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LONGITUDE HEALTH

Four Major Health Systems Create New Innovation Center!

Longitude Health sets ambitious goals to trigger advances in value-based care

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Federal Prosecution of Lab Test Fraud & Abuse

SOMETHING NEW AND DIFFERENT IS HAPPENING WITH ENFORCEMENT OF HEALTHCARE FRAUD AND ABUSE LAWS by the federal **Department of Justice** (DOJ). The number of cases being filed has increased over recent years. In turn, that means an increase in press releases announcing criminal convictions, guilty pleas, and civil settlements.

This development has become apparent over the course of the past year. Almost weekly, one or more of these cases is coming to resolution. A goodly number of them include—in some manner—fraud and abuse involving clinical laboratory tests. If one takes the time to read the DOJ press releases and consult the original court filings, the brazenness of the defendants in thinking they can beat the system and the cunning, clever schemes they create to cheat the system are remarkable. We report on the recent announcements about the resolution of some cases on pages 13-15.

Since 2010, THE DARK REPORT has covered many of these schemes as they surfaced in the marketplace. Payments to doctors for "processing and sending specimens" by specialty cardiology lab companies, drug testing scams initiated by sober house operators, rural hospital lab test pass-through fraud, the explosion of management service organizations (MSOs—particularly in Texas), and soliciting genetic tests to Medicare beneficiaries, are five different ways fraudsters game the system, typically for tens of millions of dollars. These frauds hit private payers as hard as they did the Medicare and Medicaid programs.

Now, as long as 10-15 years later, the justice system is catching up (often after litigation dragged on for six to eight years) with criminal convictions, guilty pleas, and civil settlements. The final outcomes in a number of high-profile lab test fraud cases have gone unreported by lab industry news sources, probably because **Google** and other search engines stop listing the DOJ press releases in searches just a few weeks after the date of the press release.

Among the court decisions announced in the past year is the criminal conviction of a well-known lab CEO. Sentencing is set for next year. Although this CEO's lab company was defendant in a *qui tam* lawsuit alleging illegal kickbacks to referring doctors (that was dismissed), the CEO was ensnared in an MSO arrangement that led to a criminal trial with multiple defendants being found guilty. Stay tuned for our report on this CEO's sentencing. TDR

Four Health Systems Launch 'Longitude Health'

Goal is to transform existing business models and improve performance of nation's health systems

CEO SUMMARY: For the second time in the past 16 months, respected health systems have taken steps to collaborate specifically to advance value-based care. Longitude Health joins Risant Health as the newest attempt to bring together different health systems and foster collaboration and innovation in ways that directly lead to better patient care at lower cost. If this is a trend, expect more health systems to follow the same path.

SOMETHING NEW IN THE HOSPITAL INDUSTRY SURFACED ON OCT. 8. That is when four prominent integrated delivery networks (IDNs) announced the formation of a new healthcare organization intended to advance patient care.

The new entity is Longitude Health. Its founding members said the mission is "to revolutionize the way health systems operate, delivering impactful change for patients and communities across the United States."

In statements published on the Longitude Health website, the four founding health system members pledged to "collectively make investments over the next five years towards its mission of identifying, developing and scaling solutions to enhance core operational functions and transform health system performance."

What gives Longitude Health instant credibility are its founding institutions:

- **Baylor Scott & White Health**
- **Memorial Hermann Health System**
- **Novant Health**
- **Providence Health & Services**

These multi-hospital health systems want to change the status quo in the delivery of healthcare and its financial arrangements. There are several things that are novel about this new healthcare organization. One, it brings together four major multi-hospital health systems with a stated goal to share innovations in patient care. Two, it will pursue this goal without the individual members formally merging into a single business unit.

Three, the four participating health systems serve patients from the east coast to the west coast. This makes it possible

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for Longitude Health to deploy innovations and new approaches to patient care in different geographical markets.

This would demonstrate that these new approaches to patient care can succeed in different regions of the United States.

Longitude's New CEO

The Chief Executive Officer and board member is someone familiar to long-time clients and readers of THE DARK REPORT. It is Paul Mango. He was Chief of Staff at **Centers for Medicare and Medicaid Services**, Deputy Chief of Staff for Policy at the **Department of Health and Human Services,** and **McKinsey & Co.'s** U.S. Health Care Practice Leader and Global Health Care Practice Leader.

Mango has direct experience in managing clinical laboratories. During the 1990s, he was the Executive Vice President and Chief Operating Officer at the **Institute for Transfusion Medicine**, the local blood bank service in Pittsburgh. At that time he helped create the **Reference Laboratory Alliance** (RLA).

This was a time when hospitals were forming regional laboratory networks to create negotiating clout with health maintenance organizations (HMOs) and win back network status for outreach testing services. In 1995, Mango and his colleagues launched RLA with 40 hospital lab members. Within months, RLA had managed care contracts that returned 2,500 patient requisitions per night to the RLA member hospital laboratories.

First Executive War College

It was the Reference Laboratory Alliance—with Mango's facilitation—that co-hosted THE DARK REPORT's first *Executive War College* which took place in Pittsburgh in 1995.

Since then, Mango has addressed the *Executive War College* multiple times, always with insights that made him a top-rated speaker.

Mango's multi-year experience with clinical laboratories during his tenure at the Institute for Transfusion Medicine may give him relevant perspectives on how innovations developed within Longitude Health can incorporate clinical laboratory and anatomic pathology resources to add value in patient care and contribute to lower healthcare costs.

Assisting Mango at Longitude Health will be Chief Financial Officer Brett Moraski. Previously, he was a founding Managing Partner at **SEMCAP Health**, Operating Partner at **Frazier Healthcare Partners** and **LLR Partners**, Corporate Vice President of Transformation at **Wellpoint,** and Senior Vice President of Corporate Strategy and Development at **Highmark Health**.

