grocery stores in Arizona

CEO SUMMARY: In a pilot program started in November 2015, Sonora Quest Laboratories built patient service centers in two Safeway grocery stores. That program went so well that patients filled available appointments in a matter of weeks. Sonora Quest even reported an increase in the number of walk-in, cash-paying consumers as a result of opening the two new PSCs. Following that success, Sonora Quest negotiated with Safeway to open PSCs in seven more Safeway health and wellness centers.

ARIZONA CONTINUES TO BE GROUND ZERO for efforts to expand direct access testing. This is true, in part, because of the substantial advertising that **Theranos** did in the Grand Canyon State in recent years to educate consumers about the benefits of purchasing lab tests without a physician's order.

Earlier this spring, Theranos lost its relationship with **Walgreens**, along with the specimen collection sites it operated in 40 Walgreens pharmacies in the Phoenix region. Now Theranos is exiting the clinical laboratory business (due to sanctions the federal **Centers for Medicare & Medicare Services**) imposed, creating a direct access testing (DAT) vacuum in Arizona. Two companies want to fill that vacuum and are collaborating to expand consumer access to DAT.

On August 29, **Sonora Quest Laboratories** and **Safeway** issued a press release stating that their relationship would expand. Sonora Quest will staff new patient service centers (PSCs) in nine Safeway grocery stores throughout Arizona in 2016. The two companies currently operate PSCs in five Safeway stores—three in Phoenix Metro, one each in Glendale and Sedona, and as of early October, one in Tucson. *(See TDR, December 28, 2015.)*

What is noteworthy in this expansion is that only one of the new PSCs will be in Phoenix. The others will be located in the cities of Glendale, Kingman, Sedona, and Tucson. It is a sign that Safeway and Sonora Quest believe there is consumer demand for patient service centers that are easier to access and more convenient to their daily routines.

Several Factors For Success

Several factors contribute to the initial success Sonora Quest and Safeway report with the initial sites overall, but specifically to DAT. First, DAT has been available in Arizona for more than two decades. **LabXpress** was founded in Phoenix in 1989 to provide low-cost lab tests and has a legitimate claim to be the nation's first direct-to-patient, low cost lab company. *(See TDR, October 26, 2015.)* **AnyLabTestNow** currently operates six franchise locations in Arizona, of which four are in the Phoenix Metro.

Second, Theranos convinced the Arizona legislature to pass a bill that made it legal for consumers in Arizona to order any clinical laboratory test without a physician's order. The bill was signed into law and became effective in July 2015. This story was given wide play by newspapers and TV news outlets in Arizona.

Third, Theranos spent heavily on a marketing campaign to educate consumers about the benefits of ordering their own lab tests. These ads ran for almost two years and were designed to reach the majority of Arizona residents.

Strong Interest in DAT

For Sonora Quest, consumer response to direct access testing through their My Lab ReQuest offering has been encouraging. The lab company indicates it has experienced strong volume growth from the PSCs in the first two Safeway PSCs that were opened late last year.

In addition, Christina Noble, Sonora Quest's Vice President of Business Development, told THE DARK REPORT that the state's largest clinical lab company will continue to evaluate new opportunities, technologies, and services to expand access points of convenience to patients in the healthcare market place.

In addition to the nine grocery stores that Sonora Quest has or is moving into, the parent company, Quest Diagnostics announced in June that it plans to open PSCs in 12 Safeway stores in California, Colorado, Maryland, Texas, and Virginia. *(See sidebar on page 9.)*

"The willingness of shoppers to embrace the idea of getting blood and other patient specimens collected in the grocery store has been a pleasant surprise," Noble said. "Late last year, when we started this pilot program in the first two Safeway stores, we didn't know what to predict in terms of market demand for PSCs in grocery stores. We expected the best. But, at the same time, we planned for the worst because we didn't know what would actually happen."

Some Sonora Quest executives considered that patients might not want to have blood drawn where they shop for food, she added. Those concerns turned out to be unfounded.

How Consumers Reacted

But first, Sonora Quest had to be sure that patients would get over what might be called the 'ick factor' of giving blood and other specimens where they shop for groceries, she added.

"We didn't know how this idea was going to play out with consumers because there were so many unknowns about this concept," Noble said. "However, we continue to be encouraged by the volume growth and positive feedback from patients in both locations.

