Volume XXX, Number 10 Monday, July 10, 2023

UnitedHealthcare to Require Z-codes for Genetic Test Claims

New Policy Becomes Effective on Aug. 1

(see pages 3-8)

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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

Stressful Weeks Ahead for Labs Thanks to Z-codes

WE ARE NOT ALONE IN RECOGNIZING that **UnitedHealthcare's** (UHC) upcoming mandate for Z-code use in genetic test claims has the potential to be disruptive to many clinical laboratories.

Evidence of this widespread concern was provided on June 29. That's the day that THE DARK REPORT hosted a webinar titled, "Essential Guide to Obtaining Z-codes for Molecular and Genetic Tests." Nearly 1,300 clinical lab professionals and anatomic pathologists registered for the program!

This large response demonstrates that genetic testing labs are clearly concerned about UHC's Aug. 1 deadline for molecular test claims to include Z-codes. The initial "wave one" of UHC's implementation involves genetic tests associated with nearly 250 Current Procedural Terminology (CPT) codes. Future waves will follow, expanding the number of CPT codes that require a Z-code with a genetic test claim.

On pages 3-8 in this issue, we provide you and your lab team with practical insights about the Z-code application and assessment processes. **Palmetto GBA**, the Medicare Administrative Contractor that administers the Z-codes through its MolDX program and the DEX Diagnostic Exchange registry, reviews technical assessments for elements such as analytical validity, clinical validity, and clinical utility. The MolDX medical director was a speaker during the webinar and some of his observations are provided in this issue.

This same intelligence briefing includes information about the lessons learned by **ARUP Laboratories** when applying for Z-codes. The Medicare MolDX program launched in 2011 and incorporated the Z-code registry as a requirement. Thus, ARUP has more than 12 years of experience in applying for Z-codes and providing the necessary data to support the assessments of analytical validity, clinical validity, and clinical utility.

One of the unknowns—as of this moment—is whether the DEX registry will be flooded with applications for Z-codes in the weeks remaining before UHC's implementation date. As the Aug. 1 deadline approaches, genetic testing laboratories will want to monitor UHC for updates about its Z-code policies, watch for any similar movements from other health plans, and read expert analysis of these developments, including our upcoming intelligence briefings in THE DARK REPORT. TDR

UnitedHealthcare's Z-code Policy Starts on Aug. 1

Government and private payers overwhelmed by surging numbers of novel diagnostic assays

CEO SUMMARY: UnitedHealthcare's (UHC) response to the ever-growing number of unique genetic tests and the continuing growth in the volume of those claims is a new policy. Effective Aug. 1, UHC will require a Z-code with genetic test claims. This requirement means labs serving UHC beneficiaries need to obtain a Z-code for their genetic tests. It is Palmetto GBA's MolDX DEX Diagnostic Exchange registry that accepts these applications, conducts the assessment, and issues the Z-codes.

Beginning on Aug. 1, genetic testing laboratories submitting certain molecular test claims to **UnitedHealthcare** (UHC) will need to include a Z-code. This new policy is sending ripples across the clinical laboratory profession.

On one hand, there are clinical laboratories that submit genetic tests to UHC, but have never obtained Z-codes for these assays. These genetic testing companies need to act swiftly to get their Z-code applications submitted to **Palmetto GBA's** MolDX DEX Diagnostic Exchange registry if they are to avoid delays in UHC's processing of their genetic test claims after Aug. 1.

On the other hand, there is recognition among clinical lab managers and pathologists that more private health plans are likely to follow UHC's lead by similarly requiring Z-codes on genetic test claims submitted to them for processing and reimbursement. In recent years, these lab leaders, along with The Dark Report, watched how the nation's two largest health insurers—UnitedHealthcare and **Elevance Health** (formerly **Anthem**)—initiated prior-authorization programs for genetic tests just months apart.

Elevance was first to take this step. Its prior-authorization program for genetic tests launched on Aug. 1, 2017. **AIM Specialty Health** (wholly-owned by Elevance) managed the program. *(See TDR, "Genetic Test Pre-Authorization Goes Mainstream," June 26, 2017.)*

Within 45 days of Elevance's announcement, UnitedHealthcare issued a statement that it would require prior authorization of genetic tests, starting on Nov. 1, 2017. UHC's program

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.

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was managed by **BeaconLBS**, a wholly-owned subsidiary of **Labcorp**. *(See TDR, "UnitedHealth to Start Gene Test Pre-Approval," Aug. 28, 2017.)*

In 2017, UnitedHealthcare and Elevance each covered about 40 million beneficiaries. That meant that approximately 80 million of the 160 million Americans with commercial insurance were now in a health plan requiring prior authorization for genetic tests.

Prior-Authorization Issues

Labs large and small scrambled to understand the two payers' prior-authorization requirements for genetic test claims. Neither insurer's prior-authorization system functioned adequately after their different implementation dates. During this "break-in" period, many labs experienced disruptions in the process of obtaining prior authorization, followed by delays in timely payment for those claims.

Because of their experiences with the start-up of the prior-authorization programs in 2017, executives at genetic test companies are wary about two aspects of UHC's newest requirement.

One, labs must obtain a Z-code for their genetic assays to meet the UHC requirement that commences on Aug. 1. In coming months, will there be a surge in the number of Z-code applications that causes significant delays as Palmetto GBA's MolDX DEX works to review these applications, assess the documentation for analytical validation and clinical validity, and issue Z-codes?

Claims Processing Delays?

Two, will the systems UHC uses to process genetic test claims be ready on Aug. 1 to match a genetic test's Z-code against UHC's coverage guidelines in a timely and accurate manner?

The Dark Report believes it is reasonable to expect that UHC may decide to implement a "grace period" and continue reimbursing genetic test claims for some months. By doing this, the payer would be giving labs more time to better understand how to submit and document Z-codes with their genetic test claims. It would also give UHC additional time to address any unexpected issues with its internal systems that invitably surface when a major new policy takes effect.

Clinical lab administrators and pathologists can expect that other major health insurers will be watching UnitedHealthcare as it implements its Z-code requirement. All payers are being overwhelmed by an ever-growing volume of genetic test claims, in two different ways. First is the rapid increase in the total number of genetic test claims submitted for reimbursement. Second is the explosion in the different types of genetic tests, with as many as 175,000 unique genetic assays being offered in the lab marketplace today.

Genetic Test Fraud & Abuse

Fraud and abuse is an equally significant concern for the nation's payers. **Medicare** claims data, released annually, provides ample evidence that certain genetic testing companies are submitting large volumes of claims using CPT codes for genetic conditions that are extremely rare. The implication is that these labs are encouraging physicians to order genetic tests for patients whose family and personal history do not meet the criteria to justify those genetic tests.