2nd Unorthodox Organization

Longitude Health is the second unorthodox healthcare organization to pop up in the past 24 months. It was in April 2023 that **Kaiser Permanente** made two announcements that surprised the healthcare profession. The first announcement was that it was acquiring **Geisinger Health**, based in Danville, Penn. *(See TDR, "Kaiser Acquires Geisinger Health in Value-Based Deal," May 8, 2023.)*

The second was that it was forming a new entity, to be called **Risant Health**. On its website, Kaiser states that "Risant Health's goal is to expand and accelerate the adoption of value-based care in diverse, multipayer, multiprovider, community-based health system environments and improve the health of millions of people in communities across the country."

It took almost a year for Kaiser and Geisinger to complete the regulatory review and consummate the merger, which happened on March 31, 2024.

Next, on June 21, 2024, Kaiser announced an agreement for Risant Health to acquire **Cone Health**, based in Greensboro, N.C. Cone Health operates

Latest Kaufman Hall Report: Finances of 1,600 Hospitals Reveal 40% are Losing Money

MANY HOSPITALS REPORT HEALTHIER FINANCIAL PERFORMANCE IN THE PAST 18 MONTHS. At the same time, a large proportion of U.S. hospitals have negative operating margins.

This means the gap is widening between hospitals with positive operating margins compared to hospitals with negative operating margins. This has implications for clinical laboratory administrators in the nation's hospitals and integrated delivery networks (IDNs).

The recent data on the financial performance of the nation's hospitals came from the monthly reports issued by Chicago-based **Kaufman Hall** (KH). Its June "National Hospital Flash Report" looked at the financial performance of hospitals in April compared to March and the same period in 2023.

'40% of Hospitals Lost Money'

One key finding was mentioned by Erik Swanson, KH's Senior Vice President of Data and Analytics and reported by *Becker's Hospital Review*. He stated that "40% of hospitals are losing money."

Kaufman Hall worked with the data from 1,300 hospitals, as provided by **Syntellis Performance Solutions**, a business unit of **Roper Technologies**, which also owns **Clinisys** (formerly **Sunquest Information Systems**).

Kaufman Hall reported that overall, hospital operating margins were improving. At the same time, there is a widening gap separating top-performing hospitals from those at the bottom. Kaufman Hall's analysis showed that best performing hospitals had a margin of 28.9%. By contrast, the group of worst-performing hospitals had an operating margin of 16.1%.

"While financial performance looks solid on the surface, a closer examination of the [Syntellis] data shows a greater divide between high- and low-performing hospitals," Swanson observed.

"Organizations that have weathered the challenges of the last few years have adopted a wide range of proactive and growth-related strategies, including improving discharge transitions and building a larger outpatient footprint," he added.

Inpatient Revenue Up 12%

April did show improvement for not-for-profit hospitals, with Kaufman Hall stating its margins were 4.3% in April, a gain of 33% from April 2023. Inpatient revenue climbed 12% year over year in April while outpatient revenue increased 10% during that same period.

In an interview early in 2024 with *Healthcare Innovation*, Swanson explained why rural hospitals were at risk. "Take your rural hospital and look at the cost of labor—and delivering services like women's services—and many are closing those services," he noted.

"So, we're seeing women's health deserts developing principally in rural health. And so, what does it mean to provide healthcare services in some of those geographic areas? Regulatory environment aside, absolutely, more consolidation," Swanson added.

Because 40% of the 1,300 hospitals studied by Kaufman Hall are losing money, industry analysts expect stronger health systems will continue to acquire financially struggling health systems.

This will further consolidate the hospital industry. Similarly, more sales of clinical laboratory outreach programs will happen as money-losing hospitals and IDNs take steps to raise cash and bolster their balance sheets.

five hospitals, has its own health insurance company, and participates in value-based contracting arrangements. The two parties said that the plan is for Cone to be owned by Risant and to continue operating independently under its own brand. Financial terms were not disclosed.

Is This a Trend?

Now, in the space of only 16 months, seven respected multi-hospital systems have created two different organizations designed to foster innovation through closer collaboration and a sharing of best practices and innovation.

One important common thread between the two organizations is their stated emphasis to advance value-based care. That is reflected in the statement by Greg Adams, Chair of the Risant Health board of directors, who said, "Risant Health refuses to accept that fragmented, episodic, fee-for-service care should define the future of healthcare. Risant Health has put a stake in the ground that care focused on evidence, equity, population health, and improved outcomes must be the future of healthcare."

Opportunity for Lab Leaders

Pathologists and clinical laboratory administrators within the respective hospitals in both Longitude Health and Risant Health have the opportunity to step forward with ideas on effective ways to harness lab test data and the clinical expertise of lab professionals to improve patient care and lower costs.

In fact, the lab team at Geisinger Health was one of the founders of **Project Santa Fe** and helped articulate the concept of "Clinical Lab 2.0" where clinical labs take test data and match it with other data sets to create clinically actionable intelligence that enables physicians to achieve better patient outcomes at a lower cost of care. This may be the opportunity for forward-looking lab professionals to advance the value of lab testing. TDR

Longitude Health's Four IDN Members

CHARTER MEMBERS OF THE NEWLY CREATED LONGITUDE HEALTH include the four respected health plans shown below. There is a west coast health system, an east coast health system, and two health systems in the center of the United States.