"In fact, we have seen overwhelming acceptance and actual excitement and gratitude from patients because we've made healthcare more accessible and more convenient," she added.

For evidence, Noble said that, in the Safeway stores where Sonora Quest opened the first two patient service centers last year, available appointments were filled to capacity within weeks of opening.

Boosting Patient Volume

She would not divulge any numbers for how many patients each PSC serves each day, but she did say that many of the time slots were filled from the time the centers opened in the morning until they closed in the late afternoon or early evening. "In each store, the Sonora Quest PSC has the ability to operate on a different schedule, depending on the day of the week and the demand for such services," added Noble.

"In both locations, we were definitely at target capacity and hit our goals in terms of patient experience and productivity in a matter of weeks," she noted. "We met every goal we had, meaning we grew our business and created greater access points and convenience for consumers through creating these new solutions."

In these new PSCs, Sonora Quest saw the number of walk-in consumers increase, she added. But, again, due to concerns about giving away information to competitors, Noble would not reveal the number of new walk-in customers.

"Attracting new customers was definitely one of our goals," she added. "So, to reach that goal was very satisfying for us.

"Demand has at times been high so, rather than have patients wait for testing—we made beepers available just as they would get at a restaurant," she said. "That meant they could shop and return when the beeper went off.

Positive Patient Comments

"From all this, we've received many positive anecdotal comments, and we've had positive comments in our patient surveys," said Noble. "That is reinforced by the many positive comments that patients post on our Facebook page. In fact, 91% of survey respondents stated that My Lab ReQuest is a good value for the price they paid."

One issue Sonora Quest needed to work out is how to use the space Safeway allotted most effectively. In each store, the PSC is located next to a Safeway pharmacy. One advantage of this arrangement is that the PSCs could share the space the pharmacists were using to administer IV medications and flu shots, she commented.

For Noble, the ultimate goal of offering PSCs where consumers shop is to make lab testing more convenient so that consumers get their lab tests done more quickly from the time their physicians order those tests.

"At some point, increased convenience should translate into bending the cost curve," Noble commented. "If more patients get tested because they can do so in a place where they shop several times a week, it just makes sense that we will help increase compliance with physicians' recommendations for lab testing.

"When we do that, we would expect to see costs come down and patient outcomes go up," she said. "That's what excites me about this program: the opportunity to improve care and reduce costs."

Lab administrators and pathologists will recognize that Sonora Quest Laboratories and Safeway are tapping a dual source of demand with patient service centers in grocery stores. One type of patient is the direct access patient who wants to order tests without involving a physician.

The other type of patient has a clinical laboratory test order from a physician and wants a convenient draw site or the ability to pay cash because the patient lacks health insurance or has a high-deductible health insurance plan. TDR

—Joseph Burns

Contact Laura Waldron at 480-998-2600 or lwaldron@lavidge.com.

Quest, Safeway Expand DAT PSCs into Five States

IN JUNE, QUEST DIAGNOSTICS INCORPORATED and Safeway announced the opening of 12 patient service centers in five states. In each grocery store, the PSCs will be next to the in-store pharmacy.

These arrangements are similar to how Sonora Quest Laboratories and Safeway have developed DAT specimen collection centers in Safeway stores in Phoenix. The PSCs have about 400 to 500 square feet each, including a waiting room. As Sonora Quest Laboratories has done, Quest Diagnostics gives patients pagers so they can shop while waiting for a phlebotomist to become available.

On the Quest website, the company shows PSCs in Safeway grocery stores in California (three stores), Colorado (three stores), Maryland (two stores), Texas (three stores), and Virginia (one store).

In addition, Quest Diagnostics and Safeway are doing what many retailers do today, offering initiatives, such a coupons, to reward customers.

Anticipating end of fee-for-service reimbursement

Can Clinical Labs Adjust To 'New' Healthcare System?

➤➤ *CEO SUMMARY: Month by month, there is increased clarity in the path the American healthcare system will follow as hospitals, health systems, and physicians integrate clinical care, manage populations, and practice personalized and precision medicine. While these changes play out, clinical labs and pathology groups will need to align their diagnostic services to meet the changing needs of hospitals and providers—because laboratories will soon be paid differently for the added-value diagnostic services they provide.*

By now, most lab administrators and pathologists recognize that the nation's health system has already changed in fundamental ways. That makes it essential for every lab organization to have business and clinical strategies that allow it to make the transition to be effective providers in the healthcare system of tomorrow.

