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Healthcare's Largest Ransomware Attack!

Cybercriminals Target Optum's Change Healthcare, Disrupt Prescription Orders and Reimbursement

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Successful Ransomware Attack Misses Lab Claims

HAS ANYONE NOTICED THAT CYBERCRIMINALS ARE STEADILY INCREASING THE SCALE AND MAGNITUDE OF THEIR ATTACKS? The ongoing disruption from the Feb. 21 ransomware attack on **Change Healthcare**, owned by **UnitedHealth Group**, has triggered substantial financial losses and major interruptions to the cash flow of hospitals and providers throughout the United States.

As you will read on pages 3-6, weeks after the cyberattack, Change Healthcare has yet to restore all functions of its claims clearinghouse—a clearinghouse that handles as many as 50% of all claims submitted by providers in the United States. Fortunately for clinical labs, this cyberattack primarily penetrated the part of the Change Healthcare clearinghouse that processes incoming prescriptions, transmits the prescriptions to pharmacies, and enables reimbursement for those prescriptions.

The ransomware attack is a reminder to clinical laboratories and anatomic pathology groups that their information systems probably have vulnerabilities that cybercriminals can exploit. This event should spur all lab managers to review the current state of their information systems. It is an opportunity to install protections against the latest generation of hacking tools.

To this point, THE DARK REPORT is aware of a sizeable regional laboratory west of the Mississippi River that was attacked and which continues to deal with operational, financial, and client service disruptions. The lab notified the FBI of the hack and the federal government is reviewing the case to determine if it has enough evidence to pursue criminal charges against the bad actors.

At the *Executive War College* in New Orleans on April 30-May 1, there will be several panels with attorneys, managed care professionals, and lab chief information officers. The Change Healthcare ransomware attack will be a major topic for discussion. There will also be recommendations on the best ways labs can protect themselves from these ever-larger and more sophisticated cyberattacks. For this reason, it would be a good investment to send several of your lab's key team members who oversee your lab's compliance and information technologies.

As mentioned earlier, within the U.S. cybercriminals are attacking ever-larger corporations and healthcare providers. Imagine the disruption were the bad actors to successfully hack multiple Medicare Administrative Contractors (MACs)! Now is the time for labs to proactively protect their IT systems. TDR

Change Healthcare Hit by Major Cyberattack

UnitedHealth Group finds itself in a firestorm that now includes investigations by two federal agencies

CEO SUMMARY: It was a classic ransomware attack against Change Healthcare, the business unit of Optum that is itself a division of UnitedHealth Group. On Feb. 21, this cyberattack shut down critical systems at Change Healthcare, such as those involved in accepting and forwarding prescription drug orders to pharmacies and remitting reimbursement for those prescriptions.

IT APPEARS THAT CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS dodged a bullet following the Feb. 21 cyberattack on the information systems at **Change Healthcare**. That's because the cybercriminals' penetration mostly disrupted Change Healthcare's prescription ordering and associated payment systems.

At the same time, this ransomware attack was immediately recognized as the single biggest cyberattack in the United States. That's because Change Healthcare's exchange processes between 40% and 50% of all healthcare claims and payments in this country.

Change Healthcare is a business unit of **Optum**, which is itself a division of **UnitedHealth Group**. Change Healthcare was acquired by Optum for $7.8 billion on Oct. 3, 2022. The **Department of Justice** opposed this acquisition, but it lost the court case it filed to overturn the purchase.

Managers of clinical laboratories and anatomic pathology groups will want to monitor developments, particularly since Change Healthcare handles the coding, billing, and collection services for hundreds of the nation's labs. The current ransomware attack does not appear to have disrupted the acceptance and processing of lab test claims.

But the successful cyberattack on another part of Change Healthcare's information systems is a reminder that a future cyberattack could similarly shut down the claims clearinghouse systems Change Healthcare uses to accept lab test claims and remit payment.

On Feb. 21, the attack immediately disrupted care at the nation's hospitals and providers, while at the same time preventing payments to those entities.

In a statement issued March 15, the **American Hospital Association** (AHA) reported on the results of a survey of 1,000

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hospitals. "More than 80% of hospitals said the cyberattack has affected their cash flow, and of those nearly 60% report that the impact to revenue is $1 million/day or more. In addition, the survey found that 74% of hospitals reported impacts to direct patient care as a result of the cyberattack," the AHA said.

UnitedHealth Statement

Two weeks after the public learned about the ransomware attack, UnitedHealth Group (UHG) published a statement about its timeline to restore services. Dated March 7, the company said:

We are working aggressively on the restoration of our systems and services. Assuming we continue at our current rate of progress, we expect our key system functionality to be restored and available on the following timelines:

- ***Pharmacy services:*** *Electronic prescribing is now fully functional with claim submission and payment transmission also available as of today. We have taken action to make sure patients can access their medicines in the meantime, including Optum Rx pharmacies sending members their medications based on the date needed.*
- ***Payments platform:*** *Electronic payment functionality will be available for connection beginning March 15.*
- ***Medical claims:*** *We expect to begin testing and reestablish connectivity to our claims network and software on March 18, restoring service through that week.*

Restoration of Service

As this issue of THE DARK REPORT went to press, UHG had not yet updated its estimates on the dates when it expected to restore the disrupted healthcare payment services described above.

UHG has yet to publicly describe how specifically the attack disrupted payment and billing services. News sources, however, covered three basic consequences.

First consequence: The cyberattack cut off the access hospitals and providers need to billing and care authorization portals. The inability to obtain insurance approval for services—such as drug prescriptions or medical procedures—is one source of financial strain. Providers have encountered difficulties in submitting claims and receiving payments for health care services.

Second consequence: The cyberattack prevented Change Healthcare's systems from:

- Accepting and forwarding prescription drug orders from both hospitals and other providers.
- Remitting reimbursement for those prescription drug orders.

Third consequence: The financial erosion at hospitals, physician offices, and other providers.

