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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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Interesting New Surprises for Lab Leaders

UNEXPECTED AND SURPRISING THINGS CONTINUE TO HAPPEN in the clinical laboratory industry. You might consider that to be one unifying theme to the intelligence briefings we present in this issue of THE DARK REPORT.

For example, a pathology lab company in New Jersey sued **UnitedHealthcare** (UHC) seeking payment for 46,400 molecular COVID-19 test claims that are unpaid, representing about $20 million in reimbursement. The odd fact in this case is that the lab company alleges in the lawsuit that UHC is paying a substantial number of COVID-19 test claims for patients covered by an employer's self-insured health plan, but is withholding payment for claims of patients enrolled in UHC's fully-insured plans where the insurer is on the hook for the test payment. Might this be true of how this insurer is handling the COVID-19 test claims submitted by other labs? Might your lab be experiencing a similar dichotomy in how UHC pays your COVID-19 test claims? Now you have a reason to review those claims to see if the same pattern exists. *(See pages 3-6.)*

Starting on pages 7-9, we interview the Chief Information and Technology Officer at **Labcorp** about his company's use of artificial intelligence (AI) and machine learning across a wide swath of the lab's workflow and service lines. This information will help other clinical lab managers better understand why some AI solutions are ready for prime time and can contribute to better performance in the operations of their laboratories.

Once again, THE DARK REPORT is first to identify and describe a new trend in the clinical laboratory profession. The trend is "benefits investigation." Our intelligence briefing on pages 17-18 explains how many patients, especially those on high-deductible health plans (HDHPs), are delaying genetic test orders to give them time to contact different genetic test labs and shop for genetic tests that offer prices they can afford and features they consider best for their healthcare needs.

In addition, actions by the federal government are included in this issue. Last fall, the federal **Centers for Medicare and Medicaid Services** (CMS) ordered **Gamma Healthcare** of Poplar Bluff, Mo., to cease testing services because of serious CLIA deficiencies. With that one decision, a lab serving 2,200 nursing homes in 11 states went out of business. TDR

NJ Lab Sues UnitedHealth Over Unpaid Test Claims

Pathology lab company claims UHC failed to pay 46,400 COVID-19 test claims filed since March 2020

CEO SUMMARY: New case law in how health insurers should reimburse for COVID-19 lab test claims might be one outcome if a New Jersey lab company were to prevail in a federal lawsuit it filed against UnitedHealthcare alleging non-payment of COVID-19 test claims. An interesting fact mentioned in court records is that the health insurer pays a larger proportion of COVID-19 test claims from self-insured health plans compared to claims from its own premium-funded plans.

In New Jersey, an anatomic pathology lab company has sued **UnitedHealthcare** (UHC), claiming the health insurer has failed to pay for about 46,400 COVID-19 test claims—worth more than $20 million—since last year. What gives this lawsuit a novel twist is the lab's discovery that UHC treats COVID-19 test claims differently, depending on a patient's health insurance plan.

Court documents filed by the lab company describe how UHC pays the COVID-19 test claim of a patient covered by a company's self-insured health plan much more frequently than if the patient is enrolled in one of UHC's fully-insured health plans. Stated differently, UHC shows a pattern of denying COVID-19 test claims where its own health plan must cover the cost of the test, but more readily pays COVID-19 test claims where an employer's self-insured health plan is the source of payment for that test claim.

If true, this is a significant finding and may be of value to other labs that bill UnitedHealthcare for COVID-19 tests, but are encountering high rates of denials. One lab billing expert told The Dark Report that if UHC followed a similar process in how it was processing COVID-19 test claims from other labs, this might be grounds for a group of labs to come together and file some type of class action lawsuit against UHC to recover the money owed to them, as mandated in federal and state laws passed in response to the SARS-CoV-2 outbreak.

The story started early last year, when **Genesis Laboratory Management** of Oakhurst, N.J., began performing molecular SARS-CoV-2 tests after the onset of the pandemic. It submitted these COVID-19

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test claims to UnitedHealthcare and other private and government health plans. It quickly saw that UHC was refusing to pay a high proportion of the COVID-19 test claims that the lab was submitting on behalf of patients enrolled in a health plan managed by UnitedHealthcare.

Time for Lab to Fight Back

This winter, rather than accept denials of its COVID-19 test claims stretching back more than a year, the molecular and anatomic pathology testing laboratory decided it was time to fight back using two steps.

In step one, Genesis had its attorney send a demand letter in March to UnitedHealthcare, the nation's largest health insurer, saying UHC and its subsidiary, **Oxford Health Plans**, owed Genesis $20,419,169 for approximately 46,400 claims submitted since the middle of 2020 through this year for COVID-19 diagnostic testing. Note that, as the nation's largest health insurer, UHC reported $257.1 billion in revenue last year and $22.4 billion in profit.

In the demand letter dated March 12, Genesis' lawyer, Craig Carpenito, a partner with the New York law firm of **King and Spalding**, wrote, "As described in detail below, United's failure to reimburse Genesis violates the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which govern reimbursement of testing during the pandemic."

Violations of State Law

UHC also violated state law by failing to pay Genesis' claims promptly, the letter claimed. Some of the unpaid claims date back to March 18, 2020, Carpenito wrote.

When the demand letter was unsuccessful in securing the funds, Genesis took the second step and filed a lawsuit on June 2 in **New Jersey District Court**. In the 27-page lawsuit, Carpenito made three arguments that may be difficult for UHC to challenge.

The first argument is that it is disingenuous and illegal for UnitedHealthcare to claim that it must review detailed clinical records to determine a patient's symptoms before covering the COVID-19 test, the lawsuit said. Federal guidance in the FFCRA and CARES Act states that insurers cannot use medical screening criteria to deny claims for COVID-19 testing.

