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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Feds Nail Doctors for Accepting Bribes from Labs

HALLELUJAH! FOUR DOCTORS IN NEW JERSEY HAVE PLEADED GUILTY to federal criminal charges of accepting bribes from **Biodiagnostic Laboratory Services** (BLS), the clinical lab company in Parsippany, New Jersey. Can any of you remember the last time that a federal prosecutor pursued criminal felony charges against multiple physicians who were referring lab tests to a laboratory that was paying some form of inducement or kickback to these same doctors?

In my opinion, convicting these doctors is the most important part of this federal prosecution. That's because it takes both a willing lab executive and a willing physician to commit the crime of bribery and violate federal inducement and anti-kickback laws. Yet, over the last 30 years, typically only a laboratory and its employees were prosecuted for offering a host of inducements that are bribes to get the doctors to refer their patients' lab tests to the lab. Federal prosecutors generally decided not to go after even one, let alone most, of the physicians who regularly accepted those bribes and inducements in arrangements that go on year after year.

Because of this lack of effective enforcement by federal prosecutors, physicians in many regions of the nation consider themselves safe from prosecution. They feel free to ask for inducements from labs in exchange for their lab test referrals.

Guess what... it's rational for these doctors to think that way! Of the tens of thousands of physicians out there right now with phlebotomy lease agreements and service agreements priced at outrageous levels, how many will ever see a federal investigator or prosecutor request documents about those arrangements? Most of you know the answer: zero, or close to it.

Thus, my kudos go to Paul J. Fishman, the U.S. Attorney prosecuting the BLS case. He is creating the enforcement precedents that are essential to show referring physicians that there are consequences to asking for and accepting bribes from a laboratory. But Fishman should not stop at just four doctors.

Fishman says that BLS earned "$100 million in illegal income from business brought through bribes" to physicians in New Jersey. That requires the lab test referrals from many doctors—even hundreds of doctors—to generate the volumes of lab tests required to produce that much money.

So, to Fishman and your assistant U.S. Attorneys, I say "keep going. You have the financial records and the evidence. Now is the time to send a strong message to every physician in the United States." The payoff will be immense, because physicians will finally see a vigorous enforcement of this law. And, this enforcement will do much to scare doctors away from asking for these inducements from labs. TDR

Genesis Outreach Lab Acquired by LabCorp

One more community hospital decides to exit lab outreach business and sell to a national lab

CEO SUMMARY: Sources say that Genesis Clinical Laboratory of Berwyn, Illinois, owned by McNeal Hospital, is being sold to Laboratory Corporation of America. Neither party has publicly acknowledged completion of the sale. It is the latest example of consolidation within the clinical lab industry. It is also another instance of a hospital selling its lab outreach business to a national laboratory. Genesis was apparently one of the deals that Regional Diagnostic Laboratories aimed to complete last year.

IN RECENT WEEKS, LAB INSIDERS are reporting that the owners of **Genesis Clinical Laboratory** of Berwyn, Illinois, have sold their lab outreach business to **Laboratory Corporation of America**.

This transaction removes one more independent lab company from a major metropolitan market, further consolidating the lab industry. Also, the seller is a for-profit hospital company and this sale is yet another example of a hospital selling its lab outreach business and exiting that sector of the market.

This purchase has not yet been reported publicly by either the buyer or the seller. Several sources told THE DARK REPORT that, although this transaction is consistent with similar ones done in recent years involving hospitals leaving the lab outreach business, there are interesting twists in the story of how Genesis Clinical Laboratory came to be sold. For example, Genesis came within a whisker of being purchased last summer by another buyer.

Essentially, these sources say that Genesis was uniquely positioned to be a growing, dynamic regional laboratory provider in its service area of the greater Chicago metro. Genesis was owned by 373-bed **McNeal Hospital**. In 2000, the hospital was purchased by V**anguard Health Systems**, an operator of for-profit hospitals based in Nashville, Tennessee.

Knowledgeable sources—who asked to remain anonymous—told THE DARK REPORT that the executives running Vanguard never understood the potential of Genesis to be a growing, profitable lab

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testing company. Growth at Genesis could deliver operating profits to the parent while allowing the lab to expand its in-house testing services in support of inpatient services. The additional benefit is that a productive lab outreach program would create strong relationships with office-based physicians in the community who would be in a position to refer patients to the McNeal Hospital.

For its part, Vanguard itself has been sold. Last month, T**enet Healthcare Corporation** of Dallas, Texas, said it would spend $1.73 billion to buy Vanguard Health Systems of Nashville, Tennessee. Tenet owns 49 hospitals nationwide and Vanguard owns 28 hospitals, including four in the Chicago area. At the time when the sale to Tenet was announced, Vanguard owned Genesis Clinical Laboratory.

Outreach Business for Sale

But within weeks of Tenet's announcement that it would acquire Vanguard, it was learned that Vanguard was selling the outreach business of Genesis Clinical Laboratory to LabCorp. Tenet is keeping the inpatient lab testing segment of the business handled by Genesis.

It should be recognized that, as for-profit hospital operators, over the past 15 years, neither Vanguard nor Tenet has demonstrated a consistent interest in building lab outreach businesses anchored by the community hospitals they own. This lack of interest in lab outreach was reflected in how Vanguard handled Genesis Clinical Laboratory after it purchased McNeal Hospital in 2000.

From its formation in the early 1990s, Genesis was one of the few successful hospital outreach programs in the Greater Chicago area. As a division of McNeal Hospital, it also provided inpatient lab testing for its parent. Following Vanguard's acquisition of McNeal in 2000, Genesis served three other Vanguard hospitals: the 236-bed **Louis A. Weiss Memorial Hospital** in Chicago, the 225-bed **Vanguard Westlake Hospital** in Melrose Park, and the 172-bed **West Suburban Medical Center** in Oak Park.

