Volume XXIV, Number 9 Monday, June 26, 2017

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...

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Founder & Publisher

Genetic Test Pre-Authorization Goes Mainstream

IT IS ALWAYS A BIG DEAL WHEN ONE OF THE NATION'S LARGEST HEALTH INSURERS TAKES A MAJOR STEP. That is certainly true of **Anthem's** decision to launch a new program that requires physicians to obtain pre-authorization when ordering genetic tests for its members.

THE DARK REPORT is first to report this news to the clinical laboratory industry. The nation's largest insurer, Anthem has health plans in 14 states that cover approximately 40 million Americans. Thus, this requirement will affect many labs offering genetic tests.

Moreover, whenever an industry leader adopts a major policy, it is not long before most competitors take similar actions. Thus, we can expect that, once Anthem's genetic test pre-authorization program is in place, other health insurers will introduce their own pre-authorization programs. That will further bring genetic test pre-authorization into the mainstream.

As this happens, the environment will become more challenging for the nation's genetic testing lab companies because health insurers will want solid evidence that these tests measure biomarkers accurately and that they offer clinically useful results, meaning physicians can use these test results to change patient care and generate improved outcomes.

To help you understand why Anthem is going down this path and how it will proceed, we present an exclusive interview with the executive responsible for implementing this program. We also include a list of the 45 specific genetic tests that will require pre-authorization. *(See pages 10-14.)*

Anthem is not the first to take this action involving genetic tests. In 2013, **Cigna** pioneered this approach and has expanded the list of genetic tests requiring pre-authorization since then. *(See TDRs, Aug. 19, 2013, and Dec. 15, 2014.)* **Blue Cross Blue Shield of South Carolina** (an independent Blue that Anthem does not own) is another health insurer that has a genetic test pre-authorization program in place. *(See TDR, Oct. 26, 2015.)*

Genetic testing companies and labs in academic medical centers labs would be well-advised to prepare for tougher new requirements for genetic testing. To do so will involve taking greater care to gather the clinical data to support claims of analytical accuracy and how these lab test results affect patient care. TDR

Quest Diagnostics Exits 31-Year-Old Lab Venture

Partners in this laboratory joint venture were hospital, pathology group, and Quest Diagnostics

CEO SUMMARY: News that Quest Diagnostics had exited the long-running CompuNet Clinical Laboratory joint venture in Dayton, Ohio, caught many observers by surprise. The only clues as to possible problems and the motivation of Premier Health, the 51% owner, to buy out Quest's ownership share are contained in an announcement the health system issued. The Dark Report analyzes that news and provides a history of the CompuNet lab joint venture.

ONE OF THE NATION'S LONGEST-RUNNING LABORATORY JOINT VENTURES among a hospital, a private pathology practice, and a commercial laboratory ended earlier this month.

On June 8, **Premier Health** of Dayton, Ohio, announced that it purchased **Quest Diagnostics'** ownership stake in **CompuNet Clinical Laboratories**, effective June 1.

The *Dayton Business Journal* reported that Premier Health had purchased Quest's 33% share of the lab company and now Premier Health holds an 84% ownership stake. **Valley Pathologists**, also of Dayton, holds the remaining 16% ownership stake, according to the paper.

For a hospital-commercial lab joint venture launched in 1986, it appeared to outside parties to be doing well. This end appeared to come suddenly. None of the parties was willing to speak to THE DARK REPORT about the reasons behind this change.

Important clues, however, about what motivated Premier Health to buy out Quest's share and continue operating CompuNet in conjunction with the pathologists can be found in the press release that Premier Health issued to announce the deal.

Premier Health wrote that, the "transaction is expected to ensure more rapid turn-around times for patient lab results." It also said Premier made a "move that enhances local oversight of clinical lab services and helps to maintain laboratory testing across the Dayton region to meet patients' needs."

In the press release, Premier Health President and CEO Mary Boosalis added

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

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that, "this transaction will help Premier Health achieve its vision of a more system-based approach to clinical laboratory testing. It enables us to build upon our existing laboratory capabilities, achieve greater economies of scale, and control the costs of laboratory services."

Another hint of an issue that might have motivated the partners was the statement in the news release from pathologist Atef Shrit, MD, Chairman of the CompuNet Board of Directors. "The change in ownership provides CompuNet with a greater degree of independence," he said. "With 100% local control, our ability to enhance testing capabilities which impact the community is greatly improved."

What Motivated Premier?

Taken at face value, Premier Health was saying in the announcement that, without Quest as a partner, it would:

- Gain "local oversight of lab testing services... to meet patients' needs"
- Ensure more rapid turnaround times for patient lab results
- Achieve greater economies of scale
- Control the costs of lab services
- Have 100% local control to enhance testing capabilities "which impact the local community"

All of these statements imply that Premier Health believed it was not realizing these benefits in the three-way lab joint venture.

When THE DARK REPORT called Premier Health for comment, the public communications officer responded by email, saying, "We would like for the news release to speak for itself."

Calls to Valley Pathologists for comment were not returned. Quest Diagnostics was contacted, but declined to comment as of press time.

The decision by Premier Health to end this laboratory joint venture is noteworthy for at least two reasons. First, it marks the end of a durable laboratory joint venture that lasted 31 years, survived two acquisitions of the commercial lab company partner, and, by all outside appearances, was considered to be successful and meeting the needs of the JV's three partners.

Second, it is the second time this year that Quest Diagnostics has lost a significant business relationship involving a laboratory services agreement with a regional health system. In February, **Lovelace Health System** of Albuquerque, N.M., did not renew the five-year contract in which Quest managed the inpatient labs of the four Lovelace hospitals. *(See sidebar next page.)*

Third, Premier Health's move to buy out its commercial lab partner and become the majority owner of CompuNet is a business decision that runs contrary to the message of the nation's two largest lab companies: that hospitals will benefit from selling or outsourcing their inpatient and outreach lab programs because commercial lab operators can cut hospitals' lab testing costs.