The second argument put forth by the demand letter and the lawsuit is that the health insurer must explain the steps it has taken to deny the claims, such as making extensive demands for documentation. For instance, the Genesis letter to UHC said UHC requested a place-of-service (POS) code for some claims when the place of service was Genesis' CAP-accredited and CLIA-certified lab in Oakhurst.

"UnitedHealthcare instead seems to demand reporting of an incorrect POS code—the location where the specimen was obtained," the letter added.

Self-Insured Employer Claims

The third argument is that UnitedHealthcare paid Genesis a much higher percentage of the lab's COVID-19 testing claims when the funds involved came from UHC's self-insured employer customers, the lawsuit claimed. At the same time, UHC paid far fewer claims when UHC itself would pay those claims from its own funds, Carpenito wrote.

"For example, United's abusive requests and pre-payment review processes are far less prevalent when its customers' self-funded plans are involved versus fully-insured plans where United's own dollars are at stake," he explained.

"United's tactics are not in good faith because UnitedHealthcare is simply trying to reduce its own spending rather than acting out of legitimate concern that Genesis is not properly documenting its reimbursement claims," he wrote. "Otherwise, United would not be paying such a large share of the claims of its self-funded plan customers where United is acting only as administrator."

Since the start of the pandemic, Genesis has submitted claims to UHC for COVID-19 testing for more than 51,000

Genesis Lab's Lawsuit Describes UHC's Unusual, Extensive Requests for Documentation of Claims

CLINICAL LABORATORY DIRECTORS AND PATHOLOGISTS WILL RECOGNIZE at least one of the tactics that UnitedHealthcare has used in its dispute over claims for COVID-19 testing with Genesis Laboratory Management of Oakhurst, N.J.

In a demand-for-payment letter and in a lawsuit, the Genesis lab company charged that UnitedHealthcare and its subsidiary **Oxford Health Plans** have received enough information from the lab to pay the COVID-19 claims the lab submitted after running the lab tests for UHC members. The lab also charged that by demanding more information to support the claims, UHC's request for more records violated federal law.

"For the majority of the claims at issue, United is demanding an unreasonable level of clinical documentation underlying each COVID-19 test," the demand letter said.

"United appears to be wrongfully withholding payment on these claims—and even instituting some sort of 'pre-payment review'—by sending Genesis repetitive documentation requests with tight response-time demands with which Genesis cannot feasibly comply," the letter said.

Craig Carpenito, a partner with the New York law firm of King and Spalding, represents Genesis.

"United is demanding that Genesis produce this documentation reflecting the physician decision-making process despite it being the laboratory service provider, not the physician ordering the test," he wrote.

Last year, for example, UHC demanded that Genesis produce clinical and operational documentation related to a series of patients "within 30 days from the date of this letter."

Earlier this year, UHC sent a medical records request seeking patient records such as treatment history and physical information, presenting symptoms and complaints, the physician's findings on examination, daily progress notes, X-rays, consultation reports, medication records, and physician orders for durable medical equipment, Carpenito wrote.

He also wrote that before UHC will pay Genesis' COVID-19 testing claims, it also has requested the following information:

- Test results,
- Physician orders,
- Standing orders,
- Laboratory requisitions,
- Pathology reports,
- Unspecified correspondence,
- Patient intake forms,
- Patient initial visit and consultation forms,
- Copies of CLIA certificates for six years,
- All CMS-116 applications,
- Types of equipment used for testing,
- Reagent supply lists and invoices for six months,
- List of reference labs used and tests designated as send-out tests,
- List of names, positions, and credentials of every onsite technical lab staff member,
- Specimen shipping and transport logs,
- Average daily test volumes,
- Average daily send-out test volumes,
- Inspection and proficiency test reports,
- Courier, FedEx, UPS, and USPS information for how each testing specimen is received, and
- Photographs of COVID-19 test kits used and photographs of all contents of the kits.

UHC members, even though Genesis is an out-of-network lab provider for UHC, court documents showed.

"Despite defendants' failure to pay for these testing services, Genesis has never refused to treat their members," the lawsuit stated. "In fact, Genesis was induced to continue performing testing services for defendants' members because United initially paid COVID-19 testing charges during the early stages of the pandemic before it routinely stopped doing so."

In addition to failing to pay Genesis' claims, UHC made extensive demands for documentation from the testing lab, including information that only the requesting physician would have, according to the letter and the lawsuit. Also, UHC gave Genesis what appears to be an unreasonably short time to respond to its demands for more information on the claims Genesis filed, the lawsuit said.

Under the CARES Act, if a health insurer does not have a negotiated rate with a provider, it must pay an amount equal to the cash price for such services the provider has listed on a public website, Carpenito wrote. Under the law, UHC also could negotiate a rate with the lab for less than the cash price on the website, but UHC "did not make any effort to do so," he added.

On its website, Genesis posted the cash price of its COVID-19 diagnostic tests as $256.65 from March 2020 through mid-April 2020. Genesis revised the price to $513 when the federal **Centers for Medicare and Medicaid Services** (CMS) increased its fee schedule amount for COVID-19 testing payment to labs for Medicare members, Carpenito wrote.

The legal publication *Law 360* reported that a UHC representative responded to a request for comment with an e-mailed statement, saying, "We disagree with the allegations in the complaint and intend to vigorously defend ourselves in this matter." TDR

Contact Craig Carpenito at 212-556-2142 or ccarpenito@kslaw.com; Jeffrey J. Sherrin at 518-462-5601 or jsherrin@oalaw.com.

Why Requests for 'Plethora of Records?'

SOME ALLEGATIONS IN THE LAWSUIT FILED BY GENESIS LABORATORY MANAGEMENT against UnitedHealthcare (UHC) over non-payment of COVID-19 test claims are concerning to one attorney experienced with managed care and lab test billing issues.

