Volume XXX, Number 7 Monday, May 8, 2023

An Unexpected Health System Megamerger!

Kaiser Permanente to Acquire Geisinger Health

See pages 2-7

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

Healthcare Megatrends and a Famous Book

PREDICTING THE FUTURE IS A RISKY BUSINESS. SKEPTICS ARE ALWAYS AROUND TO CALL ATTENTION TO PROPHETS WHO GET IT WRONG. One prophet whose predictions were on target was author John Naisbitt.

Those of us around in the 1980s will remember a book titled, "Megatrends: Ten New Directions Transforming Our Lives." This was a blockbuster book that still sells today. Since its publication in 1982, more than 14 million copies have been sold in 57 countries. Naisbitt's timely insights helped many business managers and investors make the right decisions to position their companies and investments to profit from the megatrends he described in his book.

I mention this today because our Editor-in-Chief, Robert L. Michel, has been spotting and describing healthcare and clinical lab industry megatrends for nearly forty years. Since its inception in 1995, THE DARK REPORT he edits has demonstrated a track record of accuracy. Its pages span four decades of helping strategic-thinking pathologists and clinical lab administrators understand key trends in ways that enabled them to position their labs for success, both clinically and financially.

Michel's current list of healthcare megatrends includes the ongoing consolidation of multi-hospital systems. In the 2000s, there were about 600 health systems. Today, that number has decreased to under 500. He's on record as predicting that the number of health systems will likely fall to under 50 within the next 10 years or so. That sounds dramatic, but the reality is each regional health system acquired or merged will continue to operate somewhat independently of the other regional health systems under the same ownership. For that reason, it is the number of independent health system owners that will shrink to under 50 at some future point.

Health system consolidation was Michel's focus during his opening remarks at last month's *Executive War College* in New Orleans. The next day, attendees learned that **Kaiser Permanente** would be acquiring **Geisinger Health,** and that Kaiser was ready to acquire other health systems as well. That particular Michel prediction was validated within just 24 hours!

Another of Michel's predictions is that labs that master combining lab test data with other sets of data will create actionable intelligence for which payers will reimburse, thus generating worthwhile streams of new revenue. TDR

Kaiser Acquires Geisinger Health in Value-Based Deal

Geisinger will be first health system in Risant Health, Kaiser's new nonprofit dedicated to value-based care

CEO SUMMARY: This blockbuster combination of two respected integrated delivery networks (IDNs) caught the hospital industry by surprise. Post-closing, Kaiser and Geisinger will have combined revenue of $100 billion. Kaiser is creating a new entity called Risant Health. Geisinger will be the first IDN put into Risant Health and Kaiser plans to acquire and add more regional IDNs to Risant. For labs, this is more evidence that hospital and health system consolidation is an ongoing trend.

IN A MOVE THAT HAS SIGNIFICANT VALUE-BASED CARE IMPLICATIONS, **Kaiser Foundation Hospitals** will acquire Pennsylvania-based **Geisinger Health**.

As part of the deal, Geisinger will become the first health system to join **Risant Health**, a new nonprofit organization created by Kaiser. Risant's goal will be to expand value-based care options to more communities across the country, and the new company intends to acquire other health systems.

This is a blockbuster deal that caught the hospital industry by surprise. When healthcare policymakers discuss the need for the U.S. healthcare system to become better at keeping people healthy and delivering better patient outcomes at less cost, they frequently cite Kaiser and Geisinger as the nation's two best examples of integrated delivery networks (IDNs).

In that respect, Kaiser and Geisinger are often considered the paragons of integrated care delivery. Now they are under single ownership. The implications from this acquisition will be studied for years to come.

Two aspects of this acquisition can help inform strategic planning at clinical laboratories and anatomic pathology groups. First, the continued financial pressure on hospitals and health systems—and by extension their laboratories—was a significant factor encouraging these two health systems to combine.

Second, the CEOs of both Kaiser and Geisinger gave detailed statements about the goal of the new Risant Health. They emphasized that their objective is to deliver "value-based quality outcomes and savings in multi-payer, multi-provider environments."

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

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

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

As health systems seek to deliver value-based care, providers need patients' longitudinal health record, including diagnostic test results, to deliver timely and appropriate care. From that perspective, labs want to be in discussions about value-based models with providers, health systems, and payers. *(See TDR, "Paths of Hospital Labs, Independent Labs Diverge," Nov. 20, 2017.)*

Risant Will Be Separate Entity

Kaiser Foundation Hospitals, based in Oakland, California, is part of the **Kaiser Permanente** integrated delivery network.

"Risant Health will operate separately and distinctly from Kaiser Permanente's core integrated care and coverage model while building upon Kaiser Permanente's 80 years of expertise in value-based care," said an April 26 news release.

Geisinger Health will keep its name but will be the first regional health system incorporated into the newly-organized Risant Health. Risant plans to operate value-based care practices, with capabilities in areas such as care model design, pharmacy, consumer digital engagement, health plan product development, and purchasing.

Kaiser and Geisinger did not disclose financial terms of the deal.

Risant to Add Health Systems

"Kaiser said it hoped to invest $5 billion in Risant over the next five years, in addition to its spending on Kaiser's core operations," *The New York Times* reported on April 26. "The company expects to add five or six health systems to Risant in that time."

Kaiser Permanente reported $95.4 billion in revenue in 2022 but had an operating loss of $1.3 billion. Geisinger had an operating loss of $239 million on $6.9 billion in revenue last year, the *Philadelphia Inquirer* reported.

Their combined revenue would be more than $100 billion, which will give Risant immediate influence and bargaining power, noted healthcare consulting and research firm **Darwin Research Group** in Scottsdale, Arizona.