To help lab executives with their strategic planning, The Dark Report offers this overview of several important trends now transforming the American healthcare system. It is expected that, as these key trends play out, they will irrevocably change the way clinical laboratories are organized and how they deliver lab testing services to the hospitals, health systems, and physicians they serve.

As healthcare's transformation moves forward, three fundamental changes will occur to the long-standing business model of the clinical laboratory industry. They are:

1) Labs will be organized in new ways to collect specimens, perform tests, and report results;
2) New reimbursement models of bundled payments and budgeted payments will dictate a radically-different financial model for clinical labs (indeed, for all providers); and,
3) Top-performing labs will become sophisticated in how they use information technology to collect, store, analyze, and create value from the huge volumes of data that ongoing advances in molecular and genetic testing technologies will produce.

As part of our analysis, it is important to recognize that the effect of these fundamental changes to the American healthcare system will be uneven across different regions of the country. Some regions will experience change at a faster pace than other regions. Remember the era of the closed-panel, gatekeeper HMOs of the mid-1990s? States such as California, Florida, and Minnesota experienced rapid and widespread adoption of this model of health insurance. Meanwhile, many states went through the decade of the 1990s with only a small proportion of patients insured under this type of HMO. The current cycle of healthcare transformation will produce the same variation in how rapidly providers in different states adopt new models of care.

➤Watch Change Leaders

Also, within different regions, it is helpful to watch the leading health systems. They are generally first to respond to healthcare trends by introducing new care delivery models and offering clinical services in innovative ways.

The successes and setbacks of these trailblazing health systems are already providing valuable insights into what works and what doesn't as the United States pursues a new vision of integrated healthcare that uses precision medicine to diagnose disease earlier and keep consumers healthier and out of hospitals.

For example, the integration of care and the creation of regional—even statewide—integrated health systems and provider networks is advancing swiftly. This is particularly true in such states as Arizona, Minnesota, and Wisconsin.

In Arizona, **Banner Health** is the main player to watch. In Minnesota, besides **Mayo Clinic** in the south part of the state, the Minneapolis-St. Paul metropolitan area has at least five health systems that have already achieved tight integration. From this foundation, they are pushing forward to improve patient care still further.

In the Minneapolis-St. Paul area, **Fairview Health Services**, **Allina**, **Health Partners**, **Health East**, and **CentraCare Health** often get national recognition for their accomplishments.

In Wisconsin, two health systems seem to anchor the statewide market. One is **Aurora Health** in Milwaukee, with 15 hospitals and 1,400 physicians. Its primary

competitor, also based in Milwaukee, is **Froedtert Hospital & Medical College of Wisconsin**, with three hospitals and 2,000 physicians.

Each of these health systems is participating in a statewide provider network. Aurora is part of "**abouthealth**," which includes five other health systems. Froedtert participates in the **Integrated Health Network of Wisconsin** which includes at least three other health systems.

Lab administrators and pathologists are likely to gain the most useful insights about healthcare's changes by studying progressive health systems such as the ones described above in Arizona, Minnesota, and Wisconsin. These systems are comprised of multiple hospitals that formed a system, then began to acquire or ally with office-based physicians and other clinical service providers.

This model distinguishes these health systems from such well-known innovators as **Kaiser Permanente** and **Geisinger Health**, for example. Kaiser and Geisinger each have decades of experience as integrated care providers that own most or all of the hospitals and physicians within their respective systems.

By contrast, such organizations as Banner, Fairview, and Aurora are still in the process of inventing themselves. They are dealing with the challenges of integrating clinical care in ways that allow physicians, hospitals, rehab providers, home care, and nursing homes to deliver seamless care to patients—regardless of the setting.

Provider-Owned Health Plans

Another element that distinguishes Kaiser and Geisinger from other health systems is that these two organizations have had their own health insurance product for decades. By contrast, Banner, Fairview, and Aurora, and other health systems are just beginning to explore how their integrated clinical care organizations will relate to both the health insurance products they may own, and to other health insurers.

The consolidation of hospitals, physicians, and other providers in communities across the nation is a positive trend for local labs and pathology groups. As the delivery of care becomes more tightly integrated, a faster time-to-answer for diagnostic tests will become more important to providers than the cheapest cost per test.

