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Fraudulent Lab Test Scheme Busted in Texas!

Federal Prosecutors Announce Settlement with Seven Doctors, One Hospital CEO (See pages 13-18)

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

COVID-19: a Fork in the Road for Future Lab Testing?

WE HAVE ALL EXPERIENCED A PANDEMIC UNIQUE IN THE HISTORY OF THE WORLD. Two elements, in particular, distinguished this pandemic from earlier global outbreaks. First, genetic technologies allowed scientists to almost instantly sequence the DNA of the novel coronavirus, once it was recognized as a unique infectious agent. That accelerated development of the vaccines.

Second was the global lockdown of ordinary citizens, accompanied by the ban on all public gatherings—be it sports, church services, concerts, or plays. Students did not go to school and parents worked from home. Cruise ships stayed in port, and the airlines carried just 25% of passengers per day compared to pre-pandemic levels.

Now, the latest stats on the Omicron variant indicate the pandemic may be winding down. On Jan. 24, 2022, the federal **Centers for Disease Control and Prevention** reported 1,025,249 new COVID-19 cases that day. As of Mar. 10, just 42,566 new COVID-19 cases were reported for that day.

These facts confront lab administrators and pathologists with the need to answer an important question: What happens to healthcare and the clinical laboratory industry as we move forward? Will the COVID-19 pandemic prove to be the fork in the road that propelled U.S. healthcare down a path that differed from what was laid out at the end of 2019?

Answer that question incorrectly and your laboratory organization may find itself moving in the wrong direction in coming years, with the consequence of lost clients and the inability to generate sufficient revenue to sustain operations. Answer the question correctly and the future could be clinically and financially robust for your laboratory, as well as for the hospitals, physicians, and payers and patients it serves.

As we've done for 27 years, your team at THE DARK REPORT has been at work gathering experts who will share useful insights and knowledge about what's coming next for healthcare and the House of Laboratory Medicine. When the *Executive War College on Laboratory and Pathology Management* convenes on April 27-28, 2022, in New Orleans, there will be 125 speakers and 75 sessions to help you understand what's coming and how to position your lab to prosper. You should reserve your place today and bring your brightest management minds to this critical strategic gathering! TDR

New Trends Reshaping Healthcare, Lab Testing

Front and center this year: staff/supply shortages, artificial intelligence, digital pathology, and more

Robert L. Michel

***CEO SUMMARY:** With an emphasis on strategic actions clinical lab and anatomic pathology leaders can take immediately, the Executive War College Conference on Laboratory and Pathology Management returns on April 27-28 in New Orleans. Participants will learn what post-pandemic changes to expect in the medical lab industry and what steps executives can take to offer the latest diagnostic technologies while generating revenue from new sources.*

With the remnants of the SARS-CoV-2 Omicron surge fading, business travel budgets recovering, and people feeling more comfortable gathering in crowds, the stage is set to welcome back clinical laboratory leaders to the The Dark Report's annual *Executive War College on Laboratory and Pathology Management*, which takes place on April 27-28 in New Orleans.

This is our 27th conference, and it will be one of the clinical lab profession's first opportunities this year to gather and learn what has changed in healthcare and the clinical laboratory testing marketplace as a consequence of the two-year-old COVID-19 pandemic. The most visible impact today is the ongoing supply chain shortage and the serious shortage of qualified professionals to fully staff hospitals, physician offices, clinical laboratories, and anatomic pathology groups.

"Obtaining adequate supplies and lab staff is certainly a daily stress for lab administrators and pathologists, and several speakers will share their innovative solutions to respond to both issues," stated Robert Michel, Editor-in-Chief of The Dark Report and founder of the *Executive War College*. "However, there are equally powerful forces of change altering how providers, payers, patients, and consumers access lab testing services and pay for those services.

"In fact, healthcare experts point out that the pandemic itself did not fundamentally change healthcare in this country," Michel continued. "Rather, they say the pandemic accelerated the adoption of trends already underway prior to the outbreak.

"For example, use of telehealth and virtual physician visits have exploded," he observed. "Today, a large proportion of physicians and patients are comfortable

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

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with a virtual office visit. This presents an immediate problem for clinical laboratories because—when the patient gets a lab test order from a doctor during a virtual exam—the lab needs a way to access that patient to collect the specimens required to perform the tests.

Innovations in Lab Logistics

"Already, new companies are springing up to give clinical labs a way to access that telehealth patient and collect lab specimens that are then transported to the central laboratory," Michel noted. "This is just one aspect of the important ways the pandemic accelerated adoption of existing trends in clinical care."

At the current pace of registrations, attendance is expected to be back to pre-pandemic levels, with 850 or more attendees. "This is a significant fact," Michel declared. "Everybody's 'been there and done that' with COVID-19. They are ready to return to live conferences, hear about the most important developments in clinical lab and pathology, and network with their peers."

Consumer Access to Care

Another important trend involves how consumers are accessing care differently. "The pandemic made consumers familiar with two aspects of diagnostics testing," he said. "First, large numbers of consumers have bought their own COVID-19 rapid tests. They found that it was easy to buy and use these kits.

"Second, many consumers are now comfortable collecting their own specimen and returning it to the lab for testing," Michel added. "In turn, this is fueling consumer demand for self-ordered testing and at-home rapid tests. Clinical lab companies serving the direct-to-consumer (DTC) test market say patients are more adept at administering certain tests for common illnesses, such as influenza."

Several sessions at the *Executive War College* will focus on meeting these evolving consumer needs—not only self-ordered tests—but also where patients are choosing to receive primary care services.

