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Major Lab Agreement Involving Hospitals in 10 States!

Labcorp, Ascension Health Ink $400m Pact *(See pages 3-5)*

labcorp Ascension

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Artificial Intelligence 'Invades' Pathology, Billing

PREDICTIONS ABOUT THE POTENTIAL OF ARTIFICIAL INTELLIGENCE (AI) to transform nearly every area of healthcare are about to become reality. For the profession of laboratory medicine, AI is making speedy inroads into two areas. The first is anatomic pathology and the second is lab coding/billing/collections—the revenue cycle management (RCM) functions essential to the financial health of every laboratory organization.

Using artificial intelligence to analyze whole-slide images of tissue and match the diagnostic accuracy of an experienced subspecialist pathologist has been the Holy Grail of companies working in this field. Now, in Europe and the United States, the first AI-powered solutions that automate digital pathology image analysis for primary diagnosis are obtaining regulatory clearance. First-mover pathology groups are in the earliest stages of incorporating AI into their daily clinical workflows. Our analysis of the US$97 million in investment capital raised by **Harrison.ai** of Australia—that includes funding from **Sonic Healthcare**—is the latest example of swift progress in advancing AI technologies to the point where they function acceptably in the primary diagnosis of many types of cancer. *(See pages 6-8.)*

The second area of medical laboratory operations where pathologists and lab administrators can expect to see a multiplicity of AI-powered products is in lab test billing, coding, and collections. There are two reasons for this: One, any contribution AI can make to automate labor-intensive functions in coding, billing, filing appeals, and collecting from patients can reduce RCM costs as well as increase the total amount of revenue collected from the same number of claims. Two, AI in various RCM functions may only need to manage a certain number of variables. For example, confirming a patient's identity may need only 10 or 15 factors to be checked, assessed, and verified. It is easy to train today's generation of AI-powered lab RCM tools to work with these factors and develop accurate answers. *(See pages 16-18.)*

Recognizing the fact that artificial intelligence is about to move into clinical labs and anatomic pathology groups for use in a variety of tasks and functions, our upcoming 27th annual *Executive War College on Lab and Pathology Management* in New Orleans is scheduling presentations by labs who are pioneering the use of AI in both surgical pathology and revenue cycle management. TDR

Labcorp to Buy Outreach, Manage Ascension Labs

It's largest lab transaction in 50 years involving a major health system and a big commercial lab

CEO SUMMARY: In a blockbuster deal valued at almost half a billion dollars, Labcorp will manage dozens of hospital labs in 10 states on behalf of Ascension Health, one of the biggest health systems in the country. Labcorp will also spend $400 million to acquire certain assets of Ascension's outreach laboratory services. Labcorp's CEO characterized the deal as "one of the most significant of its kind."

Like the Chinese adage about steady drops of water wearing away the rock, after four decades of persistent effort to convince hospital CEOs that a commercial lab can manage labs better and cheaper than hospital staff, one commercial entity has just won the biggest-ever agreement involving a major hospital system and a public lab company.

The deal is worth almost half a billion dollars and involves **Labcorp** and **Ascension Health**, the Catholic health system based in St. Louis, Mo., that operates 142 hospitals in 19 states and the District of Columbia.

Announced on Feb. 10, the deal has two primary elements. First, Ascension will sell its hospital laboratory outreach business at a number of locations to Labcorp. Second, Labcorp will manage the inpatient laboratories of many Ascension hospitals.

The new lab management agreement covers at least 75 of Ascension's hospital labs in Alabama, Florida, Kansas, Maryland, Michigan, New York, Oklahoma, Tennessee, Texas, and Wisconsin. Financial terms of this part of the agreement were not announced.

As is true in many of the hospital/health system agreements with public lab companies that have happened since the mid-1990s, Ascension will receive a substantial amount of cash. Labcorp will pay approximately $400 million for the outreach lab businesses Ascension is selling.

This cash infusion is likely a most welcome development at Ascension. The chain had operating revenue of $27.2 billion in FY 2021, including $5.7 billion in net income, according to *Hospital CFO Report*. However, the prior year, in FY 2020, Ascension posted a net income loss

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of just over $1 billion on operating revenue of $25.3 billion.

Ascension's sizeable loss in 2020 (the year the pandemic commenced) is notable for an interesting reason. Over the past 25 years, a substantial proportion of hospital/health system lab outreach sales to commercial lab companies have involved hospitals which had been losing money and needed the capital infusion that the sale of their lab outreach program would bring them.

'Notable Opportunity'

In commenting on this agreement, during a fourth-quarter earnings call on Feb. 10, Adam Schechter, CEO at Labcorp said, "this is a notable opportunity for us and one of the most significant deals of its kind in the sector."

This agreement should benefit Labcorp in multiple ways. First, Labcorp can use the Ascension lab outreach businesses it is buying in the different regions to expand its existing market share of physicians' office testing. Second, its management of inpatient laboratories at a number of Ascension hospitals will feed its esoteric testing division at the expense of other reference labs, such as **Quest Diagnostics**, **Mayo Clinical Laboratories**, and **ARUP Laboratories**.

The third potential benefit might be overlooked by anatomic pathologists. In managing inpatient labs, Labcorp is in a position to direct tissue specimens to its own pathologists, particularly the more complex cancer cases that require extensive workups and multiple diagnostic procedures. That would reduce case referrals to the local pathology groups currently serving Ascension hospitals.

Financial Returns

Labcorp's Schechter was optimistic about the positive financial impact the Ascension pact would have on his company's financial performance. The deal is probably being arranged in such a fashion that Labcorp will get to add the revenue generated by the hospital inpatient laboratories it is managing to its top-line revenue.

To that point, Shecter told investors and analysts during the call that "we expect the first-year annualized revenues to be between $550 million and $600 million from the combined hospital business and lab asset acquisition. "While operating margins are expected to be less than segment margins initially, they are expected to improve each year. The transaction is expected to be accretive to our earnings and cash flow in year one and should return its cost of capital by year two."