"The Genesis lawsuit raises very troubling concerns about whether UHC is intentionally—and without a good faith reason—denying payment for COVID-19 testing and putting ridiculous hurdles in the way of the laboratory's being able to get paid," said Jeffery J. Sherrin, attorney at **O'Connell and Aronowitz** in Albany, NY.

"There are very few exceptions to the obligation of payers to cover COVID-19 testing, and—at least from the Genesis complaint—it does not appear that the denials or delays are founded in any of these exceptions," he noted.

"Allegations in a complaint are always one-sided and we have not heard the UHC side, but what is being alleged here is symptomatic of problems labs have been having generally with UHC," Sherrin observed. "If the allegations are true, there would not seem to be a justifiable reason to treat claims funded by premiums differently than claims paid by self-funded plans. Also, I can see no justifiable reason why UHC would need the plethora of medical records it has demanded according to the complaint, when those records would not serve as the basis for denial of the claim.

"I have not heard of any other insurer making similar demands, and on their face these demands appear to be purely obstructionist," he added. "Whether or not there is some impropriety in the Genesis testing and billing that would justify these measures by UHC is to be determined, and it will be interesting to hear what UHC claims as its reasons for adopting the alleged payment practices."

Labcorp Now Using AI for Operations, Patient Care

Artificial intelligence, machine learning support improvements to lab workflow and customer service

CEO SUMMARY: In recent years, Labcorp invested significant sums to use artificial intelligence and machine learning technologies—often integrated with robotic systems—to improve work processes and gain real-time insights from vast amounts of data. In this exclusive interview, Lance Berberian, Labcorp's Chief Information and Technology Officer, discussed several of the successes the lab company is having with these solutions, which involve lab operations, customer service, and more.

FOR LABCORP, ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING ARE NOT COMING—they are here—and being applied to support the company's services to hospitals, physicians, and patients in myriad ways.

This fact should catch the attention of lab administrators and pathologists in hospital and health system labs who want to be fully competitive in all aspects of lab operations and delivery of clinical services. The current generation of AI and machine learning technologies are robust and can make a significant contribution in improving the performance of different aspects of a lab's workflow and service mix.

Labcorp is one of the world's largest clinical laboratory networks with 36 primary laboratories in the U.S. and $14 billion in revenue in 2020. The company has applied AI and machine learning across drug development and diagnostics including clinical laboratory workflow and operations.

"We use AI for a ton of different things. AI has had a tremendous impact on our operational capabilities," said Lance Berberian, Executive Vice President and Chief Information and Technology Officer at Burlington, N.C.-based Labcorp in an exclusive interview with THE DARK REPORT. "This includes right test at right location, maximizing our throughput, and minimizing turnaround time. Those are core foundational operational areas.

AI and Patient Care

"Improving the care of patients is getting a tremendous amount of effort that involves use of AI," he continued. "AI is providing a better consumer and patient experience. Similarly, applying artificial intelligence to our clinical capabilities is another aspect."

In its white paper, "How Artificial Intelligence Will Change the Clinical Lab," **Siemens Healthineers** defined AI as "sophisticated software systems that enable computers to augment, or even emulate, human intelligence and decision making."

Within AI, Siemens says, there is machine learning which "uses algorithms to parse and learn from data and then apply this learning to provide insight and make informed recommendations."

Berberian noted, "When it comes to AI, the most important thing to have is a database that is true."

Labcorp has developed its own machine learning models to manage supply distribution and identify employees needed across the company's labs.

"If you don't have supplies and labor, you don't have turnaround time," Berberian said. "If you think of AI as quality data upon which to build, you can model staff you need at a location."

Furthermore, leveraging software, mechanical, and electrical engineering expertise, Labcorp has designed and built robots that take up 7,000 square feet. This work involved **Protedyne Corporation** of Windsor, Conn., a Labcorp subsidiary that is integrating robotic hardware and software infrastructure with data management and process tracking. One such system, the Protedyne Propel Plate Accelerator (PPA), is installed in Labcorp's Burlington and Phoenix labs.

Labcorp's Robots

"We have designed our own robots to work in laboratories. Most labs do not do that," Berberian said. "In eight hours, our robot system can process 750,000 test tubes with absolute precision."

Vision-based AI enables the PPA to recognize loaded test tubes and appropriate positioning of them. While boosting lab efficiency and conserving costs, the robot also helps address the challenge of insufficient specimen quantity, which leads to the dreaded TNP (test not performed) designation, Berberian said.

PPA also records data on remaining amount of specimen. That helps Labcorp serve physicians who want to add a test after getting Labcorp's report.

"In the old days, we didn't know how much specimen remained. We didn't count it or have it. No lab did," Berberian explained. "But what the robot does—after the first order—is count the amount of liquid, so when the call from the doctor comes in we can say, 'We have enough' (to do the additional testing)."

Because of the automation of several work processes handled by this robotic system, lab workers previously tasked with tediously scanning barcodes and putting test tubes on racks, have been given more challenging assignments, according to Berberian.

AI for Better Performing Lab

Berberian next described how, in its services to hospitals and healthcare systems, Labcorp created a Performance Insights AI model to address a health system lab's workflow hiccups. The challenges often include inconsistent test names and test codes, as well as routing specimens across a wide network.

"Because of mergers and acquisitions, in the lab division of a multihospital system, the same test isn't the same test code at every site," Berberian noted. "We have a model that overlays all the labs in a health system. It ties all testing sites together with the correct tests and provides guidance to optimize workflow within the health system laboratory.

"It (the model) gives them a dashboard that is backed by artificial intelligence and by algorithms that helps them understand the performance of their laboratory," he added. "This is an overlay on top of LISs (laboratory information systems) and provides operational improvement for all lab sites. Our lab clients using Performance Insights can determine need—in advance—for reagents and other consumables at various locations."

Enhancing PSC Experience

Labcorp has deployed AI and machine learning across the nearly 2,000 patient service centers (PSC) it operates throughout the United States, specifically to enhance consumers' experience. For example, patients can use the Labcorp Pre-Check online process to make a test appointment and share insurance information.