These are a few of the reasons why lab executives and pathologists should expect expanded use of Z-codes on genetic test claims by payers. A health insurer has a responsibility to provide necessary clinical services to its beneficiaries. Currently, the CPT coding system is inadequate to properly describe the purpose of a genetic test and how it will clinically benefit the patient. The Z-code system was structured to provide information about the biomarkers being measured and how the test results will improve patient care. TDR

Assessment Challenges for Z-Code Applications

Experts offer tips to better answer clinical validity and utility questions surrounding a genetic test

Valerie Collier, MS, CGC

CEO SUMMARY: *Effective on Aug. 1, UnitedHealthcare will require Z-code submissions for many genetic tests. During a recent webinar, experts tackled a topic that may prove troublesome for labs seeking Z-codes: technical assessments. Key advice is to provide specific data about clinical validity and clinical utility of a novel genetic test.*

Gabriel Bien-Willner, MD, PhD

UNITEDHEALTHCARE'S (UHC) NEW REQUIREMENT that as of August 1 Z-codes must be provided in genetic test claims for private health plans is drawing lots of attention.

As such, there was keen interest in a webinar hosted by THE DARK REPORT on June 29 titled, "Essential Guide to Obtaining Z-codes for Molecular and Genetic Tests." A prominent topic during the program—and one that generated many follow-up questions from participants—centered on technical assessments. This story outlines what our expert speakers discussed.

Applications for new Z-codes may require technical assessments. The applicant lab needs to provide data about the analytical validation, clinical validity, and clinical utility of the molecular assay before a new Z-code is issued. Genetic testing laboratories may find themselves stymied by these assessments.

"It's a shift to put the responsibility on the lab to prove that its genetic test has strong clinical validity and utility for reimbursement," said Valerie Collier, MS, CGC, Genetic Counselor at **ARUP Laboratories** in Salt Lake City, who has experience submitting Z-code technical assessments. "ARUP views Z-codes as helping the reimbursement process for our clients and for patients. It's a lot of work up front, but we find that there is more consistent reimbursement for tests when we participate in the DEX registry."

Expansion Affects Millions

Within a matter of weeks, UHC will begin "wave one" of Z-code registration, which will include nearly 250 Current Procedural Terminology (CPT) codes typically used for genetic test reimbursement. Z-codes are administered through a molecular test identification system known as the DEX Diagnostic Exchange (DEX). **Palmetto GBA**, the Medicare Administrative Contractor based in Columbia, South Carolina, runs DEX under its Molecular Diagnostic Services (MolDX) Program.

UHC's new policy requires Z-codes with genetic test claims for its commercial and individual health plans, which cover 24.7 million people. THE DARK REPORT expects that other private payers may follow suit.

"The program that's being rolled out by Palmetto GBA to serve these commercial plans does not include writing their Z-code policies for them, but Palmetto GBA is using processes for technical assessment based on our understanding of clinical value," said Gabriel Bien-Willner, MD, PhD, Medical Director of MolDX and Chief Medical Officer at Palmetto GBA.

Assessing Genetic Tests

"Palmetto GBA assesses genetic tests for analytical validity, clinical validity, and clinical utility. These terms are often conflated or misunderstood," Bien-Willner added.

A technical assessment for a Z-code includes evaluation of a genetic test's:

- **Analytical validity**—How well does the test detect the genetic variant or compound it seeks to detect? This is usually demonstrated through analytical validations and clinical validations with samples.
- **Clinical validity**—How well does the analyte or variant relate to the presence or risk of a disease?
- **Clinical utility**—How clinically useful is the proposed test? Can it change clinical approaches to improve patient outcomes?

Valerie Collier, MS, CGC

➤"Labs have to think about what is considered a clinical sample and whether the patient samples they use really represent the test's intended population."

"The analytical validity is specific to the lab that's measuring an analyte; the clinical validity is specific to the analyte being measured; and the clinical utility is also specific to the analyte being measured, which means the impact of this analyte in the management of the patient," Bien-Willner noted.

"A test really has to demonstrate all three of these components to have medical value," he said.

When submitting a Z-code for a novel genetic test, clinical laboratories will make an effort to complete technical assessments for some tests. "When I'm preparing the submissions, the bulk of the work is putting together the technical assessment," Collier said. "Addressing clinical validity and clinical utility are where labs can be challenged as they work on technical assessments.

"For clinical validation, ARUP provides data to demonstrate the accuracy of the test when it's performed on patient samples from the intended patient population. Usually this is no problem," she observed. "But occasionally there's a test where the sample-level clinical data isn't readily available. This is why labs should brainstorm about how to approach some of these questions in the assessment.

"Likewise, clinical utility can be tricky," she added. "There are times when labs are reliant on clinical literature and guidelines. But there times—with new or innovative technology—when clinical guidelines have yet to be established and published."

Clinical Studies Prove Helpful

Some technical assessments require a literature review that establishes clinical validity and utility of the test. "When I'm working on the clinical utility section, I include all relevant guidelines," Collier explained. "If a panel varies from a guideline, even slightly, I explain why that is and in what circumstances this is intended.

"I'm looking for published studies that are representative of the intended population for the test," she continued. "When I submit MolDX tests for Medicare beneficiaries, the intended population includes individuals that are 65 years and older and located in United States. So, I use U.S.-based studies whenever possible, and I also specify whether the methods used in the article are the exact same or vary from our test."

It may be necessary for labs submitting Z-code requests to expand their data gathering initiatives. "In my experience, ARUP usually has patient samples available at the time of validation, and it's easy to provide this information," Collier noted.

"But occasionally we don't have that information," she added. "ARUP has run into this issue for some of our molecular infectious disease tests when we've used spike samples in a validation, for example. We've also had this issue when we've used previously-sequenced DNA from a national repository, which might not specifically represent the intended patient for this test.

What Are Clinical Samples?

"When these questions come up, labs must think about what is considered a clinical sample and whether the patient samples they use really represent the test's intended population," Collier noted. "This leads to a conversation with medical directors and research-and-development scientists about how many clinical samples are sufficient to show accuracy in a technical assessment."

Collier referenced a hereditary cancer panel for which ARUP had previously submitted a technical assessment. "When I put together the submission, ARUP didn't have the clinical sample data readily available in the validation," Collier recalled.

"So, we had to pull together data from Sanger sequencing and other reports that we've done over the years for variant confirmation," she continued. "As we put this data together, the team at the lab asked how many clinical samples were needed. There was not a specific answer to that. Our panel is made up of 73 genes. Do we need data for all 73 of our genes? Do we need data for all variant types for every gene on that panel? It started to get a little overwhelming as we considered the amount of data available to us.

Time to Complete a Technical Assessment?

TECHNICAL ASSESSMENTS FOR Z-CODE REQUESTS can be time consuming, said Valerie Collier, MS, CGC, Genetic Counselor at ARUP Laboratories.

"It depends on the genetic test. Our team can usually complete a technical assessment in a week if we don't run into any sample data issues," Collier said. "But it took ARUP time to figure out the best approach to managing this workload.

"We originally assigned different staff to assemble technical assessments for their areas," she recalled. "But that was problematic because people would try to figure out the process separately with limited communication. ARUP streamlined this process by designating one MolDX coordinator who puts together the documentation for the technical assessment."

"Our approach to this was to look at the clinical sample data from prior testing and validations that we did over the years," she continued. "The goal was to determine if this data was representative of what would be expected from our patient population, while understanding that pathogenic variants in some genes are rarer and others are more common."

"We ended up putting together a cohort of about 150 samples covering about half the genes on the panel with a variety of variant types," Collier added. "We felt like this was a solid data set for our panel. ARUP submitted this data, and we received approval for this panel as well as the related subpanels."