"While that kind of heft could definitely be a boon for value-based care—especially with Kaiser Permanente and Geisinger leading the way—the potential influence Risant Health could have in local markets (and nationally) may make the [**Federal Trade Commission**] wary," Darwin Research wrote in a blog. "Yet it's precisely this kind of power that may be necessary to propel value-based care forward.

"With nonprofit health systems still struggling to gain the ground they lost during the pandemic, Risant Health could be a lifeline for many—especially with retailers, insurers, and other non-traditional entities making substantial inroads into the delivery of care," Darwin Research added.

Jaewon Ryu, MD, JD, will serve as CEO of Risant Health. Ryu will transition from his current role as President and CEO at Geisinger once the deal closes.

More Hospital Consolidation

This consolidation of two leading multi-hospital health systems is a harbinger of health system consolidations yet to come. Some experts agree.

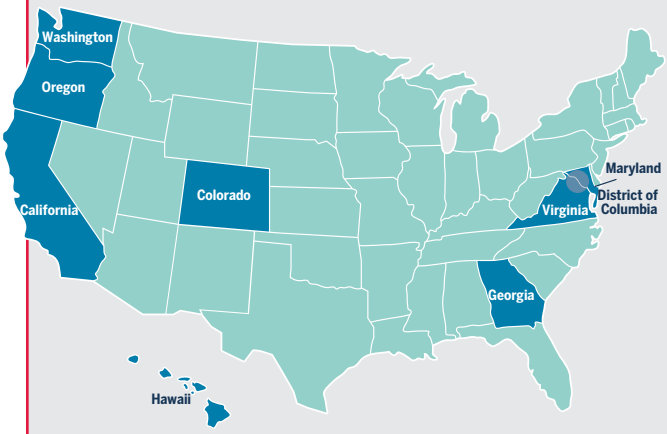
"It seems like the economy is pushing U.S. healthcare more and more toward fewer and broader care organizations," wrote Nadav Shimoni, MD, managing director with **Arkin Digital Health**, in a LinkedIn post.

"The national health system landscape will largely result in a verticalized 'payvider' oligopoly unless the feds step in and block some of these M&As," declared Raihan Faroqui, MD, an advisor to several healthcare startups, in another post on LinkedIn.

"We will continue to see mega health systems get bigger, acquire more hospitals and brick-and-mortar assets and continue to scale up. The biggest payers will also keep consolidating assets," he added. TDR

Kaiser Permanente Expands Its National Footprint with Its Acquisition of Geisinger Health

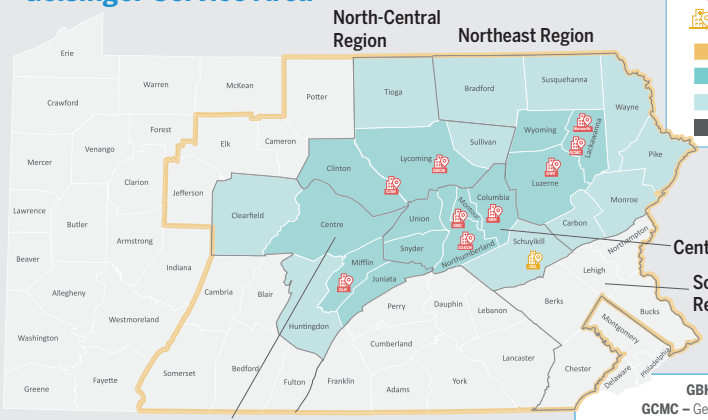
AS SHOWN BY THE TWO MAPS BELOW, Kaiser Permanente currently operates nine regional organizations that offer health plans and associated health services. Geisinger Health's primary service region is Pennsylvania.



KAISER PERMANENTE®

- **CEO:** Greg Adams
- **Founded:** 1945
- **Number of hospitals:** 39
- **Number of employees:** 223,735
- **Revenue:** $95.4 billion in 2022
- **Number of members:** 12.7 million

Geisinger Service Area



Region and Service Area Map Key

- Geisinger inpatient facility
- Geisinger affiliated hospital
- Geisinger Health Plan service area
- Primary service area
- Secondary service area
- Region outline

GBH – Geisinger Bloomsburg Hospital
GCMC – Geisinger Community Medical Center
GJSH – Geisinger Jersey Shore Hospital
GLH – Geisinger Lewistown Hospital
GMC – Geisinger Medical Center
GSACH – Geisinger Shamokin Area Community Hospital
GSL – Geisinger St. Luke's
GWV – Geisinger Wyoming Valley Medical Center
Marworth – Geisinger Marworth Treatment Center
GMCM – Geisinger Medical Center Muncy

Geisinger

- **CEO:** Jaewon Ryu, MD, JD
- **Founded:** 1915
- **Number of hospitals:** 9
- **Number of employees:** 24,000
- **Revenue:** $6.9 billion in 2022
- **Number of members:** 580,000
- **Market reach:** One million patients in Pennsylvania

Sources: Kaiser Permanente, Geisinger Health, Philadelphia Inquirer.

Kaiser-Geisinger Acquisition Sets Stage for More Deals

➤Kaiser CEO wants to purchase more health systems and fold them into newly-created Risant Health

➤➤CEO SUMMARY: Even as experts were predicting more consolidation among multi-hospital health systems at the Executive War College in New Orleans last month, acquisition of Geisinger Health by Kaiser Permanente was announced. Not only does the deal confirm the consolidation trend involving hospitals, but it also sets the stage for advances in value-based care and value-based reimbursement models.

EARLY ON THE SECOND MORNING of last month's *Executive War College* it was announced that **Kaiser Foundation Hospitals** was acquiring Pennsylvania-based **Geisinger Health**. Geisinger will become part of a new healthcare enterprise owned by Kaiser called **Risant Health**.

