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Special Expanded Issue!

>>> *A Project Santa Fe Innovation!*
How TriCore Reference Laboratories Creates New Revenue Streams by Providing Added Value to Health Insurers
(First in a series)

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

What's Coming Next for Anatomic Pathologists?

INTERESTING THINGS ARE UNFOLDING within the profession of anatomic pathology. If the adage of "follow the money" applies to understanding why things happen, then recent events support some surprising conclusions.

Take the news reported in this issue of THE DARK REPORT that **PathGroup** of Nashville is acquiring **Pathologists Bio-Medical Laboratories** (PBML) of Dallas. That brings together two regional supergroups of 75 and 48 physicians and PhDs, respectively. Match this combination with the acquisition done last December where **Sonic Healthcare** acquired **Aurora Diagnostics**. That brought Aurora's 32 pathology groups and 200 pathologists into the Sonic organization, which already had labs and pathologists in nine locations across the United States.

Although the price of the PathGroup-PBML deal was not disclosed, Sonic paid $540 million for Aurora Diagnostics. So, these two deals combined probably total $700 million. Pathologists across the country can thus make a valid conclusion that super-regional pathology groups have a future, both clinically and financially. Further, it is also valid to assume that investor money will be available to support similar regional pathology super-group purchases in coming years.

The other anatomic pathology sector with substantial investment involves what I will collectively call digital pathology, whole slide imaging, and automated image analysis. In the last issue of THE DARK REPORT, we called attention to the recent surge of capital being invested in digital pathology companies. The roll call included: **PathAI** (Boston, $60 million); **Deep Lens** (Columbus, Ohio, $14 million); and **Ibex Medical Analytics** (Tel Aviv-Yafo, Israel, $11 million).

All three companies are developing products that use automated image analysis and artificial intelligence designed to help pathologists analyze digital pathology images. Currently, only the **Philips** digital pathology system has FDA clearance for use in primary diagnosis.

Yet, if the "follow the money" adage applies to digital pathology and automated image analysis, then a safe conclusion—based on these capital investments—is that these technologies are advancing at a rapid pace. The more adventurous prediction is that the pathology profession may be surprised at the speed and number of digital pathology systems and image analysis products that are presented to the FDA for review within the next 30 months! TDR

The Bad News: Disruption. The Good News: Opportunity!

Keynote speakers agree at Executive War College, healthcare system is transforming at a swift pace

CEO SUMMARY: There was an interesting consensus that emerged from the 80 sessions and 118 speakers at this year's Executive War College in New Orleans earlier this month. The consensus centered around two themes. One theme is disruption, which is bad news for those labs that hope to maintain the status quo. The other theme is opportunity, which is good news for those labs willing to realign their lab test services to better meet the evolving needs of physicians, payers, and patients.

SOMETHING SPECIAL AND UNIQUE happened earlier this month at this year's *Executive War College on Lab and Pathology Management*. It was the first time in 24 years of this conference that every keynote speaker at every general session was in full agreement about the most powerful trends in healthcare and the clinical laboratory.

This unprecedented development is itself significant. It is a rare consensus on the direction of healthcare and the changes unfolding daily within the clinical laboratory marketplace. This consensus has at least three valuable benefits to clinical lab administrators and pathologists everywhere.

First, the themes, trends, and predictions of these keynote speakers provide all lab leaders with a useful understanding of today's healthcare system and how it will look different in coming years. It provides them with a strategic road map, endorsed by the keen insights of these nationally-recognized speakers.

Second, lab leaders who incorporate the insights and recommendations of these speakers into the clinical, operational, and financial strategies of their clinical labs and pathology groups can have confidence that they are positioning their labs for success.

Third, in attendance this year was a record crowd of just under 900 attendees from nine different countries. As they listened to the general session speakers over the two days of the conference, there was uncommon unanimity as to the accuracy of the speakers' insights and the validity of their predictions about what's driving healthcare and laboratory medicine in the United States today.

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Stated differently, there were few in the audience who voiced strong disagreement with the trends, the pace of change expected, and the most appropriate strategies labs can employ to deliver cutting-edge lab testing services in a financially-sustainable manner.

'Disruption Ahead!'

This year's opening general session kicked off with a presentation by Robert L. Michel, Editor-In-Chief of THE DARK REPORT and organizer of the conference. His very first slide set the tone for the keynote speakers that followed. It was a highway sign that read "Disruption Ahead!"

"My strongest message to lab leaders today is that disruption is happening across the full spectrum of healthcare in this country," declared Michel. "The best proof that this statement is true is to compare any sector or activity in healthcare today with how it looked just five years ago. The differences are undeniable.

"Consider the integration of care delivery as one trend," he said. "We regularly read headlines about how health system A is acquiring or merging with health system B. Examples of this trend include **Aurora Health** and **Advocate Health** forming an $11-billion organization, along with the pending merger of **Dignity Health** and **Catholic Health Initiatives** to create a huge health system operating 142 hospitals in 21 states!

Farewell to Fee-for-Service

"Next, let's look at disruption in provider reimbursement caused by the move away from fee-for-service (FFS) payment," continued Michel. "This is an established fact. **Change Health** published data that shows how, in 2018, the proportion of business aligned with fee-for-service was just 37.2%. It predicts that FFS will fall to 25.4% by 2021, just 24 months away!

"If by 2021, 75% of payments made to hospitals, physicians, and other providers are in the form of value-based and per-member-per-month arrangements, then it is reasonable to predict that private payers will be shifting a larger proportion of lab payments away from fee-for-service as we go forward," he noted. "All the signs in today's marketplace point to disruption in how providers are paid by payers and that includes clinical laboratories and anatomic pathology groups."

Michel next pointed out the disruption occurring in the actual delivery of healthcare. "It is easy to recognize the shift from what I like to describe as 'reactive' care to proactive care," he noted. "Reactive care is waiting for sick patients to show up at the doctor's office or the emergency room at the hospital. That's yesterday's model of healthcare in the United States.

"Today, proactive care requires providers to keep people healthy and out of the hospital," he added. "You notice this today when you visit your primary care doctor. He or she will devote significant time in each office visit to point out your biggest risk factors in your current state of health. Then comes advice and prescriptions designed to either prevent a chronic condition or manage an existing condition so that acute (and expensive) episodes and hospitalizations can be avoided.

Change in Mix of Lab Tests

"You can also recognize this shift in how your lab's client physicians are giving greater emphasis to preventive care by watching the changing mix of tests coming into your laboratory," said Michel. "Compared to just a few years ago, today your physician clients order a growing proportion of lab tests for the purpose of early detection, for monitoring patients on the verge of a chronic condition (like diabetes), or managing patients with chronic conditions.