Genetic testing laboratories concerned about clinical sample numbers should not hesitate to contact MolDX ahead of submitting a technical assessment.

"For some novel tests, I've found it helpful to send specific questions to the MolDX team before I submit, but other times we might need to submit the

technical assessment first because I think a reviewer needs to understand all the aspects of ARUP's tests to decide whether they agree that the analytical and clinical data is sufficient," Collier said.

"If we don't get approved the first time around, we always get helpful feedback about how we can improve for the next submission," she noted.

Orthogonal Testing Methods

Genetic testing laboratories not already familiar with orthogonal testing methods will want to become acquainted with that approach for technical assessments.

"Each clinical sample that we are putting together needs to be tested by a second reference method to determine the true result," Collier said. "It is important for clinical laboratories to be as clear and detailed as they possibly can when describing the orthogonal method and how it was validated."

Collier explained her lab's methods for establishing a second reference for the panel. "For ARUP's hereditary cancer panel—which was performed on a next-generation sequencing platform—we used clinically-validated Sanger sequencing and MLPA [multiplex ligation-dependent probe amplification] for our orthogonal methods," she noted.

"The orthogonal method should be clinically validated. It should be a different method if it's performed at the same lab," she added. "Or if the initial and reference tests are both PCR methods, they should have different targets.

Reference Method Selection

"The reference method can also be the same or different method performed at another CLIA-certified lab," Collier continued. "Occasionally, when ARUP doesn't have an in-house method that fits these criteria, we've sent out to a different laboratory for confirmatory testing so as to provide this data with our technical assessment."

Once a test is registered in DEX, it is assigned a Z-code within 30 days. Laboratories are notified if their test requires a technical assessment submission. Labs that have submitted technical assessments should not expect reviews back in days or weeks.

"The complexity of the test has a great deal of influence on how much information labs must submit to Palmetto GBA, as well as how long the laboratory's technical assessment will take to review," Bien-Willner said.

"The turnaround time to review a technical assessment is two months," he noted. "For uncomplicated tests that require no additional information, turnaround times are less than two months. They can be as soon as three to four weeks. The more substantial reviews obviously take longer."

Technical Assessment TAT

Genetic testing laboratory managers should take note of potentially months-long turnaround times for technical assessments as described by Bien-Willner and Collier. UHC's Aug. 1 deadline for Z-codes will likely result in some situations where technical assessments will not be ready for laboratories in time to meet the transition date. Concerned labs should consider having a backup plan in place should they find themselves in this unenviable scenario.

Further, given the information currently available, The Dark Report believes it is a reasonable assumption that the volume of Z-code requests will increase in the near term given UnitedHealthcare's mandate. Therefore, it's likely there will be a corresponding increase in technical assessment submissions as well.

Staying ahead of competitors in this regard should be a prime goal of genetic testing laboratories hoping to meet upcoming Z-code deadlines. TDR

Contact Valerie Collier, MS, CGC, at valerie.collier@aruplab.com; and Gabriel Bien-Willner, MD, PhD, at gabriel.bien-willner@palmettogba.com.

Dartmouth Lab Recruits and Trains More CLSs

New approach pays for CLS training in exchange for multi-year work commitment from students

Dorothy Martin MT(ASCP)

CEO SUMMARY: Keeping clinical laboratories fully staffed may be the single biggest issue confronting labs today. In New Hampshire, the lab team at Dartmouth Health crafted an innovative program that pays students as they pursue their clinical laboratory scientist (CLS) certification. In return, these students agree to a multi-year commitment to work at the Dartmouth Lab.

HERE'S A SCENARIO FAMILIAR TO MOST CLINICAL LABORATORY MANAGERS: An aging workforce, elevated labor costs, and challenges when recruiting adequate numbers of new staff.

Facing all three of these factors, Lebanon, N.H.-based **Dartmouth Health's** lab leaders decided to reset their recruitment strategy to ensure that future clinical laboratory scientist (CLS) trainees were ready to step up. The bonus from this staffing strategy is that the health system realized a return on investment (ROI) for training the CLSs.

"The lab was losing people and spending a lot of money on traveling techs," said Dorothy Martin, MT(ASCP), LSSBB, Regional and Affiliate Laboratory Manager at the Department of Pathology and Laboratory Medicine at Dartmouth. "That triggered us to make changes in how we recruit new lab staff."

Martin spoke at the *2023 Executive War College on Diagnostic, Clinical Laboratory, and Pathology Management* in April. Her session was titled, "Lab Staff Recruiting, Hiring, and Retention in Today's Competitive Market: How We Differentiate Our Lab, Attract Qualified Candidates, and Build Loyalty and Commitment."

Dartmouth Health is a modest-sized integrated delivery network that includes a 486-bed academic medical center, three critical access hospitals, a community hospital, and a number of urgent care centers. The lab's workforce concerns had been bubbling for more than five years.

Lab Workforce Assessment

Dartmouth Health is the only academic medical center located in a rural area in the United States. "Within our service region it is also the only level one adult and the only level two pediatric trauma center in the state of New Hampshire," Martin noted. "We are a tertiary care facility and we are the only children's hospital in this region. Embedded within us is the **Norris Cotton Cancer Center,** where people from all over New England are referred for cancer care.

"Given the need to support all of these clinical service lines, staff turnover and the number of unfilled positions in our lab was the perfect storm," she continued.

"Dartmouth did a workforce assessment in 2018-19. We had a significant number of open positions," Martin said. "The average ages of the workforces in New Hampshire, Vermont, and Maine are among the oldest of all the states in the nation. About 17% of Dartmouth's clinical lab workforce was 60 years or older."

Recruiting Efforts

Dartmouth Health actively recruited CLSs and others into the clinical lab, but the effort fell short. "We had a partnership with **University of New Hampshire** [UNH] but it was exclusive, where UNH sent students to Dartmouth and they were the only students the lab took into its MLT [medical laboratory technician] and CLS programs," Martin said.

"The school would be excited to have 40 students in a freshmen class in a given year," she added. "But by the time those freshman were ready for internships the UNH program would send us only four to six interns. And some of those were students who only wanted to work as a tech for two or three years and then get an advanced degree. This number of interns did not fill Dartmouth's need because our lab had all these people over 60 who were retiring."

Meanwhile, traveling CLS costs were spiraling. "The lab spent $1.64 million on traveler spend in 2018 and 2019," Martin recalled. "We had about 20 travelers on the staff out of 120 techs at the academic medical center. In addition to that, the lab averaged 10 FTEs per pay period in overtime. This was unsustainable."

Signing Bonuses Didn't Sway

The lab's attempt to recruit more new people into the workforce could not keep up with the turnover rate from older workers retiring and other people switching employers. "We had a 12.5% clinical laboratory scientist turnover rate," she said. "In response, the lab did a market analysis and increased pay.

"Our lab created sign-on bonuses to get university students to stay—like $10,000 technical sign-on bonuses for night shift positions," she noted. "But the average 22-year-old graduate doesn't want to live in a rural area. They want a little more excitement than that. So, it was hard for Dartmouth to even retain the students that it was training."