The core lab at MacNeal and the stat labs in the other three facilities were running a total of about 3.5 million clinical pathology tests per year and handling about 32,000 anatomic pathology specimens annually, a source said. Approximately half of the total test volume at Genesis came from its outreach business.

Sale of Lab Outreach

With that outreach business now going to LabCorp, the reduced testing volume at the core lab at MacNeal will decline sharply. That will require a rebalancing of the lab staff at that facility.

"The corporate owners—whether Vanguard since 2000 or more recently Tenet—didn't seem to appreciate the benefits of a thriving lab outreach program that could generate significant revenue and operating margins while building strong relationships with doctors in the area," the source said. "This is unfortunate, because at the end of 1990s, Genesis was positioned to be a successful and steadily growing enterprise.

"Executives at Vanguard did not recognize this potential," continued the source. "This meant that Genesis was not given the capital and other resources that would allow it to grow and thrive in its part of greater Chicago—a market traditionally dominated by **Quest Diagnostics Incorporated**. Doctors like a choice for their lab provider. For that reason, doctors around Chicago were interested in using other lab providers like Genesis."

Genesis Almost Sold In 2012

During the summer of 2012, talks between the newly-formed **Regional Diagnostic Laboratories, Inc.**, (RDx) of Brentwood, Tennessee, and executives at Vanguard almost resulted in the sale of Genesis to RDx. It is believed that cuts in lab reimbursement that were announced

during 2012 by Medicare caused the investors at RDx to pull the plug on the deal that was about to close. *(See TDRs, June 25, 2012, and December 10, 2012.)*

Now this latest sale to LabCorp has led to further speculation. "Having a buyer such as RDx back away from the acquisition last fall may have motivated Vanguard to be more cautious about investing in the lab outreach business," offered another source. "What unfolded was not a failure of Genesis and its lab outreach business. Instead, it was a failure of Genesis' owners to manage the business for more growth over the past 12 years."

Another source told a similar story. "Neither Vanguard nor Tenet ever understood the investment required to grow a commercial lab outreach business to get it to the next level," noted this individual. "While other community hospitals were investing in lab outreach, both Vanguard and Tenet were focused on the short term.

Shift In Total Lab Test Volume

"Specimen volume in and around the four hospitals is declining," he continued. "The lab staff employed by Genesis may decline by 30% to 40% after the sale because about half of the total test volume is shifting to LabCorp.

"What will be left at MacNeal is a core lab that services the employed physicians at the four hospitals in the Chicago market," said the source. "It appears that the nine pathologists and 204 clinical laboratory staff members will do any lab testing work that LabCorp needs to have done locally in a Chicago lab."

At a minimum, the sale of the lab outreach business of Genesis Clinical Laboratory reflects the unsettled nature of the lab testing business at the moment. Last year, a qualified buyer walked away in reaction to payer cuts to the prices paid for laboratory tests. It may be that LabCorp was able to acquire Genesis at a fire sale price because of this reason. TDR

—Joseph Burns

First Buyer of Genesis Lab Passed on the Acquisition

LABORATORY CORPORATION OF AMERICA was not the only lab company to express interest in acquiring the laboratory outreach business of Genesis Clinical Laboratory.

In the early summer of 2012, the newly-formed Regional Diagnostic Laboratories, Inc., (RDx) of Brentwood, Tennessee, negotiated an agreement with Vanguard to acquire Genesis, according to sources familiar with the situation.

"RDx was planning to invest in new technology for Genesis and perhaps a new lab facility as well," said one source. "A contract was in place for Vanguard to sell the lab to RDx for what looked to be very favorable terms.

"Because RDx intended to invest in Genesis to give it the capabilities to grow much larger, the Genesis team was supportive of this ownership change," he continued. "But that deal fell through at the last minute when the investors for RDx saw the trends toward ongoing cuts in clinical laboratory reimbursement. As a result, RDx pulled the plug on the deal and chose to walk away. *(See TDR, December 10, 2012.)*

"This happened in the fall of 2012 and that experience—and the perception that the value of the Genesis lab outreach business was less than Vanguard thought—may have led Vanguard to want to sell the lab to the first available bidder," speculated another source. "In any event, it was LabCorp that ended up buying the Genesis lab outreach business.

"Vanguard is in the hospital business and so is Tenet," he added. "They had no idea what to do with a commercial laboratory outreach business and so wanted someone to take this entity off their hands and give them cash in return. Then, they could take that cash and reinvest it in other ways."

MolDx Test Update

House Bill Introduced to Address Rate-Setting for Molecular Tests

HHS would need to justify payment rates for tests and provide a reasonable period for reconsideration

FEW PATHOLOGISTS OR CLINICAL laboratory directors would argue against revising the current Medicare payment policies for molecular and genetic tests. A bill proposed in Congress would do just that.

The process now in use by Medicare Administrative Contractors (MACs) is inefficient and opaque, according to pathologists and lab executives. The result is not many clinical labs were paid for molecular test claims submitted to MACs earlier this year. On January 1, the MACs started using a new process to assign prices to the 114 new Tier 1 and Tier 2 molecular test CPT codes on the Part B Clinical Laboratory Test Fee Schedule.

Payment Processing Slowed

In recent weeks, it is believed that most of the MACs have priced many of the new codes. One MAC priced only 22 codes, and some priced about 70 or more. MACs that have priced the new CPT codes have started to pay those labs submitting molecular test claims covered by those codes. Nonpayment caused labs to stop testing, lay off staff, and consider closing. *(See TDR, May 27, 2013.)*

To address these problems, Rep. Peter Roskam (R-Illinois), sponsored HR 2085, the Diagnostic Innovation Testing and Knowledge Advancement Act of 2013. It was introduced on May 22. According to the **Coalition to Strengthen the Future of Molecular Diagnostics**, the bill is designed to improve the process for determining Medicare payment rates for diagnostic tests. The bill would be effective on enactment and apply to tests assigned a new or revised code this year.