Provider Cash Flow

News stories have described how providers say incoming revenue crashed in the days following the ransomware attack. Hospitals and other providers told news reporters that the fall-off in cash flow was significant. This is causing some organizations to miss meeting payrolls and lack of adequate cash flow has put patients at risk.

On Thursday, March 14, UHG issued a statement describing how certain services were back online. A story posted by *pymnts.com* noted that, since the first day of the ransomware attack, UnitedHealth Group had been using **Palo Alto Networks** and **Mandiant** as part of its response team.

In the story, Wendi Whitmore, Senior Vice President, Unit 42, Palo Alto Networks, said, "To date, we have reviewed and protected a large majority of infrastructure, including the server and application space, and assisted in bringing critical services back online that allowed for more than nine million prescriptions to be filled."

Timeline of Events Triggered by Cyberattack on Optum's Business Unit Change Healthcare

FOLLOWING THE FEB. 21 CYBERATTACK AGAINST CHANGE HEALTHCARE'S essential claims and remittance systems, different government and healthcare entities took a variety of actions. The timeline below covers some of the more significant developments:

- **Feb. 21:** Optum reported its network was disrupted by a cybersecurity threat and that it had disconnected the Change Healthcare systems.
- **Feb. 22:** The American Hospital Association tells affected organizations to disconnect from Optum's systems. UnitedHealth Group (UHG) informs the **U.S. Securities and Exchange Commission** that a "nation-state" was behind the attack.
- **Feb. 26:** *Reuters* reports that ransomware group **BlackCat** (aka, **ALPHV**) had claimed responsibility for the attack. UnitedHealth Group states that of the 70,000-plus pharmacies in the U.S. that use Change Healthcare's system, 90% took steps to mitigate the cyberattack's effects, while the other 10% implemented offline processing workarounds. The company also issued a timeline for recovering the system.
- **Feb. 29:** Change Healthcare confirms that BlackCat was the attacker and that the group stated it had downloaded six terabytes of data from Change Healthcare's systems. The data included medical records, patient Social Security numbers, and information on active military personnel.
- **March 1:** Optum announces a temporary funding assistance program for healthcare providers struggling with cash flow due to the ransomware attack. Change initiates a workaround system for its e-prescribing program for pharmacies.
- **March 3:** *Reuters* reports that BlackCat was sent a $22 million bitcoin payment. UHG did not comment on the payment of ransom.
- **March 1:** Department of Health and Human Services announces programs to accelerate payments to hospitals affected by the ransomware attack.
- **March 6:** At least five lawsuits against UnitedHealth Group over the cyberattack have been filed in federal court.
- **March 7:** UnitedHealth Group issues a timeline for restoration of essential Change Healthcare systems. On that date, Change's pharmacy electronic prescribing is fully functional for claim submission and payment transmission. Change expects its electronic payment platform to be available for connection March 15. The medical claims network and software will be tested for reconnection during the week of March 18.
- **March 12:** UnitedHealth Group CEO Andrew Witty travels to the White House and is encouraged to provide additional emergency funding to providers affected by the cyberattack.
- **March 13:** Federal officials begin investigation of UnitedHealth Group and Change Healthcare relating to the cyberattack and the company's compliance with HIPAA.
- **March 15: Kodiak Solutions** reports that, based on analysis of data from 1,850 hospitals and 250,000 physicians nationwide, provider claims had fallen by more than 33%. Also, through March 9, the total estimated cash flow impact for hospitals reporting their data to Kodiak was $6.3 billion in delayed payments.

It may take months or years to work through all the problems caused by the ransomware attack on Change Healthcare. Across various news sources, it is estimated that Change Healthcare's payment processing service handles as much as 50% of all medical claims in the United States originating from 900,000 physicians, 33,000 pharmacies, 5,500 hospitals, and 600 labs.

What's Next for UnitedHealth?

As a result of the ransomware attack, UnitedHealth Group will be investigated by the federal **Department of Health and Human Services**. The agency's probe will concentrate on the company's compliance with HIPAA (the Health Insurance Portability and Accountability Act).

However, what has gotten relatively little publicity is that UnitedHealth Group is also being investigated by the federal Department of Justice (DOJ). As reported by the *Examiner News* and the *Wall Street Journal* last month, DOJ officials are looking at possible antitrust violations by the company.

The *Examiner News* of Mount Kisco, N.Y. broke the story on Feb. 26. On that date, reporter Adam Stone wrote, "I learned last week that UnitedHealth Group, Optum's publicly traded corporate parent, received notice on Oct. 10, 2023, that the Department of Justice had launched a 'non-public antitrust investigation into the company,' according to a message distributed on Oct. 24 by Rupert Bondy, an executive vice president and chief legal officer of UnitedHealth Group."

The *WSJ* reported that the DOJ is also investigating UnitedHealth Group's Medicare billing practices, including how the company documents patients' health conditions.

These two federal investigations create new challenges for UnitedHealth Group. But it will probably be years before federal officials issue reports on any sanctions or antitrust actions. TDR

No Honor among Cyberthieves

IT'S LONG BEEN SAID THAT "THERE IS NO HONOR AMONG THIEVES." That adage is proving apt once again. This time it involves the cyberthieves who orchestrated the ransomware attack against Optum's Change Healthcare, a business unit of UnitedHealth Group.

News emerged on March 5 that there was evidence that BlackCat ransomware group (also known as ALPHV) had received a $22 million bitcoin payment from Change Healthcare. UnitedHealth Group has made no statement about payment of a ransom.

What happens next is the unexpected turn in this story. *Krebs On Security* reported that the cybercriminal claiming to have given BlackCat access to the Change Healthcare systems now says it was not given its share of the ransom payment. It also says that it still has the confidential Change Healthcare data. This data was to be destroyed upon payment of the $22 million to BlackCat.

Krebs on Security also wrote that "Fabian Wosar, head of ransomware research at the security firm **Emsisoft**, said it appears BlackCat leaders are trying to pull an 'exit scam' on affiliates by withholding many ransomware payment commissions at once and shutting down the service. 'ALPHV/BlackCat ... are exit scamming their affiliates.'"