Faster Time-To-Answer

However, faster time-to-answer comes with a trade-off: a higher price for those lab tests. Here is why. To achieve the cheapest cost per test, it is necessary to funnel huge volumes of specimens into a large lab facility to achieve economies of scale. In today's marketplace, the national lab companies accomplish this by having super-sized labs in different regions of the country.

Essential to this business model of clinical laboratory testing is the need to collect lab test specimens from doctors' offices on a weekday afternoon, fly them to a big regional lab facility that evening, perform the tests during the night, then report the results the next morning or a few days later.

Essentially, the trade-off for clinicians in ACOs, medical homes, and for health insurers is that, in order to obtain the lowest price for lab tests, they must accept a delay in reporting time. In a tightly-integrated ACO or medical home, providers know they are being paid to improve patient outcomes.

Thus, having faster access to lab test results allows speedier interventions within these integrated care organizations. It also improves the throughput and productivity of providers, in part because they can avoid having to hold patient files—and a final diagnosis to start treatment—overnight or for several days while waiting the laboratory test results to be reported.

Eight Types of Reimbursement Models Now In Use within the U.S. Healthcare System

WITH MOST HEALTHCARE EXPERTS PREDICTING the demise of fee-for-service reimbursement to hospitals, physicians, and clinical labs, the question that is regularly asked is, "What takes its place?" According to **McKesson Corporation**, there are eight basic types of healthcare reimbursement models under development or already in use.

Labs will be paid differently under these models. That is why lab administrators and pathologists will want to understand how each reimbursement model works and what type of strategy is best to ensure that their lab gets adequate payment.

- **Fee-for-service:** Patients or payers reimburse the healthcare provider for each service performed. A drawback is that no incentive exists to implement preventive care strategies, prevent hospitalization, or to take any other cost-saving measures.
- **Pay-for-coordination:** Goes beyond fee-for-service by coordinating care between the primary care provider and specialists. Coordinating care among multiple providers can help patients and their families manage to a unified care plan and can help reduce redundancy in expensive tests and procedures.
- **Pay-for-performance:** In a pay-for-performance (P4P) or value-based reimbursement environment, healthcare providers are compensated only if they meet certain metrics for quality and efficiency. Creating quality benchmark metrics ties physician reimbursement directly to the quality of care they provide.
- **Bundled payment or episode-of-care payment:** Providers are reimbursed for specific episodes of care such as inpatient hospital stays. This healthcare payment model encourages efficiency and quality of care because there is only a set amount of money to pay for the entire episode of care.
- **Upside shared savings programs (Medicare or commercial):** Incentives for providers paid with respect to specific patient populations. A percentage of any net savings realized is given to the provider. Upside-only shared savings is most common with Medicare Shared Savings Program (MSSP) Accountable Care Organizations, but all MSSP participants must move to a downside model after three years.
- **Downside shared savings programs (Medicare or commercial):** These models include both the gain-share potential of an upside model, but also the downside risk of sharing the excess costs of healthcare delivery among providers and payers. Because providers have greater risk with this model, the upside opportunity potential is larger in most cases than in an all-upside program.
- **Partial or full capitation:** Patients are assigned a per-member-per-month (PMPM) payment based on age, race, sex, lifestyle, medical history, and benefit design. Payment rates are tied to expected usage regardless of whether the patient visits more or less. Just as bundled payment models, healthcare providers, such as ACOs and medical homes, have incentives to help patients avoid high-cost procedures and tests in order to maximize their compensation. Under partial-capitation or blended-capitation models, only certain types or categories of services are paid on capitation.
- **Global budget:** This model involves a fixed total dollar amount paid annually for all care delivered. However, participating providers can determine how dollars are spent. Global budgets limit the level and the rate of increase of healthcare costs and budgets typically include a quality component as well.

These are reasons why the further consolidation of providers and efforts to integrate clinical care more tightly will create new opportunities for local clinical labs and pathology groups. Local labs—often based in hospitals—are the labs that can provide the fastest time-to-answer. Of course, local labs must provide those speedier lab test results at a reasonable price-per-test, but cheapest price per test won't be the sole determining factor.