The statements Premier Health made in its news release imply that CompuNet was not fully benefiting from economies of scale that it would expect from this joint venture. Similarly, its comments about the goal of achieving improved lab test turnaround times could be interpreted as unhappiness with that performance metric and how it was affecting patient care within the health system.

History Dates to Mid-1980s

CompuNet was founded in 1986. Its three original partners were 845-bed **Miami Valley Hospital**, Valley Pathologists Inc., and **International Clinical Laboratories** (ICL). Later in 1986, **SmithKline Beecham Clinical Laboratories** (SBCL) acquired ICL. In 1999, Quest Diagnostics purchased SBCL and assumed SBCL's interest in CompuNet.

Now, 18 years after Quest Diagnostics became a part-owner of CompuNet, it has sold its interest to Premier Health, the four-hospital system that owns Miami Valley Hospital. TDR

Tracking Hospital Inpatient Lab Agreements, During 2017, Quest Diagnostics Is Up 2, Down 2

MANY HOSPITAL LAB directors are concerned that their parent organizations may decide to outsource management of their inpatient labs to one of the national commercial lab companies.

For this reason, they watch closely every deal involving a hospital or health system and a national lab company. Have enough of these deals happened to say there is a trend among hospitals to enter into agreements in which third parties manage inpatient labs?

A Question To Answer

That is a more difficult question to answer because the inpatient lab management agreements between hospitals and national lab companies that expire and do not renew seldom get national news coverage.

A case in point is the experience of Quest Diagnostics. On Jan. 27, Quest announced an agreement to provide certain lab testing services to **Montefiore Health System** in New York. Quest will not manage the inpatient labs, but will perform "a portion of low complexity diagnostics tests."

Then, on Feb. 15, Quest disclosed an agreement with **PeaceHealth** of Vancouver, Wash., to purchase **PeaceHealth Laboratories'** outreach lab business. Through a professional laboratory services agreement, "Quest will manage 11 laboratories, which PeaceHealth will continue to own, serving PeaceHealth's medical centers in three states." On May 1, this transaction became final.

Thus, year to date, Quest has increased its hospital inpatient laboratory arrangements by two clients.

Meanwhile, on or about Feb. 1, Quest ceased to be the manager of the inpatient labs at the four hospitals of **Lovelace Health System** in Albuquerque, N.M. Lovelace did not renew the five-year inpatient lab management agreement it signed in January 2012, as part of Quest's acquisition of **S.E.D. Medical Laboratories**. Instead, Lovelace entered into an inpatient laboratory management contract with **TriCore Reference Laboratories**, also of Albuquerque.

Earlier this month, a hospital partner purchased Quest's interest in the lab joint venture known as CompuNet Clinical Laboratories in Dayton, Ohio. This purchase ended a 31-year JV in which Quest was an active partner in the operation of the inpatient labs of Premier Health.

Thus, anyone keeping score on the net change in hospital laboratory management agreements that Quest holds from the beginning of 2017 through the present, the number would be zero. Quest gained two agreements that involve its participation in hospital inpatient testing. But it also lost two agreements.

Touting New Agreements

The pattern is for public lab companies to announce a new hospital lab inpatient testing agreement. News outlets publish that announcement throughout the country. But when a public lab company fails to renew an inpatient testing agreement, no news gets released about the loss of such contracts except perhaps in local newspapers, as happened with the CompuNet and Lovelace Health System transactions.

Back to the original question: Is there a trend of commercial labs winning hospital and health system inpatient lab management contracts, and is this trend gaining momentum because more hospitals are entering into such agreements? As the experience of Quest Diagnostics in 2017 demonstrates, the answer is not yet known.

Another element that would help the clinical lab industry understand more about this trend is if hospitals that terminated these types of inpatient lab management agreements disclosed the reasons for their decision.

Six Years after Launch, Med Fusion Sold to Quest

For the second time in 13 years, an effort to create a reference lab in Dallas fails to deliver

CEO SUMMARY: In Dallas, the relatively short-lived lab company known as Med Fusion has a new owner. After seven years, the lab partnership of Baylor Scott and White, US Oncology Network, Texas Oncology, and Pathologists Bio-Medical Laboratories decided to sell their ownership stakes to Quest Diagnostics. The sale comes despite $100 million of capital and the opportunity of the partners to collaborate in ways that could create diagnostic services that add value.

On the surface, **Med Fusion** is one more sale of a health-system-owned lab company being sold to one of the big national labs. That's how media outlets have reported the story. But there is a story-behind-the-story for hospital lab administrators and pathologists.

On June 12, **Quest Diagnostics** announced its acquisition of Med Fusion and its sister company, **ClearPoint Diagnostics Laboratories**. Both labs are based in Lewisville, Texas. Price and terms of the sale were not disclosed.

When this transaction closes and Quest becomes the new owner, it will mark the end of an unusual lab partnership and an unusual vision for lab testing services and integrated diagnostics. That aspect of the story should be of interest to hospital and health system laboratory managers.

It will also be the second time in 13 years that a well-funded lab start-up company based in Dallas attempted to develop a regional and a national reference and esoteric testing business serving hospitals, but was unable to achieve its goals.

Med Fusion organized in 2009 and opened for business in 2010. Four founding partners held equal shares in the business. The partners were **Baylor Scott and White Health**, the **US Oncology Network** (which **McKesson** acquired in 2010), **Texas Oncology**, and **Pathologists Bio-Medical Laboratories** (PBML). Each partner invested $10 million in start-up capital, for a total of $40 million.