In response to BlackCat's exit scam, the cybercriminal who gave BlackCat access to Change Healthcare's system still has the stolen data—giving it the option to demand additional payment or leak the information.

Assuming the basic facts reported above are true, this is another example of why there is "no honor among thieves!" It is also a reminder to clinical labs that dealing with ransomware thieves comes with many risks.

Examining Worldwide Pathologist Shortage

Experts want to answer the question: How many pathologists are needed in different countries?

CEO SUMMARY: Demand for pathology services is growing faster than the number of pathologists available to meet that demand. This is true for the United States and most other nations. Consequently, efforts are underway to more accurately measure the number of pathologists practicing in each country. Early data support the claim of an inadequate number of pathologists.

PROBABLY THE SINGLE BIGGEST CHALLENGE TODAY FACING THE PATHOLOGY PROFESSION is to supply the number of anatomic pathologists needed to meet the demand for pathology services.

This challenge is not unique to the United States. Worldwide, there is recognition that demand for pathology services exceeds the supply of pathologists. Experts studying this supply-demand gap identify these factors:

- Aging and growing populations that increase demand for pathology testing;
- Increasing complexity of lab tests that require more pathologist time to run the necessary assays and produce a diagnosis;
- Inadequate funding in some healthcare systems needed to train greater numbers of pathologists; and,
- In some countries, retiring pathologists outnumber pathologists finishing their residencies and fellowships.

According to Stanley Robboy, MD, Professor Emeritus of Pathology, **Duke University Medical Center**, Durham, N.C., the number of pathologists in a country must be considered in the context of the nation's level of medicine.

"There is very definitely a shortage of pathologists," Robboy said during an interview with THE DARK REPORT. "Further, in much of the world, the issue is how to elevate medicine. That means the goal should address two factors. One is to work to increase the number of pathologists. The second factor is to elevate the level of pathology as part of the level of medicine in many countries."

Robboy has conducted research and published papers on pathology workforce issues for more than 20 years. He is a past President of the **College of American Pathologists** (CAP).

Countries' Needs Vary

Different regions use pathology differently, Robboy noted. "For example, in Africa, pathologists may be more population-focused as compared to offering direct services to patients," he explained. "These pathologists are very involved in public health—such as fighting malaria." Robboy has a family member working in Africa who is helping people there gain access to food and clean water.

The **Centers for Disease Control and Prevention** says there were more than 241 million cases of malaria—a mosqui-

to-borne disease—worldwide in 2020, and 627,000 deaths, mostly among children residing in sub-Saharan Africa.

"In Africa, no single country has a level of medicine anywhere near Europe or anywhere near South America," Robboy observed. "Justifiably, these countries are much more concerned about malaria than having high-level medicine.

"In the U.S., we have an incredible degree of pathology services. Is it enough?" he added. "I suspect we need much more. If you look at Europe, they can use much more pathology resources than they have. Country-by-country the map is clear. It's alarming how few pathologists there are for whole populations in some countries."

Global Analysis of Supply

Robboy was referring to a map and data published in a 2023 *The Pathologist* article titled, "Constant Demand, Patchy Supply." *(To see map, run a search on the article's title at www.ThePathologist.com.)*

The authors described the map as "the first-ever attempt at a global quantification of pathology numbers: over 108,000 individuals in 162 countries and territories that represent about 98.5% of the world's population."

Data for the map was collected from 2019 through 2022 by Andrey Bychkov, MD, PhD, FRCPath, Director of Digital Pathology, **Kameda Medical Center**, Kamogawa, Japan. Bychkov co-authored the map's accompanying article as well.

In an exclusive interview with THE DARK REPORT, Bychkov told of his plans "to refresh the database every three to five years, ensuring it remains continuously updated and to allow temporary comparisons and reveal trends."

Bychkov said he "recently extended the coverage of the database to 170 countries and territories, representing 99.5% of the world's population" and indicated the only missing large country (population of more than five million) is North Korea.

"Perhaps the most notable update in terms of numbers was regarding China. My initial report mentioning 11,000 pathologists turned out to be incorrect. I have gained access to a more reliable local source which claims that there are nearly 17,000 pathologists in the country, therefore increasing the number of practicing pathologists of all subspecialties worldwide to approximately 114,500," he added.

"There is a shortage of pathologists worldwide. There is no question about that," stated Donald Karcher, MD, current President of the College of American Pathologists and Professor and Immediate Past Chair of Pathology, **George Washington University Medical Center**, Washington, D.C., in an interview with THE DARK REPORT.

"Even in countries with a lot of pathologists—like the U.S.—there are not enough pathologists," he noted. "There are certainly anecdotal data—and we are beginning to have published data—showing that we are not meeting the demand for pathologists in the U.S., and frankly, in most of the world."

Karcher acknowledged that coming up with the number pathologists in each country and in the U.S. is not easy to do.

Variety of Methods

"Dr. Bychkov did a great service by trying to determine how many pathologists there are worldwide. Using a variety of methods—including speaking directly with pathologists in each country—he was able to construct the first true snapshot of pathologists in almost all countries in the world," he said, adding that CAP has offered to work with Bychkov to refine the data on worldwide pathologists.

CAP has set up two membership categories aimed at helping increase pathologists worldwide:

- International Junior Membership, which offers up CAP resources to residents training outside the United States.

- Medical Student Membership, which is aimed at heightening study of pathology among medical students in the U.S. and abroad.

Aligning pathology services with need is important to heading off dire effects such as patient care delays and disease risk.

Delays in New Zealand

For example, the effects of pathology staff shortages in New Zealand are causing long delays in patient care, according to a recent e-briefing by THE DARK REPORT's sister publication DARK DAILY. Patients in that country may wait more than a month for clinical lab test results showing melanoma diagnoses, according to a report sourced by DARK DAILY.