New Payment Models

Another trend now unfolding in healthcare is the abandonment of fee-for-service reimbursement in favor of new payment models. This trend will have profound influence on the long-standing operational and financial model of clinical labs and anatomic pathology groups.

These new payment models all share a common goal: they are designed to disincentivize providers from earning money based on the volume of transactions. Instead, they are constructed so as to incentivize clinicians to deliver value in patient care. That value can be measured in several ways. One way is improved patient outcomes. Two other ways to measure value are fewer medical errors and reduction in the overall cost per healthcare encounter.

Serious Threat To Labs

Another feature of the new reimbursement models is seldom discussed. This feature represents both a serious threat to the clinical lab industry as it is currently structured and a once-in-a-lifetime opportunity for nimble, innovative labs that respond in appropriate ways.

The new reimbursement models now arriving in the healthcare marketplace have a common trait. In one fashion or another, the reimbursement is global. Instead of a discrete FFS payment going to each provider who treated the patient, these reimbursement models pay a lump sum and the providers involved in that patient care episode must divide the funds. *(See sidebar on page 13.)*

Bundled reimbursement is a good example. In recent years, clinical labs and pathology groups have seen the Medicare program change payment for selected episodes of care from FFS to bundled reimbursement.

On January 1, 2014, the federal **Centers for Medicare & Medicaid Services** implemented a scheme in which it bundled reimbursement to hospitals and their laboratories for outpatient clinical lab tests under the Hospital Outpatient Prospective Payment System (HOPPS). Previously, clinical lab tests performed on outpatients were paid separately under the Clinical Laboratory Fee Schedule (CLFS).

In such cases, the clinical laboratories involved in running tests for those patients must negotiate with the other providers to assign a portion of the bundled payment to them that is adequate to cover the cost of lab testing.

More Budgeted Payment

Another global reimbursement model gaining traction is budgeted payment. In simplest terms, the payer gives the integrated healthcare system (ACO or patient-centered medical home, for example) a flat payment per patient per month. The health system then provides all the care needed to the population of patients it serves for that budgeted amount.

All of the trends described above will not transform healthcare overnight. It will take several years for health systems, payers, and employers to make the transition away from current payment methods and care delivery models.

Thus, clinical laboratories and anatomic pathology group practices have time to prepare for these changes. It is important to recognize that clinical and financial strategies that worked in 2010 will not work in 2020. Innovative lab executives and pathologists will show the way forward to the rest of the lab industry. TDR

Lab Market Update

Theranos Ends Patient Testing, Sued for Deceiving Investors

As it shuts down its patient testing business, Theranos says it will manufacture IVD systems

In the early 1960s, the great bluesman Albert King wrote, "Born Under a Bad Sign," which contained the unforgettable lyric, "If it wasn't for bad luck, I wouldn't have no luck at all."

That lyric almost describes what's happened to **Theranos Inc.**, since October 2015. Although some would argue that Theranos brought this misfortune upon itself, it is, nonetheless, a long string of bad luck or at least bad news.

In recent weeks, Theranos has again been in the news for two reasons. First, it announced that it had ceased clinical testing. Second, it was sued by a hedge fund that had invested $100 million in Theranos.

On Oct. 5, Theranos posted a letter on its website stating that it had stopped doing testing for patients. The troubled company also said that it would exit the clinical laboratory testing business, shut down its CLIA-certified labs, and lay off 340 workers in its labs in Newark, Calif., and Scottsdale, Ariz.

The fact that Medicare officials have issued sanctions that would bar Theranos CEO Elizabeth Holmes from owning a lab or working in the lab industry for two years might be one factor in why the company decided to exit the clinical lab business. Also, leaving the lab business could be a way to avoid the most onerous penalties that CMS could impose.

On Oct. 10, just five days later, **Partner Fund Management LP**, a hedge fund in San Francisco, sued Theranos in Delaware Court of Chancery, *The Wall Street Journal* reported. In the suit, the fund charged that Theranos' officials lied to attract an investment from the fund of almost $100 million, making the fund the most significant financial backer of the beleaguered lab company, the journal reported.

Filed under seal, the suit was unavailable for scrutiny. The journal obtained a copy of a letter the fund sent to its investors. In the letter, the fund wrote, "Through a series of lies, material misstatements, and omissions, the defendants engaged in securities fraud and other violations by fraudulently inducing PFM to invest and maintain its investment in the company," wrote journal reporter Christopher Weaver. Investors have put about $800 million into the company, Weaver added.