Facility Housed Two Labs

A 172,000 square foot lab was built in Lewisville to house Med Fusion. The same building also would house a separate lab company that US Oncology owned. Cancer testing would be performed in that lab and the PBML pathologists were in a preferred position to provide professional component services to both lab companies.

In an interview with The Dark Report in 2010, then-CEO Keith Laughman described Med Fusions's goals. "As a source of reference and esoteric testing for hospitals and health systems, we will perform at least 95% of the laboratory testing

that is typically sent out by a hospital," he explained. "We will also provide other low volume tests that hospitals must generally perform internally in order to meet clinical service requirements." *(See TDR, March 8, 2010.)*

Raised Another $61 Million

Just four years later, in 2014, Med Fusion raised $61.245 million from 30 investors who paid a minimum of $9,000 each for equity stakes in the company, according to an SEC report. Med Fusion had intended to raise $65.745 million from the equity sales, the company reported to the SEC.

Yet, after this investment of almost $100 million, Med Fusion's owners deemed it advisable to exit the business and sell the lab company. This mirrors the experience of **American Esoteric Laboratory** (AEL), which was launched in 2004 with $70 million in private equity funding. Its goal was to develop a national reference and esoteric testing business, in competition with **ARUP Laboratories**, **Mayo Medical Laboratories**, and others. *(See TDRs, April 24, 2004.)*

AEL executives believed that its Dallas location would be a benefit in several ways. First, it made AEL a local provider for the 378 hospitals in Texas, thus helping it offer attractive turnaround times for its testing services. Second, DFW Airport's logistics services would make it easy for AEL to provide reference testing services for hospitals throughout the nation.

AEL Acquired After 3 Years

In subsequent years, however, AEL's national reference business never grew sufficiently and it acquired smaller regional clinical labs. Just three years later, in 2007, **Sonic Healthcare** acquired AEL for $180 million.

The fact that both Med Fusion and AEL were unable to develop profitable regional and national businesses in reference and estoric testing for hospitals and health systems is a sign of the level of competition in this segment of the clinical lab industry.

In the case of Med Fusion, it's disappointing that a consortium of a major health system, a strong regional pathology group, and two large oncology companies, with $100 million of capital, could not find the right key to creating an integrated and profitable diagnostic service. This effort had the potential to be innovative and ground-breaking. It had savvy players and access to a large volume of specimens.

In its effort to gain useful insights about this situation, THE DARK REPORT got no response to requests for comment sent to Med Fusion, ClearPath, Quest, and Baylor Scott and White Health. TDR

—Joseph Burns

Is Dallas a 'Black Hole' For Hospital Reference Labs?

MIGHT DALLAS BE A BLACK HOLE OR A BERMUDA TRIANGLE for new lab companies seeking to serve hospitals in the region and nationally? Lab administrators will recall that Dallas had a significant role in the eventual demise of **Nichols Institute** as an independent public company.

In 1990, Nichols Institute announced a joint venture with three hospital systems representing 18 hospitals in Dallas-Fort Worth. It would act as the general partner in an alliance with **Baylor Health System** and **Presbyterian Healthcare System**, both based in Dallas, and **Harris Methodist Health System**, in Fort Worth.

Nichols Institute built a 58,000 square foot state-of-the-art lab in Irving. But the other joint venture partners never referred enough test volume to make that lab financially sustainable. The cash flow drain from that laboratory division was a contributing factor in the eventual sale of Nichols Institute to **MetPath** (now Quest Diagnostics) in 1994.

Digital Pathology Can Be Transformative for Labs

Pathologists have opportunity to innovate with this technology to improve patient care

CEO SUMMARY: Across the nation, pathologists are at a crossroads. Now that the FDA has cleared a digital pathology and whole slide imaging (WSI) system for use in primary diagnosis, should they adopt this technology sooner or wait until later? One pathologist who has worked with WSI for many years shared the lessons learned in his lab. Pathologists should recognize the potential of combining this technology with algorithms and robotics to make earlier and more accurate diagnoses, he said.

PATHOLOGISTS ARE ONE STEP CLOSER to daily use of digital pathology and whole slide imaging, following the FDA's clearance of the nation's first digital pathology system and whole slide images for use in primary diagnosis.

In April, the FDA announced that the **Philips** IntelliSite Pathology Solution (PIPS) could be marketed for primary diagnosis in the United States. This is the first whole slide imaging (WSI) system the agency has cleared that allows diagnostic interpretation of digital surgical pathology slides prepared from biopsied tissue without traditional optical microscope review. *(See TDR, April 24, 2017.)*

Now that a digital pathology system has regulatory clearance, all anatomic pathology groups in the United States must confront the new reality: the era of primary diagnosis using whole slide images has begun. In this era, pathologists have a conundrum: Should their groups be early-adopters of digital pathology or should they wait until use of whole slide imaging is more common?

To answer this question, THE DARK REPORT sought out a pathologist who has extensive knowledge of many digital technologies and software development efforts used in research labs and academic centers: John Gilbertson, MD, who is Director of Pathology Informatics at **Massachusetts General Hospital** in Boston. He is also an Associate Professor at **Harvard Medical School** and Associate Chief for Informatics at MGH.

Digital Path As Disrupter

Disruption in anatomic pathology will not come simply from replacing glass slides and the traditional microscope with whole slide images, he said. It will come because the digitization of these images creates the opportunity to use digital technologies to analyze the images in new ways that cut time to diagnosis and generate new information about the tissue being analyzed. That can mean earlier detection of disease and a more precise diagnosis.

"When a pathology lab can digitize most or all of its slides rapidly, automatically, and in high fidelity, it can then apply computational power and network connectivity to those digital slides," observed Gilbertson. "The whole slide image allows

a pathologist to view that slide, to use algorithms to analyze that slide, or send the digital images of those slides out to all the computers across its network.