The bill's cosponsors are Brett Guthrie (R-Kentucky), Ron Kind (D-Wisconsin), Leonard Lance (R-New Jersey), Richard Neal (D-Massachusetts), Erick Paulsen (R-Minnesota), and Patrick Tiberi (R-Ohio).

If passed, the language in the bill would require Health & Human Services (HHS) Secretary Kathleen Sebelius to justify payment rates for new tests, explain the justifications clearly, and allow a reasonable period for reconsideration before the new rate is final.

Also, when setting rates, the HHS Secretary would need to consider claims data, what laboratories charge self-pay patients, what private insurers pay, what effect a new test would have on patient care, and the technical characteristics of new tests. Also to be included in the rate-setting process is a consideration of the resources labs need to develop, validate, and perform tests.

One other significant provision in the bill involves establishing a 19-member independent advisory panel that would include members with expertise in technical, clinical, and quality information. The committee could decide whether payments should be set by gapfilling or crosswalking. The bill specifies that members would have several kinds of specialized expertise and each would serve for six years. TDR

Two Omaha Med Centers Form Collaborative Lab

As part of an affiliated ACO, two hospitals formed the Nebraska Collaborative Laboratory

CEO SUMMARY: An accountable care organization with a strong clinical laboratory component is taking shape in Nebraska. The University of Nebraska Medical Center has developed a partnership with the Nebraska Methodist Health System to form an ACO called the Accountable Care Alliance. It will serve Nebraska and perhaps other parts of the Midwest. Both the pathologists and the referring physicians see opportunities to cut costs and improve clinical quality.

Since the Affordable Care Act was signed into law in 2010, clinical laboratory directors have been asking how labs will fit within accountable care organizations (ACOs).

While physicians and hospitals are forming ACOs nationwide, clinical laboratories have mostly been missing from these operations. Many observers believe clinical laboratories might be among the last pieces of the puzzle to find a niche inside ACOs.

But now, in Nebraska, comes an early example of how ACOs and clinical laboratories are finding new ways to work together. An ACO with a strong lab component is taking shape in Omaha.

"The **University of Nebraska Medical Center** (TNMC) and the **Nebraska Methodist Health System** (NMHS) have formed an ACO called the **Accountable Care Alliance**," stated Steven H. Hinrichs, M.D., Professor and Chair of the Department of Pathology and Microbiology at TNMC in Omaha. "This ACO will serve Nebraska and perhaps other parts of the Midwest.

"Health systems in Nebraska tend to be disparate and not well connected," observed Hinrichs. "But here at the University of Nebraska Medical Center, we believe we can work together. Health reform gives us the opportunity to do so."

The ACO brings together two rather large lab organizations. "The laboratory at 624-bed TNMC performed 5.04 million billable tests last year and had lab revenue of $297.4 million," said TNMC Lab Director David Muirhead. "The lab at 430-bed NMHS did 1.5 million billable tests and had lab revenue of $30.9 million last year. TNMC has 238 full-time equivalent staff and 28 pathologists while NMHS has 146 FTEs and 12 pathologists."

For Labs, Place at the Table

"The ACO was announced in 2011 and the two labs entered into a collaboration in May of this year to form the **Nebraska Collaborative Laboratory** (NCL)," noted Hinrichs. "Initially the two labs will create a single esoteric laboratory.

"This lab will perform high-level molecular testing for breast cancer, lung cancer, and sarcomas," he noted. "In addition, both entities have cooperated on purchase agreements for blood products and for reference laboratory work, saving $1 million in our first year.

"At a minimum, we aim to be a strong regional player," he continued. "By having the two labs collaborate and with the formation of an ACO involving our parent medical centers, we can move in that direction. We have the brainpower from the university and the hospitals. What we were missing was the volume. Combining our labs' volumes gives us this opportunity.

Could Labs Be Leaders?

"For our laboratory directors, the question is 'Where do we start?'" asked Hinrichs. "Our perspective is that our laboratories could lead the operation of the ACO in a number of ways and thus bring the larger organizations together.

"Our first step in the process was to create common standards across our respective lab organizations," noted James Wisecarver, M.D., Ph.D., Medical Director of the Clinical Laboratories at TNMC. "Working together, we had both labs do joint purchasing. We also aligned lab test orders and reports for referring physicians.

"Next we developed joint operations with the idea that each lab could fill the other lab's biggest needs," he said. "In working on these initiatives, we recognized the power of this collaboration."

"By having our two labs join efforts, we could keep many lab tests in house," explained Thomas Williams, M.D., Director of Clinical Laboratories at NMHS. "This would reduce the volume of tests referred to the major reference laboratories, thus improving turnaround time for inpatients and saving additional costs. That was how the two labs came together to form this partnership we have now.

"These insights came as we did our first joint request for proposals (RFPs) for blood supplies," Williams stated. "This was followed by an RFP for reference testing because we wanted the best price possible. The substantial savings and benefits from just these two deals showed us that combining our two labs would create a viable organization.

"What was interesting was, at this point in our joint activities, we saw a substantial number of opportunities to improve economies of scale," said Williams. "That's when we recognized that a sophisticated FISH laboratory would be a great benefit.

"At the time, neither of our two labs performed FISH (fluorescence *in situ* hybridization) testing," he added. "There were other FISH labs here in Omaha. If we wanted to save money on reference testing, FISH was one test we could do in house. Because we were not doing FISH testing previously, those tests were going out to reference labs."