In Canada, shortages of medical laboratory technologists and other technicians are associated with patient wait times as well—especially for elective procedures that may be scheduled out six months to one year, DARK DAILY reported. Interestingly, Robboy, Karcher, and others published a paper in 2015 in *Archives of Pathology & Laboratory Medicine* titled, "The Pathologist Workforce in the United States: An Interactive Modeling Tool for Analyzing Future Qualitative and Quantitative Staffing Demands for Services."

Using a modeling tool that factored in population aging, advances in biomedical technology, value-based care, and more, the authors estimated the demand for pathologists in the U.S. would be about 20,124 in 2024.

Sure enough, CAP data show there are slightly more than 20,000 U.S. pathologists in the U.S. today.

"The numbers are almost in balance," Karcher explained. "However, the job market is exploding. People are having a hard time recruiting pathologists. And the demand for our services has been increasing probably more than we were projecting in that paper 10 years ago."

First Global Survey of Pathology Results

DATA ON THE NUMBER OF PATHOLOGISTS IN DIFFERENT COUNTRIES was collected from 2019 through 2022 by Andrey Bychkov, MD, PhD, FRCPath, Director of Digital Pathology, Kameda Medical Center, Kamogawa, Japan. Following are data points on the number of pathologists and ratio of pathologists to one million people:

AFRICA NATIONS:

- Egypt: 750 pathologists—seven/million residents.
- Tanzania: 30 pathologists—less than one/million residents.
- Namibia: Five pathologists—less than one/million residents.
- Nigeria: 300 pathologists—less than one/million residents.

OTHER COUNTRIES:

- China: 17,000 (updated by Bychkov from 11,000) pathologists—12/million residents.
- India: 20,000 pathologists—14/million residents.
- Russia: 3,300 pathologists—23/million residents.
- Canada: 1,767 pathologists—48/million residents.
- United Kingdom: 3,900 pathologists—58/million residents.
- United States: 21,292 pathologists—65/million residents.

The global pathologist workforce is distributed by continent as follows, according to Bychkov's data:

- Asia: 46%
- North America: 23%
- Europe: 20%
- South America: 6%
- Africa: 3%
- Oceania: 2%

"There is a growing complexity of the work that pathologists do," he added. "For example, there is a steady increase in the requirements to correlate molecular and next-generation sequencing data with our diagnoses. There is also increased demand for detailed reports."

Robboy noted that in 1996, a pathologist examining a breast lumpectomy may have placed one slide with breast tissue under a light microscope to essentially answer, "Is this cancer? Is this an invasive cancer? And is the margin involved?

"Now, for this type of case, the pathologist may be looking at 40 to 50 slides," Robboy said.

Those additional views and steps to complete the diagnosis include special stains along with molecular or proteomic tests. Then, data must be assembled in a sophisticated report. "In the U.S., we can afford these additional steps. And that becomes the expectation—pathologists do those tests," Robboy noted.

Can digital pathology ease the strain?

"Definitely not," Karcher said. "Digital pathology is wonderful technology and is being adopted by more departments and pathologists. It will help workflow to a certain extent. But when you ask pathologists who use digital pathology on a regular basis, they will tell you it takes them more time to sign-out cases."

Sufficiency, Accuracy Needs

In the U.S., pathology workforce experts would also like to clarify the numbers of pathologists who work full-time and part-time. "I think there are fewer full-time pathologists than our numbers indicate. It is very hard to determine how many actually work part-time," Karcher said.

The U.S. is not alone in facing that particular challenge. "People in the United Kingdom say a lot of pathologists there are working part-time. That is one reason why they feel they are falling behind in keeping up with demand—even though the numbers there may look in balance," Karcher stated.

Another focus in the U.S. has been on pathologist data released by national organizations. "There are two separate pieces: Is the number sufficient? And is it accurate?" Robboy noted.

Robboy spoke to a record number of attendees at the 2023 *Executive War College on Diagnostics, Clinical laboratory, and Pathology Management* conference in New Orleans on the topic, "Today's Supply-Demand Gap for Skilled Pathologists: How it Happened, Why it Will Continue, and How Innovative Labs Attract, Hire, and Retain Top Talent."

Effect of a Legacy Algorithm

An analysis of data Robboy presented during his talk suggested that the **Association of American Medical Colleges** (AAMC) used a legacy algorithm that inadvertently counted only the number of general pathologists, but not those who had subspecialty training.

Today 97% of trainees have subspecialty training, so none of these people were counted, Robboy explained, adding that the AAMC is now updating the algorithm it uses.

"Subspecialty numbers have been going up dramatically in recent years. We are working with others to make this overall data more accurate," Karcher added.

These are positive developments for the pathology profession. Every healthcare system needs an adequate number of pathologists to maintain acceptable turnaround times for diagnosing cancer and other diseases. Having accurate counts of the number of practicing pathologists can help healthcare policymakers justify training more pathologists in their respective countries. **TDR**

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Regulatory Update

Attorney Discusses Federal Cases Involving EKRA Violations by Labs

Each federal prosecution involving clinical labs and violations of EKRA reveals how judges view the statute

It's been more than five years since Congress passed the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). Lab managers and their attorneys quickly recognized that, whereas the Anti-Kickback Statute (AKS) has a safe harbor that permits percentage-based sales commissions to W2 employees, EKRA does not.

The federal statutes' conflicting language on this point created a dilemma for clinical laboratories and anatomic pathology groups. The safe harbors of the AKS have been recognized for more than 50 years. But now, those business practices could expose labs and their managers to federal prosecution under EKRA.

Commission vs. Fixed Salary

Amid the confusion that arose from the apparent conflict between the two federal statutes, some compliance attorneys advised labs to move away from commission-based compensation and instead pay fixed salaries.

In the five years since EKRA became law in 2018, one attorney has watched the succession of court cases—both civil and criminal—that have resulted in judges' rulings and criminal convictions. A specialist in regulatory compliance, attorney Keith Lefkowitz, JD, of **Hendershot Cowart P.C.** in Houston, believes that it is important for laboratory executives and their lawyers to understand the ramifications of the most recent EKRA cases, particularly those prosecuted by the **U.S. Department of Justice** (DOJ).