"Another fact demonstrating how healthcare is steadily moving away from reactive care and emphasizing proactive care is a statistic published in MedPac's current "Report to Congress: Medicare Payment Policy, March 2019," he stated. "Over the 11 years between 2007 and 2017, the number of Medicare inpatient

Keynote Speakers Identify Opportunities for Labs, Discuss Disruptive Healthcare Trends

THERE WAS MUCH GENERAL AGREEMENT about basic trends in healthcare and the clinical laboratory industry among the keynote speakers at this year's *Executive War College.*

During the opening general session on Tuesday, April 30, following Robert Michel's opening address, attendees heard from these three speakers:

- Rick L. Panning, MBA, MLS(ASCP) CM, Senior Administrative Director, Laboratory Services, **HealthPartners**, Bloomington, Minn.
- Sonny Varadan, MBA, PMP, Chief Information Officer, **Sonora Quest Laboratories**, Phoenix, Ariz.
- Philip Chen, MD, PhD, Chief Strategy Officer, **Sonic Healthcare USA**, Austin, Texas

Effective Lab Strategies

The emphasis during this general session was the strategic thinking and innovations that these three lab organizations were using to deliver added value to their stakeholders. In the case of the laboratory at HealthPartners, Rick Panning described how and why his lab organization was moving certain tests out of the core lab and into physicians' offices.

The objective was to shorten the time to diagnosis and selection of therapy while the patient was still in the office. Not only does this reduce the overall cost of care, but it makes the doctors at HealthPartners more productive.

Following this presentation, Sonny Varadan and Philip Chen, MD, PhD, each spoke about the projects within their respective labs to combine lab test data with additional data, such as from EHRs and demographic and geographical data. Both clinical laboratories have collaborations with payers, accountable care organizations (ACOs), and similar provider groups where they deliver real-time, actionable clinical intelligence and are paid in separate revenue streams for this information.

Tuesday's closing general session featured Lâle White, Executive Chairman and Chief Executive Officer, **XIFIN, Inc.**, of San Diego. The story on pages 7-10 that follow covers some of her insights in detail about the PAMA law's implementation.

Important Healthcare Trends

On Wednesday, May 1, the general session featured presentations by:

- Ted Schwab, MBA, Strategist and Entrepreneur, **Babylon Health**, Austin, Texas.
- Mark D. Dixon, R.Ph., MHA, FACHE, President, **The Mark Dixon Group, LLC**, Edina, Minn.

Ted Schwab, a nationally-recognized healthcare strategist, surprised the audience with an incisive overview of how rapidly and radically some transformation was happening in healthcare. His description of how major health insurance companies were diversifying, for example, had the crowd's full attention.

Mark Dixon was next to the podium. As a former hospital CEO, he actively works with hospital and health network CEOs. He helped attendees understand the most pressing concerns of hospital CEOs. He also identified ways that labs and pathology groups can contribute to solving those same concerns at their own hospitals.

Most of the powerpoints used by these speakers are available to clients of THE DARK REPORT when they access: **https://www.executivewarcollege.com/presentations.** Audio recordings of these and other presentations can be obtained by contacting the offices of THE DARK REPORT.

discharges declined by a cumulative 20%. During those same years, Medicare outpatient visits increased by a cumulative 43.5%.

"This is an essential insight that should not be overlooked by lab administrators and pathologists," continued Michel. "Medicare data demonstrate that the nation's physicians and hospitals are getting better at keeping people out of hospitals and they have sustained that trend for 11 years. Every laboratory should consider this fact in its strategic planning and identify ways to support this ongoing transition in the healthcare system."

Michel next discussed the disruptive trends in the clinical laboratory and anatomic pathology markets. "Without question, the single most disruptive factor now active in the clinical lab industry are the Protecting Access to Medicare Act (PAMA) price cuts to the Medicare Clinical Laboratory Fee Schedule," he observed.

"Everyone knows that the PAMA law allows the federal **Centers for Medicare and Medicaid Services** (CMS) to cut lab prices by 10% each year in 2018, 2019, and 2020. CMS can then cut lab test prices by a maximum of 15% each year in 2021, 2022, and 2023.

"These Medicare price cuts are disruptive in multiple ways," he added. "First, labs are getting paid less for their Medicare Part B lab test claims. Second, many state Medicaid programs moved swiftly to drop their lab test prices in response to the Medicare program. Third, labs report that most private payers want to cut what they pay for lab tests in lock-step with the Medicare price cuts.

Will Lab Test Quality Erode?

"Collectively, this is a major disruption to the revenue labs need to maintain quality lab testing services," noted Michel. "Since 2018, our intelligence service, THE DARK REPORT, has regularly identified community and independent labs that have sold or gone out of business due to the loss of revenue just from the Medicare Part B price cuts.

"Thus, the disruption to the clinical laboratory industry will go far beyond what Congress intended when it passed the Protecting Access to Medicare Act in 2014 and will certainly be more extensive than what CMS and the **General Accountability Office** expected," observed Michel. "Labs are disappearing from many smaller communities and rural areas, thus reducing patient access to quality, local lab testing.

Regulatory, Compliance

"The second primary source of disruption to labs involves regulatory and compliance requirements," he said. "Between the actions of federal agencies and rulings in federal court cases, labs today face a different and tougher regulatory environment.

"The EKRA section of the Support Act that became law last October has language making it illegal to pay commissions for physician referrals," noted Michel. "This language conflicts with the language in the federal anti-kickback statute. That leaves labs waiting for guidance and clarity from the federal government.

"Then there are the new NCCI guidelines that address lab test bundling and took effect on Jan. 1," he added. "Lab consultants quickly pointed out that the guidelines are confusing, particularly for labs performing molecular and genetic tests.

In his closing remarks, Michel told the *Executive War College* audience that, despite these disruptive trends, there was good news for the clinical labs and pathology groups. "That good news is there is opportunity for labs of all sizes and types," he explained. "Labs should recognize the changing needs of hospitals, physicians, payers, physicians and employers, then develop services that add value.

"Labs can be paid for this value, thus creating new sources of revenue. Speakers at this conference will be sharing their successes with getting paid for their new, added value services. This is happening today, in many areas of the United States," concluded Michel. TDR

What Labs Can Expect from PAMA in 2019

There are positives and negatives for laboratories as CMS moves forward with PAMA price reporting

CEO SUMMARY: Attendees at the Executive War College learned that CMS has taken steps to expand the number of hospital labs required to report their private payer lab test price data under the Protecting Access to Medicare Act, but the unbundling of certain test panels could be problematic. Problems can occur when labs either did not code panels correctly or their Medicare Administrative Contractor mistakenly overpaid labs for those claims. One expert recommends that labs review these claims.

CLINICAL LABORATORY MANAGERS MAY BE PLEASED TO KNOW that the Medicare program appears to be making a better effort this year to collect accurate and reliable data on what commercial health insurers pay for clinical laboratory testing, according to Lâle White, CEO of **XIFIN** in San Diego. XIFIN contracts with clinical labs to help them boost their revenue.

At the same time, White said lab executives and pathologists still have reasons to be concerned about the deep cuts that the federal **Centers for Medicare and Medicaid Services** made in lab test payments since Congress passed the Protecting Access to Medicare Act (PAMA) in 2014.