This news caught the attention of attendees. That's because the trend of multi-hospital health system consolidations was a key observation made in the previous day's opening remarks by Robert Michel, Editor-in-Chief of THE DARK REPORT. *(See pages 8-9)*

➤Prediction Confirmed

Less than 24 hours later came market validation of Michel's observation and prediction that health system consolidation would be one of the most impactful trends taking place during the ongoing transformation of the U.S. healthcare system.

If we accept Michel's premise that integrated delivery networks (IDNs) will continue to acquire or merge with each other, then another premise becomes relevant. The larger an IDN becomes, the more it will require all lab tests performed on behalf of its patients at inpatient, outpatient, and outreach settings to use the same test methodology and reference ranges, and that cumulative lab data on individual patients be easily accessible by physicians and other providers within the IDN.

Reinforcing these observations are statements made by the Kaiser CEO during the announcement of the acquisition. "Our mission calls on us to find new ways to promote high-quality, affordable, and evidence-based care with equitable and improved health outcomes. Through Risant Health, we will make our value-based care expertise, technology, and services available to community-based health systems, like Geisinger, to strengthen their ability to provide value-based care models with a focus on high-quality and equitable health outcomes," said Greg. A. Adams, Chair and CEO of Kaiser Permanente.

The success or failure of Kaiser's plans for its Risant Health enterprise will be influential on how its constituent regional health systems utilize lab testing. It can be expected that Risant health will leverage the value of clinical lab testing and anatomic pathology services in new ways that

are designed to deliver more value and better outcomes.

What may be a factor in making that prediction come true is that the leadership of Geisinger's Division of Pathology and Laboratory Medicine is committed to the concept of Clinical Lab 2.0. Geisinger's lab team is a founding member of the **Project Santa Fe Foundation** in 2016.

Ramification of the Deal

Lab administrators and pathologists tasked with the strategic direction of their respective lab organizations should take time to study this development and understand its ramifications for the hospitals, physicians, patients, and payers who use their lab testing and diagnostic services.

At the same time, there are broader implications involved in Kaiser's acquisition of Geisinger. This transaction fits within several important trends now transforming healthcare in the United States.

First, the Kaiser-Geisinger merger is certainly a high profile transaction involving two highly-prominent IDNs. However, similar large deals are happening with regularity. In prior intelligence briefings, THE DARK REPORT called attention to this trend with these examples:

- **Scott & White** acquires **Baylor Health** creating **Baylor Scott & White** (51 hospitals).
- **Atrium Health** in Charlotte, North Carolina, merges with **Aurora Advocate Health** of Milwaukee and Chicago (67 hospitals).
- **Sanford Health** acquires **Fairview Health** (deal pending, 58 hospitals).

Integration of Clinical Care

Another important transformation in healthcare is the move toward proactive care—keeping patients well and keeping them out of hospitals—which requires operational and clinical integration across all classes of providers.

This dual integration of operations and clinical care delivery is where both Kaiser and Geisinger have been national leaders. The CEOs of the two organizations plan to take their collective knowledge and use it to help other IDNs.

"We know fully replicating KP's closed integrated care and coverage model is not viable in all communities, stated Adams. "By helping other health systems achieve our value-based quality outcomes and savings in multi-payer, multi-provider environments, we believe Risant Health can deliver a transformative new solution to America's systemic healthcare problems."

Role of Risant Health

Risant Health will be the vehicle to actualize that vision. In the press release announcing the merger, the two organizations wrote, "Risant Health is a new nonprofit organization, created by Kaiser Foundation Hospitals, to expand and accelerate the adoption of value-based care in diverse, multi-payer, multi-provider, community-based health system environments. Risant Health's vision is to improve the health of millions of people by increasing access to value-based care and coverage and raising the bar for value-based approaches that prioritize patient quality outcomes."

Pathologists and lab administrators who want to position their lab organizations to deliver more value in value-based healthcare systems will want to study how Kaiser uses Risant and Geisinger to replicate its "closed integrated care and coverage model."

For decades, lab leaders have bemoaned the status of lab tests as commodities when payers set prices during managed care contract negotiations. Value-based reimbursement models change this status quo. Lab leaders now have an opportunity to use lab tests to deliver value—and be paid for that value—by improving patient outcomes and lowering care costs. TDR

Major Events on Horizon to Reshape Lab Market

➤Future for labs will be as 'masters of data' as health systems continue to buy each other

➤➤CEO SUMMARY: Speakers at last month's Executive War College discussed a range of significant trends and changes happening today in the U.S. healthcare system. Two of the most important trends are consolidation of multi-hospital health systems and the growing demand for lab test data—particularly when combined with other types of data add value and improve patient care. Collectively, speakers at the conference painted a bright future for labs, but only if lab leaders act in a timely fashion.

If there was one common theme linking the sessions and speakers at last month's *Executive War College*, it was that clinical laboratories need to become masters of data and use it to deliver value.

This is an important insight. Speaker after speaker placed emphasis on the need for clinical labs, pathology groups, and diagnostics companies to beef up their information technologies, use it to gather relevant data, and then combine that data with other types of data in ways that create value, particularly for referring physicians and payers.

➤Record Attendance

The occasion was the 28th annual *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* conducted at the New Orleans Hyatt Regency Hotel on April 25-26. More than 950 senior lab executives, pathologists, and lab managers attended—a record crowd.

The concept of "labs as masters of data" was a common thread during a large proportion of the 80 sessions that featured 125 speakers and expert panelists. Collectively, this volume of knowledge—as shared from the podiums and panels at the *Executive War College*—was itself powerful evidence that the era of data mastery is now a major force in the lab testing marketplace.

➤Labs as 'Data Masters'

Data mastery is linked to another powerful trend now underway within the U.S. healthcare system. That trend is the continuing consolidation, not just of individual hospitals, but of multi-hospital healthcare networks.

"Integrated delivery networks (IDNs) are watching fee-for-service reimbursement transition to different value-based payment models," observed Robert L. Michel, Founder and Director of the *Executive War College*, in his opening remarks.