Here are profiles of the four health systems that are charter members of Longitude Health:

Baylor Scott & White Health, Dallas, Texas

- 51 Hospitals
- 800 patient care sites
- 7,300 active physicians
- 49,000 employees
- Scott & White Health Plan

Memorial Hermann Health System, Houston, Texas

- 17 Hospitals
- 320 care delivery sites
- 6,600 affiliated physicians
- 33,000 employees
- Memorial Hermann Health Plan

Novant Health, Winston-Salem, North Carolina

- 19 hospitals
- 850 locations
- 2,200 physicians
- 40,000 employees
- No health system health plan

Providence Health and Services, Renton, Washington

- 51 hospitals
- 850 non-acute care facilities
- 1,600 employed physicians
- 120,000 employees
- Providence Health Plan (PHP)

State of Whole Genome Sequencing of Newborns

Several statewide pilot programs demonstrate the value of such screening, along with an ROI

CEO SUMMARY: Genetic medicine continues to support advances in precision medicine (or personalized medicine, if you prefer). This is true in pediatrics, where several statewide pilot programs—each involving tens of thousands of newborns—are publishing studies that demonstrate how exome, whole genome sequencing, and rapid whole genome sequencing can deliver both improved patient outcomes and a return on investment.

WHOLE GENOME SEQUENCING (WGS) TESTING OF NEWBORNS continues to gain acceptance and improve patient outcomes while delivering a positive return on investment (ROI). Several programs now use this type of testing to diagnose potential conditions, allowing for earlier diagnoses and treatments.

Children's hospitals across the nation are leaders in this movement. A growing number of children's hospitals have a program to perform rapid whole genome sequencing (rWGS) on newborns that meet clinical criteria. Importantly, studies done by some of these children's hospitals provide solid evidence that—not only does rWGS improve patient outcomes—but it is a sound investment. *(See TDR, "Whole Genome Sequencing for Newborns Gains Favor," November 13, 2023.)*

Lab Profession's Holy Grail

This is the holy grail in clinical laboratory testing. Everyone wins when a new lab test improves patient outcomes while simultaneously delivering an acceptable ROI. Evidence continues to accumulate that rWGS and WGS for newborns deliver both benefits.

The latest evidence supporting wider use of WGS on newborns was issued by the Genomic Uniform Screening against Rare Diseases in All Newborns (GUARDIAN) study. It is conducted by **Columbia University** in partnership with **New York-Presbyterian** and the **New York State Department of Health**. GUARDIAN is a prospective study launched in 2022 to screen newborns for more than 450 genetic conditions to help improve their lives.

Typical newborn testing is provided free of charge to all newborns in the United States in programs managed by individual states. This testing program is based on a small sample of blood collected from the heel. The standard tests screen for approximately 50 different conditions.

It is important to understand that genetic conditions screened for under GUARDIAN are not part of these state newborn screening programs. GUARDIAN testing uses genomic sequencing to detect genetic conditions and is offered free of charge to parents

of newborns. The WGS testing under the program does not require an additional blood sample.

Genetic conditions screened for under GUARDIAN are divided into two groups. Group 1 conditions have medicines and treatments available that may prevent or minimize symptoms associated with potential illnesses. Group 2 conditions do not have any known treatments available at this time but may provide infants with early intervention services and participation in treatment options, if they become available. These babies may also be able to enroll in any future research studies for detected conditions.

Since launching the GUARDIAN study, more than 12,000 babies born at New York Presbyterian Hospitals have had their genomes sequenced, 299 of which tested positive for one of the WGS screened health conditions. **GeneDx** does the sequencing for the GUARDIAN Program. On its website, GeneDx states that, of the "rare disease cohort diagnosed by exome of gene sequencing at its lab, 21% were cases with diagnostic findings in GUARDIAN genes." *(See sidebar on page 9.)*

"For one child, it [the genetic finding] was even lifesaving," Wendy Chung, MD, PhD, clinical and molecular geneticist, Chief of the Department of Pediatrics at **Boston Children's Hospital** and leader of the GUARDIAN study, told *The Washington Post*.

Early Check Program

In North Carolina, another newborn WGS program is ongoing. Like GUARDIAN, the Early Check program is a similar volunteer project led by **RTI International** and created in September 2023 to screen babies in that state for more than 200 potentially serious genetic conditions.

Over the last year, Early Check researchers analyzed the genomes of more than 2,000 infants. They discovered that 40 of the newborns were positive for the screened conditions. One newborn was deemed to have two previously undiagnosed conditions.

"Early Check is giving parents vital information about their newborns that was previously not possible and allows them to get an early start on treatment plans when necessary," said Holly Peay, PhD, a senior research scientist at RTI International and the project's lead investigator, in a news release.

Unexplained Symptoms

"For many patients, a genetic diagnosis only comes after years of living with often unexplained symptoms, ineffective treatments, and incurring countless medical expenses," said Paul Kruszka, MD, Chief Medical Officer at GeneDx, which also provided the WGS tests for Early Check, in the press release.

"By screening for and identifying these conditions at birth, we stop the odyssey before it even begins. We hope to see more states adopting similar programs, creating more opportunities for children and their families to have improved health outcomes," he added.

Project Baby Bear

On the West Coast, Project Baby Bear is a pilot study conducted by San Diego-based **Rady Children's Institute for Genomic Medicine**. With funding by the State of California, the pilot study provided rapid whole genome sequencing (rWGS) for infants in intensive care units at five hospitals across the state.

For this project, the genomes of 178 critically ill babies were sequenced to diagnose and create personalized care. The sequencing technology helped to diagnose 76 babies with genetic illnesses, which resulted in treatment changes for 55 babies.

In the United Kingdom last October, the country's **National Health Service**

(NHS) announced plans to use WGS to screen 100,000 newborns for more than 200 rare genetic conditions in an attempt to provide early diagnoses and treatments for those conditions. To date, more than 500 blood samples have been collected at 13 NHS hospitals. The researchers plan to ramp up the study to include 40 hospitals.