In a press release, Julia Bridge, M.D., NCL's medical director, explained that, by adding FISH testing, Nebraska Collaborative Laboratory can provide supplemental diagnostic information that is based on a patient's tumor DNA, to determine the most effective course of treatment with the fewest side effects. Molecular FISH testing helps clinicians avoid treatments that will not produce a desired result in an individual patient based on the presence or absence of a gene alteration in the tumor sample, she explained.

Managing Cost of Lab Tests

"Many labs nationwide are concerned about the cost of send out tests and that was true of us, particularly after we formed the ACO," Hinrichs said. "Within the ACO, our labs have the responsibility to eliminate needless testing, especially if the test in question is costly.

"Genetic tests are a good example because they can cost $5,000 to $10,000 each and not all genetic tests have been validated in terms of their clinical utility," noted Hinrichs. "Another example comes from vitamin D tests run by labs.

"Often physicians routinely order the wrong test for Vitamin D" he commented. "With fee-for-service reimbursement, any lab getting those vitamin D test orders will perform those tests and many of these are needless tests.

"But in an ACO, the financial incentives are different," added Hinrichs. "We no longer build the business based on volume. Instead, we focus on value—which some people define as the highest quality for the lowest cost.

"Thus, to improve the process of lab test ordering, we suggested that the ACO allow us to form a lab-test utilization review committee," he said. "Our hospital administration approved the idea.

"This committee includes a laboratory director and referring physicians," stated Hinrichs. "The committee's goal is to identify high-cost tests that have low potential in terms of diagnostic value.

Best Practice Tests

"Our history has been to send out tests that have high-cost and low diagnostic potential," noted Hinrichs. "But now, we want our lab to focus on performing high-value tests in-house with high diagnostic potential. That simple change had a significant effect on the costs associated with our outpatient reference testing.

"The committee members recommend best practice tests for patients with certain conditions," Hinrichs added. "Once the entire committee agrees, that test can be added to our lab information system and to the hospital information system.

"This is a comprehensive process," he said. "We can assist physicians when they order these tests. Within the LIS and the HIS, we can give the doctors notes about the tests they are ordering or screens to ask if they want this test and, if they do, we can explain its typical clinical use.

"This shows how we are integrating best practices into the LIS and the HIS," stated Hinrichs. "In doing so, we are guiding physicians at the point of care—at the moment when they order a test."

Muirhead agreed, saying, "Our goal is to create a lab formulary that would be the counterpart to a pharmacy formulary. We believe laboratorians need to lead by playing a big role in identifying the most appropriate tests."

In ACO, Referring Docs Make Suggestions for Lab Testing

ONCE AN ACCOUNTABLE CARE ORGANIZATION was started, all members of the clinical team offered suggestions about how to control spending and improve quality. According to David Muirhead, Laboratory Director at The University of Nebraska Medical Center, that included ideas on ways to improve how physicians utilize lab testing services.

"It has been a pleasant surprise to hear all the suggestions the physicians have made about how to improve care and keep costs down," Muirhead said. "They asked, for example, if the medical center needs to do a blood draw on every patient three times a day. Because we were focusing on high-dollar tests, we didn't even think that kind of question would come up.

"But the physicians started looking at their own processes and their interactions with patients," he noted. "They asked if we needed to do a urine test every day, for example.

"By asking these kinds of questions, the physicians are looking at the laboratory as more than a place that generates test results. They are looking to the lab as a source of information and knowledge," concluded Muirhead. "That's something we haven't seen before and we welcome that kind of input because it makes both our lab and our ACO much better at delivering value to patients."

"Our history has been to send out tests that have high-cost and low diagnostic potential," noted Hinrichs. "But now, we want our lab to focus on performing high-value tests in-house with high diagnostic potential. That simple change also had a significant effect on the costs associated with our outpatient reference testing." TDR

By Joseph Burns

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Contracting with ACOs has potential for risks, rewards.

Laboratory Offers Early Lessons in Positioning for Success with ACOs

➤➤ ***CEO SUMMARY: Accountable care organizations (ACOs) are already leading the shift from fee-for-service reimbursement to population payment. ACOs are leading healthcare's evolution to preventive care, wellness, and better management of patients with chronic disease. This evolution will require that all providers, including clinical laboratories, must shift from delivering volume to producing value. In Phoenix, Arizona, Sonora Quest Laboratories has already entered into contracts with multiple ACOs. Its CEO shares insights about the process and early lessons learned.***

Under the Affordable Care Act, the U.S. healthcare system is shifting focus from one that addresses the acute care needs of patients to one that delivers wellness, illness prevention, and chronic disease care.

At this moment in time, the development of accountable care organizations (ACOs) is the primary way that hospitals, physicians, and other providers are responding to this trend. However, the big question is: how will clinical laboratories be paid by ACOs?

An early answer to this question may be found in Arizona, where **Sonora Quest Laboratories** has already entered into contracts with several ACOs organized and operated by **Banner Health**, one of its two owners. According to Sonora Quest's CEO, contract talks between his lab and the ACO quickly moved away from fee-for-service payment for lab testing in favor of value-based reimbursement.

"Labs must respond to this transition from acute care to wellness, illness prevention, and chronic care," stated David A. Dexter, President and CEO of Sonora Quest Laboratories, LLC, and **Laboratory Sciences of Arizona, LLC**, both in Tempe, Arizona. "Instead of building their business by increasing specimen volume to achieve economies of scale, clinical labs must shift toward a businesses model centered upon delivering value."

This spring, Dexter was a featured speaker at the 18th annual *Executive War College*, sponsored by The Dark Report, in New Orleans, Louisiana. His topic was "Contracting with ACOs and Health Insurance Exchanges (HIXs): Early Lessons in Establishing Lab Test Value and Price."

Sonora Quest Laboratories is a joint venture partnership between Banner Health in Phoenix, Arizona, and **Quest Diagnostics Incorporated,** in Madison, New Jersey. The partnership of a health system and the nation's largest lab company puts Sonora Quest Laboratories in a strong position for the transition to value-based care that accountable care organizations (ACOs) will deliver under health reform, Dexter added.