"Employers and payers share the goal of rewarding providers for keeping beneficiaries healthy and preventing acute events that require treatment in hospitals—the most expensive site for clinical care," he added.

"To deliver preventive care, IDNs must integrate their primary care physicians, specialist physicians, and ancillary providers, including lab, radiology, and physical therapy," Michel continued. "The larger IDNs also want to control a major share of their regional market so as to have clout with the managed care companies when negotiating contracts.

"Each factor is a driver in health system consolidation," he noted. "This has important implications for the clinical laboratories and pathology groups that serve these IDNs. For example, labs need state-of-the-art information technology capabilities that enable them to seamlessly move lab test data throughout the IDN to all providers, as well as to health insurance plans.

Combining Lab, Other Data

"At the same time, labs need the ability to take lab test data, combine it with clinical, demographic, and other sets of data, and generate insights useful to parent hospitals, physicians, patients, and payers," Michel stated. "I call this 'actionable intelligence' and pioneering labs pursuing the Clinical Lab 2.0 ideal are convincing health plans to pay them for actionable intelligence that physicians can use to improve patient outcomes and reduce the cost of care for a patient, when measured over time."

As reported in this issue on pages 3-7, less than 24 hours later, **Kaiser Permanente** announced its acquisition of **Geisinger Health** and the formation of **Risant Health**. Kaiser will operate Geisinger within Risant and intends to acquire other regional IDNs as well, and operate them within Risant specifically to development them into fully-integrated, value-based provider organizations.

It's not often a speaker can make a prediction from the podium during a national meeting and have that prediction validated by market developments the very next day.

Long-time clients and readers of THE DARK REPORT are familiar with the two themes that were front and center at the *Executive War College*: One theme being the sophisticated use of lab data combined with other types of data, and the other being the ongoing consolidation of IDNs specifically to pursue the goal of full integration of clinical care.

Growth of Precision Medicine

One interesting aspect of the expanding importance of lab test data is the steady growth in precision medicine. A precision medicine service may need to incorporate multiple types of diagnostic data, ranging from genetic sequences, proteomics, microbiomics, and metabolomics, to name the primary data types at this time.

Multiple sessions and speakers addressed the ongoing advances in next-generation genome sequencing, digital pathology, and workflow solutions. Each can be powered by artificial intelligence and machine learning.

Pharmacies Want Lab Data

One notable presentation was delivered by David Pope, PharmD, CDE, Chief Pharmacy Officer at revenue cycle management company **XiFin** in San Diego, during his keynote address. "Pharmacists are true contenders as a new provider for labs," Pope observed. "An area of pharmacy that is dependent upon labs is specialty medications."

Specialty medicines now account for an incredible 55% of all prescription spending, up from 28% in 2011. That increase was driven by growth in autoimmune treatments and oncology, Pope noted. **AARP** reported in 2021 that—because this medicine is expensive—the average annual cost for a single specialty medication used on a chronic basis was $84,442. Health plans will want to see diagnostic data that backs up the necessity for these prescriptions.

Collectively, many speakers at this year's *Executive War College* were optimistic about the financial future of clinical labs, so long as they act to convert lab data into useful intelligence that adds value and for which payers will reimburse. **TDR**

Lab Market Update

AACC Changes Name to ADLM, Seeking to Broaden Appeal

Hoping to broaden its influence within the laboratory industry, the **American Association of Clinical Chemistry** (AACC) announced that its members approved a name change to the **Association for Diagnostics and Laboratory Medicine** (ADLM).

The official launch of the new name will be at the group's Annual Scientific Meeting and Clinical Lab Expo in July.

The decision came on April 21 during AACC's business meeting in Tysons Corner, Virginia. Members voted either in person or online. The AACC did not publicly specify how many members voted yes or no. The organization's board of directors had previously voted to unanimously support the name change.

'Bold Change' for AACC

In an April 26 podcast, outgoing AACC President Shannon Haymond, PhD, DABCC, FAACC acknowledged that not every member was on board with the name change. "This is a bold change that not everyone is immediately accepting of," Haymond said.

A portion of the 12-minute podcast was spent reassuring members that the mission of AACC to promote clinical laboratory science would not change.

"The only challenge that we have here is just making sure [members] know that they have the ability to communicate to us, that their opinion does matter, and that the association will be what they make it," said President-Elect Octavia Peck Palmer, PhD, FAACC.

The AACC, which is now celebrating its 75th year, will not abandon its clinical chemistry roots, Senior Director of Communications Molly Polen commented to The Dark Report before the membership vote.

Clinical Chemistry Roots

"Though the name change and rebranding would affect the association and members in a variety of ways, it's important to emphasize that—with membership including more than 85% of total DABCC diplomats in addition to many others boarded in clinical chemistry—ADLM will remain the professional home for clinical chemists," Polen said. "In fact, the association's journal, *Clinical Chemistry*, would not change its name to reflect the new name for the association."

How the name change affects the Annual Scientific Meeting—possibly the lab industry's largest conference, which drew 17,000 last year—remains to be seen.

Polen downplayed any consequences for the conference from attendees and sponsors due to the name change. Presumably, the new ADLM name will be attached to the event in the future.

"[The new name] more accurately reflects who we are today with all our programs, including the annual meeting," she said. "Over the years, AACC's programs have grown to serve other specialty areas working in or adjacent to the clinical lab, and the new name was chosen to better represent this—to broaden our invitation to collaborate, not narrow it."

In 2022, the AACC partnered with two research firms to test 11 name options with multiple focus groups. Participants in the focus groups gravitated toward the ADLM name, Polen said. TDR

Payers Request More Claims Documentation

Labs and RCM companies confirm that more payers are denying a higher proportion of claims

Stephanie Denham

CEO SUMMARY: Both anecdotal evidence from lab professionals and numbers-based data from XiFin point to a problem: More payers require clinical labs to produce more documentation that a test claim is valid. Automated denials and inconsistencies in applying denial codes are contributors to this unwelcome trend in how payers process claims.