Probably the highest-profile federal case to date that involved a clinical laboratory and EKRA was the prosecution of the former president of **Arrayit Corporation**, Mark Schena. In October 2023, Schena was sentenced to eight years in federal prison and ordered to pay $24 million in restitution for his role in a scheme that included healthcare fraud, securities fraud, and illegal kickbacks.

In that case, a prosecution witness testified that Arrayit paid its marketing company (which handled sales to Arrayit's client physicians) a commission amounting to 20% of claims paid by insurers. *(See TDR, "Violating EKRA Earns Lab Owner an Eight-Year Prison Sentence," Dec. 26, 2023.)*

In contrast to the commission arrangements at Arrayit, there are labs with sales reps who were paid on a percentage-based arrangement. But after EKRA, these labs converted sales reps to salary-based arrangements. Lefkowitz pointed out that another federal case involving EKRA suggests that labs aren't necessarily in the clear by moving their sales reps to fixed-fee payment. Depending on how a lab arrives at that compensation, it could still be in violation of EKRA, he noted.

This earlier federal case was settled in April 2023. That is when the DOJ announced a civil agreement with **Genotox Laboratories Ltd.** of Austin, Texas. Genotox agreed to pay at least $5.9 million to settle allegations that it paid illegal volume-based commissions to marketers and submitted claims for

unnecessary drug tests to federal insurance programs. Along with the settlement, the DOJ announced an 18-month Deferred Prosecution Agreement to resolve a criminal investigation into the same matter.

Violations of AKS and EKRA

"Genotox was encouraging custom panels for urine drug testing (UDT) even as they knew the testing wasn't medically necessary," Lefkowitz said. "These included blanket test orders and routine standing orders of UDT for all patients and healthcare providers. The settlement agreement discussed how Genotox had violated various laws, including AKS and EKRA."

Between 2014 and 2020, Genotox signed contracts with independent contractors and marketing companies to promote its services, the settlement agreement stated. Virtually all were paid a percentage commission based on billings to insurers. The government said these payments violated the AKS.

In March 2019, following passage of EKRA, the company began moving to fixed-rate marketing services agreements. However, the fixed rates were based on what the sales reps had earned under the commission model.

How Salary Was Calculated

"If a marketing representative was previously paid a 30% commission, Genotox would track his or her production to help when negotiating the next fixed-rate contract with that sales rep," Lefkowitz explained.

"Let's say the laboratory paid $70,000 per year based on what it believed the marketer would have made under the commission model," he continued. "The lab would measure the marketer's performance under the current contract by comparing what the marketer would have been paid under the old commission model. The lab would then adjust the sales rep's fixed salary based on how much volume that marketer brought in. Genotox was trying to back into a fixed fee that matched what the commission would have been if the lab was allowed to put the commission rate on paper."

In the settlement agreement, Lefkowitz noted, "the federal government is basically saying, 'We know you considered the volume or value because you were tracking people's production in accordance with their commission rates before EKRA, and you can't do that.'"

What does the Genotox case mean for other laboratories? "The industry is struggling to comply with EKRA and I'm sure a lot of people are looking at the historical payment amount," Lefkowitz said. "I think the Genotox case is a clear warning that laboratories can't base salaries on past performance under a commission model, because they are indirectly considering the volume or value of referrals that they expect.

Payment on Volume or Value

"If a lab's books show evidence that it's negotiating employment contracts based on what sales reps would have been paid if they had a commission, that could be used as evidence to show that the lab is, in fact, paying its employees based on the volume or value of business generated," Lefkowitz explained.

Instead, "it's better for the laboratory to fully protect itself by having a compensation model that is legally compliant with the plain language of EKRA," he advised. "The lab might want to base the salary on other metrics that encourage productivity without being directly tied to the volume or value of accounts generated."

For example, Lefkowitz suggested that labs could consider metrics that reflect how well a salesperson deals with existing clients. "How attentive are they? How responsive are they to questions about service offerings, or issues with billing or reporting of tests? That kind of customer service will have an impact on the physi-

cian's decision to stay with Lab A versus Lab B or Lab C. It may not be the only deciding factor, but it is an element in the physician's decision."

Other metrics might reflect sales representatives' ability to bring in new business. "How often are they visiting potential new accounts? What are they discussing in their pitches? What kinds of marketing materials are they using?

Labs Have Sales Metrics

"Sales representatives in the clinical laboratory business are heavily monitored by their employers," he continued. "Much of what's monitored relates to potentially attaining or maintaining accounts. Those metrics are likely already being tracked, and if they're not tracked, tools are available for tracking them."

These metrics could also be used to calculate productivity bonuses, he said. "Bonuses should be based on encouraging behavior that leads to business, regardless of whether it does, in fact, generate new accounts."

It should be noted that both the Genotox and Schena (Arrayit) cases had other charges that went beyond charges involving compensation. In the latter case, prosecutors also alleged that Schena's company, Arrayit, submitted $69 million in illegal lab test claims to insurers. The DOJ also brought charges of securities fraud arising from false and misleading statements about the company's performance and its failure to provide accurate financial statements.

"It's not just the illegal payment model that is attractive to prosecutors," Lefkowitz noted. "Usually there's some other egregious behavior." He then further explained that clinical laboratories which strive to avoid such behavior do not necessarily have complete control over all the conditions that could lead to federal prosecution. TDR

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AKS Commissions vs. EKRA Commissions

AKS AND EKRA BOTH GENERALLY PROHIBIT REMUNERATION FOR REFERRALS OF PATIENTS FOR HEALTHCARE SERVICES, which includes commissions paid to marketers. AKS contains a safe harbor that allowed labs to pay *bona fide* employees by any methodology, including a commission-based methodology. However, "This safe harbor does not extend protection to agreements with independent contractors," said regulatory compliance attorney Keith Lefkowitz.