Called the Generation Study, the NHS project aims to identify rare genetic conditions earlier, gather genomic data for further research, and explore the risks and benefits of storing an individual's genome. The study is scheduled to run until March of next year.

UK parents can sign up for this program during pregnancy. Either an umbilical cord or blood sample is collected shortly after birth and the results are available within a few months.

Diagnosing Rare Conditions

"Diagnosing rare conditions in newborn babies at the earliest opportunity through genomic testing could be truly life-changing for families. It has the potential to give thousands of children the chance to access the right treatment at the right time, giving them the best possible start to life, and for families to better plan for their care," said Amanda Pritchard, Chief Executive of **NHS England**, in a news release.

"If we can diagnose and treat children for rare genetic conditions years earlier, we have the power to help stop debilitating conditions in their tracks and enable more children to grow up, start school, and live independently. This will be transformational for patients and for the future of medicine," she added.

Described above are multiple pioneering initiatives to deliver exome, WGS, and rWGS testing services to newborns meeting clinical criteria. Thousands of newborns are being screened in each program. A common finding of these initiatives is that a high proportion of newborns are identified as having a genetic condition where timely clinical intervention can lead to improved patient outcomes. Equally significant, there is a documented return on investment for this testing.

Clinical laboratory administrators and pathologists can expect this field of diagnostic testing to expand and be fueled by two factors. One is the continual increase in genetic knowledge that identifies new biomarkers of interest. The second is based upon continuing improvements in genome sequencing that:

- continually reduce the cost;
- further reduce time to answer; and,
- boost accuracy of the sequences. TDR

Gene Sequencing Costs for Newborn Screening

MOST OF THE EXOME AND GENOME SEQUENCING for pediatric disease in support of the GUARDIAN program are provided by GeneDx, of Gaithersburg, Maryland.

A recent report about GeneDx published by research firm **Craig-Hallum** noted certain components that need to be demonstrated to further advance the use of WGS testing for infants. They include:

- Additional studies with broader geographic scope.
- Clinical and economic utility studies.
- Faster turn-around-times.
- Reducing the costs associated with the testing.

The Craig-Hallum report says the cost of typical newborn screening ranges from $60 to $240, depending on the state. It estimates the normal cost for WGS newborn testing is $1,000 or more, and that this type of testing could result in an annual market potential of $2 billion in the United States.

The firm's report also states GeneDx estimates a global screening market of approximately $10 billion per year.

Legislative Update

Once Again, Congress Acts to Defer Medicare Lab Fee Cuts

It is the fifth year in a row that Congress passed a law to push back the next round of price cuts

Last month, Congress once again deferred **Medicare** reimbursement cuts of up to 15% for clinical laboratory tests by including this provision in a short-term government funding bill that was passed on Sept. 25.

This is a welcome development for the clinical laboratory profession. This next round of price reductions to the Medicare Clinical Laboratory Fee Schedule (CLFS) was to be implemented on Jan. 1, 2025.

Medicare Price Cuts

Cuts to the CLFS were mandated as part of the Protecting Access to Medicare Act of 2014 (PAMA). The law directed the **Centers for Medicare and Medicaid Services** (CMS) to conduct a study of the clinical laboratory test prices paid by private health insurers and then use that data to establish new prices for the CLFS.

The law only delays implementation of the next round of price reductions to the CLFS. Future rounds of PAMA-mandated test price cuts will take place in coming years. CMS is also scheduled to conduct a new study of private payer lab test prices to use in establishing CLFS prices.

Earlier this year, the **American Society of Clinical Pathology** (ASCP) described what is scheduled to happen next, stating:

> *At the moment, the Centers for Medicare and Medicaid Services (CMS) anticipates phasing in PAMA-associated payment reductions over 2025, 2026, and 2027, with reductions capped at 15% each year. The expectation is that applicable laboratories ... will collect and report the required data—HCPCS codes, private payer rates, test volumes, and National Provider Identifier (NPI)—between January 1 and March 31, 2025, so that the information can be used to update the 2026 Medicare Clinical Laboratory Fee Schedule.*

The evidence that enough members of **Congress** recognize the potential harm to Medicare beneficiaries if additional price cuts are made to the CLFS is this fact: for five consecutive years, Congress has passed legislation to defer for 12 months the next round of PAMA-mandated lab test price cuts.

Passage of PAMA—along with the much-criticized methods used by CMS to conduct the private payer lab test price study and set CLFS prices—has been corrosive to the clinical laboratory profession.

Labs Closed Due to PAMA

The Dark Report has tracked numerous small or regional independent laboratories that closed, filed bankruptcy, or sold to one of the two Blood Brothers. This has reduced access by Medicare beneficiaries to local clinical lab testing, particularly in rural areas and smaller communities. In turn, this defeats the goal of the Medicare program to serve beneficiaries. *(See TDR, "PAMA Data Projections Led to Decision to Sell Lab," Feb. 21, 2017; and "Boyce and Bynum Sells to Quest Diagnostics," Dec. 24. 2018.)* TDR

Lab Market Update

Allina Doctors Express Concerns after Quest Acquires Lab Outreach

Unusual for physicians to contact the media to discuss problems in lab outreach turnaround times

In recent years, **Quest Diagnostics** and **Labcorp**, the two behemoths of the U.S. clinical laboratory market, have been aggressively acquiring lab businesses from health systems across the country. They say that patients and providers will benefit from lower costs and better access to testing services.

But clinicians at one major health system in the Midwest publicly called foul after Quest completed such a deal, describing it as a "disastrous, chaotic mess."

