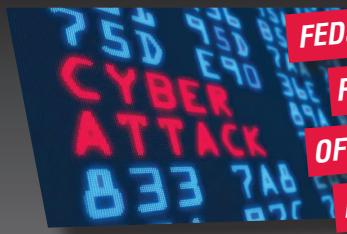
Volume XXXI, Number 7 Monday, May 20, 2024



FEDS ISSUE DRAFT RULE REQUIRING REPORTS OF CYBERATTACKS, RANSOMWARE PAYMENTS

See pages 10-15

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER

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

Why Ransomware Attacks Are a Threat to Your Lab

HAVE YOU AND YOUR LAB MANAGEMENT TEAM NOTICED THE MAJOR SHIFT in cybercrime that targets healthcare providers, including clinical laboratories and pathology groups? For years, cybercrime was primarily security breaches involving the theft of patients' protected health information (PHI). This is no longer the case.

Today, a growing proportion of cybercrime involves ransomware attacks. Whereas a cyberattack in past years represented the theft of patient PHI, today, the most frequent type of cyberattack is a complete shutdown of the targeted lab's information systems, followed immediately by a demand that the victimized lab pay ransom in order to regain access to its systems and its patient data that was stored in electronic health record (EHR) systems and laboratory information systems (LIS).

This is one reason why a federal agency just issued a draft rule on Apr. 4, 2024, that requires certain organizations: 1) To report a cyberattack within 72 hours; and, 2) To report ransom payments associated with a cyberattack within 24 hours.

Once again, your team at THE DARK REPORT is first to alert you to a significant development in the lab testing marketplace in a timely fashion. On pages 10-14, you will read about this new proposed federal rule, along with how the nature of cybercrime has evolved from simple breaches of PHI to sophisticated attacks that totally cripple the ability of clinical labs and hospitals to operate, unless a ransom is paid to the cyberthieves.

Moreover, we are first to inform you that, within the past 60 days, two important regional pathology laboratories experienced cyberattacks that shut down their operations. Of course, in both cases, the cybercriminals sent messages that they would provide the codes needed to restore services if the victimized pathology labs would pay the ransom demanded.

Collectively, these developments argue that lab administrators and pathologists should make it a priority to assess the current state of their lab's information system security against the ever-improving capabilities of cyberthieves to break into those systems. Two expert sources labs can consult as part of this effort are their primary LIS vendor and any of the national law firms they regularly use. These entities have direct knowledge about the nature of cyberattacks directed against their clinical lab and pathology clients. TDR

Significant Developments Are Shaping Lab Market

Yes! The FDA final LDT rule is the biggest story! But labs are also being challenged in multiple ways

CEO SUMMARY: With 140 speakers and 1,000+ attendees, this year's Executive War College again provided a comprehensive picture of the specific forces reshaping the U.S. market for lab testing services. Presented here is a smorgasbord of information and innovation shared by different speakers that describe and validate different developments that affect the clinical service mix and financial health of labs in coming months.

by Robert L. Michel

IT IS EASY TO DECLARE THAT THE BIGGEST STORY FOR THE CLINICAL LAB INDUSTRY in 2024 to date is the FDA's release on April 29 of the final rule defining the agency's oversight of laboratory developed tests (LDTs).

After all, a majority of labs in the United States use LDTs on a daily basis. With the FDA final rule taking effect on July 5, labs performing LDTs will need to understand all the elements in the 528-page rule and take steps to ensure they are in full compliance.

For these reasons, at this year's *Executive War College,* which took place on April 30-May 1, 2024, in New Orleans, the FDA LDT rule was the number one topic of interest. The timing was fortuitous, as the FDA released the final rule on Monday, April 29, prior to its publication in the *Federal Register* on May 6.

This gave expert speakers the opportunity to study the language of the final rule and share their findings with attendees at the *Executive War College* over the next two days.

But when considering all the forces of change now pressuring clinical laboratories, genetic testing labs, and anatomic pathology groups today, FDA regulation of LDTs is just one factor. Other equally powerful forces are reshaping the U.S. healthcare system in general and the lab testing marketplace specifically.

For example, how health plans reimburse genetic test claims is increasingly a challenge for clinical labs. Each year, genetic testing labs report more difficulties in submitting test claims and getting reimbursed for those claims.

Multiple presentations at the *Executive War College* addressed this situation. Knowledgeable speakers pointed out that

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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

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

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

health plans were unprepared to deal with both the rapid increase in the daily volume of genetic test claims along with the explosion in the number of unique genetic tests, the majority of which are LDTs.

Genetic Test Claims

Speakers explained why health plans have a double-challenge in dealing with genetic test claims. One challenge is how the growing daily volume of claims overwhelms the capacity of payers to accept and process these claims. It was also observed by several managed care insiders that, throughout the past 24 months, the major health insurance corporations reduced staff, often in successive waves of layoffs. That meant fewer humans to handle the ever-increasing number of genetic test claims.

Payers have a second challenge that may prove insurmountable. The CPT coding system has about 400-500 CPT codes to cover genetic tests. Yet there are more than 160,000 types of genetic tests now offered in the United States.

Consequently, when a payer gets a genetic test claim and tries to match the function of the specific test with: 1) the symptoms and diagnosis provided by the doctor; and, 2) the health plan's coverage guideline for this diagnosis, it is unsuccessful because of the failings of the CPT coding system in this regard.

MolDX and Z-Codes

In response to this second problem, **Medicare** established the MolDX program, which requires labs with unique genetic tests to apply for a Z-Code. That Z-Code provides more detailed information to a payer about the genetic test and how the test results will help the physician with diagnosis and treatment decisions.

UnitedHealthcare is the first major private payer to announce it will require genetic test claims for approximately 250 CPT codes to also include a Z-Code to be eligible for reimbursement. Several sessions at the *Executive War College* addressed the steps required for a lab to obtain a Z-Code for its unique genetic test. These speakers also discussed related developments in how health plans are using prior authorization as well as the steps labs can take to be more successful when submitting a genetic test for prior authorization.