White's presentation at the 24th annual *Executive War College* last month offered a mix of positive and negative developments for clinical laboratories. The positive development was that CMS has made more of an effort to collect accurate and thorough data on what private payers pay for clinical lab tests. This is the data CMS uses to set Medicare lab test payments based on actual market rates.

The negative development, however, is that CMS officials appear to believe the agency overpays clinical laboratories for testing for Medicare patients.

On the issue of collecting private payer lab test price data this year, White said, "One question has always been, 'Did we ever have a proper market pricing study of the private payer sector as PAMA intended?'" A goal of the law is to allow CMS to set prices based on what private payers pay for lab tests. Answering her own question, White said, "I think the answer is probably not, since most private payers use the earlier Medicare fee schedule as a pricing guideline."

Lab Price Reporting

This year, CMS is collecting data once again on what private payers pay for lab tests, and more labs are required to report their data. The inclusion of a great number of reporting labs may mean CMS will have the much broader data set needed to set prices accurately based on what private health plans pay, she added.

While basing prices on accurate and comprehensive data could help clinical

labs, White was concerned about the intentions CMS has for its use of the data it collects under PAMA and setting prices based on that data. In the past, it appeared CMS was using the law to set lab test prices lower than what labs might expect if prices were based on accurate market rates, she said.

"We saw with the latest GAO report that CMS and GAO are interested in a price reduction program versus a market-price based program," White said. The GAO is the **Government Accountability Office**, a federal watchdog agency that reports to congress on how tax dollars are spent.

Appropriately enough, White's presentation at the *Executive War College* in New Orleans was titled, "The Ugly Truth about Payers and PAMA: What Labs Can Expect and How to Respond."

Response to GAO Lab Report

In a report to Congress in November titled, "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments," the GAO concluded that the way CMS implemented PAMA could result in CMS paying $733 million more than it should pay for clinical lab tests from 2018 through 2020. The GAO report led Senate Finance Committee Chairman Chuck Grassley (R-Iowa) to ask federal officials to explain the potential for excess payments for lab tests. *(See, "Senator Asks: Are Lab Test Payments Too High?" TDR, Feb. 4, 2019.)*

Also, the GAO report may have led CMS officials to believe payments for clinical laboratory tests are too high, White commented. "The GAO report criticized some of the pricing calculations made by CMS because they were not based on average Medicare price, but instead were based on the national limitation amount," she explained. "And, the average price obviously would have been even a further reduction, not to mention a highly-contested methodology based on population distribution.

"In essence the $670 million savings CMS got from PAMA in 2018 versus the $390 million that CMS projected wasn't enough of a decrease for the GAO," she added. "The GAO thinks CMS should have gotten more."

The GAO report also said CMS could be overpaying for unbundled "automated multichannel chemistry" tests, White said.

Labs Responsible for Coding

In its report, the GAO criticized CMS for eliminating bundled prices for these automated tests. It said this one change alone could cause the government to pay $10 billion more for such tests. "In essence, it didn't actually cost Medicare that much, although the GAO made it seem that way when it released that report in November," White commented. "Essentially, panel ordering compared to single test orders did not materially change, and there was really no unbundling by the industry."

White made an important point about bundling, saying that when CMS implemented the PAMA-based fee schedule, it eliminated their edits for panel coding for automated multichannel chemistry tests. Labs running these tests should be aware of changes regarding such edits and should understand that they are responsible for proper coding even when Medicare does not edit for coding accuracy, she added. *(See sidebar, page 9, "To Bundle or Not To Bundle? Labs Get a Solution to a Confusing Medicare Problem.")*

More Labs to Report Data

On the efforts CMS has made to include more labs in its data-collection initiative under PAMA, White said CMS broadened the definition of which labs should submit payment data, which the PAMA statute calls "applicable labs."

"Last year, when CMS published the physician fee schedule, the agency broadened the definition of applicable labs," noted White. "This was very welcome for the clinical lab industry because obviously enough labs didn't participate when CMS

To Bundle or Not to Bundle? Labs Finally Get a Solution to a Confusing Medicare Guideline

CLINICAL LABORATORIES NEED TO BE CAREFUL ABOUT HOW THEY CODE for bundled tests, particularly multi-channel chemistry tests, XIFIN CEO Lâle White told attendees at the *Executive War College* in New Orleans last month.

"As an industry we have to be aware that providers are liable for coding errors and required to code properly for automated multi-channel chemistry tests, regardless of whether payers have the proper edits in place to recognize unbundled coding errors" she said." Also, labs should be aware that congress is considering making changes to the rules that govern how automated tests are paid.

"In November, the Government Accountability Office (GAO) suggested that labs were unbundling tests, but, in fact, labs were not unbundling," explained White. "Instead, labs were following the coding guidance from the **American Medical Association**.

"Clinical laboratories are required to code to the highest procedure code level using the most specific CPT code," she noted. "If a lab does not code properly, it is liable for the incorrect payment that can result from improper coding. None of that changed under PAMA.

"What PAMA stopped was the price bundling for automated chemistries," White added. "In other words, if your lab had a comprehensive metabolic panel, you would bill it as a panel. And, if there was any additional single chemistry test or tests ordered with that panel, Medicare would actually bundle the price and give your lab an incremental payment of maybe $1 more, instead of the actual price of the individual components ordered in addition to the panel.

"What happened was, as part of PAMA implementation, Medicare eliminated that price bundling," she continued. "But also CMS made a mistake by incorrectly eliminating the panel bundling edits that the Medicare Administrative Contractors (MACs) use to ensure that labs were using the right panel codes for those multichannel tests. For example, when a lab bills for another panel that is not an automated multi-channel panel—such as a hepatitis panel—the MAC will bundle it for the lab using its panel-coding edits.

"Accordingly, the MACs would pay the higher fees for the individual components if the provider unbundled, because they eliminated the edit that would automatically bundle the automated multi-channel chemistry tests," added White.

"Therefore, if a lab unbundled such tests or didn't bundle appropriately, the MACs probably overpaid labs for those individually submitted multichannel tests in 2018.

"Today, the MACs and CMS understand what happened, and those edits are being re-instituted in the claims adjudication systems," she warned. "That means that laboratories are responsible for making sure that they did not inappropriately unbundle or did not bundle incorrectly.

"Therefore, labs should confirm that Medicare did not overpay for those tests," she said. "If the MAC did overpay, the lab is responsible for repaying that amount."

The aggregated billing data XIFIN has for its lab clients show that, contrary to what the GAO said, labs were not unbundling tests. "There was no unbundling going on across the lab industry that was of any significance," White added. "Maybe there were one or two mistakes but there was no significant effort to unbundle.

"Nevertheless, if any labs did code tests incorrectly, they are responsible for correcting billing mistakes and repaying overpayments," said White.

collected market-price data in 2016. In that data collection effort, much of the hospital lab industry didn't participate."