Diana Richard

More payers are requiring clinical laboratories to submit more documentation to demonstrate that a test claim is medically necessary and warranted.

An informal poll during a recent Dark Daily webinar saw 90% of participants answer "yes" when asked if they have recently seen an increase in the volume of documentation requests from payers.

"All the time!" one attendee shared with Dark Daily during the live webinar.

"UHC sends lots of medical record requests, but they usually pay after that," wrote another, referring to **UnitedHealthcare**. "It's also easy because you can submit them online."

"**Blue Cross Blue Shield** and **Aetna** are hugely problematic in Pennsylvania," according to an attendee from that state.

Another participant from a molecular diagnostics lab stated that document requests were coming mostly from **Cigna** and UHC.

These anecdotal accounts were backed up during the webinar by information from revenue cycle management (RCM) company **XiFin** in San Diego. Data analyzed by the company indicated that more payers—especially UHC—are requiring providers to submit documentation demonstrating that claims are warranted.

"We see this in high volumes on clinical lab tests in particular," noted Stephanie Denham, Associate Vice President of RCM Systems and Analytics at XiFin. Denham spoke during the webinar, which was titled, "Learning from Payer Behavior to Increase Appeal Success."

Why Payers Question Claims

Claims denials by payers are a fact of life for clinical laboratories and pathology practices. However, the increased number of claims denials, in tandem with requests for more documentation, is motivating innovative labs to implement process improvements in their coding, billing, and collections work flow. These improvements in RCM can lead to more successful appeals and shorter wait times for payments.

To help labs better understand why payers deny certain claims, Diana Richard, Senior Director of Pathology and Strategic Development at XiFin, presented

an internal study during the webinar that analyzed more than 25 million claims from the company's client database of transactions with dates of service in 2021.

The study included extensive information about common reasons for claim denials, with breakdowns for the clinical laboratory, molecular laboratory, and anatomic pathology practices within XiFin's clientele.

Cases at Risk of Denial

"The most effective way to maintain manageable accounts receivable and improve the propensity to pay is to proactively capture cases at risk of denial *before* the claim is ever submitted," Richard said. "Denials will never go away, but XiFin devotes focused effort to strategically develop ways, at the front end, to mitigate that as much as possible."

The top reasons for denials included the following codes, she noted:

- CO151—The payer believes the information submitted does not support this many/frequency of services.
- CO197—Contractual obligation precertification, authorization, or notification is absent.
- CO252—Payer will reconsider the claim when additional information is received.
- CO96—Noncovered charges.
- CO50—Not deemed a medical necessity by the payer.
- CO55—Experimental or investigational test.

Among the segments tracked in the study, molecular labs had the highest denial rate at 27%, Richard said, followed by anatomic pathology at 19% and clinical laboratories at 13.6%. Each of these segments has seen varying trends in the reasons for claim denials.

"For labs in the molecular space, 'experimental and investigational with no prior authorization' denials have become very familiar over the last several years," she noted. "However, in routine anatomic pathology, prior-authorization denials continue to be one of the fastest-growing denial types."

The same is true of clinical labs, the XiFin study found.

THE DARK REPORT has previously noted the difficulty that genetic laboratories have in getting approval and payments for molecular tests. Reasons for these obstacles include a lack of trust from payers about the medical value of novel genetic testing and onerous prior-authorization practices.

"Beyond fraud, payers worry about coding troubles from clinical laboratories and pathology groups," THE DARK REPORT previously observed. *(See TDR, "How Genomic Testing Labs Can Improve Their Relationships with Payers," October 10, 2022.)*

Beyond the specific reasons for denials, there are nuanced differences in how different payers automate claims denials, Denham said.

For example, a March 25 *ProPublica* story revealed that Cigna uses an automated system to flag claims for tests or procedures that the payer believes to be inappropriate. Medical directors employed by Cigna quickly sign off on the denials without examining the cases, *ProPublica* reported.

Internal Cigna Documents

"Over a period of two months last year, Cigna doctors denied over 300,000 requests for payments using this method, spending an average of 1.2 seconds on each case," the story noted, citing internal Cigna documents reviewed by the news outlet.

In a statement, Cigna told *ProPublica* that it disputed the tenor of the reporting and that its system was created to "accelerate payment of claims for certain routine screenings," the payer wrote. "This allows us to automatically approve claims

when they are submitted with correct diagnosis codes."

In general, the idea that software is aiding a payer's review of diagnostic test claims is not surprising, Denham said during the webinar.

"In reality, every payer has some kind of front-end claim-editing system in place," she observed. "The initial claim form that goes to these payers has a limited amount of information. It has procedure codes and diagnosis codes, the patient's age, and the location of the service.

"Payers use data to edit and make decisions about whether something is likely necessary and payable," Denham added. "That is the reality in how claims are handled today."

Prior Authorization Denials

Denham pointed to other problematic practices among payers about which clinical laboratories and pathology practices should remain vigilant:

- **Inconsistency in denial codes and Remittance Advice Remark Codes.** "Sometimes payers will continue to deny a certain type of claim using these front-end edits, but they'll start using a different denial code," she said. "It is key to understand whether that is happening and whether it warrants an updated process for working with the payer."
- **Denial of claims that had prior authorizations.** "Even when labs obtain prior authorization on the front end, they get denials for medical necessity on the back end," Denham stated. "Essentially the lab must submit the same documentation that was required for the prior authorization." XiFin has noticed this concern particularly with UnitedHealthcare, but "it's probably happening in other places," she said.
- **Using the contractual allowance adjustment code to deny test reimbursement claims in full.** "CO45 is the code that says, 'The lab's charges

Process of Appealing a Denied Test Claim

STEPHANIE DENHAM AT XIFIN DESCRIBED DENIAL APPEALS as a three-cycle process based on who reviews the request: a registered nurse, an independent contractor, or an administrative judge.