Of course, artificial intelligence (AI) was front and center at this year's *Executive War College*. It would not be an understatement to declare that every company at the conference selling to clinical laboratories is incorporating AI in some manner in the instruments, automation, and solutions it sells.

What AI Can and Cannot Do

The challenge for lab managers and pathologists is to stay informed and educated about the different technologies vendors are using in their AI offerings. To help in that effort, this year's *Executive War College* put AI front and center at one of the plenary sessions, supplemented by an optional, one-day AI workshop for those lab leaders ready to take a deep dive into this subject.

In fact, one of the most popular sessions was a first for the lab profession. It was a topic that deals with what regulations and legal issues are triggered when a lab begins using AI in patient care. The speaker was pathologist Roger Klein, MD, JD, Faculty Fellow, **Center for Law, Science & Innovations, Arizona State University Law**. His presentation was titled, "Artificial Intelligence: Regulatory and other Legal Issues" and it was standing room only during his talk.

Once a lab administrator gets a basic understanding of AI and how it functions in operational and clinical settings, there is still another important question to answer: when is the right time to acquire and deploy AI solutions in my lab?

If you were to ask any of the Corporate Benefactors and Sponsors at this year's *Executive War College*, almost all of them would answer, "The time is now!"

The truth of this statement is illustrated by the list of the 2024 Corporate Benefactors presented in the sidebar at right. The only company selling lab automation or equipment on that list is **Leica Biosystems**, with its offerings in histology and pathology. In its educational contributions to the conference agenda, the Leica team featured its AI offerings in tandem with its lab equipment.

Given everything presented here about what was different at the 2024 *Executive War College*, in terms of topics, trends and sponsor support, there is an important insight for those lab executives and pathologists responsible for strategy at their respective labs.

That insight, to paraphrase an old saying, is "the lab instrumentation and automation king is dead! Long Live Big Data and the AI king!"

My working theory is that today's generation of lab automation and instruments is mature. Stated differently, when labs want to buy, for example, core lab automation for chemistry, immunoassay, and hematology, the total lab automation (TLA) solutions offered all have comparable functions and performance.

Automation at Mature Stage?

This means the biggest IVD manufacturers don't have clear differentiation in their respective products today, compared to earlier generations of TLA products following their market entrance in the mid-1990s. Assuming that statement is accurate, it could be why the major IVD manufacturers are not major sponsors at a lab management conference attended by more than 1,000 senior executives from the nation's largest lab organizations.

At the same time, the major sponsors at this same conference are offering solutions that help labs take data and convert it into valuable information. You can decide if this is incontrovertible evidence that the clinical laboratory profession is now in the Age of Big Data and AI! TDR

Shift in EWC Sponsors from Instruments to IT

PROBABLY THE BEST WAY TO ILLUSTRATE WHY MANAGEMENT OF DATA is now a major priority for clinical labs and pathology groups is to look at the companies supporting the 2024 *Executive War College* as Corporate Benefactors, the highest level of support.

Until about six years ago, major *in vitro* diagnostics (IVD) manufacturers regularly participated as Corporate Benefactors at EWC. These were the familar names of **Abbott Laboratories**, **Beckman Coulter**, **Roche Diagnostics**, **Siemens Healthineers**, among others.

This changed about three years ago. From that time forward, the Corporate Benefactors have been companies that help labs generate data, manage data, and use that data to automate manual processes in every aspect of daily operations and clinical service delivery.

This is true of this year's 13 Corporate Benefactors at EWC, listed below in alphabetical order.

Corporate Benefactors Supporting Executive War College 2024

- **Clinisys** *(formerly **Sunquest**)*
- **Coronis Health**
- **Data Innovations** *(division of **Clinisys**)*
- **Ellkay**
- **Experian Health** *(formerly **Wave**)*
- **Grace Health Technology**
- **Leica Biosystems** *(division of **Danaher**)*
- **Optum** *(acquired **Change Healthcare**)*
- **Quadax**
- **Synergen Health**
- **Telcor**
- **US HealthTek**
- **XiFiN**

The team at THE DARK REPORT wishes to thank the above 2024 Executive War College Corporate Benefactors for their support and contributions.

Regulatory Update

FDA Hosts Webinar to Explain Key Issues with Final LDT Rule

After publication in Federal Register on May 6, FDA's LDT rule becomes effective on July 5

On April 29, the **US Food and Drug Administration** (FDA) announced its final rule on oversight of laboratory developed tests (LDTs). Most lab leaders oppose FDA jurisdiction over LDTs. Now that the rule is finalized, many labs want to know how it will be implemented. With that in mind, the agency presented a webinar on May 14 that provided an overview and answered questions labs had submitted in advance.

The rule, the federal agency said, amends "its regulations to make explicit that IVDs are devices under the [Federal Food, Drug, and Cosmetic Act] including when the manufacturer of the IVD is a laboratory." The rule also specifies how the FDA will phase out its "general enforcement discretion" related to LDTs.

Regulatory Requirements

Under that policy, the agency "generally has not enforced applicable regulatory requirements for laboratory developed tests," explained Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs at the FDA's **Center for Devices and Radiological Health**. This includes "requirements related to registration and listing; reporting of adverse events to FDA; current good manufacturing practices; and premarket review of tests by FDA," she said.

The new rule, she explained, will phase out this policy so that "IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs." This will happen in five stages beginning on these dates, she stated:

- **Stage 1, May 6, 2025**: "FDA will expect compliance with medical device reporting requirements, for correction and removal reporting requirements, and complaint files."
- **Stage 2, May 6, 2026**: "FDA will expect compliance with requirements not covered during the other stages of the phase out policy, including registration and listing, labeling requirements, and investigational use requirements."
- **Stage 3, May 6, 2027**: "FDA will expect compliance with quality system requirements not required in earlier stages." These include design controls, purchasing and supplier controls, acceptance activities, corrective and preventive actions, and requirements related to records.
- **Stage 4, November 6, 2027**: "FDA will expect compliance with premarket review requirements for high risk IVDs offered as LDTs."
- **Stage 5, May 6, 2028**: "FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs." However, she added that "most low-risk IVDs are exempt from premarket review."