Under PAMA's Section 216, labs needed to collect data on what private insurers paid for lab tests between Jan. 1 and June 30, 2016, and report that 2016 payment data in the first quarter of 2017. CMS used that data to set prices for lab tests in 2018, 2019, and 2020. At the time, CMS expected to cut what it paid labs by 10% beginning last year, 10% again this year, and 10% next year.

Second Data Collection

The second-data collection period began Jan. 1 of this year and ends on June 30. Applicable labs required to report will need to submit their data to CMS next year. For this second data-collection period, CMS changed which labs need to report their private payer lab price data.

"CMS changed the majority of revenue thresholds and eliminated Medicare Part C from the calculation for revenues received from the Medicare Advantage programs," White commented.

Also, CMS began using the 1450 14X bill type to define which labs are required to report their private payer lab price data, White explained. Therefore, CMS will require more hospital outreach labs to collect and report their data in this second data-collection period. "Basically, that means most hospital outreach labs will now be included under the definition of 'applicable labs,'" she said.

More Labs Are to Report

"According to CMS data, that means CMS has added about 43% more labs to the number of labs that submitted data last time," she added. "But there are still important questions about how the second data collection will turn out for labs."

In the first data-collection period, CMS excluded most hospital labs from data collection by not defining them as "applicable labs," White said. "If you consider the entire volume of hospital labs as part of the overall lab market, once you exclude hospital inpatient testing, about 44% of lab testing data comes from hospital outreach labs, 28% comes from large labs, and another 28% comes from the rest of the lab industry," she said.

"While these outreach labs are now part of the data collection effort, in a recent clarification, CMS has excluded outpatient private payer data and indicated that data collection for hospital labs should be limited only to non-patient services," White explained. "This limitation of data, however, will greatly reduce the data that hospital labs produce to less than 20% of the entire data set. Since the CMS pricing exercise is required to use a weighted median, how much of a difference that data will make is a question still to be answered." TDR

—Joseph Burns

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Consultant Warns Labs About 'Hurricane PAMA'

IN A NOTICE SENT TO ITS HOSPITAL AND HEALTH SYSTEM CLIENTS, a consulting firm warned about what it called, "Hurricane PAMA."

Mike Kachure, Vice President of Strategic Partnerships for the consulting firm **Accumen** wrote, "Hurricane PAMA—prepare or fall victim to reimbursement damages."

For clinical labs, the Protecting Access to Medicare Act (PAMA) can feel like a hurricane to some health systems, he wrote. "This pending storm impacts a health system's ambulatory laboratory services, financial reimbursement, and hospital outreach profitability," he added. "The impact to an average hospital with Medicare reimbursement for ambulatory outpatient and outreach laboratory services of $5 million annually is projected to lose up to $1.5 million annually in net revenue by 2020, which directly impacts your bottom line."

Regulatory Update

CMS, Lab Groups Begin Talks About Issues with NCCI Edits

SERIOUS PROBLEMS WITH THE NEW GUIDELINES for the National Correct Coding Initiative (NCCI) that were implemented on Jan. 1 have caused nine clinical laboratory associations and groups to come together and voice their concerns to the federal **Centers for Medicare and Medicaid Services** (CMS).

CMS implemented those changes on Jan. 1, resulting in confusion among labs about how to bill Medicare and Medicaid for certain tests. As of last month, many labs were not getting paid, lab billing experts said. The rates of denial for labs running mostly molecular tests could range from 40% to 100% of revenue, one billing expert said. (*See "Nine Lab Groups Say New NCCI Policy Is Inconsistent," TDR April 8; and "Labs Get High Denial Rates Under New NCCI Rules," and "ACLA: NCCI Guidelines Are a 'Step Backwards,'" TDR April 29.*)

This month, however, officials from CMS and the organizations representing clinical laboratories have begun discussing how to resolve the dispute. On May 10, a spokesperson for CMS said, "We have met with several industry stakeholders regarding concerns with recent updates to the NCCI Policy Manuals and are continuing to gather additional feedback. We will continue to consider industry feedback as we evaluate these concerns."

Lab Group Met with CMS

One group representing industry stakeholders is the **American Clinical Laboratory Association**. ACLA President Julie Khani confirmed that the lab group met with CMS to express concerns over the NCCI edits. "We were grateful to have the opportunity to reiterate these concerns during a recent meeting with CMS and other stakeholders," she said. "We look forward to continuing to engage with CMS on this issue."

In a statement to THE DARK REPORT, the CMS spokesperson explained that CMS developed the NCCI and its policy manuals, "to promote correct coding and reduce improper coding leading to inappropriate payment of Part B claims." The coding policies are "based on coding conventions defined in the **American Medical Association's** CPT Manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practices, and a review of current coding practices."

'Anything but Correct'

The lab groups complained, however, that the changes CMS and the NCCI made in December appear to have had the effect of making "correct coding initiative" anything but correct, according to W. Stephen Black-Schaffer, MD, a pathologist at **Massachusetts General Hospital** and the Associate Chief, Education and Training, at MGH. He's also an Associate Professor of Pathology at the **Harvard Medical School**.

The changes have been highly disruptive because they conflict with previous NCCI policy manual instructions and coding guidance from the AMA, the lab groups said of the changes that took effect Jan. 1. The NCCI issued the new guidelines just three weeks before they took effect and they were implemented without notice to or receiving comments from stakeholder labs. TDR

—Joseph Burns

Getting paid for clinical lab 2.0 lab services that add value

TriCore Forges Ahead to Help Payers Manage Population Health

CEO SUMMARY: To develop new sources of revenue to offset declining fee-for-service payments, TriCore Reference Labs is collaborating with health insurers in novel ways to improve patient outcomes and lower healthcare costs. To achieve this, TriCore brings together data from lab tests, EHRs, patient demographics, and geography. Analytical tools allow it to assess population health while identifying specific patients with undiagnosed diseases and care gaps. In turn, insurers are paying TriCore for this information.

PART ONE OF A SERIES

In recent years, clinical laboratory leaders have heard plenty about how labs can monetize their clinical laboratory information by using it to help health insurers manage the members they serve. Until now, this enticing idea has been little more than a concept.

Today, however, health insurers are paying some labs for supplying insights—based on their clinical lab test data—that are used to add value for payers and the physicians in their provider networks. One of the nation's lab pioneers in this trend is **TriCore Reference Laboratories** of Albuquerque, N.M.

At the *Executive War College* in New Orleans earlier this month, Rick VanNess, TriCore's Director of Product Management, gave a presentation in which he explained how TriCore has developed a method that helps health insurers in New Mexico improve patient care, fill gaps in care, and manage population health. The title of his remarks was, "Your Lab Can Do Analytics with Your Payers Today: How We Used Excel Spreadsheets to Engage Health Insurers and Launch Collaborative Care Initiatives."

Over the past three years, health insurers have expressed interest in paying TriCore for these services and, at some point, may be willing to share the savings with the lab as they collaborate to achieve value-based care, VanNess said. The analytics TriCore provides would generate new sources of revenue for TriCore and would come in addition to the existing fee-for-service payments the clinical laboratory gets for the testing it does due to the additional value the insurers receive.