During the Feb. 10 conference call, Labcorp announced that its full year revenue for FY 2021 was $16.1 billion, up from $14 billion in 2020. The company's free cash flow for 2021 was $2.6 billion. A substantial portion of that free cash flow was generated by COVID-19 testing. For that reason, Labcorp has a big war chest of cash it can use to go out and do more deals with hospitals and health systems.

Collaboration in Other Areas

Schechter mentioned that Labcorp and Ascension Health may explore other areas in which to collaborate. "We believe there will be opportunities for us to work together in many different ways as we go into the future—not just with hospital work, by the way," he commented. "We're going to explore clinical trial work together, and oncology opportunities that enhance patient access."

This is where the company's **Labcorp Drug Development** (formerly **Covance**) gives Labcorp an advantage over its larger competitors. Labcorp is a major player in clinical trials and can help Ascension generate additional revenue by helping enroll its patients in a wide range of clinical trials and research studies.

One factor that may have played a role in Ascension Health's willingness to sell its hospital lab outreach businesses and engage Labcorp to manage inpatient labs at many of its hospitals is the ongo-

ing financial erosion and lost revenue attributed to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) cuts that were mandated by the Protecting Access to Medicare Act of 2014 (PAMA).

Under PAMA, lab prices were cut by a maximum of 10% in 2018 and another 10% cut in 2019. The additional price cuts scheduled for implementation in 2020, 2021, and 2022, have been delayed in response to the pandemic. Because most regional laboratories work on thin operating margins, the PAMA fee cuts have caused a significant number of community laboratories to close, to file bankruptcy, or to sell.

PAMA Price Cuts

One example of a health system selling its lab outreach business in response to the Medicare Part B lab price cuts was the decision by Eugene, Oregon-based **PeaceHealth** to sell **PeaceHealth Laboratories** to Quest Diagnostics in 2017. At the time, Ran Whitehead, CEO of the lab, told THE DARK REPORT that financial modeling indicated the PAMA price cuts would erode the financial stability of the laboratory business. Thus, the health system administration decided to shed the outreach lab business. *(See TDR, "PeaceHealth Outreach Laboratory Sells to Quest Diagnostics," Feb. 21, 2017.)*

Schechter recognized this factor during the Feb. 10 call. "We think that the future is very bright for diagnostics and our ability to grow, but it's not through pricing, and there will continue to be pricing pressure. It's more through geographic expansion, hospital deals, and continued growth in the segment itself."

Another important element to watch is how much turnover happens with the lab staffs at the Ascension hospitals where either or both the lab outreach program is being sold and the hospital laboratory will be managed by Labcorp.

Currently, the "Great Resignation" is a major trend. Across the nation, clinical labs and pathology groups are reporting an acute shortage of staff. This is true at every position, from phlebotomists, couriers, and accessioners to medical technologists (MTs), microbiologists, even CLIA lab directors.

Both hospital and independent labs report that staffing levels are only at 70% to 80% of necessary and authorized levels. To fill that gap, most hospital labs are paying substantial overtime, as well as engaging *locum tenens* med techs and other technical positions.

Lab Staff Retention

Labcorp thus faces the risk that a significant number of key technical staff at Ascension hospital labs may opt to go across town and work for competing hospitals.

Given the signing bonuses being offered to MTs by many hospitals, staff retention may turn out to be one of Labcorp's biggest challenges as it assumes operational responsibility at the Ascension laboratory sites. TDR

Labcorp Focuses on Lab Outreach Business

THE OUTREACH LABORATORY MARKET HAS BEEN A PRIME TARGET of Labcorp acquisitions over the past two decades.

For example, in July 2021, Labcorp acquired the outreach laboratory business of Minnesota-based **North Memorial Health** and began managing the system's inpatient lab. Further back, Labcorp made these similar deals:

- In 2017, Labcorp bought the lab outreach business of **Mount Sinai Health System** in New York City. *(See TDR, Jan. 30, 2017.)*
- In 2013, the owners of **Genesis Clinical Laboratory** in Berwyn, Ill., sold their lab outreach business to Labcorp. *(See TDR, July 29, 2013.)*
- In 2000, it acquired the clinical ambulatory laboratory business of **Franciscan Missionaries of Our Lady Health System** in Baton Rouge, La. *(See TDR, Sept. 14, 2000.)*

Pathology Investment in AI Signals New Trend

Deal between pathology, radiology, and AI firms shows how integration of diagnostics is advancing

CEO SUMMARY: Australian artificial intelligence (AI) company Harrison.ai got AU$129 million from multiple investors, including both Sonic Healthcare—Australia's largest pathology group—and I-MED Radiology Network. Pathology's growing interest in AI tools, along with the growing relationship between radiology and pathology business interests, indicate more opportunities in integrated diagnostics that use AI.

TECHNOLOGICAL ADVANCEMENTS IN DIAGNOSTICS—AND A BLOOMING SYMBIOTIC RELATIONSHIP—have moved the professions of anatomic pathology and radiology into closer partnerships in recent years, a business shift pathologists should be keen to follow.

The latest sign that pathology and radiology are poised for integration is the recent investment in a little-known artificial intelligence (AI) company in Sydney, Australia. On Dec. 1, 2021, **Harrison.ai** announced that it had raised AU$129 million (USD$97 million) from multiple sources, including from Australia's largest clinical pathology company, **Sonic Healthcare**.

"These companies could create an imaging powerhouse using AI," said Ajit Singh, PhD, Partner at **Artiman Ventures**, a venture capital fund in Palo Alto, Calif., and former CEO at **BioImagene**, an oncology diagnostics startup that **Roche** acquired.