Enforcement Discretion

Hillebrenner noted that the new enforcement discretion policy will exempt some LDTs, either wholly or in part.

The agency, she said, will "generally not enforce any applicable requirements," for the following:

- **"1976-type" LDTs**. These tests have characteristics in common with most LDTs available in 1976, when **Congress** passed the Medical Device Amendments to the Food, Drug & Cosmetic Act and FDA began exercising enforcement discretion. The tests, she said, use manual techniques, are performed by laboratory personnel with specialized expertise, and use components marketed for clinical use.
- **Certain Human Leukocyte Antigen (HLA) Clinical Laboratory Tests** used "to perform high complexity histocompatibility testing" for organ, stem cell, and tissue implantation.
- **Forensic tests** intended for use in law enforcement.
- **LDTs** manufactured and performed within **Department of Defense** and **Veterans Health Affairs** facilities.

Tests in these categories, Hillebrenner said, "are, in our experience, unlikely to pose significant risks, or are conducted in circumstances that themselves will mitigate the risks."

Categories of Exempt Tests

In response to comments on the previously proposed rule, the final rule added other categories of tests that will be exempted from Stage 4 and Stage 5 premarket review requirements. However, other requirements still apply. FDA will expect compliance with the Stage 1, 2, and 3 requirements for the following:

- **LDTs** approved by the **New York State Department of Health's** Clinical Laboratory Evaluation Program.
- **Modified versions** of existing 510(k) cleared or De Novo authorized tests, where the modification is minor and "does not significantly affect the safety or effectiveness of the test," she said. The test can be used only in the lab that made the modification, and the FDA expects compliance with design controls and other quality system requirements, she added.

FDA will expect compliance with the Stage 1 and Stage 2 requirements of the following, as well as the Stage 3 records requirements, but not other quality system requirements specified in Stage 3:

- **LDTs** "manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system," Hillebrenner said. One goal of this exception, she noted, is to address the challenges of treating patients with rare diseases or otherwise small patient populations. "We also recognize that it can be challenging to validate tests for rare diseases or smaller patient populations, where it is difficult to obtain clinical samples."
- **LDTs first marketed** prior to May 6, 2024, "as long as they are not modified after that date," she said, or if the modifications are limited. For example, routine instrument replacement would be allowable as long as it does not change the IVD's operating principle, or indications for use, or adversely affect performance or safety specifications.
- **Certain non-molecular antisera LDTs** used by blood establishments to determine transfusion compatibility, "when there is no alternative IVD available to meet the patient's need for a compatible blood transfusion," she said. The policy, she added, "does not apply to molecular tests used for genotyping red blood cell antigens."

One question Hillebrenner fielded related to LDTs used by public health laboratories. "The final rule does not provide a separate policy for LDTs manufactured and offered by public health labs," she said. But she noted that some of the exceptions above would apply, such as the exemption from premarket review for tests marketed prior to May 6, 2024. TDR

Lab Market Update

Labcorp, Quest Issue Q1 Earnings, Offer Comments on FDA's LDT Rule

Both clinical lab companies benefited from acquisitions of independent lab firms and hospital outreach labs

BOTH **LABCORP**, BURLINGTON, N.C., AND **QUEST DIAGNOSTICS**, SECAUCUS, N.J. REPORTED STRONG FINANCIAL PERFORMANCE during the first quarter (Q1) of 2024. Base business—diagnostics excluding COVID-19 testing—jumped about 6% during Q1 as compared to base business in Q1 2023.

Here is an overview of their financial results as well as key Q1 accomplishments.

LABCORP: Grows Q1 Revenue 4.6%; Plans Purchase of 'Select Assets' of Invitae

Labcorp shared these Q1 2024 financials as compared to Q1 2023 during its Q1 conference call on Apr. 25, 2024:

- **Revenue** grew 4.6% to $3.18 billion from $3.04 billion.
- **Base business** increased 6.7%.
- **Diagnostics lab revenue** was up 4.1% to $2.48 billion from $2.38 billion.
- **Biopharma lab services revenue** jumped 7.5% to $710.9 million from $661.3 million.
- **Volume** (measured by requisitions) grew 3.4%.

Labcorp opened its Q1 earnings call by announcing its intent to purchase select assets of **Invitae Corporation**, a San Francisco-based medical genomics company. Labcorp will pay $239 million for certain Invitae assets.

Labcorp expects to make about $275 million to $300 million in annual revenue as a result of the deal, which is expected to close in Q3 2024.

"This transaction will advance our strategy to launch and scale specialty testing in areas such as oncology rare diseases. These are strong assets in important disease areas and strategically [correspond] with our focus on specialty testing," said CEO Adam Schechter during the call.

Invitae, which had a $1.34 billion loss in the nine months ending Sept. 30, sold its reproductive health assets—including carrier screening and non-invasive prenatal screening—to Austin-based **Natera**.

During the conference call with investors and financial analysts Schechter was asked about his company's perspective on the federal **Food and Drug Administration** (FDA) final rule on laboratory developed tests (LDTs). He answered, saying "The first thing I'd say is that Labcorp was supportive of the VALID Act, which we thought was the right way to provide [Congressional] oversight of [how the] FDA [regulated] LDTs.

"We are not supportive of the current [draft] rule, although we haven't seen the final rule," he continued. "We still have to see [the final rule] to judge … exactly what's in there.