Lab-Payer Collaborations

TriCore is believed to be one of the earliest clinical labs to collaborate with health insurers in ways that meet the clinical lab 2.0 business model. The lab's collaboration with insurers makes its experience useful to other clinical laboratories seeking to develop new sources of revenue while pursuing value-based care. These new sources of revenue can be used by labs to offset the ongoing cuts to fee-for-service lab prices.

The basis for creating new value and revenue for the lab under the clinical lab 2.0 model is how it contributes to gains in quality measures, improved patient care, and reductions in the overall cost of care.

Conversations with Payers

"This is a very different conversation for our clinical lab to have with health insurers in New Mexico," VanNess explained. "It means we must come to the negotiating table prepared to document what we know about the payer's beneficiaries, where gaps in care exist, and where insurers and physicians can use our actionable information to improve outcomes and quality measures."

The key to this story is a three-step process TriCore used in its negotiations with health insurers. The goal was to convince health insurers that TriCore could contribute to the twin goals of improving health outcomes and estimating the resulting reductions in costs; then persuade those same insurers to pay for those services based on the estimated savings. TriCore's three-step process involved:

- Collecting, analyzing, and presenting actionable insights from lab test data that health insurers could use to improve quality measures, thus enabling TriCore to receive compensation on a per member per month (PMPM) fee in exchange for providing such valuable information.
- Correlating how much the insurers benefit from increased quality score payments because of helping physicians and other providers avoid adverse health outcomes. For this part of the discussion, VanNess said TriCore's estimates about improvements in patient outcomes were conservative enough that he was confident TriCore could win the health insurers' trust.

What to Expect from Series on Clin Lab 2.0

Editor's note: This special series on the clinical lab 2.0 business model is designed to give clinical laboratory executives and pathologists an inside perspective on how TriCore Reference Laboratories in Albuquerque, N.M., is transitioning to this new arrangement. To explain how TriCore generates new streams of revenue by working with health insurers, the editors have organized this series into several installments.

In this first installment, we address the overall strategy and the steps TriCore took to get the attention of health insurers. Its negotiations with insurers led to collaborations in which TriCore could provide clinical evidence from lab test data. In return, TriCore has asked insurers to pay for that information.

A future story in this series will deal with the process TriCore used to assemble data from multiple sources to identify opportunities to help payers improve patient care and reduce healthcare costs.

Additional stories will provide case studies on how the lab company has collaborated with payers to help physicians and other providers manage the care of patients with a variety of health conditions and disease states.

- Asking insurers to compensate TriCore with a portion of the estimated savings as a result of getting the information they need to improve care in measurable ways, while recognizing the clinical laboratory's role in adding value to the delivery of patient care.

TriCore's Proposal Accepted

Some of New Mexico's largest health insurers reacted positively to TriCore's PMPM proposal and enabled the lab to augment care coordination processes delivered to their members.

"This was a crucial first step in developing our value proposition with each payer," VanNess recalled. "And, the fee we offered to provide this service to the health insurer was accepted from the start of these contract negotiations."

Improving care and lowering costs are two of the most important goals health insurers pursue every day. Those twin goals are almost akin to the Holy Grail of healthcare. "In one collaboration, our actionable information contributed to a 25% increase in the insurers' efficiencies and more than a 40% reduction in adverse outcomes, such as preterm deliveries," VanNess said.

In his presentation, VanNess described TriCore's challenges in learning what insurers needed and how his lab then brought together the different types of data it would deliver to payers that would give their providers insights they could use to improve care.

Simple Excel Spreadsheets

"We started with basic spreadsheets to engage care coordinators," he said. "Using this approach to product development allowed us to identify the value of the data we had to augment their methods and to change their perception of the clinical laboratory."

TriCore already had analytics on a substantial proportion of New Mexico's population. "We knew we needed evidence before asking the insurer to pay TriCore for the data we proposed to deliver," he added. "And each care coordinator we interacted with verified the accuracy, timeliness, and overall need. At that point, we had a tangible story with data that we could present to insurance executives."

In the coming weeks, TriCore expects to name a health insurer that is willing to pay for its data and analytics. That approval is pending at the same time that TriCore is preparing to submit an article for publication in a peer-reviewed

TriCore's Rick VanNess: 'Any Lab Can Do This!'

IT DOESN'T REQUIRE MUCH FOR ANY CLINICAL LABORATORY TO DEVELOP an added value lab testing service for a health insurer. During his presentation at the *Executive War College*, Rick VanNess, Director of Product Management at TriCore Reference Laboratories in Albuquerque, N.M, offered these basic steps to engage a health insurance plan and work with it to create a collaboration that improves patient outcomes while helping the health insurer reduce healthcare costs. TriCore is a founding member of Project Santa Fe.

Steps to Creating Added Value for Health Insurers

1) **Identify your market's payer contracts, incentives, and patient needs.**
2) **Start a conversation with your health insurance companies by asking them:**
   a) **What are your pain points?**
   b) **What if you could have HEDIS data in near real-time?**
   c) **Request eligibility file (or perform a 270/272 eligibility bounce).**
3) **With the file, create a HEDIS report while reviewing health insurer's population.**
   a) **Identify number of diabetics, location, care-gaps, risk.**
   b) **Return with a live demonstration of their data and offer to do a "free study."**
4) **Present results of study, ROI, and the price your lab wants for providing this actionable information.**

health journal about the results it achieved from prenatal care coordination. Over the course of the two-day *Executive War College*, several speakers talked about how labs need to develop alternative payment models and set a dollar value on the data they can share with health insurers.

But unlike those speakers, TriCore is already doing so. "We've done that at TriCore, and now certain health insurers are willing to pay our lab differently and invite us to the negotiation table during value-based care arrangements," said Michael J. Crossey, MD PhD, TriCore's Chief Executive Officer. "It's remarkable the shift in perception that we've created. TriCore's data are no longer considered a commodity by health insurers."

In other words, TriCore is helping health insurers and physicians to achieve the triple aim, as the **Institute for Healthcare Improvement** defines the term:

- Improve the patient experience of care (including quality and satisfaction),
- Improve the health of populations, and
- Reduce the per capita cost of care.

A focus on the triple aim is an important point for lab administrators and pathologists, because on July 1, **UnitedHealthcare** will launch a new lab

network with seven preferred labs. UHC is asking those labs to help physicians and other providers achieve the triple aim. *(See UnitedHealthcare Sets July 1 Launch for New Preferred Laboratory Network," TDR, April 29, 2019.)*

Now that TriCore has as much as three years of clinical outcomes data from its collaboration with some health insurers in New Mexico, other payers are inviting TriCore to discuss similar collaborations and submit proposals.

More Payers Now Interested

"In the conversations we are having with different payers, these arrangements will be that TriCore will be paid in two ways for adding value," VanNess explained. "First, the insurer will pay our lab for traditional laboratory testing. Second, they will provide a per-member-per-month payment for these insights and include TriCore in the risk-sharing and gain-sharing models these insurers have."