"If laboratories wanted to engage marketers as independent contractors, they would have been, and are still required to, comply with the AKS safe harbor for personal services," he added. "Unlike the employment safe harbor, the safe harbor for personal services prohibits commission-based compensation models that inherently consider the volume or value of referrals generated by the marketer.

"Laboratories historically relied on the employment safe harbor in order to have a commission compensation model. Then EKRA came along and prohibited commission based compensation for both employees and independent contractors," he noted. "But that's not the only difference between the two statutes. Whereas AKS applies strictly to services billed to federal healthcare programs, EKRA also applies to services billed to commercial payers.

"Laboratory sales representatives market to physician accounts that would be covered under both AKS and EKRA because they have patients who are treated by federal healthcare programs and private programs," Lefkowitz explained. "However, because so much of their business is implicated by EKRA, laboratories need to follow the more stringent EKRA standard."

Virchow
Medicine ➤ Money ➤ Managed Care

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

Is Mobile Phlebotomy a Timely Service to Offer Health Plans?

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

CLINICAL LABORATORIES COULD BE MISSING A GOLDEN OPPORTUNITY to improve the patient experience in ways that some health plans would recognize and reward by including those labs in their provider networks.

This opportunity involves going mobile with their phlebotomy services. This is more convenient for the patient, can be less expensive for the lab, and can make certain managed care plans happy.

Why Payers Like It

In this column, we often discuss payer behavior that drives labs crazy. But to use a cliché, mobile phlebotomy amounts to a win-win for labs, doctors, patients, and health plans.

Why do health plans like it? Payers use a term called the Triple Aim to define their goals and to make doctors happy. They want to:

- Reduce costs,
- Improve population health, and
- Improve members' experiences.

To make the members happy while meeting the goals of the Triple Aim, health plans like to offer options. Mobile phlebotomy can support the Triple Aim, particularly when considering the cost of brick-and-mortar patient service centers (PSCs) which require large numbers of patient draws daily to keep the per-draw cost at a reasonable level.

Delivering More Value

If clinical laboratories want to keep their lucrative payer contracts, they need to think about different ways to provide value to the payer and patients that involve these kinds of services. If a lab doesn't have a network contract, it could approach the health plan by saying, "We have mobile phlebotomy, and we can give you coverage in this or that area."

It's about creating something that health plans need. It's a way for labs to differentiate themselves in ways that grab a health plan's interest. Another benefit is that labs with mobile phlebotomy units might find more physicians inclined to use their services.

All this tracks with the healthcare industry's move toward greater consumerism as well as larger business trends. Look at the growth in home delivery, especially since the pandemic. People are now accustomed to getting all kinds of consumer goods—groceries, meals, electronics, appliances, and more—delivered

to their doorsteps. Think **Instacart** for home delivery of groceries and **GrubHub** and **UberEats** for the home delivery of restaurant-prepared meals.

More Virtual Doctor Visits

Growing consumer acceptance of virtual doctor visits is another reason why mobile phlebotomy is a timely service for labs to consider. Payers encourage this trend because a telehealth session between patient and doctor can be less expensive than the cost of an in-office patient appointment. Payers also recognize that—following a telehealth session—the patient often must provide a specimen for the lab tests that the physician has ordered. Mobile phlebotomy is a patient-friendly solution to that problem.

"I want the 'easy' button," say consumers. "I want the self-testing diagnostic kit to come to my home. I want to sit down at the kitchen table and have my blood drawn. It has saved me all kinds of time. And now the doctor has my blood work for a telehealth visit."

Sitting on the managed care side of the table, these are reasons why a health plan would be motivated to include local labs with mobile phlebotomy in their provider networks. This is consistent with well-established trends and supports the Triple Aim.

In-house or Contract?

It should be noted that mobile phlebotomy is not a new concept. For decades, local labs sent mobile phlebotomists to nursing homes and long-term care facilities. In the 1990s, however, most public lab companies decided that this was an unprofitable line of business. Several public lab companies transferred their nursing home accounts to local hospitals as a way to exit the market.

Hospitals continued to provide mobile phlebotomy services to nursing homes and long-term care facilities because the practice supported inpatient referrals whenever nursing home patients needed hospitalization. It could be argued that hospital-based laboratories are well-positioned to leverage their existing mobile phlebotomy capabilities to serve consumers and ambulatory patients who need lab tests following a telehealth sessions with their physicians.

Labs seeking to deliver more value to health plans by offering mobile phlebotomy would do well to remember the Triple Aim. Labs should educate payers as to how their mobile phlebotomy service is consistent with the Triple Aim's goals. TDR

Consumers Support Convenient Phlebotomy

WHAT ARE THE BEST LOCATIONS FOR PATIENT SERVICE CENTERS (PSCs)? Historically, clinical labs operated patient service centers primarily in medical office buildings that were located on the campus of community hospitals.

That has changed significantly since 2016. That is the year when **Sonora Quest Laboratories** (SQL) entered into a pilot agreement with two **Safeway** stores in Phoenix to operate PSCs within the grocery stores. A PSC in a grocery store was an immediate hit with patients.

At the time, SQL executives told THE DARK REPORT that the appointment calendars for those PSCs filled up rapidly. Patients loved driving to a grocery store a few blocks from their home, getting their blood drawn, then walking to the in-store bakery for a pastry and a coffee to break their fast. *(See TDR, "PSCs in Safeway Stores Popular with Consumers," Sept. 16, 2016.)*

This success is due to the changing preferences of Gens X, Y, and Z for convenience. Mobile phlebotomy meets the preferences of these generations. It is also a good complement to telemedicine, which was accelerating even before the pandemic. Patients can schedule remote appointments and have their blood drawn in advance so their doctor can see the results.

Lab Market Update

Genetics Company 23andMe Shares Update on Cyberattack

Information from seven million people may have been accessed by the cybercriminals

Consumer genetics healthcare and biopharmaceutical company **23andMe** recently revealed that unauthorized access to millions of its customers' personal information may have started earlier than the company previously reported.