As The Dark Report has noted previously, progressive approaches like Lean Six Sigma and automating routine processes can sometimes fill a staff shortage.

But even taking those steps did not help Dartmouth's lab. "Dartmouth streamlined lab processes and put in big automation lines to improve efficiency and allow our lab to do more with less," Martin recalled. "We standardized processes across labs. The lab used Lean Six Sigma to streamline workflows and cross-trained a bunch of staff so that the lab had better coverage of the core lab, for example. That helped, but it was not enough."

New Training Gains Support

Dartmouth Health's lab needed to take a more aggressive approach to recruiting and training future CLSs. "The lab considered creating its own training plan, taking biology degree students and having them do an internship," Martin said. "But that approach is really challenging, especially if you don't have staff to do the training. How does a lab develop a program when it doesn't have the in-house didactic knowledge that's needed?"

It turned out that lab managers had another staff development approach they could adapt to their needs. Lab leaders decided to take a page out of Dartmouth Health's approach to the nursing shortage in the health system. Dartmouth had already established the **Workforce Readiness Institute** to educate students about opportunities as medical assistants and licensed nursing assistants and recruit them through a formal, paid training program.

Dartmouth Health's Lab Pays Students to Train as CLSs and Lab Shows ROI for these Expenses

TO HELP STAY FULLY STAFFED, THE DARTMOUTH HEALTH LABORATORY TEAM created a program that pays students while they train to become clinical laboratory scientists (CLSs) in exchange for their multi-year commitment to work at the lab. Not only is this program helping keep the lab staffed, but it delivers a return-on-investment (ROI) because it reduces spending on traveling CLSs, as demonstrated by the table below:

Capital Investment and ROI–Clinical Laboratory Scientist Training Program

	Year 1	Year 2	Year 3	Year 4
Program costs per trainee	• $31,200 ($15/hour) • $14,352 (tax & benefits) • $4,000 (tuition)*	• $53,000 ($25.48/hour) • $24,380 (tax & benefits) • $26,500 (on-boarding cost)	• $54,080 ($26/hour) • $24,877 (tax & benefits)	• $56,700 ($27.26/hour) • $26,082 (tax & benefits)
Annual invested	**-$49,552**	**-$103,880**	**-$78,957**	**-$82,782**
Projected reduction in traveler costs per trainee	$0	• $134,130 • $26,500 (on boarding two travelers per year)	• $134,130 • $26,500 (on boarding two travelers per year)	• $134,130 • $26,500 (on boarding two travelers per year)
Annual ROI	**-$49,552**	**+$56,750**	**+$81,673**	**+$77,848**
Net ROI	**-$49,552**	**+$7,198**	**+$88,871**	**+$166,719**

Figure 1: This chart shows how the cost of training and employing an CLS program participant eventually allows Dartmouth Health to save on traveling CLS expenses.
A federal training grant and tuition reimbursement help to fund the program.

Information provided by Dartmouth Health Laboratory

"Workforce Readiness is a division of Dartmouth's human resources department," Martin said. "They are experts at writing that didactic portion needed to develop training programs. We have 20 different programs right now for nursing assistants, medical assistants, medical lab technicians, and EEG technicians, among others.

High School Students

"Through the program, Dartmouth brings in high school students starting at their freshman year to introduce them to all of these career options within healthcare," she continued. "All of our programs are at little to no cost to the participant. People apply for open positions and are interviewed. If they're selected into the program, then on day one they become employees of Dartmouth, get paid a trainee rate to learn, and upon completion of the program they remain full-time employees."

Martin said that participants are required to work at Dartmouth after training for one to three years as part of the program. The Workforce Readiness Institute has a 95% success rate across the health system in retaining trainees for their required work commitment.

To boost MLT and CLS trainees, the Workforce Readiness Institute partnered with **Weber State University** in Ogden, Utah, which runs online MLT and CLS

programs. *(See TDR, "MT/MLT Distance Learning Goal of Collaboration: ARUP and Weber State team up to make it easier for interested lab staff to advance skills," Aug. 18, 2008.)*

"Weber can train people that come to Dartmouth either with an associate's degree or without any degree," Martin said. "There are different tracks, and we assess what applicants might need to take for prerequisites before they get into the program. The Workforce Readiness Institute team stays on top of exactly what core classes trainees need to take."

It costs Dartmouth approximately $50,000 to instruct an MLT/CLS trainee. About $10,000 of that amount stems from Weber tuition, and the rest is the pay rate and benefits that Dartmouth provides the trainee.

Cost of MLT and CLS Classes

"Weber's classes are low cost for Dartmouth," Martin noted. "Weber's costs are transparent and easy to budget. There were no hidden fees that Dartmouth needed to figure out, so that made it easy to work with Weber."

Another advantage with Weber that appealed to Dartmouth's labs is that trainees did not need to come to the university's physical campus at all.

"A number of other training programs require one or more visits to the college site," Martin explained. "Dartmouth would have to absorb the cost of that travel for trainees, and that would increase the overall cost of the program. It also might limit who could participate.

"If an applicant is a working mom, and two times in the next year this mom needs to fly out to Ogden, Utah, that's probably going be difficult for that person to manage," she continued. "So, Dartmouth didn't want to have a program that required even one site visit. That was important to us."

One-on-one training still occurs at Dartmouth Health's labs for trainees while they complete Weber's courses. "Trainees do all their coursework online and their clinical skills work in our Dartmouth Health lab," Martin said.

"Dartmouth accepts three to four students every August, and they go through the training as a cohort," she explained. "We did that on purpose because it's easier for that one-on-one, in-person training. It's less demand on lab trainers because Dartmouth still has its partnership with University of New Hampshire, that those students rotate through as well."

Five-Year Success

The Weber program has been a success in its five years with Dartmouth. "We've had 12 total students in the program," Martin said. "We graduated 10, and eight of them remain at Dartmouth Health today. We had one trainee leave because she would not get COVID vaccinations and could not get an exemption. And we had another that had to leave because he got called up to the **National Guard**. So, it's not like they failed out of the program, and we feel good about that."

MLT and CLS trainees have a two-to-three-year work commitment at Dartmouth after completing the training program. "At the end of that time, if they have a BS degree, they can sit for CLS certification," she noted. "We also have a partnership with Weber that does a transition program of MLT to CLS. We're also working with a local college, **Colby-Sawyer College** out of New London, New Hampshire, to create a CLS program. So, our newly-minted MLTs can either do a didactic CLS program online or a didactic in-person program locally to get to that next level."

Return on Investment

Numbers presented by Martin at *Executive War College* indicated that the MLT/CLS training program only takes two years to generate a minor net ROI, and within four years net ROI tops $166,000 per trainee.

"In year one we lose money. We basically pay for trainees to go to school," Martin observed. "But by the time year four rolls around we're making money [compared to the cost of a CLS traveler] because the trainees are active, full-time employees."