Unexpected Problems

In June, Quest announced that it had agreed to acquire the lab outreach business of **Allina Health**, a nonprofit health system with 1,864 beds operating out of 12 hospitals and more than 90 clinics in Minnesota and western Wisconsin. In the press release Quest issued, it said the goal of the deal was "to improve access to, and the affordability of, innovative laboratory services" in the region.

The two parties announced in mid-September that they had closed the deal. However, soon after clinicians at Allina Health facilities spoke out with a litany of complaints about the new system they were expected to use.

"This change has compromised our ability as providers to deliver high quality care to our patients and their families," said nurse practitioner Britta Kasmarik, CNP, in a statement from the **Doctors Council**, a labor union that represents Allina clinicians.

The transition "has prevented providers from being able to order labs that are pertinent to appropriately evaluating and treating our patients," Kasmarik said. "This has resulted in providers having no other choice but to send patients to Urgency Rooms (UR) or Emergency Rooms (ER)."

Lisa Schweiger, MD, a pediatrician at an Allina clinic, described the problems to a reporter at *The Minnesota Star-Tribune*. They included, "widespread confusion about how to order tests in the new system," the paper reported, and "time-consuming struggles for caregivers as they try to fix mistakes."

She added that patients had "to wait hours for routine blood draws, prompting many to go home instead and later seek lab-only appointments that are significantly delayed."

Highly Complex Transition

In statements to the media, Allina and Quest both acknowledged problems with the new system.

"The Allina Health-Quest lab transition is highly complex, and we've experienced extended wait times and other service issues, which the Quest and Allina Health teams are rapidly addressing," Quest stated. "We are making daily improvements and exploring additional options to ensure we deliver the quality services patients rightly expect of us."

And this from Allina: "We are two weeks into a complex transition and are

actively working in collaboration with Quest Diagnostics to stabilize the delivery of clinic lab services. We are implementing all operational options and clinical solutions to ensure we can meet the needs of our patients and care teams as soon as possible."

The deal with Allina applies strictly to "lab outreach assets," a Quest spokesperson told THE DARK REPORT. The **Centers for Medicare and Medicaid Services** (CMS) defines this as "A hospital-based laboratory that furnishes laboratory tests to patients other than inpatients or registered outpatients of the hospital."

"Allina continues to provide its own inpatient testing," the spokesperson said.

Bare Minimum Lab Testing

One Allina clinician expressed concerns about the deal shortly after it was announced.

"The most glaring impact of this decision is that many Allina clinics will no longer offer important same-day lab tests that we rely on to quickly diagnose common conditions like urinary tract infections and anemia (low red blood cell count)," wrote Matt Hoffman, MD, a family doctor with an Allina clinic, in a July 16 opinion piece for *The Minnesota Star-Tribune*. "Among other concerns, we are also losing our ability to immediately check a white blood count, a test we use to look for serious infections. Many clinics will only be offering bare minimum same-day testing like rapid strep tests and urine pregnancy tests."

Allina family doctor Cora Walsh, MD, echoed those points in the Doctors Council statement.

"We no longer have on site some of the critical point of care testing we relied on previously," Walsh said. "We need restoration of immediate lab results (such as a complete blood count) for timely assessment of certain acute medical issues. We need assurance that patients will not bear an increased cost of care for these services. We also need a better plan to ensure timely results are available from Quest for clinical decision making."

Benefits of Quest Acquisition

So, what benefits can patients and providers expect from the deal with Quest? "Over time, we expect providers in Minnesota and western Wisconsin will have access to Quest's expanded test menu that includes highly advanced test services, while patients (and health plans and employers) will benefit from improved affordability for many services," the Quest spokesperson told THE DARK REPORT.

Assuming the current problems are resolved, what turnaround times can clinicians expect for lab tests?

"As part of the transaction, Quest will provide access to thousands of individual tests," the spokesperson said. "Turnaround times vary based on complexity of the test and other factors. As part of our transition plan, a medical council consisting of medical experts from Allina Health worked collaboratively with Quest to create a test menu with appropriate turnaround times for the Allina Health providers."

Reinvesting Resources

Terms of the deal were not disclosed. But Allina Health, which reported a $317.8 million loss in 2023, was apparently in need of cash.

In the press release announcing the Quest deal, Allina chief operations officer Dominica Tallarico said Allina will ensure continued access to "innovative and high-quality laboratory services."

However, the transaction (sale of the laboratory outreach operations) "will also allow us to reinvest our non-profit resources to support our caring mission well into the future," Tallarico noted.

Patient care issues identified by doctors willing to speak publicly affirm the value of lab testing services which deliver speedy test results that enable physicians to diagnose and treat patients quicker. TDR

Federal Cases against Labs Result in Convictions

In recent weeks, Dept. of Justice announced numerous convictions, settlements involving lab fraud

CEO SUMMARY: Over the past 24 months, federal prosecutors have announced a steady parade of criminal convictions, guilty pleas, and settlement agreements involving fraud and clinical laboratory testing. Not only are these cases numerous, but some resolve legal actions initiated by the federal Department of Justice six to eight years ago—for fraudulent acts by defendants that date back to the early 2010s.

When it comes to winning convictions, guilty pleas, and civil settlements in federal cases involving clinical lab testing fraud and abuse, federal prosecutors are on a major win streak. Week after week, the **U.S. Department of Justice** (DOJ) is anouncing guilty verdicts, fines and sentences, and settlements in court cases involving laboratories and allegations of fraud.

In its 30 years of covering fraud and abuse in the clinical laboratory and anatomic pathology markets, The Dark Report has never seen such a large number of criminal cases involving lab fraud and abuse moving through the federal court system at the same time.