In its original **U.S. Securities and Exchange Commission** filing, 23andMe said it noticed a data breach in October 2023. But after a recent company investigation, the company "admitted hackers started accessing users' accounts five months earlier," *The Street* reported.

Nature of Attack

In a statement to customers, 23andMe described the nature of the incident and noted it involved personal information customers shared through the company's DNA Relatives feature.

"On October 1, 2023, a third party posted on the unofficial 23andMe subreddit site claiming to have 23andMe customers' information and posting a sample of the stolen data," the statement noted.

"Based on our investigation, we believe a threat actor orchestrated a credential stuffing attack during the period from May 2023 through September 2023 to gain access to one or more 23andMe accounts that are connected to you through our optional DNA Relatives feature," the company message stated.

Credential stuffing, the statement continued, is an approach used by "threat actors" to gain access to systems by "using lists of previously compromised user credentials. The threat actor accessed those accounts where user names and passwords that were used on 23andMe.com were the same as those used on other websites that were previously compromised or otherwise available."

23andMe is working with third-party security experts and encouraging customers to reset their passwords and to use two-step verification to login.

Type of Data Accessed

DNA Relatives allows 23andMe customers to "find and connect with genetic relatives," 23andMe explained on its website, adding that this is performed through the use of 22 autosomal chromosomes and the customer's X chromosomes.

Personal information from 5.5 million people who opted into the DNA Relatives feature was accessed, a 23andMe spokesperson's told *Tech Crunch*.

"The stolen data included the person's name, birth year, relationship labels, the percentage of DNA shared with relatives, ancestry reports, and self-reported location," *Tech Crunch* reported.

The spokesperson explained to *Tech Crunch* that another group of 1.4 million people who chose to be in DNA Relatives also "had their Family Tree profile information accessed."

Thus, the breach of 23andMe data actually affected nearly seven million people, or half of the company's 14 million customers, *Tech Crunch* reported. TDR

Lab Market Update

Labcorp, Quest Diagnostics Discuss Q4 & 2023 Earnings

Both lab companies reported modest growth in specimen volume and pricing during 2023

DURING RECENT EARNINGS CALLS WITH FINANCIAL ANALYSTS AND INVESTORS, both **Labcorp** and **Quest Diagnostics** discussed their fourth quarter (Q4) and full year 2023 financial results. Each reported some stability in the market for clinical laboratory testing services, reflected in the numbers reported for test volume and pricing.

Quest Diagnostics' earnings call was first, on Feb. 1. The company reported that "total volume, measured by the number of requisitions, increased 1.9% versus the fourth quarter of 2022, with acquisitions contributing 50 basis points to total volume. Total base testing volumes grew 5.2% versus the prior year. Revenue per requisition declined 3.5% versus the prior year driven primarily by lower COVID-19 molecular volume ... base business revenue/requisition was up 0.2%."

During Labcorp's earnings call on Feb. 15, the company reported that Q4 organic test volume increased by 0.3%, with acquisition test volume adding another 2.1%. It further stated that "Base Business volume increased 5.2% compared to the Base Business last year. Price/mix was up 2.4% in the Base Business compared to the Base Business last year."

Given the two public lab companies' market share of testing for office-based physicians, their reports of modest increases in test volume and prices for the full year indicate a degree of stability in the overall lab testing marketplace during 2023. Below are highlights from each lab company's Q4/full year earnings call.

LABCORP: Year 2023 Revenue Grew 2.5% to $12.16 billion

Labcorp announced these Q4 2023 and full year 2023 financial results as compared to Q3 2022 and full year 2022:

- **Q4 revenue** was up 3.5% to $3.03 billion from $2.93 billion.
- **Q4 Diagnostic laboratories revenue** was up 2.6% to $2.35 billion from $2.29 billion.
- **Q4 Test requisition volume** grew 2.4%.
- **Q4 COVID-19 test revenue** plunged 73%.
- **Q4 Biopharma laboratory services revenue** was up 7.1% to $694.8 million from $648.8 million.
- **Full year 2023 revenue** was up 2.5% to $12.16 billion from $11.86 billion.
- **2023 Diagnostics laboratories** revenue increased 2% to $9.41 billion from $9.20 billion.
- **2023 Biopharma laboratory services revenue** was up 3% to $2.77 billion from $2.69 billion.

Labcorp CFO Glenn Eisenberg addressed the increased costs associated with the staffing shortage that currently plagues the lab industry. Throughout the United States, labs have had to raise compensation to attract enough clinical laboratory scientists and other support positions.

On Labcorp's situation with staff compensation, Eisenberg stated, "Our general premise is that the labor market inflation

for labor is around 3%—you can say 3% to 4%—but within that range ... For us, a 3%, give or take, increase in our labor, call it merit in particular, would be a little bit over $100 million, and again, we target that $100 million to $125 million a year."

Two regulatory issues of major concern to all labs were discussed during the earnings call. On the subject of the federal **Food and Drug Administration's** (FDA) proposed rule on laboratory-developed tests (LDTs), Labcorp CEO Adam Schechter stated, "With regard to LDTs, we do not support the FDA's current thinking in terms of taking legislation that was created for the device industry and applying it to the diagnostic industry. We were very supportive of [the pending VALID ACT] legislation that would give FDA oversight of laboratory-developed tests. We think that's the right path to go. We'll continue to work with the trade organization to see if we can make progress there, but we think legislation that is fit for purpose for the diagnostic industry is the right path forward."

Also discussed were solutions to the PAMA problems. "We continue to support SALSA [Saving Access to Laboratory Services Act], and we continue to be optimistic that SALSA will get passed," Schechter said. "We have support from both sides of the aisle, and ACLA [**American Clinical Laboratory Association**], our trade organization, is working really hard to get that legislation passed. If it doesn't get passed, then we'll try to see if there's a way to get another year's delay."