"But [what] I worry about most ... is speed to market of LDTs," Shechter explained. "[At the same time, the] patients who need these LDTs are typically smaller groups of patients. Other people aren't necessarily developing [diagnostic] tests for them. And they need to test as quickly as possible. So, the real question to

me is going to be how fast the FDA will be able to review the new LDTs and get them into the marketplace."

QUEST DIAGNOSTICS: Boosts Q1 Revenue 1.5%; Staffing Challenges at Hospital Labs Lead to More Test Referrals

During its Q1 earnings call on Apr. 23, 2024, Quest Diagnostics reported these Q1 2024 financial results as compared to Q1 2023:

- **Revenue** was up 1.5% to $2.37 billion from $2.33 billion.
- **Diagnostic information services revenue** grew 1.7% to $2.29 billion from $2.25 billion.
- **Base business revenue** jumped nearly 6%.
- **Volume** (measured by number of requisitions) increased 1.6%.
- **Base business volume** was up 3.3%.

Quest's acquisition of Brooklyn, N.Y.-based **Lenco Diagnostics Laboratories**, contributed to revenue gains, according to CEO James Davis, who spoke during an earnings call. "Our M&A pipeline continues to be robust, and we are making progress with several promising opportunities," he noted.

Davis also said that staff challenges at hospital-based labs contributed to growth during Q1, especially in reference testing.

"Hospitals are sending us more reference testing largely because of our innovation, our quality, and our value. They also face persistent challenges with staffing certain roles in specialized fields like histology, microbiology, and cytotechnology," he said. "Many hospitals and health systems are approaching us with a heightened sense of urgency for help with their lab strategies. As a result, our pipeline of both professional lab services and outreach opportunities remains strong."

Early in the first quarter earnings call, Davis commented on the pending release of the FDA's final LDT rule. "We still encourage the Administration to withdraw the proposed rule and engage in advancing appropriate legislation that preserves the critical role of laboratory diagnostics," he said.

"We are disappointed that the FDA continues to move forward with this regulation which we believe, if enacted, will compromise patient access to critical lab testing, slow diagnostic innovation and add unnecessary healthcare costs," Davis continued.

"We also believe that the rule raises serious legal issues, including that the FDA lacks the statutory authority to unilaterally regulate these services," he added. "While we will be prepared to comply with the rule, we will continue to work with our trade association, **ACLA**, on potential next steps."

For lab executives and pathologists watching growth in the demand for direct-to-consumer testing (DTC), this topic was discussed during the Quest conference call. "Consumer-initiated testing revenues grew by double digits, while base business revenues nearly doubled as it built on the gains we delivered last year from our consumer-facing platform questhealth.com," Davis stated.

"Some of our most popular test categories included general health panels, STDs, and tuberculosis," he noted. "We also continued to expand our test menu, such as with our launch of PFAS [per- and polyfluoroalkyl substances] testing for assessing potential exposure to dangerous 'forever chemicals' and are extending our reach through various partners."

During the call's Q&A portion, an analyst asked about possible impact of the **Change Healthcare** cyberattack on Quest. Davis said that less than 2% of Quest's test requisitions "moved through those pipes … they're somewhere between a $15 million and $20 million cash impact, but not revenue impact," he said. TDR

CEO SUMMARY: There is another federal rule that will require compliance by clinical labs. An agency of U.S. Dept. of Homeland Security published a draft rule on April 4 that requires certain organizations—including hospitals, clinical labs, and pathology groups—to report, within 72 hours, any cyberattack and the payment of any ransom payments associated with a cyberattack. Labs and other healthcare providers have until June 3 to submit comments about the draft rule. Meanwhile the number of cyberattacks continues to increase.

Rule proposed by the federal Cybersecurity and Infrastructure Security Agency

New CISA Draft Rule Mandates Rapid Reporting of Cyberattacks

Last month, federal regulators published a new draft rule that compels certain healthcare providers, including many clinical laboratories, to report cyberattacks within 72 hours.

Not surprisingly, the majority of lab managers and pathologists remain unaware of this proposed rule for speedier reporting of cyberattacks to federal officials because during the same period their attention has been focused on the FDA's publication of the final rule on regulation of laboratory developed tests (LDTs). *(See pages 6-7.)*

It was the federal **Cybersecurity and Infrastructure Security Agency** (CISA) that published this new proposed rule. It includes two requirements. One is that certain healthcare providers must report cyberattacks within 72 hours. The second is that covered entities must report ransomware payments within 24 hours.

The proposed rule was mandated by the Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA), which **Congress** passed in 2022. The rule establishes regulations for implementing the statute's reporting requirements. CISA, an agency within the **U.S. Dept. of Homeland Security**, published the proposed rule on April 4 and is accepting public comments through June 3.

This proposed rule was announced as healthcare providers across the nation were dealing with the fallout from the recent **Change Healthcare** ransomware attack. However, "this rule doesn't have anything specifically to do with Change Healthcare," said Taylor Sample, JD, an attorney with **Bass, Berry and Sims** in Nashville, Tenn. Sample specializes in healthcare fraud and abuse as well as data privacy and security.

"The Change Healthcare attack happened on a large scale, but I think the law itself was a reaction to a growing number of healthcare related and healthcare specific cyberattacks," he said. *(See TDR, "UnitedHealth Group Faces Department of Justice Antitrust Probe," April 29, 2024.)*

Lab executives and pathologists will want to study the proposed rule on the reporting of cyberattacks and payment of ransom. They have until June 3 to submit comments on the proposed rule to CISA.

There is another reason why clinical labs and anatomic pathology groups should want to give closer scrutiny—not to just this draft rule—but to the vulnerability of their labs to cyber and ransomware attacks. Cybercriminals are attacking medical labs with increasing frequency.

In just the last two months, The Dark Report has learned of ransomware attacks against two major regional anatomic pathology groups. Both attacks caused major disruption to normal testing activities and the financial condition of the two groups.