"Also, pathologists will find additional uses that draw upon the computational power and network connectivity that have been the power drivers of innovation, discovery, and productivity across a wide range of industries," he added.

Gilbertson advised pathologists to recognize that the technology trends and market forces transforming all industries, including healthcare, will propel swift adoption of whole slide imaging in anatomic pathology. As change happens, pathology groups must be ready to acknowledge this change and act decisively to protect their clinical relationships while delivering the additional value needed to thrive as fee-for-service payment disappears.

Using Artificial Intelligence

"Today, my pathology organization is looking at our ability to get involved early with artificial intelligence," stated Gilbertson. "At this stage, our primary interest is in different ways we can use digital imaging to change how our pathologists diagnose disease. Changing workflow is a benefit, but not the emphasis. The change in workflow will certainly come after we have determined how we will change the diagnostic step.

"These are important reasons why I say this is a major advancement in technology for the profession of pathology," he added.

Gilbertson and other pathologists at MGH have worked with the Philips Intellisite Pathology Solution since 2011. "Before 2012, we had the system for a period of evaluation," he said. "Then, starting in 2011 and 2012, we began using the system primarily for education, but also for clinical conferences."

Today, Gilbertson's lab needs additional scanning capacity. "We are oversubscribed with our current scanner in terms of education and clinical conferences," he noted. "The plan is to add more scanners just for those two applications. Of course, we regularly find more reasons to digitize the glass slides."

MGH Pathologists were involved in some clinical trials that Philips ran as it pursued FDA approval. "There were a number of big studies that Philips did," Gilbertson explained. "Several years ago, we worked with them on an immunohistochemistry study designed to demonstrate that use of digital images resulted in diagnoses comparable to those done from glass slides. We found the digital images to be comparable.

"Our pathology lab also did a pilot study with Philips to help design and power the pivotal study," he said. "MGH was not involved in the pivotal study, which was the non-inferiority study. However, one of my colleagues, David Wilbur, MD, and I were on the advisory board. That's how we know about it." Wilbur is a pathologist at MGH and a Professor of Pathology at Harvard Medical School.

Another study in which MGH participated was a device-precision study. "This was to look at the reliability and consistency of the device itself," stated Gilbertson. "For example, if a pathology lab were to use three devices to scan a single slide, would each device reproduce the same image? If two devices are in two different places, do you get the same image? That was a large study for us."

This early experience with the digital pathology system and use of whole slide images at Partners Healthcare encouraged deployment of WSI to other locations within the healthcare system.

"During the time of the studies, we had as many as five scanners running to produce the images we needed for these studies," he continued. "At the moment, we have only one scanner running. Our current plan is to purchase more, and we are in the process of doing that." TDR

—By Joseph Burns

Contact John Gilbertson, MD, at jrgilbertson@partners.org or 412-657-5853.

CEO SUMMARY: Pre-authorization of genetic tests is coming to physicians serving patients insured by Anthem, Inc. Its specialty benefits management company, AIM Specialty Health, will manage the program. AIM will work with InformedDNA, a company that specializes in genetic testing clinical decision support and genetic counseling for health insurers. Anthem has about 40 million members in 14 states.

Nation's largest health insurer to require pre-authorization

Anthem Launches Program to Manage Genetic Tests

WHAT IS EXPECTED TO BE the nation's largest genetic testing management program will begin on July 1. In 14 states, **Anthem** will require in-network physicians serving its members to obtain pre-authorization for certain genetic tests.

Anthem's Genetic Testing Solution will require physicians to use an online portal or to call utilization management to get prior-authorization for genetic tests that fall under one of 45 of Anthem's genetic testing coverage criteria, as outlined on Anthem's Medical Policies and Clinical UM Guidelines site.

AIM Specialty Health, a specialty benefits management company that Anthem owns, will manage the program. For the program, AIM plans to work with **InformedDNA**, a company in St. Petersburg, Fla., that specializes in genetic testing clinical decision support and genetic counseling for health insurers.

In 2013, **Cigna** announced that InformedDNA would provide independent genetic counseling for some gene tests for Cigna members. Last year, Cigna expanded that program. *(See TDRs, Aug. 19, 2013 and Dec. 15, 2014.)*

The fact that Anthem is launching a genetic test management program is significant because it is one of the nation's largest health insurers by enrollment. In its most recent quarterly report, Anthem said it has 40 million members in California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, and Wisconsin.

Nearly all health insurers struggle to meet the demand for genetic testing and to develop systems to manage requests for these tests. Last year, almost 70,000 genetic testing products were available, according to **Concert Genetics**, which tracks such tests.

Concert Genetics defines a testing product as an individual gene test or multiple gene panels. The nation's labs introduce more than 10 new genetic tests every day, Mark Harris, PhD, MBA, Founder and Chief Innovation Officer of Concert Genetics, reported at the *Executive War College* in May.

"Anthem recognizes that the appropriate use and interpretation of genetic testing is a priority, not just for all health plans but also for physicians and for patients," stated Karen Lewis, a genetic counselor with extensive experience working in clinical and genetic testing labs.

The Director of AIM's Genetic Testing Solution, Lewis said, "The vast majority of health plans—whether they are large or small—are looking either for outside help or they are doing their own internal reviews of genetic test requests. As they see the volume of requests rise, it was just a matter of time before health plans put some solution in place."

The AIM Genetic Testing Solution is available to other health plans. One health plan in the Northeast will begin using AIM's program this fall and three others will begin on Jan. 1, 2018, explained Lewis.

Inappropriate Test Orders

When it announced the program in April, AIM cited research showing that 30% to 50% of genetic tests may be ordered inappropriately. Incorrect test orders push up costs unnecessarily and lead to poor patient care, AIM said.