Quest Diagnostics®

QUEST DIAGNOSTICS: Full Year 2023 Revenue Was $9.3 Billion, Down from $9.9 Billion in 2022

Quest Diagnostics reported these Q4 2023 and full year 2023 financial results as compared to Q4 2022 and full year 2022:

- **Q4 revenue** was down 1.9% to $2.29 billion from $2.33 billion.
- **Q4 base business revenue** was up 4.7% to $2.25 billion from $2.15 billion.
- **Q4 COVID-19 testing revenue** plunged 79.8% to $37 million from $184 million.
- **Full year 2023 revenue** was down 6.4% to $9.25 billion from $9.88 billion.
- **2023 base business revenue** was up 7.1% to $9.03 billion from $8.43 billion.
- **2023 COVID-19 testing revenue** dropped 84.7% to $223 million from $1.45 billion.

Lab labor cost increases at Quest are in the same ballpark as at Labcorp. During the earnings call, Quest CFO Sam Samad stated, "We assume the labor inflation to be in line with what we saw in 2023. So, somewhere in that 3% to 4% growth range—not necessarily expecting it to get worse, but not necessarily expecting it to get better either."

Quest CEO Jim David commented on the proposed FDA LDT rule saying, "In terms of LDTs, I think we've said in the past about 10% of our tests are considered LDTs. We'll wait to hear from the FDA in April what the final rule is, and then we'll make decisions as an industry from there."

Quest is experiencing success with its direct-to-consumer lab testing program. "Our consumer-initiated testing service, questhealth.com, generated revenues of approximately $45 million in the full year 2023, with strong base business growth. Our return on ad spend and customer acquisition costs remained favorable in the fourth quarter."

Efforts to deploy AI at Quest were discussed during the earnings call. "In 2023, we expanded the use of AI in microbiology to help identify bacteria as well as in cytogenetics to identify chromosomal abnormalities," David said. "We are encouraged by the opportunities to use AI in several additional clinical areas including cytology, pathology, and parasitology. In 2023, we deployed an AI tool at our Clifton lab that helps laboratory staff continuously identify ways to be more productive in their daily routines." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In California last month, **Quest Diagnostics** entered into a settlement agreement with California Attorney General Rob Bonta and nine local district attorneys. *KCRA News* of Sacramento reported that the "settlement resolves allegations that the company unlawfully disposed of hazardous waste, medical waste, and protected health information. The illegal disposal was said to occur at all of the company's diagnostic laboratories statewide." Quest will pay $5 million in penalties. It stated that it has already changed a number of its business practices and continues to address the issues identified in the settlement.

MORE ON: *Quest Diagnostics Settlement*

KCRA wrote that investigators had made 30 inspections of Quest facilities throughout California. "During those inspections, investigators found hundreds of containers of chemicals, batteries, unredacted medical information and medical waste, along with other items that violate the Hazardous Waste Control Law, Medical Waste Management Act, Unfair Competition Law, and other civil laws."

KAISER SETTLED WITH CALIF. AG

State and county officials in California may be on the alert for these types of violations. In Sept., 2023, *The HIPAA Journal* reported that **Kaiser Foundation Health Plan Foundation Inc.** and **Kaiser Foundation Hospitals** had settled with the California attorney general and several counties for $49 million to resolve allegations of improper disposal of hazardous waste, medical waste, and protected health information. These two cases are reminders to clinical laboratories that they can be sanctioned by state and federal agencies if they do not properly handle the disposal of all types of waste and materials containing patients' protected health information.

TRANSITIONS

- Pathologist Jerry W. Hussong, MD, retired from **Sonic Healthcare USA** after five years as CEO. Former positions were with **ARUP Labs**, **Cedars-Sinai Medical Center**, **Laboratory Medicine Consultants**, and **University of Utah Health**.

- Stepping into the role of Interim CEO of Sonic Healthcare USA is pathologist Cory A. Roberts, MD, MBA. He is currently President of Sonic Healthcare USA's Anatomic Pathology Division. Roberts' prior positions were with **ProPath**, **Glenview Capital**, and the **University of Nebraska Medical Center**.

- Michael Fraser, PhD, MS, CAE, FCPP, was announced as the new Chief Executive Officer at the **College of American Pathologists**. Fraser's previous positions were with **Association of State and Territorial Health Officials**, **Association of Maternal and Child Health Programs**, and **National Association of County and City Health Officials**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 8, 2024.

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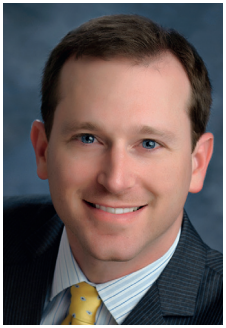
SPECIAL SESSION

EXECUTIVE WAR COLLEGE

April 30-May 1, 2024 • Hyatt Regency • New Orleans



Gabriel Bien-Willner, MD, PhD
Medical Director, MolDX & Z-Code
Palmetto GBA

29 YEARS

MolDX and Z-Code Update: Current Developments and What's Coming Next

Much is changing with how Medicare and private payers handle genetic test claims. When you join us at the *Executive War College*, you will have two opportunities to hear and learn from Dr. Bien-Willner about what's coming with the MolDX program and private payer requirements for using Z-Codes with certain genetic test CPT codes.

Dr. Bien-Willner will present during the opening general session. Later, he will conduct an extended discussion with attendees that will include a Q&A. It's your opportunity to gain a better understanding of how the MolDX program is evolving, along with insights that can help you and your lab obtain Z-Codes for your genetic tests.

His sessions are "must-attend" events for genetic testing labs that want to better align their coding and billing to the requirements of the MolDX program. Register your team today to guarantee your place!

It's Our 29th Anniversary!

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

UPCOMING...

- ***EHR vendors charge excessive fees for interfaces: How federal transportability rule may help labs.***
- ***Federal Health and Human Services finalizes rule on artificial intelligence transparency.***
- ***Justice Department probes UnitedHealth/Optum over antitrust concerns.***