More pathology groups and clinical laboratories may be experiencing cyber and ransomware attacks. There are many sound business reasons why the public is not made aware of these attacks. The lack of public disclosure about these ransomware attacks against pathology labs makes it tough for other lab leaders to understand two key aspects of these attacks.

First, is the number of labs experiencing a cyberattack increasing? Second, are more labs paying ransomware to regain access to their systems and their data—and restore normal cash flow?

The Feb. 21 ransomware attack on Change Healthcare, a business unit of **Optum Health** (itself a division of **UnitedHealth**), disrupted hospitals and providers across the nation for weeks. The cybercriminals blocked large numbers of prescription orders and billions of dollars in prescription reimbursement.

February Cyberattack

"The Change Healthcare attack happened on a large scale, but I think [CIRCIA] was a reaction to a growing number of healthcare related, specific cyberattacks," Sample noted. *(See TDR, "UnitedHealth Group Faces Department of Justice Antitrust Probe," April 29, 2024.)*

REGULATORY • COMPLIANCE • LEGAL UPDATE

The rule, according to Sample, aims to provide guidance on specifics related to the law. "Who would fall under the law? What types of incidents would have to be reported? This proposed rule helps to flesh out the broad strokes," he noted.

Healthcare is one of 16 "critical infrastructure sectors" covered by the law, Sample explained. "I think the real purpose is to start gathering information and allow the federal government to understand trends about cyberattacks," he said.

"Currently, if a small critical access hospital in a rural county suffers an attack, it doesn't have an obligation to report that to the government within 72 hours," he said. "This regulation is meant to get that information to CISA in short order so it can tell other rural hospitals, 'Hey, these types of attacks are happening,' and then the hospitals can put protections in place hopefully to prevent future attacks."

Under the rule, he said, covered entities must report "substantial" cyber incidents as well as ransom payments within the specified timeframes. As defined in the rule, a cyber incident is "an occurrence that actually jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information on an information system, or actually jeopardizes, without lawful authority, an information system."

Reporting Requirements

For example, it could apply if an organization is subjected to a distributed denial-of-service (DDoS) attack that disrupts its operations for an extended period. But companies would not be required to report a DDoS attack that merely causes a website to be inaccessible for a short time, or a malware attack that's successfully countered by antivirus software.

The proposed rule notes that HIPAA and the HITECH Act breach notification rules "are generally focused solely on data breaches and do not require reporting of other types of cyber incidents." But those rules also give providers much more time to report the breaches.

Not all organizations within the 16 critical sectors are covered by the rule's disclosure requirements. Most notably, it exempts small businesses as defined by the **Small Business Administration** (SBA), Sample said. That standard varies according to the company's industrial classification: A medical laboratory is regarded as a small business if it has less than $41.5 million in annual revenue.

Reporting Categories

Within the healthcare sector, the proposed rule also designates specific categories of organizations that would be subject to reporting requirements regardless of size. They include hospitals with more than 100 beds, as well as "critical access" hospitals.

The latter are generally small hospitals in rural areas. "They typically have fewer than 100 beds, but they're in an area where they are the only outlet for healthcare," Sample said.

The rule notes that CISA considered adding medical laboratories as a sector-specific category but chose not to do so because "a sufficient number of entities already will be captured under the size-based criterion that applies across all critical infrastructure sectors."

However, the rule does specify that manufacturers of Class II or Class III medical devices would be subject to the reporting requirements, even if they qualify as small businesses.

"If an entity manufactures Class II or III medical devices, in addition to other functions that do not meet one of the sector-based criteria, the entire entity is the covered entity, and any substantial cyber incident experienced by any part of the entity would need to be reported, regardless of whether the underlying incident impacted the manufacturing of Class II or III medical devices," the proposed rule states.

Cybercrooks Learning to Make More Money with Ransomware, Compared to PHI Attack

CYBERCRIMINALS ARE INCREASING THEIR ATTACKS ACROSS ALL INDUSTRIES. These threat actors consider healthcare organizations to be a particularly lucrative target for ransomware attacks.

This is true for two reasons. First, most healthcare providers—whether they be hospitals, clinical labs, or pathology groups—are often willing to pay a ransom quickly to restore patient services and restore cash flow.

Second, the hackers can make more money by selling the patient data captured during a ransomware attack on the Dark Web. Cybercriminals have no scruples about collecting ransom from a targeted provider—and then also selling the hacked protected health information (PHI) of the victimized provider's patients to earn a second payday from the same cyberattack.

THE DARK REPORT recommends that all clinical laboratories, genetic testing companies, and anatomic pathology groups make it a priority to review their organization's current cybersecurity status. This advice is for several reasons.

First, although this has not been widely reported by national news media, the nature of cyberattacks against healthcare providers has changed substantially in recent years. Prepandemic, the majority of cyberattacks were penetration of a lab's information systems specifically to steal patient PHI. The hackers could then profit by selling the patients' personal data.

However, in recent years, cybercriminals have shifted their focus from simply stealing PHI to sell on the Dark Web. Instead, they now more frequently launch ransomware attacks. When hospitals and labs are hit by such attacks, they are denied access to all their computer systems and electronic health records.

THE DARK REPORT is aware of two regional pathology laboratories that experienced ransomware attacks in the last 60 days. These attacks are not disclosed to the public for reasons of security. Thus, if we are aware of two such cyberattacks in only 60 days, the actual number of ransomware attacks on labs across the country can reasonably be expected to be much greater.

It is for these reasons that all lab organizations should elevate the priority they give to the security of their software and computer systems.

Now that the FDA has established that laboratory developed tests (LDTs) are medical devices under its jurisdiction, does this mean that any clinical laboratory that employs LDTs would be covered by the CISA rule?