In this way, TriCore is bridging the gap between the volume-based fee-for-service payment model that dominates healthcare today and the value-based model being developed nationwide. It can bridge that gap because it will earn a separate source of revenue in exchange for offering clinical insights based on the lab test data it provides to health insurers.

"Success as a clinical lab 2.0 organization requires our lab team to be more involved in understanding why each particular patient needs the test the physician is ordering and how the test result will affect the patient's outcome," Crossey said.

Specific Patient Outcomes

"We want to know how our lab can tie that specific lab test result to an actual outcome," he added. "This allows us to produce actionable interpretive results that physicians and other providers can use to coordinate care for their patients.

"Right now, at TriCore, we are measuring the effect of producing actionable results in real time," he added. "Payers recognize that we no longer simply sell tests."

Under the direction of David G. Grenache, PhD, TriCore's Chief Scientific Officer, TriCore has a division whose sole mission is to reposition the clinical laboratory in healthcare by developing actionable insights. "We have employed clinical pharmacists who help developers create algorithms," he said. "Then they work with payers and providers to measure better outcomes and increase quality scores.

"For TriCore—and for any lab—this is an entirely new product that needs to be marketed in a new way," he explained. "But doing so can definitely change how consumers view the clinical laboratory." Grenache also is the President-elect of the **American Association for Clinical Chemistry**.

Each year, TriCore learned lessons in how to bring together different sets of data. Besides its lab test data, TriCore is getting patient health records, diagnosis codes, and demographic and geographic data. After starting with Excel spreadsheets, it later acquired analytics software from the **Rhodes Group** that allows it to analyze and present data in many more useful ways.

Better Analytics than Payers

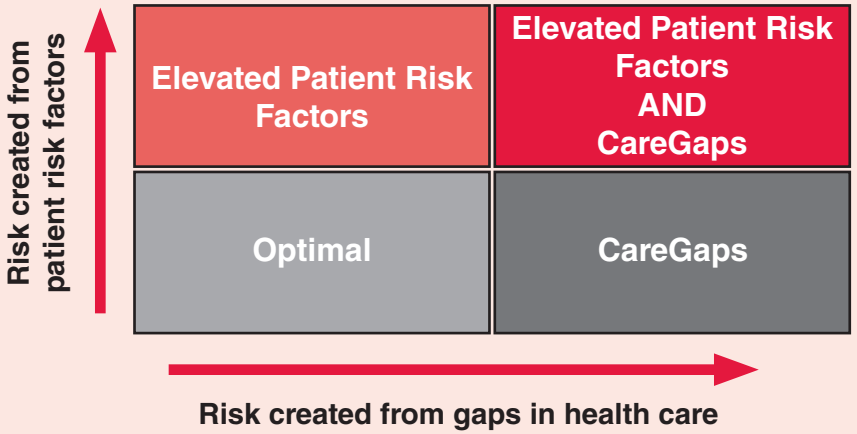
"Today, TriCore has better analytics than the insurers have," VanNess said. "We just need the chance to prove it to them. It took several years for us to convince the first health insurers. However, now we are racing to keep up their demand for new insights."

While VanNess did not want to name its health insurance customers, he did say that one insurer is a fully-integrated health system. It also is one of the largest employers in the state and serves a significant percentage of the state's residents. It manages a physician group with more than 100 clinics and nine hospitals and provides health insurance to more than

Risk Stratification Method for Using Lab Data to Create Actionable Intelligence for Payers

CLINICAL LABORATORIES KNOW A GREAT DEAL ABOUT PATIENTS by simply looking at patients' current and past test results. At TriCore Reference Laboratories, the goal was to add value to lab test data in ways that would allow a health insurer to assess a patient's risk for different diseases and chronic conditions. The payer could also use this knowledge to work with patients to close care gaps and reduce risk in an appropriate and proactive manner.

That led TriCore to create the quadrant table below. It uses the colors of blue for elevated risk factors, green for optimal, yellow for care gaps, and red for elevated risk factors AND care gaps. It can identify specific patients that fall within each category and do that in near real-time for the insurer.



25,000 state residents. Also, it's one of three health insurers serving the state's Medicaid population.

"Clearly, they are a gorilla in our region," VanNess said. "When our team looks at any potential customer, we must understand their pain points. We ask ourselves: How do we approach them in a new fashion with a new product to help them eliminate those pain points?

"For its electronic health record, this payer has a delivery-system-wide installation of an EMR," he said. "That might be considered a disadvantage for us, but we immediately provided a useful fact: There are many beneficiaries not accessing your health system and the test-ordering location of these specific beneficiaries was the first piece of data we presented to them.

"New Mexico is a rural state and its population of two million people is diverse," he added. "Because they live all over the state, there is a high likelihood not all of them are in the MCO's system. Knowing that fact alone was an opportunity for us."

Claims Data Is Not Enough

There was another advantage that TriCore's data provided, Grenache said. "Health insurers' claims data doesn't necessarily reflect the patient's actual diagnosis," he added. "The insurer may have lab orders for the glomerular filtration rate, for example. But that data does not necessarily include the calculations needed to show the difference between two eGFRs more than 90 days apart."

Calculating the difference between two eGFRs is a critical piece of analysis that labs can provide. "This is an opportunity to enhance information the MCO has on diabetics who have chronic kidney disease," Grenache explained.

Understand the Pain Points

"Of course, there also are more typical pain points that any healthcare system faces. Such as, how does the system provide prenatal care?" he asked. "That's a huge problem in many states and it certainly is in New Mexico.

"In addition, hepatitis C is a big problem because there are complexities associated with not treating those patients," Grenache continued. "These are just some of the pain points we know they have under their contractual obligations to provide care to Medicaid recipients." *(See sidebar on page 19, "Why a Clinical Lab Knows More about Patients with HCV than Health Insurers and Even Doctors.")*

TriCore also knew that, with regard to prenatal care, New Mexico lagged behind other states in terms of timeliness of delivering prenatal care, Grenache said. "To provide that care in a timely manner, a health system needs to find women in the first trimester of their pregnancies and then alert the health system so that it can provide the prenatal care they need," he explained.

Gaining such insights about insurers' members affords TriCore an opportunity to approach payers about the value of clinical laboratory data. One way to gain these insights is to ask a health insurer to provide its eligibility file. Getting an insurer to provide this file is no easy task. Payers guard that data closely, VanNess said. Instead, they will want to know that a clinical lab has a significant purpose in requesting the file and a way to use that data to serve the health insurer's needs.

"If our lab has the eligibility file, then we can extract the insurer's members from TriCore's immense patient registry to offer insights that could serve those patients better," VanNess said. "One payer's initial response was, 'No thank you.'"

When he got this answer VanNess was prepared with a reply: "What if we identify the exact percentage of your health plan beneficiaries who are not accessing your health system?" he asked. "The problem is you don't have that data because you're just looking at what's in your data."