Calculating Training ROI

The chart on page 11 provides more details on the costs Dartmouth paid and the ROI it achieved per trainee. Martin said clinical laboratories that want to emulate Dartmouth Health's approach should take the following actions:

- **Determine the lab's biggest need.** "What can a lab do in the next 90 days to make things better if it's in the same situation as Dartmouth's lab?" Martin said.
- **Investigate MLT and CLS programs that are nearby and online.** "Are there local colleges that are looking for internship sites?" she asked. "I know many hospitals have not been taking interns, so there may be a demand in your community."
- **Work with executives to gather support and create ROI.** "Think about the lab's current spend on travelers and staff overtime when educating administrators about staffing issues," she suggested. "Also, what does the lab's current staff turnover rate look like?"

Visiting High Schools

Among the steps that the lab team at Dartmouth Health took to increase the number of students interested in a career in laboratory medicine was to go into local high schools and educate these students about the role of clinical laboratories in supporting patient care. This has helped the lab team recruit and train phlebotomists, along with students interested in training as medical laboratory technicians, then continuing their education to earn their clinical laboratory scientist certification.

Four-year CLS Training Program Timeline

HERE IS the timeline of Dartmouth Health lab's clinical laboratory scientist (CLS) training program:

- **Year 1**—Participants are full time in MLT training, culminating in MLT certification through ASCP.
- **Year 2 and 3**—New MLTs work full time at Dartmouth Health lab.
- **Year 4**—MLTs are eligible to sit in for clinical laboratory scientist (CLS) certification if they have the appropriate bachelor's degree. Otherwise, MLTs can begin transition training to become a CLS.

Years 2-4 are part of a work commitment at Dartmouth after training is completed.

Dartmouth Health's lab also has a career ladder. "Our career ladder is clinical lab scientists one through five," Martin explained. "One is an MLT, straight from school. Two is a CLS straight from school at a total of six years [two years education, four years experience; four years education, two years experience].

"Most of the people working in our labs are CLS three," she added. "The people who are the lab's lead educators are CLS five. They are considered a technical specialist. Their support is the CLS four, the team lead."

"This has been our model for a long time," Martin observed. "It recognizes the different levels of contributions and rewards them appropriately."

With many labs across the country suffering from staffing shortages—particularly CLSs—Dartmouth Health's innovative approaches show that there are multiple, effective approaches that can improve both the recruitment and retention of these skilled laboratory professionals. TDR

Contact Dorothy A. Martin MT(ASCP), LSSBB at dorothy.a.martin@hitchcock.org.

HCCI Reports Higher Prices for Hospital Outreach Tests

HCCI says health insurers,self-insured employers often pay a big mark-up for hospital outreach tests

Jon Harol

CEO SUMMARY: It's another shot across the bows to hospital and health system lab outreach programs that use inpatient test prices when billing health insurers for outpatient/outreach lab tests. In its report, the Health Care Cost Institute documents how these hospital lab outreach programs price their tests from three to five times higher than independent labs and POLs.

Hospital outpatient laboratory tests cost self-insured employers three to five times more than the same tests performed by independent clinical laboratories and physician office labs (POLs), a study by the **Health Care Cost Institute** (HCCI) found. HCCI is nonprofit research group in Washington, D.C., that analyzes employer-sponsored insurance data.

The title of HCCI's report tells the story: "Price Markups for Clinical Labs: Employer-based Insurance Pays Hospital Outpatient Departments 3X More than Physician Offices and Independent Labs for Identical Tests." The report was issued last summer.

Highest-Priced Hospital Labs

In recent years, major health insurers began taking aggressive steps against the highest-priced hospital labs. In some cases, payers expelled from their networks those hospital labs that used inpatient prices on their outpatient/outreach test claims. In other cases, payers required these hospital labs to agree to accept lab test prices comparable to private clinical lab companies.

This trend was spotted early by The Dark Report. The HCCI report can be considered one more nail in the coffin of those hospital laboratory outreach programs that submit claims using their hospitals' inpatient lab test pricing.

For example, in 2019, we reported on strategic steps **UnitedHealthcare** (UHC) was taking to drop higher-priced labs from its network while creating a preferred laboratory network that favored labs that agreed to lower prices and could offer test services that added value. *(See TDR, "Lower Prices, More Data in UHC's New Lab Network?," Feb. 4, 2019.)*

HCCI's report is consistent with this trend of payers identifying the highest-priced hospital laboratories. HCCI's report was directed at self-insured employers and smaller health insurance companies. It was designed to help them understand the magnitude of higher lab test prices charged by certain hospital laboratory outreach programs

Four bullet points in the report succintly describe what the authors want to communicate to self-insured employers, payers, federal health policymakers, and state health regulators to inform

their thinking about these situations. The report authors wrote:

- "Employer-based insurance is typically paying three times (3X) more for clinical lab tests when billed by hospital outpatient departments compared to identical tests billed by physician offices and independent laboratories.
- "Total spending on clinical lab tests in hospital outpatient departments has grown over 30% from 2016-2019, due almost entirely to price growth.
- "In seven states, the markup for lab tests from hospital outpatient departments was over six (6) times the median price for the same tests from physician offices in 2019 (Colorado, Indiana, Nevada, New Mexico, North Carolina, Texas, and West Virginia).
- "State policymakers could consider implementing regulations to reduce the price markups associated with outpatient hospital-based laboratory tests for insurance plans regulated at the state level."

$200 Test versus $9 Test

"Under commercial insurance, some hospital outpatient departments are being paid over $200 for a metabolic panel, which has a median, office-based price of $9," the report states. HCCI collaborated on the study with nonprofit **West Health** in La Jolla, California. *(See the sidebar, "HCCI Lists Lab Tests with Highest Mark-ups.")*

In the report's conclusion, HCCI urged action to address the higher lab test prices charged by certain hospital laboratory outreach programs. The authors said, "Where negotiations are possible, health insurers and self-insured employers may also have the opportunity to limit site-based payment differentials for their enrollees and employees."

"Private payers negotiate contracts with independent clinical labs and physician office laboratories at a very reduced rate, whereas hospitals are able to charge private payers what would be 200% of the **Medicare** rate," said Jon Harol, President at **Lighthouse Lab Services**, a medical lab consulting and recruiting firm in Charlotte, North Carolina.

"One factor in this situation comes down to negotiating power. The difference in pricing [as detailed in the HCCI report] has little to do with how efficiently labs run tests or patient outcomes. Instead, it is a result of outsized leverage that hospitals have when negotiating with private payers," he explained.

Hospital Market Power

Harol is referring to the market power that many hospitals and health systems have when negotiating managed care contracts for inpatient services with health insurers. These institutions are often in a position to tell a payer that—if the payer wants the hospital to be in-network—the agreement needs to cover the hospital's laboratory outpatient and outreach

HCCI Lists Lab Tests with Highest Markups

ACCORDING TO THE HEALTH CARE COST INSTITUTE STUDY, the tests with the most markup by hospital outpatient labs as compared to physician office labs (POL) and independent labs include the following:

- **Urinalysis**—$2.72 office/independent lab; $21.39 hospital outpatient. More than seven times price markup.
- **Comprehensive metabolic panel**—$8.85 POL/independent lab; $47.13 hospital outpatient. More than five times markup.
- **General health panel**—$22.97 POL/independent lab; $127.97 hospital outpatient. More than five times markup.
- **Basic metabolic panel**—$7.75 POL/independent lab; $38.44 hospital outpatient. Five times markup.