Registered Nurse Review: "The first level is what labs do day in and day out," she said. "The provider [lab] sends information back to the payer saying, 'We don't think you should have denied this claim. Here's all documentation to prove why you shouldn't deny this claim. We want you to review this documentation and pay the claim.'"

This request will typically be reviewed by a registered nurse or someone with similar training, "but not necessarily a healthcare professional with experience in that specialty or with that type of testing," Denham explained.

One key in the response will be to describe the procedure in a way that aligns with that level of knowledge. "If you know there's a payer policy related to this type of testing, maybe the report includes language straight from the payer policy about why this was medically necessary," she suggested.

Contractor and Judge Reviews: A second-level appeal will likely go to an independent contractor with medical knowledge. Here, too, the quality of documentation is important, Denham said.

Finally, a third-level appeal would be heard by an administrative law judge, but this is an aggressive step by a clinical laboratory and should be used sparingly, she noted.

About 82% of successful appeals come at the first level, according to data from XiFin. "Obviously, shortening the timeframe from service rendered to money in the bank is the goal," concluded Denham.

are higher than the contract allows, so the charges are being adjusted down.' That's fine. Labs will have that in their contracts with payers," Denham said. "But we had an incident years ago where payers were using this code incorrectly in high volume, and essentially adjusting the claim to zero instead of the allowed contracted amount. Labs should stay alert for that problem."

Coping Strategies

For clinical labs, one key method for handling denials is providing high-quality documentation, Denham said. "Any time labs must submit an appeal or any type of documentation to payers, labs open up the medical records for that payer to review," Denham said.

"The payer may only be looking for one piece of information, but the lab has to send the whole record," she added. "That's why it is very important that every patient encounter has documentation that supports three key pieces of information: 1) that the testing was ordered; 2) that it was actually performed; and, 3) that it was medically necessary."

Labs should also be prepared to deal with specific edits that are commonplace. For example, under the **Centers for Medicare and Medicaid Services**' National Correct Coding Initiative (NCCI), a claim might be denied with code CO97.

Not Billed at Same Time

"This indicates that the codes used for billing should not go together or should not be billed at the same time," Denham explained. "The payer did not think it was necessary for the lab to perform both of these services. However, in such a case, it's likely that the provider performed the services because of some medically necessary reason."

Labs should document this reason in the medical record, but with NCCI edits, an appeal probably isn't necessary, she said. Instead, the provider can add a modifier and submit a corrected claim.

Judge Dismisses Part of NJ Lab's Lawsuit

DENIAL OF LARGE NUMBERS OF COVID-19 LAB TEST CLAIMS is the key issue in a two-year-old lawsuit filed by **Genesis Laboratory Management** against **UnitedHealthcare** (UHC).

In 2021, **Genesis**, based in Oakhurst, N.J., sued UHC in New Jersey District Court for allegedly not paying more than $20 million COVID-19 test claims. *(See TDR, "NJ Lab Sues UnitedHealth over Unpaid Test Claims," July 26, 2021.)*

Among Genesis' arguments was that UHC violated the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Genesis also contended that UHC imposed extensive demands for documentation for test claims.

On March 6, Judge Evelyn Padin dismissed some of the complaints under the suit, including the claim that UHC violated the CARES Act. The court concluded that the CARES Act and FFCRA did not provide private parties with any right of remedy. Said another way, it would be up to the government to enforce the CARES Act.

"Even if Congress intended to create a personal right of reimbursement for providers, like plaintiff, through the FFCRA and the CARES Act, there is nothing in the text or structure of those acts suggesting that Congress intended to afford a privately enforceable remedy to plaintiff," Padin wrote.

Part of the suit was allowed to continue contingent on Genesis filing an amended briefing.

The DARK DAILY webinar is available on demand for free by going to *www.darkdaily.com/webinar/*. TDR

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Lab Execs Allegedly Lied to FDA about Faulty Tests

Parent company of Magellan Diagnostics ready to resolve case of alleged inaccurate test results

CEO SUMMARY: Three former executives of a lab testing company face criminal charges. Federal prosecutors claim that the three plaintiffs who previously worked at Magellan Diagnostics flagrantly hid information from the Food and Drug Administration about inaccurate lead poisoning test results delivered via its devices. Corrections were later made to the product, sold under the LeadCare brand.

PROSECUTORS FILED CRIMINAL CHARGES AGAINST THREE FORMER EXECUTIVES FROM A DIAGNOSTIC LABORATORY on fraud charges stemming from alleged faulty devices used to test blood for lead poisoning.

The intriguing twist is that the defendants allegedly knew the devices had problems yet hid that information from the **U.S. Food and Drug Administration** (FDA), stated the **U.S. Attorney's Office**.

For clinical lab leaders, the case highlights a new tactic from prosecutors: pursuing criminal charges against decision-makers who work at established labs.

The case centers on **Magellan Diagnostics** in Billerica, Massachusetts, which sold sensors that analyzed blood samples to detect lead poisoning. The devices are marketed as LeadCare, which hospital labs and physician offices use.

"We believe these executives knew about this malfunction for years but failed to come clean to their customers and the FDA about it in order to boost their company's bottom line," said Joseph Bonavolonta, Special Agent in Charge of the **FBI's** Boston Division, in a statement on April 5. The FBI and federal **Department of Justice** (DOJ) aided in the investigation.

Meridian Biosciences in Cincinnati acquired Magellan in 2016 for $66 million. Meridian was bought by South Korean **SD Biosensor** in January 2023.