The reason most of these cases go unnoticed by many in the lab profession is that that they don't involve the headline-grabbing claims by federal prosecutors that an individual lab submitted false lab test claims in the hundreds of millions of dollars, such as the high-profile case of lab fraud committed by the now-defunct **Health Diagnostic Laboratories** (HDL) of Richmond, Virginia.

In just 60 months—between 2010 and 2014—federal prosecutors claimed that HDL had submitted $500 million of fraudulent claims to the Medicare and Medicaid programs. They also identified two owners of **Blue Wave Healthcare Consulting** who were paid $242.8 million by HDL in sales commissions for originating these lab test claims. *(See TDR, "Feds Show How Labs Took $500 Million from Medicare," and "Meet Richest Sales Reps In Lab Testing Industry," Sept. 14, 2015.)*

Feds Pursue HDL Managers

Sales managers Floyd Calhoun Dent, III, and Robert Bradford Johnson; along with Tonya Mallory, former CEO of HDL, were sued by the DOJ in 2018. Federal prosecutors won a $144 million judgement, which was upheld by a federal appeals court in 2021. *(See TDR, "Insights from Jury Verdict in HDL, BlueWave Case," Feb. 12, 2018.)*

Convictions and settlements in recent federal lab cases typically involve fraud that totals a few million to tens of millions of dollars. There is value in following the cases filed by federal healthcare prose-

cutors where lab test fraud is the issue. First, it allows lab managers to understand specific schemes involving different forms of inducement that prosecutors assert violates federal law. Fraudsters are continuously crafting new ways to induce physicians to order medically unnecessary tests. By understanding these schemes, lab managers can then work with their legal counsel to review current sales practices to have confidence their labs conform with the federal Anti-Kickback Statute (AKS) and the EKRA law.

Educating Client Physicians

Second, lab managers can use news of the convictions of lab owners, lab managers, and the doctors who referred medically unnecessary tests in return for illegal inducements to educate their client physicians about: 1) the fact that federal prosecutors are filing criminal charges against physicians alleged to have engaged in fraudulent test ordering; and 2) that they (client physicians) should be alert to fraudulent practices when approached by sales reps from lab testing companies who offer inducements in exchange for lab test referrals.

Here is a brief summary of recent federal civil and criminal cases involving allegations of lab test fraud:

- **Oct. 9, 2024:** Eric Troyer, MD, an addiction medicine specialist located in Landis, N.C., agreed to repay the U.S. government $429,254 and $195,746 to North Carolina to settle allegations he violated the False Claims Act as part of a kickback scheme dating from August 2015 to November 2021 with **Labtech Diagnostics LLC**, a medical lab company located in Anderson, S.C.
- **Oct. 2, 2024: Precision Toxicology,** DBA **Precision Diagnostics,** in a federal civil case, agreed to pay $27 million to settle allegations of fraud and abuse involving inducing physicians to order "medically unnecessary urine drug tests" from Jan. 1, 2013, through Dec. 31, 2022. The company is based in San Diego and operates a laboratory in Dartmouth, Mass. In the DOJ press release, it was disclosed that whistleblower "Bryce Hudak will receive $2,743,002 from the federal False Claims Act recovery."
- **Oct. 1, 2024:** Lexington, Kentucky—In a civil settlement, a hospital, a laboratory, three lab employees, a referring physician, and his office manager agreed to pay $7.2 million "to resolve allegations they defrauded healthcare programs through unnecessary or tainted laboratory testing." **Physicians Medical Center** is a 10-bed hospital in New Albany, Ind. It operated the now-defunct laboratory **United States Medical Scientific Indiana**. The DOJ press release states that two of the lab's sales reps—Bobby Sturgeon and Steve Moore—each signed civil settlements. The owner of Jackson, Kentucky-based **St. John Neumann's Extended Hours Clinic**, Pablo Merced, MD, and his wife and office manager, Theresa Merced, entered a settlement to resolve allegations of fraud. This appears to be an example of the use of a cash-strapped rural hospital for pass-through billing of laboratory tests, particularly drugs of abuse screens. *(See TDR, "Why Lab Companies Buy Bankrupt Rural Hospitals," May 29, 2018.)*

More Recent Settlements

- **Oct. 1, 2024:** Zishan Alvi, owner of **LabElite**, a company based in Chicago, pleaded guilty to providing fake negative COVID-19 test results to people undergoing testing, then billing the federal government for $14 million. He will be sentenced on Feb. 7, 2025.
- **Aug. 4, 2024:** Thomas Carnaggio and his company, **South Ventures LLC** agreed to pay $400,000 to resolve allegations that from January 2017 to January 2020, they offered thousands of dollars in kickbacks to physicians in North and

South Carolina. The kickbacks were often in the form of disguised payments of purported office space rental or phlebotomy payments, and were intended to induce the doctors to order laboratory testing. Carnaggio and the company allegedly received commissions from the laboratory as independent contracts based on the volume and/or value of Medicare and TRICARE referrals received by the laboratory.

- **July 24, 2024: Guardant Health, Inc.**, based in Palo Alto, Calif., agreed to a federal settlement "to settle allegations that it knowingly violated the False Claims Act (FCA). Guardant Health voluntarily disclosed the conduct to the Office of the Inspector General (OIG) and will pay $913,932.93 to settle the FCA allegations and $31,082.00 in an administrative settlement with the **Defense Health Agency**. There is an unusual twist in this case of healthcare fraud. The DOJ press release states that a client physician asked Guardant to hire his step-daughter. It then said, "The step-daughter was considered but rejected for a position in Guardant's Screening Division. However, in or around February 2022, two Guardant employees arranged for the family friend to be promoted, thereby creating an opening in the Oncology Division for employment of the step-daughter. These employees knew of the relationship between the step-daughter and the physician, and that the step-daughter was not qualified for the role. The physician then ordered significantly more Guardant tests per quarter after both hirings. This physician's test referrals violated the physician self-referral law."