While the deal itself is not a blockbuster in scope, it marks the second time in five months an AI company has been involved in a partnership with a clinical laboratory, commented Singh, who is also Adjunct Professor at **Stanford Medicine's** Rad/Molecular Imaging Program and serves as an adviser to **Ibex Medical Analytics** in Tel Aviv, which develops AI-based cancer detection software for pathology. In July, **PathAI**, a technology company in Boston that develops image analysis software, acquired **Poplar Healthcare Management** of Memphis, an anatomic pathology group with a large national base of clients. *(See TDR, Sept. 7, 2021.)*

AI Tools for Diagnostic Use

The new funds mean Harrison.ai has raised AU$158 million (USD$118 million) over the past two years, which the company is using to develop AI tools for clinical use.

The most significant part of the deal may be new equity investments from two Australian companies:

- Sonic Healthcare, which runs clinical and pathology labs and performs radiology imaging.
- **I-MED Radiology Network**, which handles the largest number of radiology exams in Australia.

Also funding the deal were venture capital companies **Horizons Ventures**, **Blackbird Ventures**, and **Skip Capital**.

The equity investments are important because Harrison.ai also announced a

partnership with Sonic to co-develop new clinical tools in pathology that will use AI to improve the efficiency of pathology diagnostics.

Bridging Two Professions

In an interview with THE DARK REPORT, Singh explained the significance of this announcement.

"For the past two decades, pathologists and radiologists have talked about the importance of integrating the two professions," he said. "This funding announcement from Harrison.ai seems to have moved the two sides even closer to the altar.

"The implications of this deal are far and deep," he added. "In Australia, three reasonably significant players in radiology and pathology are involved in this deal. Keep in mind that, as a country of about 26 million people, Australia is about the size of Canada, making it an important market in the English-speaking world."

Harrison.ai straddles the radiology and pathology markets, although it specializes in diagnostic imaging. Singh said the company's new investments from I-MED and Sonic are newsworthy as the pathology industry looks to the future.

Integration of Diagnostics

"Just imagine what could develop now that these three companies are working together," Singh noted. "I-MED, the largest radiology company in Australia, is now working with Sonic, which is the largest pathology company in Australia and the third largest pathology company in the world after only **Labcorp** and **Quest Diagnostics**. I-MED and Sonic are now working with Harrison.ai to develop AI tools for use in both worlds.

"In one way or another, imaging involving radiology and pathology encompasses almost all of diagnostics," he added. "I would estimate that when you combine all the imaging that's done in radiology and anatomical pathology, you get about 70% or so of all diagnostics work worldwide. What's left after imaging is routine diagnostics, which makes up the remaining 30% or so. That's why I say that the strategic implications of this deal are significant."

The equity investment that Sonic is making in Harrison.ai is important because AI companies working in diagnostics need patient cases so that they can demonstrate the potential value of applying AI tools to patient care, Singh explained.

"After all, the goal of AI in diagnostics is to improve the consistency and efficiency of pathologists and radiologists by supplementing what diagnosticians do," he said. "Any company developing artificial intelligence tools for radiology or for pathology needs to find customers to buy that software. Therefore, companies developing AI tools for diagnostics need to have the backbone that comes in the form of a pathology network or a radiology network."

Multiple Challenges

From that perspective, the new Australian partnership solves challenges on multiple levels: Harrison.ai can now weave itself into a network with patients, while Sonic and I-MED gain greater access to AI technology.

"The pathology and radiology companies have recognized that if they don't have AI, they will have a problem in the future because they need AI to increase efficiency and throughput," Singh said. "And the AI software companies have recognized that without a big source of patients and a constant flow of images, they have a problem."

THE DARK REPORT reached out to Sonic Healthcare and Harrison.ai for comment. A spokesperson said Sonic had no further comment beyond the joint announcement about the deal that the parties issued on Dec. 1. Harrison.ai did not respond back.

Observers in the anatomic pathology world watching these and similar deals should reach two conclusions.

Market Transactions Show How AI Companies and Diagnostics Providers Need Each Other

IN JULY, A BOSTON TECHNOLOGY COMPANY called **PathAI** that develops artificial intelligence (AI) software for pathologists bought **Poplar Healthcare**, a clinical laboratory in Memphis, Tenn.

In that deal, PathAI acquired access to patients served by Poplar, a national pathology provider, as well as Poplar's lab facilities, management team, and 350 employees, including 25 pathologists. PathAI also got Poplar's library of 50,000 patient samples, dating back to the company's founding in 1995. The move was significant because it was the first time an AI developer acquired a pathology lab.

AI in Digital Pathology

In more recent news from Australia, **Harrison.ai** is teaming up with Sonic Healthcare to pursue AI-related work, including in digital pathology. For Ajit Singh, PhD, the latter development dwarfs the deal involving PathAI and Poplar.

"The lab that the Boston company bought was a deal worth several million dollars," Singh commented. "In the big picture, that deal is relatively small. The scale of the Sonic deal is orders of magnitude bigger, and it's significant because it shows that both pathology and radiology companies have invested in AI."

This melding demonstrates that AI has come of age, meaning that the technology is useful in helping pathologists and radiologists work more efficiently to improve patient care. Does that mean AI is as good at identifying tumors or any malignancies as human physicians?

"That's a very good question," Singh said. "AI is not going to replace what pathologists or radiologists do. But over time, AI has become more useful in clinical settings. However, it still has limitations."

AI Solves Inconsistencies

One of the major limitations is AI doesn't work well for all healthcare applications. "It's good for those applications where the number of variables is small," Singh said. "If you apply AI to breast cancer, for example, the number of free variables is very large. That's a difficult problem for AI to solve." *(See TDR, "Artificial Intelligence Ready for First Use in Anatomic Pathology," Apr. 12, 2021.)*

"On the other hand, if you apply AI to prostate cancer or melanoma, the number of free variables is small," he added. "Therefore, AI is much more effective. Similarly, in radiology, if you apply AI to brain imaging, the number of variables is much higher than if you apply AI to identifying fractures, polyps, or lung nodules."

Also, despite common misconceptions, the purpose of AI is not to "beat" the best pathologists or radiologists. Instead, AI helps physicians make more consistent diagnoses.