In addition, AIM cited a market prediction from 2015, "Genetic Testing: A Global Strategic Business Report," by **Global Industry Analysts** that forecast that the global market for genetic tests would reach $7.4 billion by 2020.

Physicians have no experience with AIM's genetic testing management program when seeking pre-authorization for genetic test orders, so Lewis could not say if physicians will find it easier than the current system Anthem uses. She did say, however, that Anthem's current system is labor intensive. However, when physicians in other specialties use AIM's provider portal system to order tests and procedures, surveys show those physicians have a 96% satisfaction rating for ease of use.

"For physicians ordering genetic tests, Anthem has 45 genetic testing medical policies," Lewis said. "That makes it difficult for them to wrap their arms around those policies efficiently. *(See sidebar on page 13.)*

"Our program is designed to work with those policies so that providers can easily identify the tests they need and get the authorization for those tests in a timely fashion," she continued. "It's all done electronically. So, depending on what genetic test a physician orders and the policies behind that test, the physician could have an authorization in less than a minute."

A minute for prior authorization for a genetic test? That would seem to be much faster than the lab test pre-approval processes most health plans use today.

"To be honest," Lewis responded. "Many requests for pre-approval of a genetic test will take more than a minute. Obviously, it depends on the test. Some genetic tests require complicated algorithms. And some tests involve a lot of questions and answers over a few minutes.

"But if it's a cystic fibrosis carrier screening test, then that request takes a minute. A physician will be in and out of the system easily," she noted.

A Portal For Entry

"Most physicians working with Anthem will use the provider portal for pre-approval of genetic testing," said Lewis. "Also, they can call in to request approval for a genetic test. Many of our providers prefer to use the AIM portal. It allows them to select the genetic test and select the lab. Then, if there are questions, they can answer them online and get an authorization.

"That's a very efficient way for providers to access genetic testing and for our client-payers to adjudicate requests against their policies," she commented.

"Like most payers, Anthem requires counseling for many genetic tests, and when counseling is required, we make sure that happens," she said. "Many doctors who regularly order genetic tests may already have a network of genetic counselors, or they do the counseling themselves.

"Physicians who are uncomfortable with genetic testing or don't have access to a network of genetic counselors can access a database of genetic counselors through AIM," Lewis said. "Genetic counseling can be done by phone, via telehealth, or face to face." One of the companies that provides genetic counselors is InformedDNA.

Easier Than Current System

"Allowing physicians to use AIM's provider portal to order genetic tests will be much easier than the current system Anthem's in-network physicians use for test ordering," Lewis explained. "Currently, the onus is on the provider to verify a genetic test order against medical policy and to verify whether a test meets Anthem's medical necessity requirements. The physicians also must verify whatever lab they intend to use.

"After they do all that, then they submit the paperwork requisition to the lab, and the lab runs the test," she explained. "The problem with this process is that it is a post-service review. In this scenario, if the lab runs the genetic test without an approval, there could be a denial of coverage, and no one is happy about that.

"The benefit of using AIM's provider portal or calling on the phone is that the physician would get the pre-authorization *before* the lab runs the test," emphasized Lewis. "At that stage, the physician knows that the lab is in-network and both the physician and the lab know the medical policy for the genetic test in question. And they know all of this information before they run the test.

"For this reason, we should see a tremendous decrease in post-service denials," she added. "Post-service denials are a problem because once the genetic test is done, the lab wants to get paid and often they bill the patient. Patients don't like that, obviously, and neither do physicians.

"The expectation is that most genetic tests that in-network physicians will order will go through in-network labs," said

Anthem Lists 45 Genetic Test Policies

- GENE.00001 Genetic Testing for Cancer Susceptibility
- GENE.00002 Preimplantation Genetic Diagnosis Testing
- GENE.00003 Genetic Testing and Biochemical Markers for the Diagnosis of Alzheimer's Disease
- GENE.00004 Janus Kinase 2 (JAK2)V617F Gene Mutation Assay
- GENE.00005 BCR-ABL Mutation Analysis
- GENE.00006 Epidermal Growth Factor Receptor (EGFR) Testing
- GENE.00007 Cardiac Ion Channel Genetic Testing
- GENE.00008 Analysis of Fecal DNA for Colorectal Cancer Screening
- GENE.00009 Gene-Based Tests for Screening, Detection and Management of Prostate Cancer
- GENE.00010 Genotype Testing for Genetic Polymorphisms to Determine Drug-Metabolizer Status
- GENE.00011 Gene Expression Profiling for Managing Breast Cancer Treatment
- GENE.00012 Preconceptional or Prenatal Genetic Testing of a Parent or Prospective Parent
- GENE.00014 Analysis of KRAS Status
- GENE.00016 Gene Expression Profiling for Colorectal Cancer
- GENE.00017 Genetic Testing for Diagnosis and Management of Hereditary Cardiomyopathies (including ARVD/C)
- GENE.00018 Gene Expression Profiling for Cancers of Unknown Primary Site
- GENE.00019 BRAF Mutation Analysis
- GENE.00020 Gene Expression Profile Tests for Multiple Myeloma
- GENE.00021 Chromosomal Microarray Analysis (CMA) for Developmental Delay, Autism Spectrum Disorder, Intellectual Disability (Intellectual Developmental Disorder), and Congenital Anomalies.
- GENE.00022 In Vitro Companion Diagnostic Devices
- GENE.00023 Gene Expression Profiling of Melanomas
- GENE.00024 DNA-Based Testing for Adolescent Idiopathic Scoliosis
- GENE.00025 Molecular Profiling and Proteogenomic Testing for Evaluation of Malignant Tumors
- GENE.00026 Cell-Free Fetal DNA-Based Prenatal Testing
- GENE.00027 Combined PALB2 and BRCA2 Mutation Testing for Oncologic Indications
- GENE.00028 Genetic Testing for Colorectal Cancer Susceptibility
- GENE.00029 Genetic Testing for Breast and/or Ovarian Cancer Syndrome
- GENE.00030 Genetic Testing for Endocrine Gland Cancer Susceptibility
- GENE.00031 Genetic Testing for PTEN Hamartoma Tumor Syndrome
- GENE.00032 Molecular Marker Evaluation of Thyroid Nodules
- GENE.00033 Genetic Testing for Inherited Peripheral Neuropathies
- GENE.00034 SensiGene® Fetal RhD Genotyping Test
- GENE.00035 Genetic Testing for TP53 Mutations
- GENE.00036 Genetic Testing for Hereditary Pancreatitis
- GENE.00037 Genetic Testing for Macular Degeneration
- GENE.00038 Genetic Testing for Statin-Induced Myopathy
- GENE.00039 Genetic Testing for Frontotemporal Dementia (FTD)
- GENE.00040 Genetic Testing for CHARGE Syndrome
- GENE.00041 Short Tandem Repeat Analysis for Specimen Provenance Testing
- GENE.00042 Genetic Testing for Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) Syndrome
- GENE.00043 Genetic Testing of an Individual's Genome for Inherited Diseases
- GENE.00044 Analysis of PIK3CA Status in Tumor Cells
- GENE.00045 Detection and Quantification of Tumor DNA Using Next Generation Sequencing in Lymphoid Cancers
- GENE.00046 Prothrombin G20210A (Factor II) Mutation Testing
- GENE.00047 Methylenetetrahydrofolate Reductase Mutation Testing