LDTs are Medical Devices

"If the LDTs meet the Class II or III medical device definitions, that would bring the labs under the reporting requirements according to the current proposed rule, even if they are below the SBA threshold for revenue," Sample said. However, Keith Lefkowitz, JD, a regulatory compliance attorney with **Hendershot Cowart P.C.** in Houston, doubts that this was CISA's intent. "I would expect almost every lab to have LDTs," he said. "LDTs are ubiquitous. When considering if additional criteria was needed to cover the laboratory industry, CISA determined that a sufficient number of labs would be covered under the small business size standard."

He said that he would expect to see comments asking CISA to clarify this point or provide an additional carve-out. On the other hand, he added, clinical laboratories should be mindful of the rule

if they're approaching the SBA threshold and anticipate passing it.

"Cybersecurity incidents don't always resolve in one day. They can take months or years to fully resolve, and the lab will have reporting requirements if at least part of a covered cyber incident occurs when the lab becomes a covered entity."

Ransomware Notification

In addition to requiring notification of cyberattacks, the law requires covered entities to report ransomware payments within 24 hours. This was an issue in the Change Healthcare incident. Both *Reuters* and *Wired* reported that Change Healthcare's parent company **UnitedHealth Group** (UHG) likely paid a $22 million ransom to the group responsible for the attack. But that information did not come from UHG. It came from a post in a hacker forum.

With the new reporting requirements, will ransomware payments become public knowledge? That's not likely, Sample said, because reports filed under CIRCIA are exempt from disclosure under the Freedom of Information Act and other similar sunshine or disclosure laws.

"The law is designed to give confidence that when labs report the information, CISA won't turn around and make it public," Sample said.

How Labs Should Prepare

"Labs and other healthcare providers should make sure they have written plans in place, including incident response plans," Sample advised. "Those plans should include procedures to quickly notify the federal government, because there won't be much time for delay."

Lefkowitz concurred. "Under HIPAA, labs have 60 days to report a breach, and here we're talking about 72 hours," he said. "That's an extremely short turnaround time."

Sample added that "labs and other healthcare providers should be doing tabletop exercises, so that when this happens, they can respond quickly enough to meet the reporting deadlines and also contain and mitigate the harm from the attack itself."

Lefkowitz notes that many labs, especially the larger ones, already have HIPAA required policies and procedures addressing security incidents, emergency operations, and disaster recovery that could be used to address and mitigate the effects of cyber incidents.

"Covered labs would need to modify these policies to address CISA reporting requirements," he stated.

The law provides for financial penalties, Sample said, "but the main thing that drew my eye was that the rule will grant CISA subpoena power if they have reason to believe that a covered entity has not reported accurately. They'll send a subpoena that will compel the company to provide information. That can be expensive and time-consuming."

If a company fails to respond, or otherwise refuses to cooperate, CISA can refer the case to the **U.S. Department of Justice**.

Does It Apply to Us?

For many laboratories, the key challenges will be determining whether the law applies to them, and whether the incident itself is reportable.

"If they have no in-house counsel, they should have some kind of quick mechanism in place to get a legal review by an attorney," Lefkowitz advised. "Otherwise, if a layperson reviews it and misinterprets the law, it might not end well."

Sample noted that CISA is accepting voluntary disclosures, so clinical laboratories can reach out now before the law takes effect, even if they don't meet the requirements. TDR

Contact Taylor M. Sample at taylor.sample@bassberry.com; Keith Lefkowitz at klefkowitz@hchlawyers.com.

Lab's Innovation Center Encourages Staff Ideas

Staff at Sonora Quest Laboratories now have way to share ideas to improve service, deliver more value

Tom Leggett

Sky Soom

CEO SUMMARY: At a time when health plans consider lab testing a commodity, the team at Sonora Quest Laboratories deliberately set out to encourage ideas and innovation from its staff by creating the "Innovation Center of Excellence." One innovation involves helping health plans and physicians close care gaps of their patients

Clinical laboratories that seek to foster innovation in their business operations might find a good model in the "Innovation Center of Excellence" (ICOE), a business unit launched in 2022 by **Sonora Quest Laboratories** (SQL) in Phoenix.

Within the laboratory, ICOE has a mission to gather and evaluate ideas for innovation that come from staff. Two participants, Tom Leggett, Senior Director of Business Development, and Sky Soom, Innovation Analyst, discussed the innovation center during a breakout session at last year's *Executive War College* in New Orleans.

Innovate to Lead

SQL is a joint venture established in 1997 between **Quest Diagnostics** and **Banner Health**, a large hospital system headquartered in Phoenix.

"From Sonora Quest's inception, innovation was ingrained into our DNA," Leggett said. "Our CEO, David Dexter, understands that if clinical laboratories want to stay ahead of the curve and be relevant in the marketplace, they have to innovate and lead. If they don't, they simply get commoditized, and then it's just a race to the bottom with pricing."

ICOE, he explained, began as an effort to formalize innovation within the laboratory. But first they had to define what they meant by the term.

"Is innovation just building your own proprietary technology and integrating it into your laboratory?" he asked. "Is it integrating a vendor's proprietary technology? Or is it using existing resources in an innovative way to solve a new need in the market? It could be any of those things, depending how one chooses to define it."

Also, "What range of ideas are we considering?" he continued. "Testing? Patient access? Analytics platforms? What organizational buckets do they fall into? Who needs to be involved in decisions if an idea falls into one of those buckets?"

One imperative early on was "to understand the perspectives of our joint venture parents, Banner Health and Quest Diagnostics," Legget explained. "We took care so that anything we did would complement them and not be compet-

itive in any way. For example, if our lab established urgent care centers all over Arizona, Banner would probably not look upon that very favorably. However, if we wanted to do retinal imaging in our patient service centers, perhaps that would be a good idea."

Aligning Ideas with Goals

The ICOE team also had to ensure that the innovations aligned with the laboratory's overall strategic goals, he said. In 2022, those goals included use of new technologies to improve the patient experience, patient access to care, and the lab's presence in the women's health market. The overarching goal for 2023 was to use innovation to drive growth and efficiency.