Upon arrival at PSCs, consumers may place driver's licenses and insurance cards

on a tray without manually entering information. From there, a complex neural network developed by Labcorp works with cloud computing and optical character recognition to read card data. "Even though there are thousands of formats, we recognize the card type and the member ID," stated Berberian.

Berberian heads a team of data scientists and bioinformatics professionals who develop Labcorp's machine learning models for use in its laboratories and with customers. The company calls on vendors for some projects such as one with **Ciox Health**, an Alpharetta, Ga.-based health information management company, and another with **PathAI**, a Boston-based provider of AI research tools for pathology. *(See sidebar at right.)*

Investment in AI

A deep dive into AI also requires a deep investment. The Siemens white paper says 69% of clinical laboratory leaders responding to an "Artificial Intelligence in the Diagnostic Lab" survey believe AI will be implemented in the lab by 2022. But 54% do not know where to begin.

"Your lab has to be willing to invest in these technologies," Berberian advised. "People who report to me have PhDs.They are credentialed. This is not an inexpensive venture. Even with talented people, your lab team may not get to the end goal. We made the necessary investment, and it is hard to adapt these technologies on a small scale.

"I believe we are a better laboratory because of our applications of artificial intelligence and machine learning," Berberian concluded. "AI supports our patients and our customers and I believe that it will be a pivotal technology going forward for our company."

Lab administrators and pathologists may want to reassess the current state of artificial intelligence and how it might be valuable when used in their labs. TDR

Contact Lance Berberian at 336-436-8263.

Labcorp Works with Ciox Health, PathAI

LABCORP AND CIOX HEALTH ARE COLLABORATING to use artificial intelligence (AI) as part of a comprehensive patient data registry built from de-identified information on patients who were tested for COVID-19. It is aimed at helping researchers better understand COVID-19 diagnoses and treatments.

The data set is expected to offer up a "complete view of clinical paths and outcomes," as it is supplemented with additional longitudinal medical record data, according to Labcorp and Ciox.

"Ciox retrieved medical records and returned them to us. We then had to turn that into structured data," said Lance Berberian, Labcorp EVP and CIO, in an exclusive interview with THE DARK REPORT. "We applied natural language processing that included an artifical intelligence model we use. That allowed us to extract data and load it into a dataset. Once we generate that information for the medical records, we merge it with Labcorp's historical information for those patients."

Labcorp is also collaborating with Boston-based PathAI to expand computational pathology applications in oncology. This involves the analysis of digital pathology images.

The project entails deployment of PathAI's algorithms in prospective clinical trials of cancer and other diseases managed by Labcorp Drug Development, according to a PathAI statement.

The need for AI-powered pathology, according to Berberian, stems from two parallel trends: an aging population and fewer pathologists.

"The question becomes: How to optimize the time of pathologists so they can have higher output without sacrificing quality," he added.

Market Update

XIFIN to Open New Office in South Carolina for Lab Billing

Lab revenue cycle company says overall volume of clinical lab tests is 130% of pre-pandemic levels

Since February, the total number of people vaccinated grew steadily even as the number of tests for COVID-19 declined sharply in the United States. But overall test volume has remained steady at 130% of pre-pandemic levels, said Brian Kemp, Vice President of Revenue Cycle Operations for **XIFIN**, a revenue-cycle management company for clinical laboratories.

Such higher levels of testing have created a need for XIFIN to open a new office next month in Charleston, S.C. Current test volumes are a sign of better times for the clinical laboratory industry.

Strong Test Volume

"Despite the fall-off from the peak volume of COVID-19 testing at the start of the year, XIFIN's Lab Volume Index currently is about 130% of the pre-pandemic level for all types of tests combined," Kemp noted.

This increased level of testing is one factor behind XIFIN's decision to open a new office in South Carolina. Since the lab-specific revenue-cycle management company was founded in San Diego in 2001, XIFIN has seen steady growth in lab testing overall, along with a corresponding increase in the volume of bills it processes for hospital labs and independent labs.

Along with that growth in testing, more clinical labs are interested in having consulting and lab-billing management firms take over their billing operations, Kemp said. "As XIFIN expanded beyond its core area of being a respected revenue-cycle software company providing software-as-a-service (SaaS) for the laboratory diagnostic space, we have seen the opportunity to offer an outsourced-billing service," Kemp explained.

During the past 20 years, public payers—including Medicare, Medicaid, and commercial health insurers—have become more sophisticated in managing how they process and deny bills from all providers, including clinical laboratories. In that time, XIFIN has seen a growing need to help labs get paid more efficiently and an increased need among its lab clients to collect all of what they submit in claims, he said.

In addition, there is a growing need for more face-to-face contact with XIFIN clients. "We have customers across the United States, and we wanted to have locations that were convenient for all of them," Kemp added. "And we definitely wanted to locate the new office on the East coast because roughly two thirds of the hospital beds in this country are east of the Mississippi."

Starting next month, XIFIN will open the new office under Kemp's leadership. Over the next two years, the company plans to invest $25 million in creating 150 new jobs and capital expenditures in the Berkeley County region around Charleston. Although not mentioned by the XIFIN team, THE DARK REPORT believes that other factors in the decision to locate the new office in South Carolina include California's high tax and regulatory environment, and lower housing costs for staff in South Carolina. TDR

Amazon Now Interested in Home Testing Services

In a stepwise fashion, the internet retailing giant assembles the pieces to be major source of lab tests

CEO SUMMARY: In the past year, internet retailing giant Amazon has built sizeable clinical laboratories in the United States and the United Kingdom. Now it has regulatory clearance to sell a molecular COVID-19 test to consumers for home collection. Comments made in the past month by an Amazon spokesperson describe Amazon's diagnostic testing activities as "large scale" and as "creating new testing capacity at no cost to the healthcare system."