"Value is going to be even more important in the coming months and years because the health system is moving away from volume," declared Dexter. "This is a warning for all pathologists and clinical lab directors. The old lab paradigm that volume is your friend may not be true under the ACO model of care delivery.

"That's because ACOs are going to transition over time from fee-for-service payment to population payment," he explained. "As ACOs do this, that change will be truly transformational as clinical care concentrates away from acute care and emphasizes preventive care, wellness, and managing patients with chronic disease.

➤Essential Role of Lab Testing

"Lab work is essential to delivering illness prevention, wellness, and chronic disease management," continued Dexter. "In fact, that work is right in our sweet spot because labs affect greater than 70% of all diagnostic decisions and our data represents more than 50% of the elements in electronic health records (EHRs). These numbers show that health information exchanges (HIEs), ACOs and HIXs will not be effective without lab test result data.

"In addition—and this is the key message I want to deliver—is that the formation of the ACOs and HIXs, in tandem with the expansion of Medicaid under Obamacare that takes place in 2014, all will drive a profound, fundamental shift in healthcare," he emphasized. "How this unfolds and directly affects what we do as clinical laboratories is not easy to predict.

"The projections by experts indicate that the coming changes will be significant," stated Dexter. "For example, Banner Health expects that ACOs will reduce hospital census rates by about 22%. This drop will cause a corresponding decline of 7% to 10% in hospital lab testing. That's profound.

"Many of us have already seen significant shifts in our regional health insurance

markets," he noted. "In Arizona just three years ago, 64% of people were covered by commercial, traditional employer-based health insurance. Today that number has declined to 46%!

"Of equal significance, among those 46%, about a fourth of them are in high-deductible plans," added Dexter. "That's higher than the national average for high-deductible health plan enrollment, which is about 19%.

"By design, high-deductible health plans force consumers to focus more on their discretionary spending for their healthcare services," he said. "That's only natural. If you're responsible for the first $3,000 to $10,000 of spending out of your own pocket, you will want to look long and hard at how you will spend that money.

"To be successful in this new marketplace, HIEs, ACOs, and HIX networks will need data," noted Dexter. "You can think of an ACO as a mini-HIE. ACOs will need to connect to HIEs for robust exchange.

David A. Dexter

➤"...any lab that simply reports lab test results will probably be treated as a commodity.. such a lab is vulnerable to losing the business if another lab comes along and offers more value to the ACO."

"Here in Arizona, our HIX is in development," he continued. "We have a number of ACOs in different stages of deployment, and—in our HIE—we have eight health plans working collaboratively with major health care providers in the state in a Phase I deployment.

"Other markets will be different," he added. "But what they all have in common is that lab data is essential for ACOs seeking to coordinate patient care and for HIXs serving all other elements of the healthcare marketplace.

"For this reason, labs are an enabler for the newly-reformed healthcare system," stated Dexter. "But few of the people establishing ACOs and HIXs recognize this fact. They are focused on structure and governance. They often fail to see the value of lab data. That's why pathologists and lab directors need to be out there waving the flag.

➤Lab Needs To Send Message

"Waving the flag is important, as our own experience has shown," he said. "Here's why: We have a national health plan that has a contract with a national lab that is a competitor of Sonora Quest Laboratories.

"That national health plan has already delegated those exclusive lives to the ACO in Arizona and the ACO is using Sonora Quest," noted Dexter. "That's significant for us because it means we have taken some of the business that would have otherwise gone to a national lab company.

"The bigger lab companies have economies of scale and significant IT capabilities." he observed. "For those reasons, they may be better suited to serve ACOs than hospital labs in some places. But the deciding factor may be your lab's value proposition—meaning how your lab delivers more value to the ACO and its providers.

"Stated differently, any lab that simply reports lab test results will probably be treated as a commodity," said Dexter. "Even if it offers a low price per test, such a lab is vulnerable to losing the business if another lab comes along and offers more value to the ACO. This is why clinical labs need to do more that just produce lab results.

➤Labs Need To Offer Value

"Laboratories that just produce lab results generally will be last at the ACO contract table," declared Dexter. "With few exceptions, that means such labs will not be ACO participants.

"In the case of Sonora Quest Laboratories, ACOs in our community see us primarily as a data partner, not so much as a lab," he noted. "We recognize

As ACOs Take on Many Forms, Lab CEO Offers One Workable Definition

AS THEY DEVELOP ACROSS the country, accountable care organizations (ACOs) are taking on many different forms.

In fact, David A. Dexter, President and CEO of Sonora Quest Laboratories, LLC, in Tempe, Arizona, warned that each ACO is uniquely suited to serve its own market and so it is not like another. As a result of seeing a number of ACOs under development, Dexter offers a workable definition.

"We've seen many of definitions of ACOs but the one I use most frequently is this: An ACO is essentially a partnership between health insurers (either for-profit, non-profit, or government), hospitals, and primary care physicians," he said. "The ACO is designed to manage the entire continuum of healthcare for a set population of patients. The ACO's goal is to improve quality and patient care outcomes and reduce costs.

"ACOs can be structured in different forms," stated Dexter. "Banner Health, an ACO in Arizona, owns 800 physician practices and has affiliations with 1,500 physician practices. All these physicians are in what's called the Banner Health network. They actually created their own non-profit entity with their own management team to contract with the Banner Health ACO.

"Also in Arizona, the insurer **Health Net** delegated a certain number of lives from its HMO into an ACO," stated Dexter. "**Aetna** also delegated a certain number of lives into a typical ACO model.