"If I run the same slide five times, I should get the same results, I should not get five different results," Singh said. "When pathologists or radiologists are inconsistent, that creates a lack of confidence even among the best clinicians. AI solves the consistency problem."

First, pathology and radiology groups may pack a one-two punch for future investors, a new status that is worth exploring.

Second, more AI vendors are seeking partnerships with pathology groups to meet their pathology business needs, which opens doors for opportunities and new services that pathology groups can offer their clients. TDR

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Notable People

LIS Pioneer and Entrepreneur Sidney Goldblatt, MD, Dies at 87

He served as CEO at Sunquest Information Systems and co-founded many clinical lab-based companies

In the 1970s, the arrival of automated lab analyzers—such as the **Technicon** SMAC 6 and SMAC 12—also coincided with the introduction of the first laboratory information systems (LIS). Probably no single pathologist had a bigger role in developing useful LIS products than Sidney Goldblatt, MD, who founded **Sunquest Information Systems** in 1979.

Last month, the family of still-active pathologist Goldblatt, 87, announced he had died on Jan. 3, 2022. A cause of death was not released. He was described 20 years ago in THE DARK REPORT as "one of the lab industry's shrewdest minds." *(See TDR, March 11, 2002.)*

Sidney Goldblatt, MD
1934-2022

"Sid's interests, his intellectual abilities, and his drive did not have to do with money. Instead, they had to do with advancing healthcare and advancing laboratory systems," said Dennis Winsten, President at **Dennis Winsten and Associates**, an LIS consulting firm in Tucson, Ariz. Winsten worked with Goldblatt at Sunquest Information Systems in the 1980s.

Pioneer in LIS Technology

Goldblatt—known simply as "Dr. G" to many—was among the few pioneers for laboratory information systems as that technology debuted in the late 1970s. Intrigued by the need to move away from paper-based lab charts that were prone to human error, Goldblatt dabbled with building his own LIS in the 1960s while working as a pathologist at **Conemaugh Valley Memorial Hospital** (now known as **Conemaugh Health System**) in Johnstown, Pa.

"Sid paired up with a sophisticated IT professional and built a homebrew LIS system in his lab," said Bruce Friedman, MD, Emeritus Professor of Pathology in the Department of Pathology at **Michigan Medicine** and the **University of Michigan** in Ann Arbor, Mich. "They thought that their system had a broader potential."

That technology in part led Goldblatt to co-founding Sunquest Information Systems in Tucson, Ariz., in 1979. Eventually, he became CEO there, a position he held from 1986 until its sale to **Misys Healthcare** in 2001 for $404 million. During that time, Goldblatt helped the company go public in 1996 before the Misys acquisition eventually brought Sunquest back as a private company.

In 2012, **Roper Technologies** in Sarasota, Fla., bought Sunquest for $1.4 billion. Just last month, Roper-owned **CliniSys** announced it would combine the LIS technology of Sunquest and **Horizon Lab Systems**. *(See TDR, Jan. 31, 2022.)*

Early on, Sunquest and **Cerner Corporation** in Kansas City, Mo., were

the two major LIS vendors. Goldblatt's dedication to the data and how to properly use it served him well over the years, Friedman noted. "It's an exacting, precise, regulated field," he said. "It is not for fly-by-night businessmen and systems."

Focus on Lab Customers

When Goldblatt became CEO of Sunquest, he and the late Neal Patterson—former CEO at Cerner—were known as the top leaders steering the technology, but both stayed focused on customers.

"It was a smaller industry then," Friedman recalled. "You could get Sid or Neal Patterson on the phone. It was a much more informal relationship back then between [health information technology] companies and customers."

Friedman first got to know Goldblatt at an industry event that Friedman started in 1983 called Automated Information Management in Clinical Labs (AIMCL). The conference was held at the University of Michigan. Sunquest participated at the first conference. "He was often there personally," Friedman said of Goldblatt's frequent attendance at the events. AIMCL ran for 21 years.

The pathology industry first got involved with automation and data analysis in the late 1970s, largely because of the amount of patient information clinical laboratories generated. "When I started in February 1982, there were only a few pathologists involved in the field that would later be called pathology informatics," Friedman said. "Sid was one of them."

'It Sticks in Your Mind'

One day while he was working at Sunquest as the Director of Marketing, Winsten had a memorable meeting with Goldblatt to discuss an issue. Winsten had traveled to Pennsylvania to talk to his CEO while the latter was performing an autopsy.

"Sid was still working as a practicing pathologist for many years at Conemaugh Valley Hospital," Winsten remembered. "I needed to go there and talk with him about the LIS system. And he was doing an autopsy.

"I was talking business with Sid while he's weighing the lungs of some poor deceased coal miner," he added. "If you've ever seen a miner whose lungs were totally black, it sticks in your mind."

Goldblatt continued to perform autopsies throughout his career at **ForensicDx**, located in Windber, Pa., which Goldblatt ran with his son, Curtis Goldblatt, MD, who followed in his father's footsteps and became a pathologist.

After leaving Sunquest in 2001, Goldblatt founded other companies besides ForensicDX. He started **Goldblatt Systems** in Tucson in 2001 and served as CEO until his death. Goldblatt Systems offers a platform that provides structured clinical data to provider and payers.

Cancer Genetics, PGx

He also founded **MolecularDx** in Windber in 2014, which focuses on cancer genomics and pharmacogenetics. At one point, the company's office was in a space at the **Chan Soon-Shiong Institute for Molecular Medicine at Windber**.

"When we first started the research institute at Windber, Dr. Goldblatt would come to my office on a regular basis to discuss the type of genomic and proteomics work we were doing," F. Nicholas Jacobs, founding president of the institute, told *The Tribune-Democrat* in Johnstown, Pa.

Despite the success of commercial labs, Goldblatt said in 2002 that hospital-based laboratories held stronger relationships with patients—a notion that he likely held until his death.