Nation's Health Insurers Struggle To Meet Fast-Growing Demand for Genetic Tests

ALL THE PROBLEMS ASSOCIATED WITH GENETIC TESTING were obvious to Karen Lewis, who is the Director of Genetic Testing Solution for AIM Specialty Health, a division of Anthem. The need for a genetic test management program was obvious.

Health insurers were struggling to stay up with the demand for genetic tests. Physicians and patients were frustrated because too often requests sent to health insurers for approvals were denied or took too long. Labs that performed the genetic tests were unsure they would get paid.

These factors led Anthem to create AIM Specialty Health and its Genetic Test Solution. In her role, Lewis will oversee the launch of AIM and Anthem's national genetic testing management program that begins next month.

"Once Anthem started this program for its own physicians and beneficiaries, many other payers came to us asking for help," said Lewis. "They said requests for genetic tests were so far beyond the scope of their comfort level that they needed assistance from someone.

"From personal experience, I knew how insurers struggle to evaluate and approve these tests," she said. "Here in Michigan, I worked on an insurer's technology assessment policy committee. Its managers needed help writing medical policies governing the use of genetic tests as well as help in reviewing claims. They also needed help to understand the growing volume of genetic tests introduced every day.

"Even now, many payers are just barely getting by as they attempt to keep up with the demand for test approvals," she added. "They find it challenging. That's why they contacted AIM and asked us for help. This led us to create AIM's Genetic Testing Solution for one payer starting this fall. As of Jan. 1, multiple payers will begin to use the solution.

"Currently, Anthem is our largest customer, but we are adding other insurers as well," said Lewis, a board-certified genetic counselor who has more than 25 years of clinical experience in laboratory, prenatal, adult, and cancer genetics. For one insurer, she worked as a medical policy administrator and genetic counselor.

Lewis. "If an out-of-network lab offers a genetic test that no in-network lab offers, then the provider portal is likely to approve the order, despite the fact that the lab is out of network."

In conclusion, Lewis explained that Anthem and AIM sought to design a pre-approval process for genetic tests that would meet the needs of patients, providers, and labs. "What's the common ground in this whole space?" she asked. "Labs want people to order genetic tests and get paid, and physicians want access to good testing and they don't want their patients to be liable for large out-of-pocket costs. As a health insurer, we want patients to have access to good useful genetic testing that will affect medical decision making."

The design of Anthem's Genetic Testing Solution is intended to be win-win for all parties, Lewis added. "The goal is that, when a provider gets an authorization for a certain lab for a certain genetic test, the lab will be reimbursed for that test," she observed. "That avoids the nightmare of whether and how much the lab will be paid.

"Labs want to know upfront that they will be guaranteed payment and they want to know how much they're going to get paid," she said. "The Genetic Test Solution and its pre-authorization process are designed to provide that certainty." TDR

—Joseph Burns

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Legal Update

Labs: Watch for Whistleblowers! You Can't Predict Who's Filing

Whistleblowers aren't just lab employees or insiders, but include physicians and even HMO med directors

NEWS STORIES ABOUT TWO DIFFERENT FEDERAL WHISTLEBLOWER CASES against lab companies provide a reminder that managers of every clinical laboratory and pathology group must be vigilant about compliance, because potential whistleblowers can emerge from the unlikeliest of places.

The first example involves **Piedmont Pathology** in Hickory, N.C. In May, it agreed to pay the federal government $601,000 to settle allegations of submitting false claims. The *qui tam* case was filed by pathologist Kim Geisinger, MD, who previously worked at Piedmont Pathology from March 2012 through February 2014. The whistleblower received 20%, or $120,000, of the settlement amount.

The lawsuit claimed that Piedmont "lacked medical necessity for the special stains conducted on certain gastric biopsies before a pathologist reviewed the routine H&E stained specimen."

Surprisingly, this wasn't the first time this pathology group had to deal with a whistleblower lawsuit. In November, 2015, **Piedmont Pathology Associates, Inc.,** and **Piedmont Pathology, PC**, agreed to settle a different *qui tam* case and pay the federal government $500,000.