"Meanwhile, Blue Cross Blue Shield of Arizona has developed a joint venture ACO with Banner Health System," he continued. "My point here is that each of these ACOs has a different mix of lives that is unique. In general, this means that, if you've seen one ACO, you've really seen one ACO because each has a different structure and mix of patients.

"In the United States, the federal **Centers for Medicare & Medicaid Services** (CMS) has designated 32 Pioneer ACOs," said Dexter. "Banner Health happens to be one. There are 33 health outcomes measures that CMS will use to monitor patient outcomes.

"In addition to the Pioneer ACOs, there are more than 400 other ACOs that CMS has certified and 200 others are under development," he added. "It's estimated that 25 million to 30 million people are already enrolled in these ACOs. That number is expected to rise significantly. For example, Banner Health currently has 185,000 members in its ACOs and it projects that number will increase to 1.2 million members within two years."

the value we can deliver as a data partner and the opportunities for us to be paid by the ACO for the value of the data and the clinical knowledge that we provide.

"This shift in our lab's business strategy is important," Dexter continued. "That's because our nation's transition to accountable care is a transformational change on a scale as yet unseen. It is essential that all lab directors and providers recognize a key point: Every provider in healthcare—including labs—needs to reassess and establish its value proposition. Otherwise, that provider will not be successful in meeting the needs of its customers as they go through healthcare reform.

"In Arizona and in other markets around the country, it's possible to see that the walls of traditional healthcare are shifting," he commented. "As the walls shift, everyone in healthcare is hedging their bets. It means that yesterday's competitor could very well be tomorrow's collaborative partner. In the past two years,

companies that once viewed us with a jaundiced eye as a competitor no longer view us that way.

"Here's one example," stated Dexter. "Among its many responses to the shift toward proactive healthcare, Banner is forming a joint venture with the largest insurance plan in the state, **Blue Cross Blue Shield of Arizona**.

"That means the largest hospital system in the state has formed a formal joint venture with the largest health plan in the state," he said. "Such a move was almost unheard of just a few years ago; it's transformational.

David A. Dexter

➤"Today, the new paradigm for growth in the lab business is diagnostic testing combined with information services."

"Banner also purchased a Medicare Advantage health plan," added Dexter. "This strategy, when taken to its height, makes it possible for Banner to eventually become an integrated health system similar to **Kaiser Permanente** in California or **Intermountain Health System** in Salt Lake City, Utah.

"Recognizing the need to shift away from acute care and toward wellness, illness prevention, and chronic disease management, Banner Health is currently building 24 new health centers around Maricopa County," said Dexter. "Ranging in size from 6,000 to 120,000 square feet, these health centers will allow Banner to move to the episodic side of care and thus will no longer be focused exclusively on building volume on inpatient care.

"All these changes show the fundamental ways that healthcare is changing," he stated. "In the clinical lab business, the old paradigm of growth depended on increasing the volume in diagnostic testing handled by a lab organization.

"Today, the new paradigm for growth in the lab business is diagnostic testing combined with information services," he observed. "In fact, at Sonora Quest Laboratories, our vision is to be the trusted leader in diagnostic testing and information services.

➤Lab Data Represents Value

"But we believe it's not enough to have the data and the technology to share it with providers," stated Dexter. "We must also learn to leverage it to deliver the value that ACOs need, recognize, and for which ACOs are willing to pay.

"More specifically, labs have to find a way to deliver actionable information to providers to help them improve quality and reduce costs," noted Dexter. "We all know providers—be they hospitals or physicians—are interested in reducing costs.

"The numbers show the opportunity," he continued. "For example, an astounding 78% of total healthcare spending in the United States goes to treat patients with chronic disease.

"Next, just 5% of patients account for more than 50% of the total U.S. healthcare spending," noted Dexter. "In contrast, nearly 50% of the U.S. population accounts for only 3% of the total healthcare spending.

"Where does this money go?" asked Dexter. "Hospital inpatient costs alone represent 31% of total spending and pharmaceuticals represent 23% of total U.S. healthcare spending. In contrast, national laboratory outpatient spending—including anatomic pathology—represents only 3.8% of total spending—or about $59 per patient encounter.

➤Part Of The Solution

"These numbers show that labs are not the cost problem in the U.S. healthcare system." he observed. "To the contrary, clinical labs should be a big part of the solution, which means we need to leverage the data we have to help ACOs manage patient care.

"Here's how that works. In many ACOs, an insurer will designate a block of its patients—perhaps 5,000 lives—to an ACO," said Dexter. "The insurer will then assign 100% of the financial risk of caring for those lives to the ACO. Essentially, to care for these patients, the insurer will give the ACO a flat fee payment for each member each month or each year.

Bundled Payment To ACOs

"Insurers also will be paying ACOs a bundled payment for patients with certain conditions," he explained. "Insurers will ask ACOs to deliver all the care those patients need for specified conditions, such as asthma or diabetes, for a single bundled payment.

"At Sonora Quest Laboratories, we've put a lot of time and effort into learning how those bundled payments will work in Arizona," said Dexter. "We cannot share that data and most of our numbers might not apply to other markets anyway.

"But I encourage all labs to understand how these bundled payment systems work in their markets," he noted. "For the lab to be paid appropriately, it must know how each patient in an ACO will get care and how the lab will be paid for work done for each patient.

"Further, this will be true whether the patient is a Medicaid beneficiary, is in a Medicare Advantage plan, or is a commercial health insurance patient," explained Dexter. "For each one, the differences in how bundled payments are developed will be significant."

The executive team at Sonora Quest Laboratories has already engaged in payment negotiations with different ACOs. Several valuable lessons have been learned.

"The most important issue facing the lab industry is how ACOs and similar care models will pay for lab testing services," noted Dexter. "Payment of lab testing services comes as a result of how payers adjudicate claims.