"Hospital labs have an advantage over **Quest Diagnostics** and **Labcorp**," Goldblatt commented back then. "They have strong physician relationships, local access, inpatient and outpatient services, and complete patient records. These are assets that hospital labs should use to provide a better quality of lab testing services." TDR

Lab Market Update

Quest and Walmart to Expand Consumer-Initiated Test Options

More than 50 common clinical laboratory tests are offered online through new agreement

Serving consumers interested in ordering their own clinical laboratory Tests is a goal in an expanded collaboration involving **Quest Diagnostics** and **Walmart**. This is also consistent with The Dark Report's prediction that retail pharmacies are poised to expand the diagnostic testing services they offer to customers.

The development gives Quest a greater chance to meet patients online while also capitalizing on the growing familiarity of consumer-initiated testing, said Cathy Doherty, Senior Vice President and Group Executive of Clinical Franchise Solutions and Marketing at Quest.

$2 Billion Market Opportunity

"The consumer-initiated testing market is poised for breakout growth," Doherty told The Dark Report via comments provided through Quest's communications office. "We expect this market will continue to evolve and grow over the next five years. We have done our best to size it, and we estimate that consumer-initiated testing overall could be a $2 billion market."

The new agreement builds on the Quest–Walmart relationship that began with a pilot program involving 15 Walmart stores in Florida and Texas starting in 2017. Under the new agreement, Quest in Secaucus, N.J., will offer more than 50 different tests for online ordering.

The tests to be offered will be for digestive health, allergies, heart health, women's health, sexually-transmitted disease, and infectious disease. Consumers purchase tests via a website *(walmartquestdirect.questdiagnostics.com)*. The orders are reviewed and, if found to be medically necessary, ordered by a physician. Depending on the test, consumers either receive at-home collection kits or are prompted to schedule an appointment at a Quest location or at certain Walmart pharmacies.

The service also includes access to a telehealth provider for an explanation of test results and prescriptions, if needed. "We recognize the value of the patient/physician relationship and have worked with physicians to ensure we offer consumers a responsible menu of tests that can be incorporated into a physician-directed health and wellness plan," Doherty explained.

Doherty added that the SARS-CoV-2 pandemic accelerated the trend of consumers taking more initiative for how they manage their own healthcare. However, she emphasized that trend was building well before the onset of the pandemic.

Labcorp Home Testing

In related news, **Labcorp** in Burlington, N.C., announced on Feb. 4 that it launched its own direct-to-consumer testing program. Consumers can order tests online, collect samples at home, and schedule test appointments at Labcorp patient centers, including at Walgreens locations.

These moves by the nation's two largest laboratory companies show that they see opportunity in serving the growing number of consumers who want to manage their healthcare needs. TDR

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Regulatory Update

Labs Should Be Cautious about 'Surprising' EKRA Ruling

In civil case in Hawaii, judge rules a clinical laboratory sales rep's commission did not violate the law

Confusion about when it is legal under two federal laws to pay commissions to sales reps based on volume and/or revenue has existed since the passage of the federal Eliminating Kickbacks in Recovery Act of 2018 (EKRA). Now, a district court judge in Hawaii has surprisingly ruled that payments of percentage-based sales commissions to clinical lab sales representatives do not violate EKRA.

From its enactment in 2018, the language in EKRA has clashed with provisions in the Anti-Kickback Statute (AKS), particularly regarding the permissibility of sales commissions for clinical laboratory sales reps. The AKS makes an exception for commissions paid to employees who receive a W2 tax form, while EKRA does not. Laboratory sales teams have faced confusion from the conflict.

However, attorneys familiar with the case warn clinical laboratory directors and pathologists to be wary of the Hawaii judge's opinion.

Caution about Judge's Ruling

"I would definitely urge caution," said Alexander Porter, a partner at **Davis Wright Tremaine** in Los Angeles. "The ruling does carry some weight because it's the only court to have actually interpreted what EKRA means. But that doesn't mean that other courts are necessarily going to follow what this court said."

It's also not clear yet how the **U.S. Department of Justice** (DOJ), which enforces EKRA, thinks about the ruling, said Porter, who is a former Assistant U.S. Attorney and Health Care Fraud Coordinator in California. "What is DOJ's view on EKRA? Do they agree with this case? My bet is they don't," he noted.

EKRA Rules and Termination

The Hawaii case, **S&G Labs Hawaii** vs. Darren Graves, stems from an employment contract dispute. Graves, the defendant, was a sales account manager at S&G Labs. He received an annual base salary of $50,000 plus percentages of monthly net profits generated by his client accounts and by the client accounts handled by the employees whom he managed, according to records from **U.S. District Court in Hawaii**. Graves' total annual compensation could have reached $1 million.

In early 2019, the company's general counsel informed the CEO that EKRA prohibited S&G from compensating sales employees based on the number of tests S&G performed for their client accounts. The CEO attempted to renegotiate Graves' contract but was unsuccessful; she later suspended Graves and then fired him in September 2019, at least partially because Graves had contacted a competing lab about working there and urged other S&G sales representatives to also leave.

S&G filed suit against Graves in March 2020 for breach of contract. Graves filed a counterclaim against S&G for unlawful termination and for not paying his previously agreed upon compensation.

A hearing was held on July 16, 2021, to address the applicability of EKRA aspects to the case. The court issued its ruling on EKRA on Oct. 18, 2021. Other parts of the case will continue to trial.

"The commission-based compensation provisions of Graves' employment contract with S&G did not violate EKRA, and therefore S&G's failure to pay him according to those provisions constituted both a breach of contract and a violation of Hawaii [law]," concluded U.S. District Judge Leslie Kobayashi.

Attorney David Gee, a partner at Davis Wright Tremaine, observed that the ruling bucks the general belief that payments of sales commissions that are based on the volume or value of patient referrals from the sales rep's account run afoul of EKRA and—for contract sales reps who receive a 1099 tax form—the AKS.

"The opinion is a little bit surprising from my standpoint as somebody who has advised labs since EKRA was issued," Gee said. "There are also some Anti-Kickback Statute cases that have followed the same reasoning as the Hawaii court, that a sales rep isn't really referring anything. But that's a minority view."