Recent actions by **Amazon**, the world's largest internet retailer, indicate that it is serious about offering clinical laboratory services to consumers. The company just obtained regulatory clearance for a direct-to-consumer molecular SARS-CoV-2 test kit designed for at-home collection by the customer.

Several news outlets reported that the **Food and Drug Administration** (FDA) had issued an emergency use authorization (EUA) on May 28, 2021, for the "Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2." The test was developed by **STS Lab Holdco** (a subsidiary of Amazon.com Services LLC).

In a story about Amazon's plans for diagnostic testing, *Business Insider* wrote "'Amazon decided early on during the pandemic that COVID-19 testing would be a critical tool to ensure the health and safety of front-line employees,' an [Amazon] spokesperson told *Insider*. 'Since then, we have been working closely with the FDA to build and enable large-scale testing capacity using a state-of-the-art lab we built from scratch—creating new testing capacity at no cost to the healthcare system. We continue to innovate to support the safety of our employees, their families, and the communities where they live,' the spokesperson continued."

This declarative statement should get the attention of clinical laboratory administrators and pathologists. It is public acknowledgement that Amazon is on a path to provide diagnostic tests. It already has the market reach to sell lab tests directly to consumers, which is what it intends to do with its new COVID-19 test.

Amazon's Unique Capability

But Amazon also has a unique capability that would immediately make it a tough competitor in the market for clinical laboratory tests originating in doctors' offices. It has a first-class distribution network already in place that covers nearly the entire United States and could be used to pick up lab specimens from medical clinics.

The ubiquitous Amazon Prime vans are regularly visible in business and residental neighborhoods throughout the nation. Also, these vans deliver during the evenings and on weekends. It would not take much for Amazon to add lab

specimen pickups to its existing delivery network.

That idea was reinforced by Nathan Ray, a director in the healthcare and life sciences practice at business and technology consulting firm **West Monroe**. Ray told *FierceHealthcare*, "Labs are a particularly good fit for the core strengths of Amazon. Distribution and supply chain, scale and cost advantage, and digital customer and patient engagement are all pointed at reducing friction and likely ultimately improving use and access frequency."

Amazon Builds Big Lab

In May, 2021, The Dark Report published an intelligence briefing on Amazon's construction of clinical laboratory facilities scaled to provide COVID-19 tests for the company's one million employees.

At that time, we said it was unlikely that Amazon would invest substantial capital to build one or more high-volume, highly-automated core laboratories and close those facilities once the pandemic had ended. Rather, these large clinical labs would end up doing regular lab testing.

Initially, that post-pandemic testing would probably be for the clinical needs of its employees covered by the Amazon health plan. But it would be easy to offer diagnostic testing services directly to office-based physicians, hospitals, skilled nursing homes, and other medical providers. *(See TDR, "Amazon Building Labs to Do COVID-19 Testing ," August 3, 2020.)*

Employees First, Then Market

Michael Abrams, a managing partner at consulting firm **Numerof & Associates**, agrees with the progression of first providing health services to Amazon employees, before then offering the same services to the wider market.

"When Amazon puts a lot of money into something that has potential in the healthcare marketplace, they try it out with their employees and, if it works well, they take it public," he told *FierceHealthcare*.

To illustrate that point, he described how Amazon Care, a primary care service, was launched for the company's employees and is now being sold to other companies as an employee benefit they can provide to their staffs.

Abrams went further and predicted Amazon could use lab test data in an entirely different service it could sell to employers. "There is the potential [for Amazon] to help employers receive better population-level information on their entire workforce, including those that do not frequently engage with the health system," he told *FierceHealthcare*. "It could also be an interesting market for new diagnostic test providers and even for your own physician to more easily and regularly order testing [from the Amazon website]."

Abram's comments above are consistent with the Clinical Lab 2.0 model, which calls for clinical laboratories to move beyond simply reporting an accurate test result within the target turnaround time (Clinical Lab 1.0). Instead, innovative labs should integrate lab test data with other clinical, demographic, and geographical data to provide actionable clinical intelligence that informs patient care at the micro level and guides population health initiatives at the macro level. *(See TDR, "CEO Describes Characteristics of the Clinical Lab 2.0 Model," May 15, 2017.)*

Amazon's Diagnostics Play

The information provided here and in the sidebar at right shows that Amazon recognizes the importance of diagnostic testing as a cornerstone of almost every aspect of healthcare. The company is in the midst of a multi-year effort to assemble the skills, capabilities, and infrastructure required to provide clinical laboratory testing directly to hospitals, physicians, and other providers while also providing access to tests to consumers.

It may be timely for lab administrators, pathologists, *in vitro* diagnostics (IVD) companies, and lab informatics companies to view Amazon as more than just a new

In 2018, Amazon Considered Acquiring a Consumer Home-Test Diagnostics Company

NEWS ACCOUNTS GOING BACK TO **2018** have reported Amazon's interest in offering diagnostic tests to consumers for use at home. For example, at the end of 2018, it was reported that Amazon had considered acquiring **Confer Health**, a start-up company in Boston working to develop diagnostic tests that can produce clinical-grade results at home.

At that time, *CNBC* covered this development in detail, describing several projects at Amazon involving diagnostics. *CNBC* interviewed analysts about Amazon's interest in healthcare and diagnostic testing, writing that, "medical diagnostics experts say that Amazon is uniquely positioned to succeed in the healthcare space, where many start-ups have struggled."

CNBC added, "If Amazon moves ahead, 'the notion of being able to connect consumers to a health testing product that sits in the home, as well as delivering treatments, would be quite revolutionary,' said Greg Yap, a tech-driven life sciences investor with **Menlo Ventures**, who does not have direct knowledge of Amazon's plans."