Other challenges Leggett discussed at the 2023 *Executive War College* were:

- **Conceiving the Right Structure.** "How do we bring ideas into ICOE, work them through, and come out the opposite side with a commercial program? The healthcare market is rapidly evolving. Ideas have expiration dates. If we don't act on them as quickly as possible, they could be irrelevant by the time they get launched."
- **How to Measure Success.** "We had to look at economic considerations, processes, and roles. It was important to establish analytics and metrics so we could report back to senior leadership on the success or failure of these projects after they launched."
- **Identifying the Decision-makers.** "Who will be in the room making decisions on certain ideas? Generally, we went with department heads, people from Finance, Compliance, IT, Operations, and Sales."
- **Getting Support throughout the Organization.** "Constituents within the company must see the program works. When they do, they submit more ideas."
- **Forging Strategic Relationships.** "People inside the lab have great ideas, but we also wanted to get ideas from academic institutions and government agencies like the **CDC** and the **Department of Defense**. Not only do they have the ideas, but they have the funding to help make those ideas possible."
- **Understanding the Regulatory Environment.** "The last thing we want is to work on a project for a year, and then **CMS** drops a ruling that wipes it off the map. It helps to have lobbyists and people embedded in those institutions, so we understand where the winds are blowing."

For the submission of ideas, the ICOE team employs **ServiceNow**, an online software platform often used in corporations for submissions of job tickets to IT help desks.

As SQL's Innovation Analyst, Sky Soom performs an initial vetting of the submissions. He then passes the most promising ideas to a steering committee which ultimately decides which of them goes forward. Soom explained that the system was built to anticipate failure. "I think our CEO expects about 30% of what comes through ICOE to really make hay," he said. "Failing is not a bad thing. It's a learning experience. We don't sit and dwell on it. We learn from it and move on to the next thing."

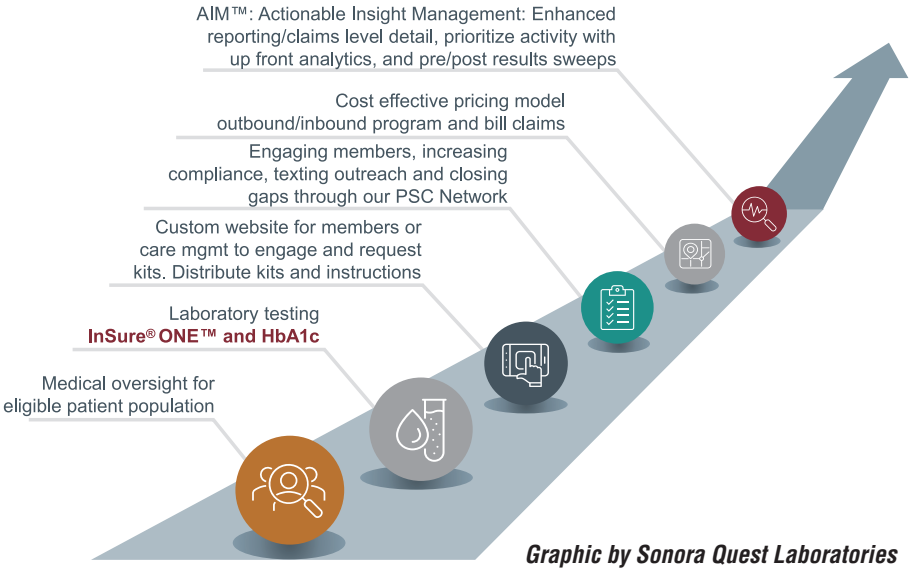
Leggett and Soom both emphasized the need for buy-in from employees. To encourage submission of ideas, SQL distributes companywide emails touting ICOE and flashes messages about the program on big screen TVs in the laboratory, Soom noted. And when people successfully submit ideas, "that drives more submissions," he added.

It is important to structure work roles to accommodate the innovations, he said. "We all have too much work to do. When new ideas are implemented, we might hand them over to operations, and they'll go, 'Really? Where am I going to fit this in?' But innovation is embedded into our company. When you've partitioned time

Sonora Quest Lab's Innovation Center Idea Helps Payers, Physicians Close Care Gaps

ONE IDEA INTRODUCED BECAUSE OF THE INNOVATION CENTER OF EXCELLENCE (ICOE) at Sonora Quest Laboratories was to organize a program designed to help health plans and physicians close care gaps. One element in this plan was to arrange for patients to do a self-collection at home. To collect specimens for colorectal cancer screenings, patients use InSure One Fecal Immunochemical Test (FIT) cards. For HbA1c testing, patients collect their specimens by using filter paper cards. The chart below shows the steps in this process.

Engaging Patients to Collect Specimens At Home to Close Care Gaps



Graphic by Sonora Quest Laboratories

for innovation into that person's day, they're more receptive to it," Soom noted.

When setting up the system to spur innovation, the team decided to make the submission process as friction-free as possible. "We wanted a simple format where people could put in their idea and they are not asked to evaluate the return on investment," Leggett said. "If we set the bar too high, we won't get any good ideas."

If someone's idea has not moved forward, Soom said he will often discuss it with them. "Maybe it's a super-expensive idea or there are legislative issues they didn't see," he stated. "That helps people understand other factors that must be addressed. Before ICOE, they were just told, 'No, we don't have the resources.' And I always ask a follow-up question: 'Did we miss something in the submission? Did you mean something different than what I had interpreted?' Maybe it can go through another iteration," Soom said.

Keeping All Ideas

Even if an idea doesn't pass the initial vetting process within ICOE, it stays in the system, Soom noted. "Maybe there's a fantastic idea that just doesn't fit in the roadmap today," he continued. "We might

not have the bandwidth or dollars or personnel to make it a priority. But don't lose hope. Innovation does not equal immediate change. Things may need to evolve.