Specific Language in EKRA

Kobayashi centered her decision on a specific part of the EKRA law that states it is illegal to:

- Receive any payment or renumeration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory;
- Pay or offer renumeration to induce a referral of an individual to a recovery home, clinical treatment facility, or lab;
- Pay or offer renumeration in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory.

The judge drew a distinction between an individual as noted in the law and an organization.

EKRA Confused Labs from the Start

IT WAS CONGRESSIONAL EFFORTS TO COMBAT THE OPIOID CRISIS IN THE U.S. that spawned the Eliminating Kickbacks in Recovery Act of 2018 (EKRA).

EKRA was part of the related Communities and Patients Act that lifted restrictions on medications for opioid addiction and sought to limit overprescribing of opioid painkillers. Originally, EKRA was designed to target practices of sober homes and substance abuse treatment centers.

Late in the process of drafting the bill in Congress, clinical laboratories were added to the list of providers named in the Act. *(See TDR, Dec. 3, 2018.)*

A long-standing point of contention is that EKRA's anti-kickback provisions cover all payers, while the Anti-Kickback Statute (AKS) applies just to federal healthcare programs.

Thus, conduct protected under the AKS is treated as a criminal offense under EKRA—including certain common clinical lab practices, such as compensating sales reps on a commission-based formula related to any third-party-payer business they generate.

The first conviction under EKRA occurred in January 2020. The case involved a provider who requested a bribe from a clinical laboratory in exchange for referring patient specimens to the laboratory. *(See TDR, Feb. 17, 2020.)*

Theresa Merced, a manager at an opioid treatment center, pleaded guilty to three counts: soliciting a bribe, making a false statement, and attempting to alter evidence in the case.

Merced was sentenced to five months in prison followed by five months of home detention, and she was ordered to pay a $55,000 fine, according to the U.S. Department of Justice.

Kobayashi's reasoning was that Graves, by virtue of his employment, was not referring specific individuals to S&G for testing, but rather received commission for getting client organizations to use S&G.

"Undoubtedly, Graves' commission-based compensation structure induced him to try to bring more business to S&G, either directly through the accounts he serviced himself or through the accounts of the personnel under his management," Kobayashi wrote. "However, the 'client' accounts they serviced were not individuals whose samples were tested at S&G."

Rather, the clients were physicians, substance abuse counseling centers, or other organizations in need of having people tested, she emphasized.

Other EKRA Arguments

It didn't take long for another party in an unrelated case to try and use the Hawaii decision to dismiss similar allegations.

Mark Schena, president at **Arrayit** in Sunnyvale, Calif., faces various charges of healthcare fraud from federal prosecutors. In part, the government alleges Schena and others paid one or more marketers to recruit physicians to order blood-based allergy testing from Arrayit for their patients.

On February 3, 2022, Schena's lawyer filed a motion in the U.S. District Court of San Jose, Calif., to have some counts against his client dismissed based on the Hawaii ruling. "Based upon the analysis in S&G Labs [and] the text of EKRA itself … this court should dismiss counts four through six of the superseding indictment because the conduct that is alleged in those counts is not cognizable as an offense under EKRA," according to the motion to dismiss.

Two important points stand out to Gee and Porter regarding the U.S. vs. Schena case. First, the DOJ criminally indicted Schena and will prosecute EKRA's provisions in that light. The S&G vs. Graves case, however, is a civil matter that raised issues about enforceability under EKRA of the compensation terms of a sales employee agreement, Gee said.

"The burden of proof is different for criminal and civil," he explained. "And it's not entirely clear what precedent the Hawaii case has as far as the breadth of EKRA because it's a criminal statute. It's prosecuted by the Department of Justice."

In criminal cases the prosecution shoulders the burden of proving guilt beyond a reasonable doubt.

But in civil cases the plaintiff has the burden of proving the matter by a preponderance of the evidence. In other words, that it is more likely than not that the claim is true, according to the **Legal Information Institute at Cornell Law School** in Ithaca, N.Y.

Put another way, what Graves had to prove regarding EKRA in the Hawaii case is likely a different standard than what Schena will have to show.

Yet to come is the second, and bigger, point of the U.S. vs. Schena motion: the DOJ's response to it.

The government is expected to file an opposition to the motion to dismiss on Feb. 28. The Dark Report will provide updates in future issues.

The opposition statement will likely reach far beyond the U.S. vs. Schena case, Porter said.

DOJ Will Explain Its View

"My guess is that the Department of Justice is going to say, 'We don't agree with the Hawaii case, and this is why,'" he commented. "If that's the position the DOJ takes, it doesn't mean they're necessarily right.

"But it still means that from an enforcement perspective, that's the approach that the DOJ is going to take until they're told that they're wrong by many different courts, or the **Court of Appeals**, or the **Supreme Court**," he added.

Many eyes will be on the DOJ's wording in its opposition given that there is little official guidance on EKRA from the government.

So where does the Hawaii decision leave clinical laboratories and pathology groups? From Gee's perspective, that answer is simple: Continue trying to comply with EKRA.

"There have been lots of efforts to get the attention of the DOJ and Congress to do something else with EKRA," Gee said. "To my knowledge, nothing has yet happened. Keeping in mind that it's a criminal statute, labs need to take steps to demonstrate that they're not intending to break the law."

For lab leaders, that means crafting careful compliance and compensation programs.

Lab Compliance with EKRA

"You've got to think about what you can do to make your sales compensation program avoid the things the government has had such a problem with, even if you're not sure exactly how to compensate under the language of EKRA or how you're supposed to develop a useful incentive compensation plan when you can't pay commissions," Gee explained.

Expect other cases involving alleged lab fraud to jump on the Hawaii opinion. "If there are cases involving labs with significant resources, they will challenge the language of the EKRA statute," he said.