Theranos Issued A Response

In response to the hedge fund's suit, Theranos posted a notice saying, in part, "The suit is without merit, the assertions are baseless, and the plaintiff is engaging in revisionist history. Most of the company statements the plaintiff has cited in its suit were made *after the time the plaintiff invested*, and could not possibly have been the original basis for investment. This wholesale reliance on post-investment statements, therefore, negates the claim that the plaintiff was misled." *[Editor: Theranos added the italics.]*

It is believed that the hedge fund invested sometime after Sept. 8, 2013, when the journal published a mostly flattering

interview with Theranos CEO Elizabeth Holmes, and before June 12, 2014, when *Fortune* magazine published an article touting the ideas and technology that Theranos planned to use to disrupt the clinical lab industry. In October 2015, the journal was first to report a number of failings in the operations and technology Theranos has used. Two months later, in December 2015, the *Fortune* writer followed up the earlier story with one that carried this headline: "How Theranos Misled Me."

Until then, the company's future had looked promising, meaning investors might have a strong case against the company now. The investors could claim that Theranos failed to disclose a number of material defects in its technology and processes.

Consumer Class Action Cases

Theranos also faces a number of class action suits from consumers who make many claims against the company and against its former partner, **Walgreens Boots Alliance**, which allowed Theranos to draw patients' blood for testing in its wellness centers in Arizona, California, and other states.

In one suit, plaintiffs charged, "Walgreens and Theranos misled consumers and induced them to purchase Theranos tests with false claims and material omissions," and that, "Theranos' labs were negligently maintained and operated and did not follow proper procedures and policies," among other charges.

Most of Theranos' problems began on Oct. 16, 2015, when journal reporter John Carreyrou wrote that the lab company could not accurately perform dozens of tests using only a few drops of blood. The idea that it could run many tests with small samples of blood taken with only a finger prick had helped to drive Theranos' stock to a self-declared valuation of $9 billion in 2014.

However, an investigation by Carreyrou, Weaver, and other journal reporters showed the company used its small-sample technology for only a few tests, that it used testing devices that conventional manufacturers made, and that it released questionable test results to patients.

Since then, Theranos has voided thousands of test results and faces federal civil and criminal investigations, the journal reported. Also, it has appealed a decision by the federal **Centers for Medicare & Medicaid Services** to revoke the license at its California clinical laboratory. In response to questions about the CMS action, the company has said it is cooperating with investigators and working closely with CMS to resolve the problems the agency cited in an inspection last fall. *(See TDR, July 25, 2016.)* TDR

—Joseph Burns

Elizabeth Holmes: A Case of 'Never Say Die'

HOPE SPRINGS ETERNAL with Theranos CEO Elizabeth Holmes. Her lab testing company faces severe CLIA sanctions, a criminal investigation by the **U.S. Department of Justice** and a civil probe by the **U.S. Securities and Exchange Commission**, along with multiple class action and investor lawsuits. Despite these circumstances, Holmes paints a rosy future for her company.

In the Oct. 5 letter to Theranos' stakeholders, Holmes wrote, "We have decided to close our clinical labs and Theranos Wellness Centers, which will impact approximately 340 employees in Arizona, California, and Pennsylvania. We will return our undivided attention to our miniLab platform. Our ultimate goal is to commercialize miniaturized, automated laboratories capable of small-volume sample testing, with an emphasis on vulnerable patient populations, including oncology, pediatrics, and intensive care. We have a new executive team leading our work toward obtaining FDA clearances, building commercial partnerships, and pursuing publications in scientific journals."

Cost Control Update

How Reference Pricing Encourages Patients to Help Cut Cost of Care

CalPERS uses reference pricing to contain costs for hip and knee surgery, also for common procedures

USE OF REFERENCE PRICING by **Safeway** to lower the cost of clinical laboratory tests was the subject of a study published by *JAMA Internal Medicine* in July. In a special issue, THE DARK REPORT analyzed the study, which showed that reference-based pricing helped slash the cost of clinical laboratory tests by 32% in just 24 months! *(See TDR, September 6, 2016.)*

Reference pricing is used to drive down what healthcare providers charge for services and in so doing, it narrows the wide variation purchasers pay for healthcare services. This intelligence briefing is a follow up to that special issue of THE DARK REPORT. Our editors interviewed experts at companies that have extensive experience with reference pricing.