In the Dept. of Justice press release, it stated that, "The government found that Piedmont Pathology provided EMR software licenses at little to no cost to nine physicians' practices close in time to when those practices entered contracts to refer specimens to their pathology lab. This conduct violated the Anti-Kickback Statute."

The press release described the whistleblower as "a former contract salesperson for the practice." This individual received 15%, or $75,000, from the proceeds of the settlement.

Insurer's Medical Director

The second example is a whistleblower case against **Boston Heart Diagnostics Corp.** (formerly **Boston HeartLab**). Filed in 2015, the case is still under litigation.

The allegations are that the lab company performed certain genetic and non-genetic tests that were medically unnecessary for specific diagnostic codes.

What is noteworthy in this case is that the whistleblower is a medical director for a national health insurance company. Tina D. Groat, MD, is one of the plaintiffs and is the National Medical Director of Women's Health and Genetics at **UnitedHealthcare**.

These federal *qui tam* lawsuits demonstrate that all labs are being watched for illegal behavior, not just by insiders and employees, but by healthcare professionals outside the lab. The cases show how even outsiders have enough access to documents and the motivation to initiate a successful whistleblower lawsuit. TDR

Mass Spec Tests Struggle To Gain Insurers' Attention

➤Why are payers, providers missing the opportunity to make this low-cost testing technology available?

➤➤CEO SUMMARY: Since 2014, a toxicology lab at the University of Colorado has used mass spectrometry to offer low-cost, accurate multi-analyte test panels that can detect hundreds of therapeutic drugs and drugs of abuse. However, CU Toxicology's chief medical officer says health insurers are slow to accept this diagnostic technology, despite its demonstrated clinical benefit and relatively low testing costs. Meanwhile, high schoolers' 'fish bowl' pill parties are a new diagnostic problem.

IT'S A DIAGNOSTICS TECHNOLOGY that is ideal for value-based care. Mass spectrometry is a relatively low-cost system that can detect minute traces of illicit and legitimate drugs in patients. Yet, adoption has been slow among health insurers.

So, what's the problem? That's a question Jeffrey Galinkin, MD, is trying to answer. He is a professor of anesthesiology and pediatrics at the **University of Colorado School of Medicine.** Formerly Galinkin was chief medical officer for CU Toxicology, a lab at **Colorado Children's Hospital** that runs mass spectrometry analyzers. He is currently medical director for **Claro Scientific Laboratories** in Aurora, Colo.

Three years ago, Galinkin developed a multi-analyte test panel that can identify trace amounts of 130 chemicals and hundreds of brand-name and illegal drugs at once and therefore has a wide variety of uses. This testing costs $100 to $200.

In Colorado, the CU Toxicology lab runs mass spec tests to identify drugs in unconscious patients who have overdosed. To manage polypharmacy in elderly patients, mass spec tests can identify prescription drugs that older Americans may be unaware they've taken. And mass spec is used for patients in drug clinics to demonstrate that they are clean and sober—or not. Physicians managing patients in pain also use this technology.

There are a wide variety of uses for mass spectrometry in clinical diagnostics. A few years ago, a long-term care facility in Colorado used the mass spec toxicology panels from CU Toxicology to find one resident was dealing cocaine. **Kaiser Permanente Colorado** also refers these tests to Galinkin's lab. *(See TDR, Feb. 24, 2014.)*

➤Billing Issue Slows Adoption

"Despite the high sensitivity and low cost, mass spec-based assays are not widely recognized for what they could do for the U.S. healthcare system," noted Galinkin. "It's a technology that is slow to be adopted because of the billing implications. We are having discussions about spinning off this technology. But for now, we can't bill for these tests efficiently

'Fish Bowling' and Pill Parties Are Latest Abuse of Prescription Drugs; Mass Spec Is a Solution

AT FIRST, JEFFREY GALINKIN, MD, thought news stories about how growing numbers of teenagers were taking their parents' prescription medications was nothing more than an urban legend.

He heard that high schoolers were participating in a risky practice known as 'fish bowling' or 'pill parties.'

"Students at these parties collected as many different kinds of medications from their parents' medicine cabinets as they could," said Galinkin, the former chief medical officer of CU Toxicology at Colorado Children's Hospital. "Then, they would place them in a large bowl on a table. Anyone who wanted to get high at this pill party could take fistfuls of these medications."

A professor of anesthesiology and pediatrics at the University of Colorado School of Medicine, Galinkin frequently speaks to parents' groups about drug use among teenagers. "Many parents are unaware that their kids would take all the pills they could find in the house, including all their parents' drugs," Galinkin said. "They were probably taking medications for high cholesterol or thyroid medications. Who knows? At the pill parties, the teenagers would put them in a bowl and kids would just take handfuls of them."

These 'fish bowling' and pill party events create a challenge for emergency room physicians. "When a user at this party would pass out and ended up in an emergency department, there was no way to identify what types of medications and how many of each that the teenager had taken," explained Galinkin.

"You hear stories from teenagers who say that the accessibility of drugs is incredibly high," he said. "I wasn't even sure these stories were true. But then I heard from an emergency medical technician who said he sees this happening at parties with teenagers all the time."

For teenagers who are incapacitated in this way, mass spectrometry's ability to test for and identify hundreds of different types of drugs makes it an ideal technology, Galinkin said. "This technology is useful for this testing because—at the end of such a party—there might be three to four kids unconscious on the floor. When the EMTs bring them in, we can identify what meds they're on. And inevitably, on a single patient, we are finding all kinds of different medications."

because health insurers have been slow to understand this technology.

"At Colorado Children's Hospital, billing for our physician group is done through the University Physicians group," he explained. "The billing for our lab test is too complex because normally physicians don't bill for lab tests. That's why we're considering different ways to run this operation."

While billing is one problem, there's also not much interest in this relatively new diagnostic technology for another reason. "Many labs prefer to do more traditional toxicology testing that generates more income," offered Galinkin.