Judging from the number of recent convictions, guilty pleas, and settlements, federal prosecutors from the U.S. Department of Justice have gained momentum in prosecuting cases involving fraud by clinical lab companies and clinical laboratory executives. TDR

Federal Prosecutors Pursue Lab Fraud Cases for Years

IN THE PAST SIX TO EIGHT YEARS, FEDERAL PROSECUTORS have filed numerous cases of healthcare fraud and abuse that involve—in some form or fashion—schemes to pay illegal kickbacks in return for medically unnecessary clinical laboratory test referrals.

Some of these schemes were complex. For example, two different arrangements became widespread during the decade of the 2010s. One was the use of rural hospitals to be the vehicle for pass-through billing of lab tests. *(See TDR, "Lab Scheme Recruits Hospitals to Bill as In-Network Providers," Oct. 30, 2017.)*

The other involved the use of management service organizations (MSOs). Organizers would sell physicians shares in these MSOs. The physicians would then earn "dividends" based on the profits generated by the lab tests (and other services) they referred to the MSO. *(See TDR, "Allegations of Lab Test Fraud Involve Multiple Defendants," Jan. 22, 2018.)*

By the end of the last decade, U.S. attorneys in different regions began filing cases against the owners of these rural hospitals and MSOs, along with physicians who had referred medically unnecessary lab tests in return for illegal inducements.

Almost annually since 2019, the US Department of Justice would issue a press release to announce that hundreds of defendants in multiple cases were being charged with billions of dollars in Medicare fraud and abuse.

These federal cases were either criminal indictments of the defendants or civil cases seeking restitution via a settlement agreement. The resolution of relevant cases will be covered in coming issues of THE DARK REPORT.

Legal Update

Epic Sued for Antitrust Violations by Small, Start-up Company

Data platform Particle Health filed antitrust lawsuit against Epic after months of disagreements

It's being called a "David versus Goliath" spat. Last month, **Particle Health** of New York City filed an antitrust lawsuit against **Epic Systems Corporation** of Verona, Wisc.

Particle's lawsuit claims Epic is violating the Sherman Act—a law the defines unfair competition. *Becker's Health IT* reported that "Particle alleges that Epic has limited its access to patient records within the **Carequality** network over the past six months to block the company's entry into the payer platform market."

The dispute centers around services in a new sector of healthcare, the payer platform space. *MedCity News* wrote, "The payer platform space refers to the emerging market for digital platforms that allow payers to access and analyze patient data at scale for a variety of purposes, including improving care coordination, designing population health programs or streamlining claims processing. Particle's complaint alleges that Epic is preventing the startup from competing in this space by cutting off Particle customers from accessing Epic's EHR data."

Payer Platform is New Sector

Clinical lab executives and pathologists may be unaware of this sector. However, because it involves data and claims that include lab test data, continued growth in the use of payer platforms—particularly by the health plans offered by integrated delivery networks may cause them to interact more directly with clinical labs.

Payer platforms are still a nascent business industry. Particle Health was founded in 2018. *MedCity News* reported that "Epic launched its payer platform in 2021, allowing insurers to request, receive, store and analyze health records at scale. When Particle decided to compete in 2023, Epic had firm control of the emerging market, including contracts with the seven largest health plans in the nation, according to the complaint."

Other Smaller Young Firms

Also competing in the payer platform sector are **Zus Health**, **Clarify Health**, and **Health Gorilla**. Like Particle Health and Epic, these three companies are also part of Carequality's exchange network. More than 400 million clinical records per month pass through Carequality's network.

In March, Carequality received a formal complaint from Epic. The EHR company claimed that Particle was taking patient data and providing it to payers. Because the payers were not using this data for clinical care, these actions are violations of HIPAA. Epic's actions are part of Particle's antitrust lawsuit against the EHR giant.

The lawsuit may never make it to trial. Nevertheless, what the lawsuit represents is the ongoing, much bigger issue of control of patient data and how it can be accessed. Because labs generate huge volumes of patient data, any solution to this problem will be of interest. TDR

Virchow

Medicine Money Managed Care

This column is named after the famous German pathologist Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Physicians Tempted by Lure of In-Office Labs, Payers Balk

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

PHYSICIAN OFFICE-BASED LABORATORIES (POLs) ARE CURRENTLY VALUED at around $11 billion and projected to reach $18.3 billion by 2030, according to studies from the **Health Industry Distributors Association** and **Grand View Research**. No doubt this is an alluring prospect for physicians: Install a lab and get quick test results, more timely diagnoses, more convenience for patients, and perhaps an opportunity for new revenue streams. Or so it seems.

But what does this mean for clinical laboratories? In recent years, payers have watched health systems gobble up many physician offices. Typically, the health system's hospital-based clinical labs assume some responsibility for the POLs by overseeing CLIA compliance and other operational activities. But there are still many office-based physicians contracting with commercial laboratories for testing services.

Either way, the growth of in-office POLs creates potential competition for clinical laboratories. What may be surprising is that payers are not thrilled by the prospect, either. Let's dig in to see why.

First, let's stipulate that no one has a problem with low-risk CLIA-waived tests performed at point-of-care: Urine pregnancy tests, simple urinalysis, or simple glucose tests, for example.

The red flags arise when a physician wants to perform moderately complex tests—CBCs, lipid tests, comprehensive metabolic panels, etc.—and even more so if they'd like to offer highly complex genetic tests. What I'm hearing anecdotally is that more physicians want to offer at least the moderately complex tests.