"Keep in mind that one major area of waste in the U.S. healthcare system is the huge amount of money that is spent on claims adjudication," he said. "That opens the door for a clinical lab to add value by working with the ACO and the insurer to better manage the adjudication of lab test claims.

"Every lab director knows the problems that result when lab test claims are rejected," noted Dexter. "That problem may get much worse in the future because ACOs are not set up to adjudicate claims. Thus, lab directors would be wise to anticipate this issue and develop strategies to help ACOs and payers efficiently process lab test claims.

David A. Dexter

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"Next, labs are typically last to the negotiation table," he added. "Most all the financial arrangements have already been set within the ACO. That's a problem for clinical labs.

Claims Adjudication

"ACOs could partner with or contract with health plans to adjudicate claims and some will do so," noted Dexter. "Keep in mind that, in moving to bundled payment for patients with chronic diseases, for example, these are complex cases and ACOs will not have all the cost data that health plans have. However, if an ACO is moving to bundled payment for patients with specific conditions, why would the ACO want to pay extra to have an insurer handle claims?

"Our lab saw an opportunity to address this issue," he continued. "First, we took historical rates from our fee schedules, or capitated rates if we had those in place. We compared these arrangements to our revenue run rates.

"Next, we brought those numbers to our ACOs," he said. "This allowed the ACOs to look at our revenue run rates as their cost run rates. It was these numbers that were the basis for our contracts with the ACOs.

"The intent by both parties is to make spending for lab tests revenue cost-neutral at the beginning of the ACO's operation," explained Dexter. "That was our approach. As a result, each one of our ACO product contracts is different. That was a surprise to us.

"We had another surprise regarding co-payments," he said. "As I mentioned earlier, depending on the product involved, ACOs will expect patients to pay substantially larger deductibles and co-pays. We already have one ACO product in which patients pay the entire lab bill as a co-pay! We never anticipated that.

David A. Dexter

➤"The intent by both parties is to make spending for lab tests revenue cost-neutral at the beginning of the ACO's operation... As a result, every one of our ACO product contracts are different."

"High deductibles and co-pays for patients are ways that ACOs and insurers are shifting the downside of financial risk to patients," noted Dexter. "But, for the most part, labs are not participating in the potential financial upside with their ACO partners.

"We looked at how our lab could share in the financial upside risk and had internal and external lawyers look at how to do so," recalled Dexter. "Unfortunately, the preliminary result of that review is that sharing in the upside financial risk may not apply to labs. Every lab should do its own legal analysis on this question.

"Following that research, we viewed the issue in this way," he continued. "If our lab testing is less than 3.8% of the total cost, why should our lab accept risk for such a small upside potential—especially when utilization is expected to increase with the management of chronic disease?

"Another last caution I would offer about financial risk and ACOs comes from our experience in Arizona," he stated. "It's been our experience that ACO infrastructure vendors tend to over-promise and under-deliver.

➤A Word of Warning

"We have examined a number of ACOs both in Arizona and in other states," explained Dexter. "Two of the ACOs that we have been working with have already jettisoned and replaced their ACO infrastructure because they were dissatisfied with it. That's to be expected as ACOs develop and lessons are learned. But it is certainly a lesson for labs contracting with ACOs because a lot of interface work may have to be modified: Be forewarned."

THE DARK REPORT believes that Sonora Quest Laboratories may have signed contracts with more ACOs than any independent clinical laboratory, other than the two national lab companies. For that reason, the experience and insights shared here represent the first public discussion of how a respected independent lab company is actually transacting business with ACOs in its service region.

➤High Co-Payment Risks

One useful insight is that, in the earliest stages of ACO formation, the laboratory is in a position to offer a capitated rate to the ACO that is revenue neutral to both parties. Moreover, because the capitated rate eliminates the need for the ACO to spend time and money to adjudicate individual, fee-for-service lab test claims, it considers this arrangement to be added value.

This early experience provides insights that other pathologists and lab executives can use in their negotiations with ACO administrators. It also shows several different ways that lab leaders can develop services that are value-added to ACOs. TDR

—Joseph Burns

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Four Docs Plead Guilty In N.J. Lab Bribery Case

More arrests of physicians are expected, according to U.S. Attorney prosecuting case

CEO SUMMARY: As of July 24, four New Jersey doctors had pleaded guilty to federal criminal charges. Each of the doctors accepted bribes in exchange for referring patient lab testing to Biodiagnostic Laboratory Services (BLS) of Parsippany, New Jersey. This landmark criminal prosecution includes criminal charges associated with sham lease and service agreements between labs and referring physicians. Doctors and labs are now on notice that criminal charges may result from these activities.

TWICE IN LATE JULY, U.S. Attorney Paul J. Fishman announced that physicians in New Jersey had entered guilty pleas and admitted accepting bribes in exchange for referring laboratory tests to **Biodiagnostic Laboratory Services** (BLS), of Parsippany, New Jersey. The cases involve criminal charges against certain physicians and employees of BLS.

This is a development of importance for both clinical laboratories and office-based physicians. THE DARK REPORT believes this may be the largest federal case to prosecute both a clinical lab and the physicians who accepted kickbacks, inducements, and bribes after agreeing to refer specimens to the laboratory.

Doctors Face Jail Terms

The doctors face heavy jail terms, large fines, and severe financial penalties. More importantly, this case can make it easier for U.S. attorneys in other districts to successfully prosecute labs and physicians for many common practices that violate Medicare inducement and anti-kickback laws.

On July 24, Frank Santangelo, M.D., of Boonton, New Jersey, pleaded guilty in U.S. District Court in Newark to charges that he violated the Travel Act, laundered money, and failed to file tax returns, Fishman said. An internist with offices in Montville and Wayne, Santangelo received more than $1.8 million in bribe payments from BLS for referrals, according to Fishman, who also reported that Medicare and other insurers paid BLS more than $6 million for this lab testing.