Prior to its acquisition, Meridian was a publicly traded company. In its 2022 Form 10-K—an annual financial report submitted to the **U.S. Securities and Exchange Commission**—Meridian acknowledged the Magellan investigation.

"As of December 31, 2022, in accordance with applicable accounting guidance, the company believes a loss is probable in the DOJ LeadCare legal matter and has accrued $42 million as an estimate of the cost to resolve the DOJ LeadCare legal matter," the Meridian 10-K noted.

Parent Company Hopes to Settle

The Boston Globe reported on April 5 that Meridian "is negotiating a payment with federal officials over the issue and has set aside funds for that purpose." Meridian is not a defendant in the case.

The following former executives were charged with conspiracy to commit wire fraud, wire fraud, conspiracy to defraud a U.S. agency, and introduction of misbranded medical devices into interstate commerce with intent to defraud:

- Amy Winslow, 51, of Needham, Massachusetts (Magellan's former CEO from 2011-2016).
- Hossein Maleknia, 64, of Bonita Springs, Florida (Magellan's former Chief Operating Officer from 2012-2021).
- Reba Daoust, 66, of Amesbury, Massachusetts (Magellan's former Director of Quality Assurance and Regulatory Affairs from 2012-2017).

At press time, attorneys for Winslow and Daoust did not return requests for comment. THE DARK REPORT was unable to find an attorney for Maleknia.

Winslow and Maleknia worked to set up Magellan for a sale during the period in question. "After Magellan was acquired by Meridian … Winslow received a bonus of approximately $2 million, and Maleknia received a bonus of approximately $448,000," the indictment said.

Magellan's devices—LeadCare Ultra, LeadCare II, and LeadCare Plus—detected lead levels using venous or fingerstick samples. Tens of thousands of patients allegedly received inaccurate test results from the sensors, the indictment stated.

Lies to the FDA Are Alleged

In 2013, Magellan sought FDA clearance for LeadCare Ultra. During that period, the company allegedly discovered a malfunction that misread lead levels depending on how long samples sat in a reagent. An employee forwarded these results to Daoust, who then alerted Winslow and Maleknia, according to the indictment.

The company allegedly did not report the malfunction to the FDA, which cleared LeadCare Ultra in August 2013. The defendants conducted subsequent studies, which confirmed the malfunction in LeadCare Ultra and also LeadCare II, the indictment stated. The company did not tell customers about the problem.

Then, in August 2014, LeadCare Ultra customers started to uncover the malfunction on their own, the government said. The defendants allegedly directed other Magellan employees to tell complaining customers that the company was surprised to hear about the problems.

When a consultant hired to analyze the malfunction threatened to tell the FDA if the company did not do so on its own, Magellan notified the agency in April 2015. But Magellan allegedly lied about how long it knew of the problem.

In May 2017, the FDA issued a recall of LeadCare Ultra, LeadCare II, and LeadCare Plus for venous samples. Replacement materials have since allowed these tests to be sold again. TDR

Meridian Biosciences' PT Testing Brouhaha

LONG-TIME READERS MAY RECALL that Meridian Biosciences—which is cooperating in the fraud case involving a subsidiary that sold allegedly faulty devices to detect lead poisoning—was involved in a publicized situation regarding proficiency tests it produced in 2004-2005.

A strain of Influenza known as A/H2N2 was included in virology PT kits prepared by Meridian and shipped to thousands of laboratories participating in the PT programs of the **College of American Pathologists**, among other groups. *(See TDR, "Ramifications from the 'H2N2' Virus Affair,'" May 9, 2005.)*

A transplant patient was accidentally cross contaminated by one of the kits, starting off a firestorm of criticism from public health agencies about why the kits included a flu strain that killed up to four million people in 1957-58.

However, THE DARK REPORT noted that the hubbub was downplayed by clinical laboratorians, who were not nearly as concerned about kits with live H2N2 virus. They suggested the outcry was simply designed to improve the standing of public health officials.

Lab Market Update

Quest, Labcorp Both Report Growth in Base Lab Business

Quest optimistic about consumer-initiated testing growth, centered on seasonal allergies and STDs

During the latest quarterly earnings reports from **Quest Diagnostics** and **Labcorp**, it was largely "same old, same old" as base business continues to improve post-pandemic, while COVID-19 test demand drops.

However, interesting insights about the status of the clinical lab marketplace were shared during the first quarter earnings calls.

During the Quest Q1 2023 earnings call on April 27, CEO Jim Davis stated the company saw growth in consumer-initiated testing. Quest, based in Secaucus, New Jersey, did not provide dollar figures associated with this increase.

Davis noted there has been strong consumer demand for allergy testing in 2023 due to spring allergy season coming earlier than usual. The lab company also saw a notable uptick in sexually-transmitted disease (STD) testing. In both cases, consumers order the tests online, pay for the tests, and go to a Quest service center to provide samples.

"Our STD category continues to exhibit very strong growth," Davis told analysts. He said a segment of consumers prefer to order STD tests on their own rather than involve a physician.

In April, the federal **Centers for Disease Control and Prevention** (CDC) released figures showing that chlamydia, gonorrhea, and syphilis infections increased from 2020 to 2021. Further, in 2021, 51% of all reported cases of these three STDs were among people ages 15 to 24.

"Those are consumers who want to remain anonymous and just pay out of pocket [for STD testing] for lots of reasons" Davis said.

The potential of consumer-initiated and over-the-counter testing isn't just limited to national laboratory companies. THE DARK REPORT noted last year that hospital-based and independent labs can also successfully promote on-demand testing in the right circumstances. *(See TDR, "Hospital Lab Outreach Taps On-demand Testing," Aug. 8, 2022.)*

COVID-19 Testing at Labcorp

Financial analysts are closely watching COVID-19 test volumes at the two national lab companies. Although it is recognized that testing demand for SARS-CoV-2 has declined rapidly over the past year, the drop was even more pronounced in Q1.