Complete HCCI brief: https://tinyurl.com/HCCI-brief

POLs Have Some Test Pricing Advantages

STEADY IMPROVEMENTS IN DIAGNOSTIC TECHNOLOGIES are creating new opportunities for office-based physicians to establish clinical laboratories within their practices.

"We help a lot of physicians bring laboratory testing in-house, and they are able to bill for it and capture revenue," Harol said. Lighthouse launches about 25 POLs each year. In May, it acquired **Pathology Lab Solutions**, a physician lab design, set-up, and compliance firm.

Certain clinical specialties are suited to POLs, according to Lighthouse, including gastroenterology, dermatology, and pain management.

Pain management clinics with POLs can earn revenue and shorten test turnaround times, which can be six to eight days for urine toxicology tests sent to large independent labs, Harol said. Other lucrative tests for POLs, he added, include molecular PCR testing, anatomic pathology, cytology, and some genetic tests.

A POL contributes from 1% to 3% of a medical practice's revenue, according to the **Marwood Group**, a New York healthcare advisory and financial services firm. More than 100,000 POLs exist in the U.S., and they are growing in number, the firm noted.

A POL can be feasible when a practice is sending out 100 urine toxicology tests or 50 molecular tests for infectious diseases per month, Lighthouse has found.

testing (which will be billed to that payer using inpatient test prices).

"When certain hospitals charge more to run outpatient tests than independent lab companies, this often has nothing to do with cost structure," Harol told THE DARK REPORT. "In these cases, it has everything to do with the way the contracts between the hospital and health insurer were negotiated."

Study of Price Differentials

Payers need to push hospital outpatient labs to cease upcharging for outpatient tests, advised the **Employee Benefit Research Institute** (EBRI) in a study of price differentials between hospital outpatient labs, POLs, and independent laboratories. EBRI is a research institute in Washington, D.C.

"[Third-party payers] can exert pressure on hospitals to shift from discounted-charge contracts based on a multiple of Medicare to some other prospective case rate," EBRI noted in a 2021 issue brief. "Employers could also exert such pressure on health plans to do the same with the hospitals in their networks."

EBRI suggested two other tactics that health plans, payers, and POLs could take:

- One, in the spirit of price transparency, publicize test price markups charged to payers by outpatient labs.
- Two, health plans can steer patients away from a hospital's outpatient lab to independent clinical laboratories and POLs by removing a hospital's outpatient lab testing options from that health plan's network.

EBRI acknowledged that such approaches require influence within a market by payers, along with the availability of independent labs and POLs in the region served by these health insurers.

The financial pressure is on those hospitals and health systems that bill their outreach/outpatient lab services using inpatient prices. THE DARK REPORT has tracked national lab purchases of sizeable health system lab outreach businesses that occured within months of a major payer forcing the outreach program to switch from inpatient test prices to the much-lower market prices common in the competitive outpatient/outreach market. TDR

Contact Jon Harol at jon.harol@lighthouselabservices.com or 860-833-0489.

FDA Expected to Publish Proposed LDT Rule in August

At same time, VALID Act is again before Congress to give FDA oversight of laboratory-developed tests

Gail Javitt

***CEO SUMMARY:** Congressional lawmakers and the federal Food and Drug Administration are again eyeing changes that would bring greater oversight to laboratory-developed tests (LDTs). Leaders at clinical laboratories and pathology groups should monitor these proposals, both of which could have long-term ramifications for labs that use LDTs.*

ACTION TO INCREASE REGULATORY OVERSIGHT OF LABORATORY-DEVELOPED TESTS (LDTs) on two fronts once again picked up at the onset of summer, as has been the case for the past two years.

On one front, the federal **Food and Drug Administration** (FDA) indicated it may publish a notice of proposed rulemaking about LDT requirements sometime in August. For the past several years, the FDA has supported the idea of increased oversight of LDTs but has not taken steps to put forth regulations.

"Given problems we have seen with some laboratory-developed tests, we are moving forward with rulemaking under our current statutory authority," an FDA spokesperson told THE DARK REPORT. "The FDA intends to publish a notice of proposed rulemaking regarding LDTs generally in August 2023. The rulemaking process includes an opportunity for public comment, which we will consider as we finalize the regulation."

On the second front, the VALID Act is again before the **U.S. House of Representatives** as bill number H.R.2369. The formally-titled Verifying Accurate Leading-edge IVCT Development Act was scrapped from a year-end congressional spending bill in December. The VALID Act was seemingly on its way to being passed in 2022 before—among other voices in opposition—a large group of anatomic pathologists from academic medical centers made a sustained protest that caught the ear of lawmakers.

'Roadmap' for FDA Rule

The VALID Act seeks to add *in vitro* clinical tests, such as LDTs, to the federal Food, Drug, and Cosmetic Act. By doing so, many LDTs would need either pre-market review or a technology certification order from the FDA. Currently, LDT oversight falls under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

"The VALID Act gives a roadmap of what the FDA might propose, as do previous position papers the FDA has written indicating they want a tiered, risk-based system of oversight for LDTs," said Gail Javitt, a Director at law firm **Hyman, Phelps & McNamara** in Washington, D.C.

The FDA's stance is that there are enough questionable LDTs on the market to warrant greater monitoring. "The FDA believes that all patients deserve to have access to accurate and reliable tests regardless of where they are made," the agency spokesperson said. "While laboratory developed tests … play an important role in our healthcare system, the FDA is very concerned about problematic LDTs currently used in the U.S. that might not provide patients with accurate and reliable results."

At issue is whether the FDA has enough data from labs that develop their own tests to gauge whether LDTs perform safely, particularly given how rapidly new genetic tests come to market. Last October, two former FDA commissioners—Scott Gottlieb, MD, and Mark McClellan, MD, PhD—penned a piece in *JAMA Health Forum* about what the agency hopes to achieve with greater LDT oversight.

"The new pathway would give the FDA clear authority to oversee tests and ensure that all tests meet certain common requirements for demonstrating that they reliably produce the molecular and genomic findings that they are intended to generate," McClellan and Gottlieb wrote.

What Risks Does FDA See?

Javitt said she would like to see any proposed rulemaking from the FDA clearly and specifically address risks the agency sees with LDTs. "Labs have heard assertions that there are risky tests out there and that patients are being harmed," she observed. "The rulemaking is an opportunity for the FDA to be transparent about the magnitude and precise nature of harms for which the agency has evidence. The more the FDA articulates that, the more it can potentially craft a carefully tailored approach that is nuanced and targeted rather than overly restrictive."

Javitt also said greater clarity from the FDA would be welcome regarding how the agency would apply manufacturing concepts to clinical laboratories. "What does it mean for medical device regulations to apply to LDTs?" she asked. "LDT labs are not classic manufacturing establishments. Yet the FDA's regulations are very much designed around the concept of a manufacturer. So, how do you adapt things—like the quality system that manufacturing plants use—to a laboratory environment? These are complicated questions."

Authority to Regulate LDTs?

In April, David Gee, JD, a partner at law firm **Davis Wright Tremaine LLP** in Seattle, told *Dark Daily*—an online sister publication to *The Dark Report*—that a 2022 **U.S. Supreme Court** decision concerning the **Environmental Protection Agency** (EPA) may have some bearing on LDT regulation from the FDA.