Laboratory directors and pathologists should pay close attention to government's reaction to the Hawaii case and how the DOJ responds to the U.S. vs. Schena motion to dismiss. Savvy observers will note that regardless of the immediate noise these cases are making about EKRA, any significant changes will take years to happen, if at all. TDR

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DOJ Views COVID-19 Fraud via EKRA Lens

ONE INTERESTING TWIST WITH FEDERAL ENFORCEMENT of the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) is the government's willingness to go after fraud allegations related to SARS-CoV-2 testing.

The case U.S. vs. Malena Badon Lepetich provides a good example of this. Lepetich was the owner of **MedLogic**, a clinical laboratory in Baton Rouge, La. She allegedly solicited and received kickbacks in exchange for referrals of urine specimens for medically unnecessary tests, according to the U.S. Department of Justice.

In addition, Lepetich allegedly offered to pay kickbacks for referrals of specimens for COVID-19 and respiratory pathogen testing. Court documents claim Lepetich filed more than $10 million in laboratory test claims to **Medicare**, **Medicaid**, and **Blue Cross Blue Shield of Louisiana** for panels of expensive respiratory testing that was medically unnecessary.

A grand jury indicted Lepetich on various healthcare fraud charges last year. At the time Congress passed EKRA, the law was primarily aimed at fraudulent activity in opioid treatment centers, including related lab testing. Thus, the government's use of the EKRA statute in the prosecution of Lepetich is notable and establishes a precedent.

"The government had really only used EKRA in the context of addiction treatment space," said Alexander Porter, a partner at law firm Davis Wright Tremaine in Los Angeles. "The Lepetich case shows that the government's going to use EKRA beyond that context and go into other areas where they think that it can be useful—in particular, in the area of COVID-19 testing."

Latest Lab Billing Trends Are AI, More Transparency

Lab coding, billing, and collection companies are incorporating AI into their service offerings

CEO SUMMARY: From predictive analytics to data curation to improved online payment options, the newest trends in billing allow clinical laboratories and anatomic pathology groups to boost their financial bottom lines without putting more pressure on patients. Technology is at the core of these developments, particularly software that analyzes and curates clinical and patient data. One might even say that a revolution in lab revenue cycle management (RCM) is underway.

More laboratory billing firms are embracing artificial intelligence (AI) to help maximize their accounts receivable process. Among the benefits are increased transparency into problematic claims and predictive analytics to identify actual dollars that could be collected.

Incorporating AI-powered solutions into the coding, billing, and collections functions is a major trend with both clinical laboratories and anatomic pathology groups. AI automates many manual processes while simultaneously improving the accuracy of these processes. This, in turn, leads to a larger proportion of clean claims at first submission, generating more revenue to the lab.

These developments are coming at a time when federal regulatory changes are putting increased pressure on billing companies to keep up with the ever-evolving world of lab billing and coding. AI is helping clinical laboratories increase revenues through a reduction in accounts receivable and front-end denials, as well as faster turnaround in resubmission of denied claims.

For clinical laboratories and pathology groups, a sound knowledge of current trends in revenue management is a must. It can make negotiations with vendors more fruitful—whether it is to determine a renewal of a prior agreement or evaluate a new service. Consider it a positive when a service provider is familiar with one or more of the advancements below.

Predictive Analytics

For example, one big change in laboratory revenue cycle management (RCM) in recent years is the use of predictive analytics to identify which claims are most likely to be paid. This allows billing companies to focus their resources on the claims for which they presumably will collect payment.

Problematic claim submissions make up a significant portion of revenue loss for clinical laboratories and pathology groups, observed Mick Raich, founder of **Vachette Pathology** in Toledo, Ohio. The most common reasons for claim rejections include missing or inaccurate patient information, lack of proper authorization indicated on the claim, and incorrect ICD-10 codes.

Predictive analytics uses AI to allow billers to analyze large volumes of data and predict outcomes. For example, AI can identify which types of claims are most likely to be paid on first submission and which claims may be denied, Raich explained.

"AI allows billers to say, 'Here are our top 25 denial codes, and if we clean up these three denial codes, that equals $26,000,'" he said. "It allows billers to work the right claims at the right time."

Predictive Analytics Tool

Advanced Data Systems (ADS) in Paramus, N.J., provides billing and outsourced RCM services for laboratories and healthcare providers. It uses its MedicsPremier platform, a predictive analytics tool, to determine true accounts receivable, allowing clinical laboratories and revenue cyle management firms to focus their resources better, explained Jim O'Neill, Laboratory Services Business Development Manager at ADS.

"When we know the actual dollar amount that stands to be collected, we can allocate the appropriate staff to gather the missing information," O'Neill explained. "By putting an actual dollar figure on the claims, it gives incentives for the RCM company and the laboratory to fix those claims as soon as possible."

In addition to identifying which types of claims are most likely to be paid, predictive analytics also highlights problems in denied claims, enabling clinical laboratories to improve their submissions from the start, Raich said.

Analyzing Denial Codes

"Once you analyze your denial codes, you can see what you're doing wrong," he added. "This way, you can make those fixes up front to improve the likelihood that those claims will get paid."

Increased transparency into what is happening with claims is another technique allowing RCM firms to improve collections on behalf of their clinical laboratory clients.

Billers have long used dashboards to give their clients information on accounts receivable, but too often those dashboards simply offer a snapshot in time and do not give full transparency into what is happening with the claims. RCM vendors now are improving the usefulness of these dashboards by giving clients more insight into the claims process.

ADS, for example, recently introduced a new tool that gives 100% transparency between laboratory staff and the ADS response team, O'Neill explained. Laboratory customers now have on-demand access to all data used by a given revenue management company. As soon as the billing system identifies a problem with a claim, it is assigned to an ADS team member, who works closely with the lab staff to resolve the issues.

Replacing Cumbersome Tools

"Previously more cumbersome tools handled this process," O'Neill said. "Labs and RCMs were passing data back and forth through Excel, which can be time consuming and even result in lost data."