What is interesting is how Yap connected several Amazon products in ways that would make Amazon a viable provider of a full range of healthcare services. *CNBC* wrote, "Yap said there are a lot of potential hurdles, including regulations that require a physician to interpret the results." Other analysts say Amazon's use of telemedicine might help resolve that issue by giving it access to physicians who could order tests and review the results remotely, using a smartphone or a laptop. Prescriptions could also be handled in this same way.

In this story, Yap called attention the fact that Amazon's Alexa voice assistant was already used in more than 40-million people's homes. He thought Amazon could leverage that ability to connect physicians and patients, including the reporting of diagnostic test results.

Recently, *FierceHealthcare* reported that Amazon's launch of its Amazon Halo Fitness Tracker in 2020 gives it another way to integrate and support a consumer's or patient's access to healthcare. It interviewed Michael Abrams, a managing partner at consulting firm **Numerof & Associates**.

Synergistic Opportunities

Abrams told *FierceHealthcare*, "The Halo device can monitor the vitals of someone with a chronic disease. Alexa can then remind them that it's time to make an appointment, they can do a virtual visit, and also get a test kit in the mail for lab testing ... Amazon Care is synergistic with Amazon Pharmacy and both of them would be synergistic with a diagnostics line of business as well."

These developments are signs that Amazon is moving forward with an ambitious and comprehensive plan to disrupt healthcare. Given the essential role of clinical laboratory testing for diagnosis, guiding selection of therapies, and monitoring patients, it is reasonable to assume that Amazon's forward steps to build its own CLIA-certified laboratory and obtain an EUA for the COVID-19 test it now sells to consumers are key parts of its goal to expand into healthcare.

competitor in the healthcare marketplace. Amazon could start sending sales reps to hospitals and doctors' offices to win their lab test referrals and build market share. This would create a total vertical disruption to the healthcare industry, just as Apple did to the CD/Vinyl music industry with its iPod streaming music device. TDR

CMS Shuts Missouri Lab Due to 'Immediate Jeopardy'

➤Lab company served 2,500 nursing homes in 11 states, but CMS ordered it to cease testing

➤➤CEO SUMMARY: CMS ordered Gamma Healthcare to close its two labs, revoked the owners' CLIA licenses, prohibited them from operating a lab for two years, and ordered payment of more than $55,000 in civil penalties. The two lab facilities had been running COVID-19 and other tests for about 2,500 nursing homes in 11 states. This forced nursing homes and long-term care facilities in those Midwest states to find other labs to serve elderly patients during the pandemic.

Last fall, another important provider of clinical laboratory testing to nursing homes and skilled nursing facilities went out of business. This time it was **Gamma Healthcare**, which operated lab facilities in Popular Bluff and Springfield, Missouri.

Consequently, Medicare beneficiaries in 11 states lost access to lab testing services, particularly those beneficiaries living in nursing homes. This comes on top of the numerous lab companies serving nursing homes that went out of business in recent years due to substantial reductions to Medicare Part B clinical lab test prices as mandated by the Protecting Access to Medicare Act (PAMA). The drop in Medicare revenue put these labs into financial distress and led to their bankruptcies or closures.

In the case of Gamma Healthcare, the immediate cause of the lab's closing were orders by the federal **Centers for Medicare and Medicaid Services** (CMS) requiring the lab company to close its laboratory testing operations. CMS revoked the licenses for the labs' owners to operate the two facilities, prohibited them from operating a lab for two years, and ordered the lab to pay a civil penalty of $55,666.

By closing the two lab facilities that had been running COVID-19 and other tests for about 2,500 nursing homes in 11 states, the federal agency left patients without a lab provider. Since then, nursing home and long-term care facilities in Arkansas, Illinois, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and Texas have scrambled to find other clinical laboratories to fill the gap.

➤Judge Declined to Intervene

In an attempt to remain open, Gamma Healthcare filed a temporary restraining order against CMS on Oct. 23. Less than a week later, the *Associated Press* reported that U.S. District Judge M. Douglas Harpool refused to intervene in the case after Gamma Healthcare's lawyers asked the judge to keep both lab facilities open.

In response, CMS argued that two of Gamma Healthcare's analyzers produced false-negative test results on more than

25% of known-positive COVID-19 samples over several months and that the regulators found multiple false-positive COVID-19 test results, the *AP* noted.

Gamma Healthcare's troubles began just over one year ago when on June 22, 2020, inspectors from CMS conducted an inspection at the Poplar Bluff lab. In an eight-page report of deficiencies that CMS issued the next day, the inspectors cited eight failures in the lab related to COVID-19 testing.

Lab Inspections Conducted

In what CMS calls a 2567 report, the agency listed deficiencies such as:

- Failure to have a laboratory director who meets CMS' qualification requirements.
- Failure to arrange analyzers to prevent contamination of patient specimens.
- Failure to set policies and procedures for COVID-19 testing.
- Failure to have a policy to address COVID-19 specimen acceptability, submission, handling, and rejection.
- Failure to ensure analyzer verification procedures were adequate before running COVID-19 PCR tests.
- Failure to ensure all personnel have appropriate training for COVID-19 testing.

On July 1, 2020, CMS inspectors went to Gamma Healthcare's facility in Springfield. In their second 2567 report, the inspectors cited four deficiencies, including failure to set performance specifications for interfering substances before reporting patient test results, failure to ensure that technical personnel performed test methods as required for accurate and reliable results, and failure to ensure that staff identified problems and potential problems for COVID-19 patient testing.

The report explained that during a review of the laboratory's validation reports for an analyzer, CMS found that the Springfield lab failed to verify specificity for interfering substances for COVID-

CMS Issues Notice of Final Sanctions

ON JUNE 10, 2021, the Division of CLIA Laboratory Improvement and Quality of the federal Centers for Medicare and Medicaid Services (CMS) sent two Notice of Final Sanctions to the management of Gamma Healthcare in Missouri.