Santangelo is scheduled for sentencing on October 24. He faces five years in prison and a $250,000 fine for bribery; 20 years in prison and a $500,000 fine for money laundering charge; and, one year in prison and a $100,000 fine on the tax charge.

It was on July 17, a week earlier, when Fishman announced guilty pleas from three other doctors: Dennis Aponte, 46, of Cedar Grove, Claudio Dicovsky, 51, of Fort Lee, and Franklin Dana Fortunato, 63, of Montville, each pleaded guilty in Federal District Court in Newark to violating the Federal Travel Act because they illegally used the mail for criminal activity.

Each physician faces up to five years in prison and a $250,000 fine. Sentencing for all three doctors is scheduled for October

22. Further, the U.S. Attorney's office said that Aponte has agreed to forfeit $235,000, Dicovsky has agreed to forfeit more than $220,000, and Fortunato has agreed to forfeit more than $635,000.

Fortunato also pleaded guilty to filing a false tax return. The numbers reveal the scale of the bribes flowing from Biodiagnostic Laboratory Services to Fortunato. In the U.S. Attorney's press release, it said that Fortunato admitted in court that, for the years 2004 through 2008, he failed to report more than $640,000 in bribe money and patient co-pays for laboratory tests.

Additionally, Fortunato failed to pay more than $160,000 in taxes he owed as a result of that unreported income, according to a press release from Fishman's office. Fortunato faces up to five years in prison and a $250,000 fine for the tax crime.

More Docs To Be Charged?

What's fascinating about this case is that many more physicians could be charged in the coming weeks. How many more is the subject of speculation.

"The investigation is ongoing and we expect more arrests," was all Matthew Reilly, a spokesman in Fishman's office, would say when contacted by THE DARK REPORT. Fishman is the U.S. Attorney for the District of New Jersey.

According to court documents, BLS employees and their associates conspired to pay millions of dollars in bribes to physicians over several years in exchange for blood sample referrals worth more than $100 million to the laboratory, according to an announcement from Fishman's office. Many of the blood samples were not medically necessary, Fishman said.

Sham leases for phlebotomy space and similar services between labs and referring physicians figured prominently in this case. It is a scheme that is quite common in many regions across the country.

Court records show that Santangelo was paid more than $800,000 from BLS through sham lease agreements and sham service agreements between 2006 and 2010. "After that, he began receiving bribes from BLS through a third party—often tens of thousands of dollars a month—totaling more than $1 million between 2010 and his arrest in April 2013," Fishman's office said.

Bribes Paid, Tests Referred

In a similar fashion, Aponte admitted to taking $3,000 in cash bribes each month in exchange for referring blood specimens to BLS from his patients from October 2012 to March 2013, Fishman said. The lab made more than $175,000 through testing on these specimens.

Dicovsky also admitted to accepting bribes in exchange for referring blood specimens, Fishman reported. To disguise those bribes, Dicovsky and BLS entered into sham agreements in which the monthly bribe payments of more than $5,000 were characterized as "lease" and "service" payments, noted Fishman.

According to the press release, while the lease agreement purported to be for 1,000 square feet of space, little or no space was allocated to BLS in Dicovsky's medical office in Paterson, New Jersey. Between November 2006 and August 2009, Dicovsky received more than $224,000 in bribe payments from BLS, and BLS made more than $800,000 through testing on blood specimens referred by Dicovsky.

Laboratory compliance officers and their legal advisors should study this case to understand how U.S. Attorney Paul J. Fishman successfully prosecuted both the lab employees and the referring physicians. Because tens, if not hundreds, of New Jersey physicians were involved in these kickback arrangements, more prosecutions of physicians might be announced in the coming months. TDR

—By Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another national health insurance corporation is preparing to institute pre-authorization for genetic tests. **Cigna Corporation** announced on July 23 that it had selected **InformedDNA**, to administer its new genetic testing and counseling program. Pathologists and laboratory administrators should note that one goal of Cigna's new program is "to prevent the ordering of inappropriate genetic tests," according to its press release.

MORE ON: *Cigna*

Lab executives should expect more payers to institute these programs. One goal is to provide genetic counseling to patients. Equal emphasis will be given to how physicians utilize genetic tests. Managed care experts predict that payers will exclude most labs from providing genetic tests to their beneficiaries. One of the first national health insurance companies to initiate this type of program was **Humana Inc.**, which selected **DNA Direct** to manage its genetic test program in July 2009. Humana now operates that program internally.

ZIMBABWE FORMS PATHOLOGY COLLEGE

Last month, the Zimbabwe Health and Child Welfare Deputy announced the launch of the first **Zimbabwe College of Pathology** (ZCP). This is another sign that health systems in developing nations in Africa are recognizing the need to upgrade diagnostic testing as a linchpin to improving patient outcomes.

TRANSITIONS

• **Sensus Healthcare** of Boca Raton, Florida, named Clay Cockerell, M.D., as its Medical Director. Sensus is a medical device company with products used in the dermatology field. Cockerell is a noted dermatopathologist and dermatologist. He is director of **Cockerell & Associates Dermpath Diagnostics** and owner of **Cockerell Dermatology Consulting Services**, both located in Dallas, Texas.

• This month, **Quest Diagnostics Incorporated** named Mark J. Guinan as its new Senior Vice President and Chief Financial Officer. He has held executive positions with **Hill-Rom Holdings Inc.**, **Johnson & Johnson**, and **Procter & Gamble**.

• Leaving Quest Diagnostics this month in a planned transition is Robert A. Hagemann, currently Senior Vice President and Chief Financial Officer. Hagemann assumed this position in 1998. His past executive positions included **Corning Life Sciences**, **Prime Hospitality, Inc.**, and **Crompton & Knowles, Inc.**

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 19, 2013.