The ability of an RCM company to resolve problematic claims in collaboration with the clinical laboratory can result in faster turnaround on collections. For ADS customers, increased transparency has led to a seven-to-10-day improvement in customers getting claims filed and rejected claims resubmitted, O'Neill noted.

"This results in fewer denials, faster turnaround on collections, and less time spent by lab staff on billing issues," he said, adding that the improvements in lab billing have helped ADS lab customers increase revenue by an average of 20% in a year.

One challenge that all clinical laboratories and RCM firms face is locating important information that is absent from claims. Missing or bad data is a

significant pain point in the billing cycle, Raich noted, who added that from 10% to 18% of data in lab billing claims is bad. Such flawed information can be a result of many factors, ranging from a patient moving to a new address to that person switching health insurers.

Automating Data Curation

Typically, to locate missing information, RCM staff need to make phone calls or send e-mails to providers, a task that is time consuming and costly. In response, many revenue cycle management firms are turning to data curation to fill those holes and save themselves back-and-forth communication with providers. Essentially, curated data is a collection of datasets selected and managed to meet the needs of a specific group of clients.

Several companies specialize in gathering and curating data specifically related to healthcare claims. ADS, for example, partners with **Wave HDC** in Philadelphia to gather missing claims information without needing to engage with the physician or the patient. Wave uses multiple methods to find, verify, and correct data attributes, such as patient demographics, medical insurance information, and medical beneficiary identifiers.

Adding Missing Data to Claims

"We can add missing data to claims—such as insurance information—then resubmit those claims," O'Neill said. "This has helped us recoup hundreds of thousands to millions of dollars for our laboratory clients."

As clinical laboratories face increasing challenges in obtaining payment for their services, advancements in revenue cycle management can help labs improve their collections, often without inconveniencing patients. What may be most striking to observant laboratory directors and pathologists is how vendors who provide clinical lab services are themselves incorporating other companies' systems and products into their own service menu. The resulting service or product delivers more value to the lab client. This arrangement is not limited to the clinical laboratory industry, but is true throughout the business-to-business software world.

When lab managers are researching RCM companies, it is worth asking vendors how they incorporate the products of partners into their lab services. This fuller picture can better illustrate the RCM capabilities for which a clinical lab or pathology group will pay. A vendor may not outwardly advertise predictive analytics, for example, but that doesn't mean such a function isn't at work behind the scenes. TDR

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Online Features Ease Payment for Lab Tests

ANOTHER WAY OF INCREASING LAB CLAIMS COLLECTIONS is simply to make it easier for patients to pay their bills. Revenue cycle management (RCM) firms can help in this regard.

"Insurance companies now put more of the responsibility on patients, so labs and RCMs must be responsive to this development," said Jim O'Neill, Laboratory Services Business Development Manager at Advanced Data Systems (ADS) in Paramus, N.J. "More companies now use online tools for bill paying, but the tools are only effective if the online invoice matches the invoice the patient has in hand."

For example, ADS allows clinical laboratories and RCM companies to collect payment from patients through their mobile phones or on their computers. As patients use the online system to schedule their next appointments, they can view outstanding balances and receive a prompt to make a payment. The system also sends automated alerts if patients miss their payments.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Scopio Labs, a medical imaging company in Tel Aviv, recently landed $50 million in Series C venture capital funding as it moves to more fully enter the clinical laboratory market, *TechCrunch* reported on Feb. 9. Scopio has developed a scanner that can magnify a whole blood sample by 100 times. The digital imaging system provides clinicians with a view of all areas of the scan, including the peripheral edge. The company has raised a total of $85 million so far.

MORE ON: *Scopio*

One significant aspect of Scopio's blood sampling technology it that it allows smear tests to be done remotely from any laptop, CEO Itai Hayut told *TechCrunch*. Other potential benefits of cell-imaging systems in general include reduced eyestrain for lab techs, lower labor costs, and easy archiving abilities, according to *TechCrunch*.

LABCORP BUYS SEQUENCING TECH

Labcorp bought the technology of Sterling, Va.-based **Aperiomics** in late 2021, according to the *Washington Business Journal*. The technology uses genomic sequencing and machine learning to identify pathogens.

PATHOLOGIST WHO STUDIED 1918 FLU DIES AT 97

Johan Hultin, MD, a pathologist who contributed to a breakthrough in the origins of the 1918 flu pandemic, died on Jan. 22 at age 97. In 1997, Hultin led a scientific trek to excavate a mass grave of 1918 flu victims near the Arctic Circle, according to the *Washington Post*. He removed a lung from a corpse and sent it to molecular pathologist Jeffery K. Taubenberger, MD, at the **Armed Forces Institute of Pathology** in Washington, DC. By 2005, Taubenberger's team had deciphered the complete genome of the 1918 virus, the *Post* reported.

CMS DELAYS CLIA PT UPDATE

The **Centers for Medicare and Medicaid Services** (CMS) has delayed a planned revision to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In 2019, CMS published plans to update CLIA proficiency testing (PT) regulations to address current analytes and newer technologies. However, due to the COVID-19 pandemic, CMS has decided to release the updated PT requirements in 2023.

TRANSITIONS

• Genetic testing and technology company **Centogene** in Rostock, Germany, has named Kim Stratton as CEO. Stratton previously served as the company's interim CEO. Prior to joining Centogene, she was CEO at biopharma company **Orphazyme** and Head of International Commercial for **Shire Pharmaceutical's** rare disease business.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 14, 2022.

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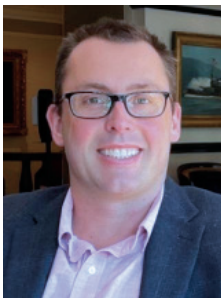

Jason Hipp, MD, PhD
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UPCOMING...

- ***Dept. of Justice successfully prosecutes Texas doctors and hospital CEO for lab test fraud.***
- ***Repurposing PCR automation for other testing: how clever labs build new streams of specimens.***
- ***A perfect storm for labs? "Great Resignation" meets continuing supply chain shortages.***