"COVID PCR testing volumes declined during the quarter, more than expected, totaling more than 870,000 tests performed and averaging 10,000 tests per day," commented Adam Schechter, CEO at Labcorp in Burlington, North Carolina, during an investors call on April 25. "We expect COVID testing to continue to decline."

When the federal public health emergency (PHE) for COVID-19 ends on May 11, Labcorp expects Medicare reimbursement for these tests to be cut in half.

Quest ran 1.3 million COVID-19 tests in Q1, down five million from Q1 2022. "COVID-19 molecular volumes have declined faster than we expected over

the last several weeks," explained Sam Samad, Chief Financial Officer (CFO) at Quest. "We now expect minimal volume contribution from the retail [pharmacy] channel post-public health emergency."

Quest Diagnostics Base Revenue Up

For the three months ending March 31, 2023, Quest reported the following Q1 numbers:

- Overall revenue was $2.33 billion, down 10.7% from Q1 2022.
- Base business revenue (excluding COVID-19 test earnings) was $2.21 billion, up 10%.
- COVID-19 test revenue was $119 million, down 80.2%.
- Revenue per requisition decreased 7.7%, and requisition volume went down 3.8%.

Quest did not provide actual figures for the requisition performance. However, despite the overall drop, Davis said certain tests performed well, including Quest's new Alzheimer's blood test, cardiometabolic tests, prenatal genetic tests, blood-based tuberculosis screening, and hepatitis B and C screening.

"General health and wellness visits have a high test-per-req [rate] because you're testing across the entire human body," Davis noted. "So, I think our tests per req were really powered by that."

Of note during Q1 was Quest's acquisition of **Haystack Oncology** in Baltimore, which develops liquid biopsy tests for cancer, for $300 million. Look for more analysis of this acquisition in a future issue of THE DARK REPORT.

Labcorp: Diagnostics Revenue at $2.38 Billion for Q1

For Q1 2023, Labcorp reported:

- Overall revenue was $3.8 billion, down 3.1% compared to Q1 2022.
- Base business earnings grew 10%. Labcorp did not provide an exact dollar figure for base business.
- Diagnostics revenue for the quarter was $2.38 billion, down 2.9%.
- Requisition volume dropped by 3.3% and price per requisition went up 0.4%.

The drop in test volume was attributed to a decrease in COVID-19 testing compared to a year earlier. That was a time when the Omicron variant was spreading widely and there were surges in the demand for SARS-CoV-2 testing. TDR

Quest Enters Supply Chain Agreement

QUEST DIAGNOSTICS CONTINUES TO PUSH INTO SUPPLY CHAIN SERVICES for selected hospital clients. It represents another way the lab company wants to deliver value.

On Feb. 16, Quest announced a multi-year agreement with **Tower Health** in Reading, Pennsylvania, to provide lab supply chain expertise, including the purchase of capital equipment, supplies, and reagents. Tower is an integrated delivery network with four hospitals.

In September, Quest revealed that it was now offering supply chain assistance to customer labs, hoping to capitalize on global supply chain problems that have rocked many industries. *(See TDR, "National Lab Says It Will Help with Supply Chain Services," Jan. 23, 2023.)*

Typically, *in vitro* diagnostics (IVD) companies have filled this supply chain role for labs. It's not clear how IVD firms will view this move by Quest, as its relationship with IVD manufacturers—which likely sell supplies to Quest—turns into more of a pseudo-competitor.

Another question yet to be answered is whether health system labs that partner with Quest for supply chain services are doing so at a reduced cost compared to IVD supply agreements these labs can obtain on their own.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Responding to the need to expand access to training for diagnostic testing professionals, the **CDC Division of Laboratory Systems** has launched OneLab TEST (Timely Education and Support of Testers). OneLab TEST is an online network for those who perform diagnostic medical testing at non-laboratory sites, such as retail pharmacies, physician offices, and schools. The CDC started OneLab in 2020 to connect clinical and public health laboratory workers with ongoing learning. The overall group has more than 2,500 members.

MORE ON: *OneLab TEST*

OneLab TEST provides free, online education, training courses, and job aids, according to the CDC. The network also lets members connect with their peers to learn from one another. To register for an account, go to *reach.cdc.gov/onelabtest*.

PATHOLOGISTS AMONG DOCTORS WITH SALARY INCREASES

Pathology was among the 10 specialties that saw the largest increase in average salary from 2021 to 2022, according to **Doximity's** "2023 Physician Compensation Report." Data from the professional medical network indicated that the average annual compensation for pathologists in 2022 was $357,384, up 2.7% from the prior year. The specialty with the biggest increase? Emergency medicine physicians, with a 6.2% increase.

LAB SETTLES FALSE CLAIMS ACT CASE FOR $5.9M

Genotox Laboratories in Austin, Texas, will pay $5.9 million to resolve False Claims Act allegations, according to the federal **Department of Justice** (DOJ). From 2014-2020, Genotox paid volume-based commissions to third-party marketers and submitted claims to **Medicare** for medically unnecessary drug tests. "Genotox admitted and accepted responsibility for offering healthcare providers order forms known as 'custom profiles' for each provider to pre-select the tests to order, which Genotox then performed and billed … generally at the highest reimbursement categories," the DOJ stated.

TRANSITIONS

- Sarina Rodriques, FACHE, has been named COO at **Simple Laboratories** in Chicago. She held similar roles at **ClinPath Associates** and **Pathology Specialists** of Arizona.

- **Precipio, Inc.** in New Haven, Conn., appointed Bill Breit as Vice President of Pathology Sales. Previously he served at **Eurofins**, **Integrated Laboratory Solutions**, **Solstas Lab Partners**, **Quest Diagnostics**, **Dianon**, and **Labcorp**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, May 30, 2023.

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