"Some legal experts have suggested that one significant new legal challenge FDA may face is the Supreme Court's West Virginia v. EPA decision last summer that limited the ability of the EPA to cap power plant emissions by regulation due to the EPA's lack of explicit congressional authority to do so," Gee said. "The West Virginia v. EPA ruling provides support for those in the clinical lab industry who point to the FDA's lack of clear statutory authority to regulate LDTs and therefore fundamentally disagree with FDA's longstanding position that LDTs are medical devices subject to FDA's authority to regulate."

Javitt agreed that there would at least be debate on the FDA's statutory authority with LDTs. "There is a legitimate legal argument that laboratories are not within the scope of the Food, Drug, and Cosmetic Act," she explained. "I don't know which way a court would come out on that debate."

When the VALID Act was not included in the year-end spending bill in December 2022, many observers pointed

to the influence of pathologists from academic medical centers who decried the VALID Act as an obstacle to future LDT innovation. *(See TDR, "Might Valid Act Support Be Waning in Congress?" July 18, 2022.)*

A source familiar with academic medical center deliberations noted to THE DARK REPORT that pathologists in those settings have discussed spearheading another effort to bring their LDT concerns before lawmakers. However, given that the VALID Act is before a House subcommittee and not close to a full vote, the group of academic medical center pathologists do not yet have concrete plans.

"We remain incredibly concerned about LDT regulation," the source said. "We're starting to discuss it, but I don't think we know exactly what's going on yet with the FDA's plans or the VALID Act in Congress."

The Food and Drug Administration hinted that it may seek—via Congressional lawmakers—to attach the VALID Act to a reauthorization of the Pandemic and All-Hazards Preparedness Act. The current iteration of the PAHPA is due to expire on Sept. 30 without reauthorization.

"VALID remains one of the FDA's top legislative priorities for reauthorization of the Pandemic and All-Hazards Preparedness Act," the FDA spokesperson told THE DARK REPORT. "The FDA stands ready to continue working with Congress on diagnostic testing reform."

Call to Action

For clinical labs and pathology groups that use LDTs, there are several key actions to consider over the coming weeks:

- Submit comments to the FDA when a proposed regulation is published. "Labs and other stakeholders should be prepared to carefully review any proposed rule and submit comments that are particular," Javitt advised. "To the extent labs disagree about the FDA's approach—and to the extent that labs think that there are unforeseen consequences—get those comments in."
- Contact local representatives in Congress about the VALID Act. This approach resulted in lawmakers rethinking their support for the VALID Act in 2022. The bill's bipartisan sponsors have noted patient safety concerns with LDTs, so labs may want to provide a counterargument.

"Experts in science and clinical laboratory medicine also need to weigh in to ensure an informed conversation from a medical and a health policy perspective," Javitt said. TDR

Contact Gail Javitt at GJavitt@hpm.com.

ProPublica Questions Accuracy of Prenatal LDTs

PROPUBLICA published a story on June 14 about the **Food and Drug Administration's** (FDA) announcement that it intends to pursue rulemaking involving laboratory-developed tests.

ProPublica's reporting over the last 12 months has largely been critical of the agency's lack of oversight for LDTs, pointing in particular to prenatal screening tests.

"*ProPublica's* investigation of prenatal genetic screenings detailed how the FDA doesn't review the tests before they reach patients, nor does it verify marketing claims made by companies that sell them," the news outlet wrote. "False positives, false negatives, and uncertain results about genetic anomalies have sometimes led to devastating consequences for families, the investigation found."

The **Association for Molecular Pathology** told *ProPublica* that it will propose an alternative approach to LDT reform that doesn't rely on the FDA. Instead, the effort will aim to modernize existing lab test regulations, likely through the Clinical Laboratory Improvement Amendments of 1988.

Cyberattack Victims Sue Enzo Biochem, Labcorp

➤Lawsuit contends the companies, now in midst of an acquisition, did not protect sensitive data

➤➤CEO SUMMARY: It's the latest reminder that clinical laboratories and anatomic pathology groups are at risk for two threats. One threat is a cyberattack that shuts down a lab's IT system while stealing patient data. The other threat involves lawsuits against the same lab by patients unhappy that their protected health information was stolen by hackers. Earlier this year, Labcorp agreed to buy the clinical laboratory division from Enzo Biochem. Labcorp stated it is not a proper defendant in the case.

Aspects of a new class action lawsuit filed by at least nine patients against **Labcorp** and **Enzo Biochem** point to potential fallout when a clinical laboratory experiences a cyberattack.

The suit also brings up an interesting debate about patients who do not realize their tests—and thus their diagnostic and protected health information (PHI)—are being handled by a third-party commercial laboratory of which the patients may not even know the name.

"Defendants' breach differs from typical data breaches because it affects consumers who had no relationship with defendants, never sought one, and never consented to defendants collecting and storing their information," stated the plaintiffs in their lawsuit.

The lead case in the class action involves a patient named Eliana Epstein of Cambridge, Massachusetts, who sued Labcorp in Burlington, North Carolina, Enzo Biochem in New York City, and **Enzo Clinical Labs**. The case was filed in **U.S. District Court for the Eastern District of New York**.

The class action suit asserts four broad allegations:

- Epstein did not have a formal relationship with either Labcorp or Enzo Clinical Labs, yet those companies had access to her PHI and mishandled the protection of this data.
- Enzo and Labcorp's IT safeguards were inadequate to prevent a cyberattack, putting millions of patients' personal information at risk.
- Enzo and Labcorp waited too long to notify affected patients about the breach.
- The breach violated HIPAA and **Federal Trade Commission** (FTC) statutes.

➤Test Information Accessed

It is not clear in the court documents how Epstein's personal data arrived in the possession of Enzo Clinical Labs.

"Plaintiff is unsure how defendants got her information but assumes a healthcare provider she received treatment from provided defendants with her sensitive information," the suit stated. Epstein received notification of the data breach from Enzo Clinical Labs.

Her PHI was accessed and, according to the lawsuit, stolen from Enzo's network during the cyberattack.

"On April 6, 2023, we identified a ransomware incident on our computer network," Enzo Clinical Labs wrote in a data breach notification posted on its website. "We immediately took steps to secure our systems and began an investigation with the assistance of a cybersecurity firm. The investigation determined that an unauthorized party accessed files on our systems between April 4, 2023, and April 6, 2023. The files contained patient names, dates of service, clinical test information, and, in some instances, Social Security numbers. Patient financial and payment information was not involved in this incident."

It was not noted in either Enzo's notification or in Epstein's lawsuit whether a ransom was paid after the incident to restore lost files, or whether the lab's IT team was able to replace the data on its own.

Millions Affected by Breach

Enzo Clinical Labs notified the federal government on June 5 that the cyberattack occurred on a network server and affected 2,470,000 individuals, according to an online listing of breaches from the **U.S. Department of Health and Human Services' (HHS) Office for Civil Rights**.