CMS addressed one Notice of Final Sanctions to the senior management of Gamma's lab in Poplar Bluff, including Laboratory Director David L. Smalley, PhD, four owners of the lab, and Jerry Murphy, Chairman of the Board.

In the notice, CMS explained that sanctions were imposed, "based on the finding of condition-level non-compliance that resulted in the determination of immediate jeopardy to health and safety.

"Due to the revocation of Gamma Healthcare Inc.'s CLIA certificate, you, as the owner(s), operator(s), or director of the laboratory at the time it was found to be in non-compliance, are barred from owning, operating, or directing any laboratory, in fact or by proxy, for a period of two years from the date of the revocation, or until May 26, 2023," the notice stated.

Also on June 10, CMS sent a similar Notice of Final Sanctions to the Springfield facility addressed to Laboratory Director Stacy Walz, PhD, previous Laboratory Director M. Keith Burson, to Jerry Murphy, and to other owners.

That letter restates the demand for payment of $55,666 and the bar from owning or operating a lab for two years. It's unclear if each lab needs to pay that amount or if that amount would cover the civil penalties for both facilities.

CMS did not say whether it had received the payment as scheduled on June 25.

19 testing before testing patient samples on April 7, 2020. Between April 7 and July 1, 2020, some 26,239 patients were tested for COVID-19, the report noted.

"Interview with the technical supervisor #2 on July 1, 2020, confirmed the laboratory failed to establish performance specifications for interfering substances before reporting patient test results," the report stated.

That same technical supervisor, the report added, told CMS' inspectors that on June 29 the laboratory contacted the technical support staff of the analyzer's manufacturer and confirmed that its positivity rates required corrective action.

As a result of issuing those reports in late June and early July 2020, CMS required Gamma Healthcare to correct all 12 deficiencies within 60 days.

A Back-and-Forth Dispute

From late June until late October 2020, a back-and-forth dispute occurred between Gamma Healthcare and CMS. Over those four months, CMS sent at least 15 documents and letters to the lab's senior management requesting confirmation that the deficiencies were corrected, according to documents CMS provided to THE DARK REPORT.

Gamma Healthcare filed a temporary restraining order against CMS on Oct. 23 in a last-ditch effort to stave off the potential loss of its license to operate under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Judge Harpool denied that request on Oct. 28.

Negotiations continued between CMS and the labs' managers into the spring of this year. On May 25, 2021, CMS entered into a settlement agreement in which Gamma Healthcare waived all appeal rights to contest suspension of the laboratory's CLIA certificate, cancellation of the laboratory's approval to receive Medicare and Medicaid payments, revocation of the laboratory's CLIA certificate, and civil monetary penalties of $21,410 per day for Oct. 3 through Oct. 6, 2020. Also, CMS agreed to reduce the financial penalty by 35%, but still required Gamma Healthcare to pay $55,666 by June 25.

No Comment

All requests by THE DARK REPORT to principals of Gamma Healthcare went unanswered. Following a request for comment, Blake H. Reeves, a shareholder in the **Polsinelli** law firm in Kansas City, Mo., who represented Gamma Healthcare in its dispute with CMS, responded by email in June. "My client would prefer not to comment at this time other than to say Gamma Healthcare's complaint for injunctive relief filed in federal court in October was one of several efforts aimed at preventing CMS from suspending its certificates to operate," he wrote. "Unfortunately, the litigation was unsuccessful, and GHC is now winding down its lab business operations."

Gamma Healthcare was an important provider of lab testing to thousands of nursing homes. It was part of a company founded in 1981 that, along with clinical laboratory testing, also provided services in portable radiology services and medical waste management. Because no principal of the company was willing to talk about its problems, the specific reasons for the problems with COVID-19 testing identified by CMS inspectors are unknown.

Medicare Fee Cuts a Factor?

It is reasonable to assume that the multi-year cuts to Medicare clinical lab test payments triggered by PAMA shrank the company's cash flow in recent years to a level below its costs. As that happened, the lab managers may have cut corners to keep the lab operating with a hope that better days were to come.

However, that also meant the lab may have been operating in a sub-standard fashion, which the CMS inspection team recognized when it first arrived in the spring of 2020. TDR

Managed Care Update

Benefits Investigation Is Growing Issue for Genetic Testing Labs

Patients with high-deductible health plans want to investigate cost of test before proceding

QUIETLY AND WITH LITTLE NEWS COVERAGE, a new complication is challenging clinical laboratories that offer genetic testing. It involves a steady growth in the number of patients who do a "benefits investigation" before allowing their physician to order a genetic test.

Benefits investigation is the "term of art" that describes a patient (or provider) who wants a cost estimate before an expensive genetic test is ordered.

This trend is directly associated with consumers who have high-deductible health plans (HDHPs). They want to know how much they will have to pay for a genetic test before that test is ordered and performed. Many labs and lab billing companies report that benefits investigation is becoming a major and time-consuming activity.

Benefits Estimator Tool

Unless a clinical laboratory has a benefits estimator tool, the clinical laboratory or the patient will have to contact the patient's healthcare benefit plan to find out what their plan covers.

"One pain point associated with the need to do a benefits investigation is when the patient tries to decide if they want the test, but they wait a week to get the benefits investigation done," explained Heather Agostinelli, Vice President for strategic revenue operations, with **XIFIN** Inc., a revenue cycle management firm based in San Diego. "At that point, the sample may have already been sent to the lab and processed."

Agostinelli was speaking during a recent DARK DAILY webinar, titled, *"State of the Genetic Testing Marketplace–Getting Paid for All Your Lab's Genetic Test Claims: What's Changing, What's Not, and What's Working Best."*

Genetic Test Criteria

"Benefits investigation requests are typically made by the ordering physician, although they may be made by the patient, as well," Agostinelli continued. "A benefits investigation involves the clinical laboratory contacting the patient's healthcare insurance company to find out if the test is a covered benefit, and if so, whether the patient meets the inclusion criteria for the test. The lab may also need to determine how much of the patient's deductible has been met and the amount of their co-pay or coinsurance.