David Cowling, PhD, is at the Center for Innovation at the **California Public Employees Retirement System**, (CalPERS). As one of the nation's largest purchasers of healthcare, CalPERS spends $7.5 billion annually to buy health plan benefits for 1.38 million members in California's more than 1,200 public agencies and schools. It has learned lessons from using reference pricing with several clinical services.

The first lesson came when CalPERS used reference pricing for joint replacement surgery. "In that program, we found that higher-priced providers were willing to drop their prices," noted Cowling. "It meant CalPERS met its goal even though the program was designed to have consumers drive down prices by choosing low-cost, high-value providers.

"The second lesson came when CalPERS used reference pricing for more common and lower-cost procedures, such as colonoscopy, cataract, and arthroscopic surgery," he continued. "In this program, consumers drove down the average price by choosing among providers based on price."

The lesson for clinical lab managers is that reference pricing drives down the cost of care. This means more purchasers, including employers, could adopt reference pricing when seeking to eliminate wide price variation in clinical lab testing and to drive down those costs.

Big Price Variation

"We see a lot of pricing variation, and—to us as the purchaser—it's not clear why there would be such a high pricing variation," stated Cowling. "Large pricing variation is one of those things to which we definitely pay attention, especially where the service is perceived as a commodity and there's not much difference in the service being provided in terms of quality."

Hip and knee surgery is not considered a commodity service because there is a belief that the providers' quality of care may differ. But CalPERS' use of reference pricing for hip and knee surgery was successful because providers themselves drove down the costs of these surgeries, Cowling said.

"In 2012, when we looked at pricing variation for hip and knee replacements, there were. very large variations, ranging from about $15,000 up to $110,000," he

said. "The interesting thing about the hips and knees program was that it was designed to have consumers make the choice about which provider to use.

"But what was surprising and what's unique about CalPERS' hips and knees program is that the hospitals responded to the possibility of losing volume by lowering their prices. That doesn't happen usually with reference pricing," Cowling said.

Lower-Priced Surgeries

Following the success of that program, CalPERS introduced a reference pricing program for colonoscopies, a service for which consumers can choose providers based on cost and where the quality of care is generally similar from one provider to the next. In that way, colonoscopies are like lab tests: high volume, and similar quality among providers.

The large pricing variation in hip and knee replacement surgeries caught the attention of CalPERS. In 2012, it developed a strategy to limit price variation. It decided to use reference pricing for patients who needed hip and knee surgeries.

"In that program, we saw what we were expecting with the hips and knees, which was that consumers changed their behavior," he said. "There was a big shift in terms of members going to the reference-priced facilities. For colonoscopy surgery, something like 93% of members went to the reference-priced facilities.

"In that program, we had a different mechanism that produced the same result: lower costs and less variation," he said. "So, here at CalPERS we are getting the effects that we're interested in seeing and those effects are still occurring.

"We don't have reference pricing for clinical lab testing right now, but we do have a partnership with **Castlight Health** to use their price transparency tool," Cowling concluded. "CalPERS wants to get members engaged in looking at price when they purchase all healthcare services to help keep costs down." TDR

—Joseph Burns

Contact Bill Madison at CalPERs, 916-795-0482 or Bill.Madison@calpers.ca.gov; Howard Willson at 415-829-1400 or hwillson@castlighthealth.com.

Reasons Why Employers Use Reference Pricing

ONE COMPANY SUPPORTING REFERENCE PRICING PROGRAMS is Castlight Health, a company in San Francisco whose users include consumers and self-insured employers looking to contain healthcare costs with Castlight's health benefits program.

Howard Willson, MD, is head of clinical strategy at Castlight. He explained that reference pricing is a tool that clinical lab managers need to understand. "It should be on their radar, particularly if employers in their area are focusing on it," he said. "Both reference pricing and price transparency have plenty of momentum and will be part of every healthcare consumers' life in the same way consumers use online sites to shop for travel and so many other goods and services.

"Medical services such as lab tests and imaging are perceived by employers and patients as being like commodity services—meaning they are services where quality is not as much of a factor as it is with other healthcare services," explained Willson. "Pathologists may not want to hear that. But from a patient's perspective, clinical laboratory tests are a reasonable choice for reference pricing.