Billing Challenges

Why are payers concerned? It boils down to administrative burden. One problem is that physicians often underestimate the unique challenges of filing lab-related claims to the relevant health plan. This creates all kinds of opportunities for mishaps.

Each health plan has its own policies for covering lab tests. One plan might say that an older patient can have only so many of a specified test in a certain time frame. Does the practice know that? Do they have personnel who can keep up with changes to those policies?

Maybe a medical group has poor billing practices and submits claims that look like fraud to the insurer's payment

integrity department. So, the group gets a prepayment flag and payments stop. The payer doesn't have the resources to send an inspector to verify that the POL is a real lab, so they could end up having a conversation with the **HHS Office of Inspector General** (OIG) to avoid getting into trouble. Even POLs with years of experience dealing with payers can be flummoxed by these issues.

Regulatory Issues

Physicians will also have to ensure compliance with the federal Stark Law and the Anti-Kickback Statute (AKS). Stark prohibits physicians from referring **Medicare** or **Medicaid** patients for specified health services—including clinical laboratory services—if they have an ownership interest in the entity that receives the referral.

The AKS prohibits covered entities from offering anything of value in return for patient referrals, if the service is reimbursable by a federal healthcare program. Both laws contain safe harbors, and the physician practice must operate within those safe harbors to avoid serious penalties.

Suppose a practice lacks good supervision in its lab and gets exposed for a Stark or AKS violation. Anybody can file a complaint with the OIG for these violations and that can even be a disgruntled former partner. Then the health plan gets pulled into the dirt along with the medical group, even if both were acting in good faith.

Revenue Shortfalls

Physicians also appear to be overestimating the revenue potential of establishing their own labs.

To open the lab, the practice will need the appropriate CLIA certification. But first, it needs to purchase and install the equipment, establish operating procedures, appoint a supervisor, and do everything else required for setup. This must all be in place before the practice can even apply for a CLIA certificate.

To submit insurance claims, the practice will need contracts with managed care plans. Even if it's a small lab, those services should be integrated with electronic medical records, so the practice can report data back to the plan.

As we noted in a recent column, a lab might land a new contract and assume that it can bill 120% of Medicare. Then, reverse sticker shock sets in when it learns that a Medicare Advantage plan pays only 45% to 60%. *(See TDR, "Payer Contracts with Labs: Getting the Contract Is Just the Start," April 29, 2024.)*

So, the medical practice that thought it could pull in $2 million per year from a POL ends up with a fraction of that, despite a considerable investment in clinical lab equipment and staff.

Laboratory Perspective

Now let's revisit this issue from the standpoint of clinical labs. If a lab has contracts with independent medical groups, it now faces the prospect of losing revenue as those practices use POLs to bring lab testing in-house. But now payers are offering labs what amount to talking points.

A lab's marketing rep might hear that a medical group is eyeing its own in-house lab. Here are some questions to ask:

- What type of laboratory is the group considering? Moderately complex? Complex?
- Does the practice meet the exceptions in Stark/AKS rules?
- What type of supervision will be in place?
- Does the practice have an integrated EMR system?
- Can it report data to payers?
- Does the practice know how much it will be reimbursed?

A hospital laboratory charged with overseeing a clinic's entry into lab testing will have to deal with its own questions: How does it help the lab get in-network with payers? How does it minimize billing issues? How does it ensure Stark and AKS compliance? TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Babson Diagnostics of Austin, Texas, received a "strategic investment" from **Becton, Dickinson and Company** (BD). The amount of the investment was not disclosed. In the past year, Babson launched an innovative lab testing service with retail pharmacies in Austin and other Texas communities that includes sites operated by the **H-E-B** supermarket chain. Babson's proprietary blood testing is engineered to work with capillary blood specimens and is branded as "BetterWay."

MORE ON: *Babson*

Babson and BD started their collaboration in 2016. BD developed "a novel blood collection device to support Babson's innovative blood testing analyzers." The two companies reported that, in December 2023, the federal **Food and Drug Administration** (FDA) issued a 510(k) clearance for the BD Mini-Draw Capillary Blood Collection System. Babson says it has incorporated BD's device into its "proprietary system for sample preparation and hand-warming technologies" specifically to enable "retail pharmacies to collect high-quality capillary specimens without requiring phlebotomists and laboratory technicians." Babson's vision is to provide an approach to specimen collection that would help ease the shortage of phlebotomists. **Siemens Healthineers** is one of the early investors in Babson Diagnostics, along with **Emerald Development Managers LP**.

TRANSITIONS

- **U.S. HealthTek** of Haymarket, Virginia, named Jamie Papp as Vice President of Sales and Marketing. Papp previously held executive positions at **Gestalt Diagnostics** and **Ellkay**.
- **Siemens Healthineers** selected Nicholas J. Urban to be Senior Vice President and Head of Sales North America, Diagnostics. Formerly, Urban worked at **Thermo Fisher** and **bioMérieux**.
- Robert Johnson was announced as the new Senior Vice President of Strategic Communications and Marketing for the **College of American Pathologists** (CAP). Previous positions were with **Riester Influence**, **U.S. Department of Transportation**, and multiple news agencies.
- **Thermo Fisher** promoted Sierra McGarity to be Director of Sales in North America for Genetic Testing Solutions. She held prior positions with the **University of Alabama at Birmingham** and at **St. Jude Children's Research Hospital**.
- Matthew Lurken, MBA, PA (ASCP) has been named the new Senior International Product Manager for Pathology Work Area at **Roche Diagnostics**. His previous positions were with **UAB Medicine**, **Mercy One**, **University of Minnesota Physicians**, **Hospital Pathology Associates**, and the **Mayo Clinic**.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, November 4, 2024.

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