According to the lawsuit, Epstein and others were notified by letter. "Defendants waited almost two months before informing class members even though plaintiff and approximately 2.5 million class members had their most sensitive personal information accessed, exfiltrated, and stolen, causing them to suffer ascertainable losses in the form of [damages due to misrepresentation] and the value of their time reasonably incurred to remedy or mitigate the effects of the attack," the lawsuit stated.

Earlier this year, Labcorp agreed to buy Enzo Biochem's clinical lab business for $146 million. The deal has not formally closed, according to Labcorp. For that reason, Labcorp should not be a defendant, the company told THE DARK REPORT.

Labcorp Comments on Suit

"Labcorp generally does not comment on pending litigation," a Labcorp spokesperson said. "We note, however, that Labcorp is not an appropriate party to lawsuits arising from the ransomware attack reported by Enzo Biochem.

"Although Labcorp entered into an asset purchase agreement in March 2023 to purchase certain assets from Enzo Biochem, that transaction has not closed [as of mid-June] and, in any event, would not make Labcorp an appropriate party to the lawsuits," the spokesperson added. "For this and other reasons, Labcorp's inclusion in these lawsuits is erroneous."

Enzo Biochem declined comment about the lawsuit. Epstein's lawyer, James Bilsborrow at the firm **Weitz and Luxenberg PC** in New York, did not respond to a request for comment from THE DARK REPORT.

Complaint Points to HIPAA

Epstein's lawyers argued that by virtue of IT systems being infiltrated, Enzo and Labcorp did not do enough to prevent the attack.

"Despite recognizing their duty to do so, on information and belief, defendants have not implemented reasonable cybersecurity safeguards or policies to protect their consumers' sensitive information or supervised their IT or data security agents and employees to prevent, detect, and stop breaches of their systems," according to the court papers. "As a result, defendants leave significant vulnerabilities in their systems for cybercriminals to exploit and gain access to consumers' sensitive information."

HIPAA generally sets requirements for providers, health systems, and other entities to protect patient health informa-

tion. HIPAA's Security Rule sets measures to prevent ransomware attacks, including a procedures to detect malicious software.

Among the allegations in the lawsuit is that Enzo and Labcorp failed to carry out policies and procedures for systems that maintain electronic PHI. "Simply put, the data breach resulted from a combination of insufficiencies that demonstrate defendants failed to comply with safeguards mandated by HIPAA regulations," the complaint stated.

THE DARK REPORT has previously noted that clinical and operations leaders in medical laboratories should work with their IT colleagues to verify that technology and processes protect patient data as intended. A technology audit is one approach to accomplish this goal. *(See TDR, "Labs Must Audit Their Cybersecurity Measures," Oct. 10, 2022.)*

Also, HIPAA requires that after a data breach involving PHI, "individual notifications must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach," according to HHS.

The lawsuit stated that Epstein received notification of the breach on June 8 via a mailed letter that was dated May 31. Enzo Clinical Labs noted that it discovered the breach on April 6.

FTC Violations Alleged

The suit alleged that the breach meets criteria for unfair practices as governed by the FTC. "The FTC recommends that companies not maintain information longer than is needed for authorization of a transaction; limit access to sensitive data; require complex passwords to be used on networks; use industry-tested methods for security; monitor for suspicious activity on the network; and verify that third-party service providers have implemented reasonable security measures," the lawsuit states.

It also said the breach violated Section Five of the Federal Trade Commission Act. Section Five is a broad regulation that prohibits any action that "is likely to cause substantial injury to consumers, which is not reasonably avoidable by consumers themselves," according to the FTC.

Epstein and the other defendants in the class action are seeking unspecified damages, according to the lawsuit. TDR

Lawsuit: 'Fullz' Threat Is Real for Breach Victims

HERE'S CYBERCRIMINAL LINGO THAT LABORATORY PROFESSIONALS may not recognize: "fullz."

Fullz is a slang term used by fraudsters and cybersecurity companies to describe stolen material that is "full" of personal information, according to fraud management company **Fraud.net**.

"Fullz usually contains a person's name, address, SSN, driver's license, bank account credentials, and medical records, among other details," Fraud.net noted.

The lawsuit over a data breach of patient records at Enzo Biochem and Labcorp contended that the victims of the breach will be subject to fraud through fullz-related tactics. "The development of 'fullz' packages means that stolen sensitive information from the data breach can easily be used to link and identify it to plaintiff and the proposed class's phone numbers, email addresses, and other unregulated sources and identifiers," the lawsuit argued.

"In other words," the complaint added, "even if certain information such as emails, phone numbers, or credit card numbers may not be included in the sensitive information stolen by the cybercriminals in the data breach, criminals can easily create a fullz package and sell it at a higher price to unscrupulous operators and criminals (such as illegal and scam telemarketers) over and over. That is exactly what is happening to plaintiff and members of the proposed class."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

General health panels submitted under CPT code 80050 are among the most expensive—and potentially most wasteful—diagnostic tests, according to a new study published in June by **Avalon Healthcare** Solutions in Tampa, Florida. These panels include a metabolic panel, complete blood count, and thyroid stimulating hormone level. Avalon reported that 80050 is likely a prime example of "panel stuffing," in which clinical labs add tests with no clinical value to panels and then bill for them. "This abusive behavior costs billions of dollars every year," stated Avalon, a laboratory benefit management (LBM) company.

MORE ON: *General Health Panels*

Out of the roughly 80 million lab tests that Avalon managed in 2022, it identified the top five routine lab tests with the highest prices. The costs associated with CPT 80050 were $6.76 per member per year in plans managed by Avalon. That ranking puts the panel at number four on the list and marks the first time the panel appeared on the tally since Avalon began reporting these results in 2021. "A lab test price can vary dramatically (up to several-fold differences) depending on where it is performed," Avalon noted in the report. "Site neutral payment legislation may reduce the disparity between site of service."

CDC SUGGESTS RAPID TEST FOR HCV

Barriers to hepatitis C virus (HCV) detection must come down to increase the amount of people who receive diagnostic testing for the disease, according to new research from the federal **Centers for Disease Control and Prevention** (CDC) and **Quest Diagnostics** in Secaucus, New Jersey. More than two million people in the United States have HCV, yet only 40% are aware of it, the CDC estimated. Diagnosing HCV requires an antibody test, and if positive, a nucleic acid test to confirm infection, which is a cumbersome process, the CDC stated. The agency suggested that a rapid, point-of-care viral test would improve the rate of HCV diagnosis.

TRANSITIONS

- Brittany Vaughn is the new Global Director of **ValuMetrix**, a lab consulting division at **QuidelOrtho** in San Diego. She previously worked at **Becton, Dickinson and Company** based in Franklin Lakes, New Jersey, and St. **John Health System** in Tulsa, Oklahoma.

- Michael Roehrl, MD, PhD, MBA, has joined **Beth Israel Deaconess Medical Center** in Boston as Chief of Pathology. He was previously at the Precision Pathology Center at **Memorial Sloan Kettering Cancer Center** in New York and at **University Health Network** in Toronto.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 31, 2023.

Executive Publisher: Bob Croce *bcroce@darkreport.com*
Editorial Director: Scott Wallask *swallask@darkreport.com*
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*
Managing Editor: Michael McBride *michaelmcbride58@gmail.com*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*