"Once the clinical laboratory has this information, it will need to contact the ordering physician and/or the patient to determine whether to proceed with the test," she added.

All this takes time. In some cases, the specimen is collected before the benefits investigation is complete. In other cases, it is not collected until after the patient and ordering physician have given the go-ahead.

GeneDx, a wholly-owned subsidiary of **BioReference Laboratories Inc.**, an **OPKO Health** company, automatically orders a benefit investigation for every test it performs, says Gina Wesley, Vice President, Payer Relations Operations for

BioReference. The investigation is conducted by XIFIN, the lab's revenue cycle management firm.

If the cost to the patient will be more than $100, GeneDx will contact the patient before proceeding with the test. Prior to hiring XIFIN as its billing company, GeneDx did its own benefit investigations, which was often time consuming, Wesley noted.

Automated Tool on Website

BioReference Laboratories has an automated tool on its website that providers and patients can use to estimate the patient's financial responsibility. The automated tool is also available at BioReference's patient service centers. The online estimator, while helpful, does not always alleviate the need for further investigation into the patient's financial responsibility.

"Another pain point is that this is an estimate at a particular point in time," Wesley said. "It can change based on where the patient is in terms of their deductible or changes to their plan. The price can fluctuate. Also, the estimate does not guarantee that the test will actually be covered by the insurer."

One of the trickiest areas of benefits investigation is getting estimates for testing through the **Blue Cross Blue Shield** Blue Card program (BlueCard), which allows members of one BCBS plan to receive care while traveling or living in another plan area. Often this means that an estimate might be done under one plan, while the benefit is actually processed under another plan.

"We'll receive a quote and then it goes through the process of adjudication and comes back substantially different than what we were quoted," Wesley said. "The BlueCard out-of-state program can be difficult for patients when obtaining accurate benefits investigations."

Jessie Conta, a genetic counselor and manager of the laboratory stewardship program at **Seattle Children's Hospital**, conducts benefits investigations on behalf of the hospital. When genetic testing is performed, the laboratory bills the hospital, which then will collect the patient's share of the cost when appropriate.

"Sometimes you can get an immediate answer from insurers," she noted. "Many health insurers have portals that support benefits investigation, including preauthorization requirements. Ideally, the portal would also provide information about the patient's co-pay and deductible, but often the patient has to contact the insurer directly to get that information."

Improving Lab Test Utilization

The benefits investigation can be an opportunity to help guide providers in selecting the most appropriate test for the circumstance, Conta adds. "The first thing you have to ask is, is this test the right one for the patient," she says. "Your lab needs to have systems in place to help providers select the right genetic test. It's a commitment to stewardship." TDR

Contact Heather Agostinelli at 843-364-5127 or hagostinelli@xifin.com; Jessie Conta at 206-987-3353 or jessie.conta@seattlechildrens.org; Hillary Titus at 201-406-9968 or htitus@bioreference.com.

GeneDx Has FAQs for Benefits Investigation

GENEDX, A GENETIC TESTING LAB OWNED BY BIOREFERENCE LABORATORIES INC., uses FAQs (frequently-asked-questions) on its website to educate providers and patients on how to conduct a benefits investigation. The FAQs can be accessed at this URL: *https://tinyurl.com/pccke3b9*.

GeneDx writes that "requesting a benefits investigation (BI) in the GeneDx Healthcare Provider Portal is fast and easy. The majority of benefits investigations generate an immediate patient out-of-pocket (OOP) estimate, while the remainder will usually be returned in 3-5 business days."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Did the SARS-CoV-2 virus infect people in the United States earlier than the first case diagnosed on Jan. 19, 2020? A newly-published study in *Clinical Infectious Diseases*, says there is evidence of COVID-19 infections in December 2019. The research team included scientists from the **National Institutes of Health**. The source of the specimens was the "All of Us" program. Blood samples collected from 24,000 people during the first three months of 2020 were analyzed for the novel coronavirus. Using an antibody biomarker, researchers determined that seven study participants were infected earlier than originally reported in their regions. The earliest infection was prior to Christmas Eve 2019.

MORE ON: *COVID-19*

The researchers emphasized that the findings from this study were not definitive, in part because the antibodies identified during testing provided protection from other strains of the coronavirus. One significant finding of the study was that none of the seven COVID-19 positive study participants lived in either New York City or Seattle, where the first COVID-19 cases where diagnosed in January 2020. "The question is how did, and where did, the virus take seed?" asked Keri N. Althoff, PhD, from **Johns Hopkins University** and the study's lead author. Her answer was that the new study indicates "it probably seeded in multiple places in our country."

MILITARY HOSPITAL BACKLOGGED WITH 600 PATH CASES

This spring, a backlog of 600 pathology cases was reported at 120-bed **Fort Belvoir Community Hospital**. Located outside Washington, DC, and operated by the **Department of Defense**, the hospital services military personnel and their families. The *Military Times* reported that the backlog was attributed to a surge in patients who had deferred care during the pandemic. However, the backlog was not addressed until an anonymous source contacted the *Military Times*. The delayed cases involved biopsies and resections. Pathologists at other military hospitals helped to work down the backlog of pathology cases at Fort Belvoir Community Hospital.

TRANSITIONS

- **GeneDx,** a subsidiary of **OPKO Health**, announced the selection of Katherine Stueland as its new CEO and President. She previously held positions at **Invitae**, **Vivo Communications**, **Dendreon Corporation**, and **WCG**.

- Mark Szewczyk is the new Chief Commercial Officer at **Strata Oncology** of Ann Arbor, Mich. Previously he served at **Abbott Laboratories**, **Philips Healthcare**, and **Cleveland Clinic**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 26, 2021.

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