At that point, VanNess offered to provide the MCO with data on its patients from HEDIS, which is the Healthcare Effectiveness Data Information Set from the **National Committee for Quality Assurance**.

"We already provide HEDIS data to all of our customers," he said. "Once we knew the insurer's members, we could match our lab test data with the MCO's eligibility file and change the conversation. Over 60% of their members don't access their delivery system, which confirmed for us that we had a significant opportunity to enhance their care delivery processes."

Eligibility Data Is Valuable

Getting the eligibility data was the key to starting TriCore's three-step process. This makes it possible for the lab to then collect and analyze the data needed to demonstrate ways it could provide actionable information that health insurers could use to actually improve patient care.

"Once our lab has the eligibility data, we know who the insurer's members are, where they live, and what health conditions they have," VanNess said. "Possessing that information means that we will have a completely different conversation when we return for the next discussion because then we can start talking about improving patient outcomes.

"Right now, this MCO sends us their eligibility file every day," he said. "Some insurers send us that file once a month.

Why a Clinical Lab Knows More about Patients with HCV than Health Insurers and Even Doctors

FOR MANY DISEASES AND CHRONIC CONDITIONS, A CLINICAL LABORATORY has test results from a variety of assays that provide a fuller picture of a patient's condition than would come from a single lab test result. During his presentation at the *Executive War College*, Rick VanNess, Director of Product Management at TriCore Reference Laboratories used the example of hepatitis C (HCV) to make this point.

He showed the slide reproduced below. It identifies each type of lab test and its role in identifying different aspects of how an HCV infection could be active within a patient. Tricore, like other labs, can use these test results to identify patients who are undiagnosed for HCV, who may be undiagnosed for the other types of complications for the disease, or who have care gaps. This information is actionable by health insurers and the providers in their networks. This is a powerful way that a laboratory can add value for payers, helping them produce better patient outcomes while lowering the overall cost of care by a substantial amount. Health insurers will pay for this type of actionable information.

HEPATITIS C: LAB KNOWS ALL

SCREEN	DIAGNOSE	TREATMENT/MONITORING
Hepatitis C Antibody	Hepatitis C Quantitation	Hepatitis C Quantitation (SVR)
	Hepatitis C Genotype	
• Identifying level of cirrhosis		
Platelets	AST/ALT	BIL/ALB
• Identifying risk of complications		
HIV	HBV	Diabetes (HA1c, Glucose)

TRICORE REFERENCE LABORATORIES
Powered by rhodesgroup

However, this MCO is more engaged and that allows our lab to match our data to the MCO's data every day. Now we can look at this insurer's hepatitis C rates and its pregnancy rates and, when we go back to them, we will have the background information we need to take the conversation to the next level," he said.

This first installment on how labs can succeed with the clinical lab 2.0 business model will be followed by additional stories about how TriCore is working with health plans on specific diseases and chronic conditions. TDR

—Joseph Burns

Contact Rick VanNess at 505-938-8906 or Rick.VanNess@tricore.org.

Market Update

Pathologists Bio-Med Labs Is Purchased by PathGroup

TWO ANATOMIC PATHOLOGY SUPERGROUPS in two different regions joined forces this month. This happened when **PathGroup** of Nashville, acquired **Pathologists Bio-Medical Laboratories** (PBM) of Dallas.

Both groups are similar in that they are very large and do a combination of anatomic, clinical, and molecular testing. PathGroup has 75 physicians and PhDs on its staff and PBM has 48 physicians and PhDs listed on staff.

Operations in 33 States

The acquisition means that PathGroup will operate in 33 sites in 10 states across the Midwest and Southeast. In its announcement, PathGroup said that by combining the two companies, the new, larger entity would have more than 1,800 employees who work in more than 75 hospitals.

Terms of the deal were not announced and experts from PathGroup and PBM did not return requests for comment before our deadline.

By adding PBM, PathGroup will have more than 123 pathologists, which PathGroup said would make it "the most comprehensive pathology network in the country."

The *Nashville Post* reported that the private investment company **Pritzker Group Private Capital** of Chicago acquired PathGroup in 2016. Pritzker invests in what it calls "middle-market businesses" in manufacturing, services, and healthcare. When Pritzker bought PathGroup, the group had about 80 pathologists and 1,200 employees, the newspaper reported.

As part of the acquisition, PathGroup announced a recapitalization with Pritzker Group. "Pritzker Group Private Capital and co-investors including **Vesey Street Capital Partners** invested alongside PathGroup's management team and pathologists," Pritzker said, adding that the pathologists would continue to hold a significant ownership stake and would lead the company's growth.

The last sizeable acquisition of anatomic pathology groups was in December, 2018. That's when **Sonic Healthcare** of Sydney, Australia, agreed to buy all of **Aurora Diagnostics**, of Palm Beach Gardens, Fla., for $540 million.

That deal marked the end of the independent life of Aurora Diagnostics, a company founded in 2006 to acquire and manage anatomic pathology group practices. At the time, Aurora said it had 220 pathologists in 32 practices located nationwide. Since it was founded, Aurora Diagnostics had struggled to find a profitable business model.

Pathology Consolidation

Both the PathGroup and Sonic Healthcare acquisitions of large anatomic pathology enterprises are sentinel events for the anatomic pathology profession. At a minimum, it is a market signal that size and scale are necessary to compete as healthcare continues to consolidate and integrate.

At the same time, these transactions may be evidence that the era of small, private practice pathology groups is drawing to a close. Healthcare's ongoing transformation may favor pathology groups with large regional coverage over pathology groups that serve just a handful of hospitals. TDR

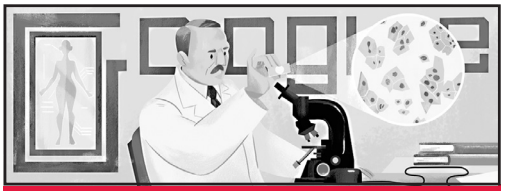
—Joseph Burns

Lab Briefs

Dr. Papanicolaou Honored by Google Doodle on May 13

Pathologists and medical laboratory professionals the world over had a surprise on May 13 if they used **Google** for an Internet search. The doodle on the Google search home page honored pathologist Dr. Georgios Papanicolaou, who developed the Pap smear test used to screen for cervical cancer.

Papanicolaou was born in 1883 in Greece. He studied medicine in Greece and Germany. In 1913, he emigrated to the United States. As early as 1928, he had noted that uterine cancer cells could be detected in vaginal smears.



Google Doodle of Dr. Georgios Papanicolaou

Wikipedia reports that "At a 1928 medical conference in Battle Creek, Michigan, Papanicolaou introduced his low-cost, easily performed screening test for early detection of cancerous and precancerous cells. However, this potential medical breakthrough was initially met with skepticism and resistance from the medical community.

"Papanicolaou's next communication on the subject did not appear until 1941 when, with gynecologist Herbert Traut, he published a paper on the diagnostic value of vaginal smears in carcinoma of the uterus. This was followed two years later by an illustrated monograph based on a study of over 3,000 cases. In 1954, he published another memorable work, the *Atlas of Exfoliative Cytology*, thus creating the foundation of the modern medical specialty of cytopathology," said *Wikipedia*.