"The power of the ServiceNow module is that we don't throw an idea in the trash," Soom observed. "We can go back and revisit ideas that are still in the hopper if new technologies come along, or if the ROI changes."

At the same time, labs implementing a system like this should expect an immediate influx of pet projects, "things that somebody's been trying to fund for the last five years," Soom noted. "They say, 'Oh, here's a new avenue where I can push this idea to fruition.'"

Leggett recalled one idea that came up during the pandemic: Using drones to deliver specimens. "People said, '**Walmart** and **Amazon** are using drones. We need to use a drone. We won't need couriers. How much will we save?'" he recalled. "But the patient still had to get the swab back to the laboratory. It was determined that it would cost in the range of $2.5 million to set this up and we couldn't demonstrate an ROI."

At-Home Collection Program

One initiative that came from ICOE was an effort to promote at-home collection of test samples. SQL had already been distributing **InSure One** Fecal Immunochemical Test (FIT) cards to patients for colorectal cancer screening, Leggett explained. This new project was aimed specifically at helping payers close care gaps by promoting sample collection for the colorectal cancer test as well as a hemoglobin A1c test for diabetes. *(See sidebar on page 17.)*

SQL was one of the first labs in the nation to adopt Lean Six Sigma management principles, including the use of personas to characterize customers. "For patients, we have five personas," Soom explained. "People who are extra cautious, people who are really engaged, the uninsured, those type of things."

Those personas came into play as SQL implemented the program of at-home specimen collection. A first task was to build a website to allow payers to upload lists of patients, known as attribution lists, to target for outreach efforts.

Patient Relationships

"We looked at our relationships with the patients," Leggett said. "If patients have a relationship with us, that informed how we engaged them." For example, with the program to help doctors close care gaps, "if the patient happened to walk into one of our service centers because the doctor gave [him/her] another lab order, then we had the hemoglobin A1c kit sitting there ready for [him/her] to complete."

But for patients with identified care gaps who do not have that kind of lab relationship, "we would have to work faster and harder to get those people to respond to us."

To make the program cost-effective, SQL also had to develop a pricing model that accounted for shipping, handling, and other costs in addition to the cost of the test. They tracked the program's progress using Actionable Insights Management (AIM), a software platform developed by **SQL** for population health management.

"We provided the payers with an end-to-end reporting platform that looked at who requested a kit, who we shipped it to, who returned it, and who did it correctly so we could report results," Leggett explained.

He acknowledged that it was a learning experience. "We did a small pilot and it worked great, but when we started to scale, we ran into some problems," he said. For example, "we didn't set our expectations with the logistics team appropriately to make them aware of how quickly they needed to respond when a patient requested a kit." TDR

Contact Tom Leggett at tom.leggett@sonoraquest.com; Sky Soom at sky.soom@gmail.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last month, members of a class action lawsuit against **Theranos** and other defendants received settlement checks. Members of the class included TDR's Editor-in-Chief, Robert Michel, and his wife, Deborah. On behalf of THE DARK REPORT, the Michels had investigated the actual laboratory testing practices of Theranos by undergoing clinical laboratory testing on themselves. Robert's check was for $64.00 and Deborah's was for $39.09. The class action lawsuit was filed in July, 2022, in the U.S. District Court for the District of Arizona by **JND Legal Administration**.

MORE ON: *Theranos Class Action Lawsuit*

Defendants were Theranos, Inc., **Walgreens Boots Alliance, Inc.** and **Walgreen Arizona Drug Company** (together called "**Walgreens**"), Elizabeth Holmes, and Ramesh Balwani (collectively, "Defendants"). It is Case No. 2:16-cv-2138-DGC. Final settlement in this case was February 6, 2024. Walgreens agreed to pay $44 million and the entity handling the remaining Theranos assets agreed to contribute assets valued at $1.33 million. In the spring of 2015, THE DARK REPORT was first in the nation to report that Theranos had ordered its patient service centers to cease collecting capillary specimens—the much bragged about technology innovation—and was only collecting venous blood samples. *(See TDR, "Theranos: Many Questions, But Very Few Answers," April 20, 2015.)*

Sale of Associate Pathologists, LTD to Versant Diagnostics

Versant Diagnostics, based in Grapevine, Texas, acquired **Associate Pathologists of Joliet, Ltd.**, based in Joliet, Ill. The deal was announced on May 14. The transaction brings five more pathologists into the Versant organization, which was founded in 2021.

TRANSITIONS

- **QuidelOrtho** appointed Brian Blaser as President and CEO. Past executive positions have been with **Abbott Laboratories**, **Ortho-Clinical Diagnostics**, **Eastman Kodak**, and **General Motors**.
- **Vitalacy** of Los Angeles appointed Brian Zinkil as Vice President of Partnerships. Zinkil formerly worked at **Phunware**, **Midmark Corporation**, **Ronco**, **Viewics**, **Aperio**, **Dako**, and **Abbott Diagnostics**.
- **LIMSABC** of Fort Lauderdale, Fla., selected Skye Shearer as its new Chief Executive Officer. Prior positions were with **TGB Labs** and **MultiLab Management**.
- **Bio-Rad Laboratories** announced that Andrew Last, Executive Vice President and Chief Operating Officer, will retire by early September of 2024. He previously served at **Berkeley Lights**, **Intrexon Corporation**, **Affymetrix**, **BD Biosciences**, **Applied Biosystems**, **Incyte Genomics**, and **Monsanto**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 10, 2024.

Publisher: Robert L. Michel *rmichel@darkreport.com*
Executive Publisher: Bob Croce *bcroce@darkreport.com*
Managing Editor: Michael McBride *me@michaelmcbride.com*
IVD Reporter: Donna Pocius *donna11019@att.net*
Legal/Compliance Reporter: Stephen Beale *sbeale58@gmail.com*
Regulatory Reporter: Jillia Schlingman *jpschlingman@yahoo.com*