"We compete against billion-dollar lab companies that are set up to charge $1,200 to $1,400 a sample," he commented. "For many reasons, their methods generate more revenue.

Lab Staff In Doctor's Offices

"Then there are the situations where certain lab companies that do toxicology and pain management testing have people implanted in doctors' offices to help collect patients' samples and send them to certain labs," noted Galinkin. "Those companies don't want to change their ways."

Another hurdle involves testing for therapeutic drugs and drugs of abuse in

patients seeking to cheat on their drug tests. "Most labs offering this type of testing prefer to have patients use the pee-cup method for specimen collection because they don't understand the deficiencies of common technologies used in such testing," said Galinkin. "They don't realize that many patients know how to get around that testing.

"For example, a patient can drink a liter of cranberry juice just before the test," he explained. "Then acidity in the juice screws up the result.

"Some people will just drink a gallon or more of water to mess with pee-cup samples," explained Galinkin. "Addicts know how to substitute someone else's urine. There is also an entire industry that sells urine substitutes designed specifically to help patients cheat on their drug tests.

"But our mass spec-based testing can identify when patients try to fool the system," he declared. "We can detect when a sample is too acidic and when a sample was tampered with because we can show the molecular signature of the patient and the sample. Mass spec resists this type of sample-tampering.

Advantages Not Recognized

"Yet, health insurers have not yet recognized that mass spec has these advantages, along with lower costs compared to existing test methodologies," Galinkin said.

In Colorado, Kaiser Permanente has contracted with CU Toxicology, but that's just one health plan, he added. In an interview for THE DARK REPORT in 2014, Galinkin explained that the mass spec test panel they designed detects 112 chemicals.

Mass spectrometry technology has improved since then. "CU Toxicology has upgraded its machines from the AB Sciex 5500 to the AB Sciex 6500," noted Galinkin. "Now, the molecules are easier to detect because the machines are more sensitive, which makes the testing even easier.

"The CU Toxicology lab still does tox testing for University Hospital, Colorado Children's Hospital, some work for Kaiser, and for the adolescent abuse centers around the city," Galinkin explained. "Most of those tests are done on a fee-for-service basis. For some tests, the hospital will pay us a fee and then bill an insurer. That turns out to be a much more manageable solution than for our physician group to bill insurance companies directly.

Significant Investment

"For us to bill an insurer would require making a significant investment with a company that specializes in billing insurance companies and understands the coding and claims processes for clinical laboratory tests," he explained. "That would be one way to move forward, but it's costly for us."

Meanwhile, a technology that would be ideal for clinical labs to use to deliver value-based care is not reaching its full potential, he said. "To me, it's shocking that health insurers have yet to recognize what this technology can do," observed Galinkin. "As a diagnostic tool, mass spec is too much of a money-saving technology to go unnoticed for too long. At some point health plans will realize the value. It's just not there yet."

Experts predict that mass spectrometry will play ever-greater roles in both clinical laboratories and anatomic pathology labs because of the substantial and ongoing technology advances in this field. Developing areas in this field include tandem mass spectrometry (MS/MS) combined with separation technologies such as gas chromatography (GC), liquid chromatography (LC), and ion mobility spectrometry (IMS). These allow ever smaller concentrations and metabolites to be targeted. An emerging approach to study proteins uses macromolecule ionization methods, such as electrospray ionization (ESI) and matrix-assisted laser desorption/ionization (MALDI). TDR

—By Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Theranos is back in the news again. *The Wall Street Journal* reported earlier this month that the troubled lab company is close to negotiating a settlement with **Walgreens** after being sued for $140 million in a breach of contract lawsuit filed by the national pharmacy chain. According to the journal, the settlement amount may be as little as $30 million.

MORE ON: *Theranos*

In its reporting on Theranos, the journal estimated that Theranos probably has cash reserves of about $54 million, before paying a $30 million settlement to Walgreens. The journal also said that Theranos has shrunk from 900 employees to 170 and is spending about $10 million per month, the greatest amount of that for legal fees.

SINGULEX HEADS TO TEXAS

On June 14, **Singulex, Inc.**, of Alameda, Calif., announced that it was relocating its **Veridia Diagnostics** clinical lab facility to Round Rock, Texas, just north of Austin. The new facility will be 36,000 sq. ft. and will employ about 100 people. Because of this relocation, Singulex's Medicare administrative contractor (MAC) will change from **Noridian** (responsible for Calif.) to **Novitas** (responsible for Texas).

TRANSITIONS

• The **College of American Pathologists** announced the appointment of Stephen Meyers as its new CEO. Prior to joining CAP in 2003, Meyers worked at **Bell & Howell Company**, **PwC**, and **McDonalds**.

• John David Nolen, MD, is joining the Department of Pathology at **Children's Mercy Hospital** in Kansas City, Mo. Previously, Nolan served at **Cerner Corporation**, **CSI Laboratories**, and **LifeSouth Community Blood Centers**.

• Effective June 30, Francisco R. Velázquez, MD, SM, is resigning his position as President and CEO of **PAML** in Spokane, Wash. Prior to PAML he held executive positions at **Quest Diagnostics** (**Nichols Institute** and **Focus Diagnostics**), **University of Texas Southwestern Medical Center**, **Detroit Medical Center**, **Boston Medical Center**, **Boston City Hospital**, and **Kaleida Health**.

• Michael Grilliot is now Director of Hospital Sales for the **Cleveland Clinic Laboratories**. He formerly worked at the **College of American Pathologists**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...a study published in *Nature* by researchers at the **Princess Margaret Cancer Centre** in Canada showing that mutations in three genes (BRCA1, BRCA2, and ATM serine/threonine kinase) were associated with aggressive forms of prostate cancer.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 17, 2017.