A comprehensive trial of the techniques Papanicolaou developed for non-invasive sampling of cells from the vaginal tract was conducted in the first half of the 1950s. After this time, Pap smear testing was adopted in countries around the world.

Medscape reports that "Worldwide, approximately 500,000 new cases of cervical cancer and 274,000 deaths are attributable to cervical cancer yearly, making cervical cancer the second most common cause of death from cancer in women. Fortunately, the incidence of cervical cancer has decreased by more than 50% in the past 30+ years, largely due to the increasing use of cervical cancer screening with cervical cytology."

This reduction in deaths from cervical cancer is the reason that the Pap smear is often called the most significant medical laboratory test ever developed.

In 1961, Papanicolaou was invited to the **University of Miami** to lead and develop the Papanicolaou Cancer Research Institute there. He died in Miami on February 19, 1962, at the age of 78.

Future in Testing Dogs for Cancer?

Might pathologists find a good stream of revenue from testing dogs for cancer? At least one company thinks there is a profitable future in canine cancer testing. **One Health Company**, founded in Philadelphia in 2015, is developing cancer diagnostics and therapeutics for canines. The company's flagship product is FidoCure.

One Health Company will use the same biopsy tissue that was collected for diagnosis. Once it sequences the genes in the tumor tissue, it will recommend a targeted therapy for each dog. These therapies are the same as approved for use in humans.

One interesting aspect to this approach is dogs are often used to test cancer drugs. Thus, there is information about how dogs with different genes reacted to different therapies during these trials.

CNBC reported last month that "The company is working with 35 veterinarians in 11 states, including California, Washington, Colorado, Florida, Illinois and New York, and is looking to bring that total to 200. Those doctors have used FidoCure for 116 dogs in the past 14 months, with more than 50 in just the last three months. One Health is expecting to have mapped 1,000 canine cancers within the next year."

There is no published information about the cost of this service. However, **Global Market Insights** reported that "the market for pet cancer therapeutics is growing at 10.8% annually, and will increase from $178 million in 2018 to $300 million by 2024."

iPads, iPhones for Lab Test Reporting

In Australia, the 325-bed **Wagga Wagga Base Hospital** in the City of Wagga Wagga, New South Wales (NSW), Australia, is about to launch a pilot program to deliver medical laboratory test results in real time to the iPads, iPhones, and Apple Watches of emergency department physicians.

This is a proof-of-concept project overseen by **NSW Health** and the **Murrumbidgee Local Health District** and supported by industry partners.

"We want to give clinicians fast access to meaningful data insights which can help them to identify patients at risk of deterioration, and provide more timely mobile access to pathology [medical laboratory] results and X-rays," said Dr. Stephen Wood, the hospital's emergency department director.

The project will use the Miya Precision clinical decision support tool from **Alcidion** to send notifications to clinicians. "The platform is able to deliver additional clinical insights, including deteriorating kidney function, coagulation management, antibiotic stewardship, management of gram-negative bacterial infections, low blood glucose, and sepsis monitoring," said Alcidion Group CEO Kate Quirke.

'All of Us' DNA Project Hits Milestone

In 2015, the **National Institutes of Health** (NIH) announced the creation of the "All of Us" initiative. The goal is to genetically sequence and collect health data on one million people here in the United States.

Recent numbers released by the NIH reveal that 192,000 people have enrolled. Of that number, 143,000 people have finished with all the initial steps involved in their participation.

On May 6, the NIH also announced that it was releasing the beta version of its interactive data browser. This will allow interested parties to see the data that NIH is making available for health research.

Patient privacy is getting full attention in the All of Us program. *FierceHealthcare* reported that the NIH "is storing participant data on a secure, encrypted platform that receives routine updates. The program strips data of personal identifiers, such as names and addresses, and displays information only in aggregated groups. The public data browser also limits cross tabulation, or analyses of data using two or more variables such as age and sex." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Canada faces a similar shortage of medical technologists (MTs) as exists in the United States. "We have reached the point now where some laboratories have been closed for weeks due to insufficient staffing, which is a cascading problem for patients and the healthcare system," stated Maria Klement, President of the **Canadian Society for Medical Laboratory Science** in an interview with *Global News*. It also reported that there are currently 14,000 members of CSMLS in Canada.

MORE ON: *Med tech shortage in Canada*

Klement also said, "About half of all medical laboratory technologists [in Canada] will be eligible to retire in the next 10 years. Shortages are already being felt in communities across Canada and the new supply of graduates will not be enough to offset retirements in virtually every province and territory." *Global News* reported that 400 new students must be trained annually to stay up with these retirements.

FEDERAL JUDGE SENDS LAB REP TO JAIL FOR 4 YEARS

Former clinical laboratory sales representative Seth Rehfuss, 44, of the Somerset section of Franklin Township, N.J. is the first of three sales reps to be sentenced in a federal court case involving fraudulent lab tests. On May 10, a federal judge gave Rehfuss a 50-month sentence. Rehuss also agreed to pay restitution of $434,963 and forfeit an additional $66,844. Waiting to be sentenced are former sales reps Sheila Kahl, 47, of Ocean County, N.J., and Kenneth Johnson, 39, of Lorton, Va. Both have pled guilty and will be sentenced in coming weeks.

MORE ON: *Lab Fraud*

It was U.S. Attorney of the District of New Jersey, Craig Carpenito, who indicted Rehfuss, Kahl, and Johnson. His press release about Rehfuss' sentencing said, "To get the tests authorized, Rehfuss used advertisements on Craigslist to recruit healthcare providers for the scheme. The healthcare providers were paid thousands of dollars per month by Rehfuss and others to sign their names to [laboratory test] requisition forms authorizing testing for patients they never examined or had any interaction with." The press release said that two clinical laboratories performed lab tests that were billed to the Medicare program, but the labs were not named. This case is a reminder for lab executives and sales reps that U.S. attorneys are willing to criminally prosecute principals in medical labs that fail to follow federal law.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 10, 2019.

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Process Improvement Institute

Pursuing Excellence in Continuous Improvement

October 15-16, 2019

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New this year:

Proven steps to offset PAMA revenue losses with smart cost-cutting while boosting productivity of automation, analyzers and staff performance

plus…

Sessions on how your lab team can add value and generate new streams of lab revenue!

It's everything about quality and management in clinical laboratories and pathology groups!

For updates and program details, visit www.labqualityconfab.com

UPCOMING…

- ***Lab Added-Value Breakthroughs at Executive War College: Successful Collaborations in Managing Opioid Use/Abuse.***
- ***Protecting Professional Pathology Income: Proven Steps to Trim Costs while Sustaining High Quality and Service.***
- ***Saving Mobile Phlebotomy Service after Sale of Local Lab: One Lab Manager's Innovative Solution to Help Patients.***

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