"Employers use reference pricing for four different reasons. They are:

"One is to generate savings and reference pricing is the only benefit design that pretty much guarantees savings to employees by defining the maximum that an employer or other purchaser will pay.

"Two is to educate members about the importance of shopping for services. With reference pricing, individuals are compelled to pay attention to dramatic price variation in order to avoid overpaying.

"Three is that employers want to pull their employees away from paying for the most expensive providers because the most expensive providers are the real outliers.

"Four is to disrupt the market by sending a signal to providers that, by using reference pricing, these employers will not pay more than is necessary," concluded Willson.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Quebec's provincial health authority is moving forward with what may be one of the largest consolidations of clinical laboratory testing undertaken in North America during the past 30 years. The goal is to bring the lab testing currently done in as many as 500 locations throughout the province into 11 "high-volume processing centers." The project, called OptiLab, was announced in 2012. After several years of planning, the provincial health authority is now beginning to implement the plan. It is reported that 191 million lab tests are performed annually in the province.

MORE ON: *Quebec's Optilab*

Critics of the plan to consolidate medical laboratory testing point out that as many as 70% of all test samples will need to be transported to the 11 core labs. Doris Levasser Bourbeau, President of the **Professional Order of Medical Technologists of Quebec**, told the *Montreal Gazette* that moving this volume of specimens could result in errors and lost or ruined samples. Other union leaders in the province expressed the same concern about the risk of moving such a large volume of lab specimens within the province. Proponents of the lab consolidation project have yet to point out that, for decades, large volumes of lab specimens move vast distances daily in Canada, the United States, and Australia without risk or harm to patients.

LABCORP ACQUIRES CLEARPATH DIAGNOSTICS

Another anatomic pathology lab company is now owned by **Laboratory Corporation of America**. On October 4, it was announced that **Shore Capital Partners** had sold **Clearpath Diagnostics** of Syracuse, NY, to LabCorp. Terms of the deal were not announced. It was in 2011 when Shore Capital invested in ClearPath, which has five pathologists.

TRANSITIONS

• **Laboratory Corporation of America** has named Gene Heidt as Vice President, Corporate Strategy. Heidt has held executive positions with **HealthLab at Northwestern Medicine**, **Genesis Clinical Laboratory**, and **National Health Laboratory** (before and after the merger that formed LabCorp).

• John Pouk is the new Chief Commercial Officer for **10x Genomics** of Pleasanton, Calif. He formerly worked at **Agilent Technologies**, **Stratagene**, and **Fisher Scientific Company**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 7, 2016.

SPECIAL WEBINAR!

'Big Bang' of Antimicrobial Stewardship Programs Comes to All Hospitals on January 1!

Mike Broyles, PharmD

Director, Clinical Pharmacy & Lab, Five Rivers Med Center

How Labs, Pharmacies, and Clinicians Must Collaborate to Meet New Medicare, Joint Commission Requirements

Is the antimicrobial stewardship program ready at your hospital and laboratory for January 1, 2017? As of that date, both the Centers for Medicare & Medicare Services and The Joint Commission are requiring antimicrobial stewardship programs as part of their respective accreditations.

This is a major development and has many hospitals, health systems and their clinical labs scrambling to assemble the components of an effective antimicrobial stewardship program. With just nine weeks left before the New Year, it is essential that your lab and hospital team be ready. To give you the right head start, we've arranged for Mike Broyles, PharmD, at Five Rivers Medical Center, to share with you the successes in his institution's antimicrobial stewardship program.

You'll learn the secrets of effective physician/lab/pharmacy collaboration, how lab tests are used more effectively, what informatics capabilities optimize success, and pitfalls to avoid. This is your best source of the information and experience you need to energize your hospitals' antimicrobial stewardship program! **Register today!**

For information and to register, visit:
www.darkdaily.com/webinars

Webinar: November 16, 2017 at 1:00 PM Eastern

UPCOMING...

- ***TDR's 'ALL PAMA Market Price Reporting Issue.'***
- ***For Labs That Must Report: Newest Developments, Essential Advice, Avoiding Pitfalls and Penalties.***
- ***For All Other Labs: Estimating Financial Impact, Is Your Lab Really Exempt from Reporting?***

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