Trends have already begun that will bring more consumers to their local retail pharmacy instead of their doctor's office for routine exams and point-of-care testing. *(See TDR, "Newsmaker Interview: Labs, Pharmacies Learn from Each Other as Barriers Drop," Jan. 31, 2022.)*

The fastest-moving trend may be the adoption of artificial intelligence (AI) across almost every aspect of clinical care and operational functions in hospitals, physicians' offices, and clinical labs. This is especially true of AI-based services in digital pathology and in lab coding, billing, and collections.

AI Developments for Labs

"The use of artificial intelligence is growing across a wide span of activities in healthcare, particularly in diagnosis," Michel explained. "There are numerous companies developing AI-powered solutions for the analysis of digital pathology images. The FDA has already cleared one product, and expectations are that a surge of applications for FDA review of AI-powered digital pathology analysis products will be forthcoming." *(See TDR, "First Digital Path AI Tool Cleared for Market by FDA," Sept. 27, 2021.)*

Speakers at the 27th annual *Executive War College Conference* will not only delve into the role of artificial intelligence in digital pathology, but also into how AI influences other areas of clinical laboratory operations, including revenue cycle management and automation.

Because of lockdown and travel restrictions over the past two years, significant changes have taken place in how labs comply with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and how the deeming organizations conduct the required assessments of clinical laboratories and pathology groups.

To help lab professionals tasked with this compliance requirement, there will

be a CLIA accreditation-themed panel discussion featuring directors from the **College of American Pathologists**, **The Joint Commission**, and **COLA**. At one time and place, lab managers can learn how each accreditor is innovating in response to the pandemic. This session will also focus on best practices to maintain continuous survey readiness and explore top survey deficiencies.

Under the Clinical Laboratory Improvement Amendments of 1988, a lab must be inspected every two years by an authority that is deemed to review the lab on behalf of the federal **Centers for Medicare and Medicaid Services** (CMS).

"This is the first time that three of the CLIA deeming organizations will appear at the *Executive War College* during the same session to share insights about the most common deficiencies and how CLIA inspections are being conducted because of COVID-19," Michel explained.

Additional Key Topics

Other valuable session topics that will be presented include:

- Latest legal developments involving compliance regulations.
- How clinical laboratories can better handle staffing shortages and recruiting challenges that stem from the "Great Resignation."
- Post-pandemic strategies for hospital laboratory outreach programs that build specimen volume and bring in additional revenue.
- Managed care panel that identifies effective ways for labs to add value to earn additional revenue from insurers.
- Sessions on proven ways to be paid for COVID-19 and genetic test claims.

"It's important for clinical lab executives to recognize that—as intense as it was to manage a lab during the COVID-19 pandemic of 2020 and 2021—rapid advances in technologies such as artificial intelligence, virtual meetings, and next-generation genome sequencing are each game-changers in their own right," Michel noted. "These technologies are at work today, changing the way hospitals deliver care, physicians treat patients, and consumers access lab tests.

"Collectively, these are reasons why every lab organization should have their managers and best strategic thinkers attend this year's *Executive War College* on April 27-28," Michel concluded. "This is the time and place for them to learn from the profession's best innovators and gain insights they'll need to keep their laboratories at the cutting edge of clinical excellence in a financially sustainable manner." TDR

Contact Robert Michel at 512-264-7104 or rmichel@darkreport.com.

COVID Precautions Will Continue at EWC

AS THE NUMBER OF DAILY NEW COVID-19 CASES DROPS thanks to slowing of the Omicron variant surge, organizers of the *27th annual Executive War College on Laboratory and Pathology Management* continue to fine-tune health and safety measures for attendees.

"It's important all those attending this year's event know that screening COVID-19 protocols will be in place to ensure the health and safety of all participants," said Robert Michel, Editor-in-Chief of THE DARK REPORT and founder of the *Executive War College*. "We did a large lab conference in the fall of 2021 that included protocols for COVID-19 and the attendees told us they appreciated the protection provided by those protocols."

The *Executive War College* takes place April 27-28 in New Orleans. It will follow updated COVID-19 guidelines from the federal Centers for Disease Control and Prevention, along with any state and local directives in effect as of April 27. Visit *www.ExecutiveWarCollege.com* to review the latest COVID-19 safety protocols for the gathering.

Questions Remain about California's Valencia Lab

➤COVID-19 testing laboratory continued to operate with dozens of deficiencies that put patients at risk

➤➤CEO SUMMARY: Despite multiple investigations citing more than 60 deficiencies, including some that caused immediate jeopardy to patient safety according to state inspectors, the Valencia Branch Laboratory never closed. The California Department of Public health said the state lab now meets all current compliance requirements. But questions linger about whether more stringent action should have been taken.

One important question about California's state-owned COVID-19 testing laboratory is this: Why was the lab never sanctioned or closed after state and federal inspectors found more than 60 deficiencies—including deficiencies putting patient safety in immediate jeopardy—during three separate inspections in February, March, and May 2021?

In a 123-page report that the **California Department of Public Health** (CDPH) issued on Feb. 17 last year, officials reported finding 37 deficiencies at the COVID-19-specific testing lab, known as the **Valencia Branch Laboratory** (VBL), including deficiencies that could put patients at risk of harm.

Two months later on April 22, in a 43-page report, state inspectors identified 14 deficiencies, 10 of which were identical to those found during the February inspection.

Then on May 6, inspectors from the **Centers for Medicare and Medicaid Services** (CMS) issued a 21-page report identifying 12 deficiencies, seven of which were violations that state inspectors had found. All three reports (two from state inspectors and one from CMS) cited deficiencies in lab administration and leadership, and in the clinical laboratory's analytical processes.

Clinical laboratory directors and pathologists aware of these findings by state and federal lab inspectors wonder why this state-owned laboratory seemed to have avoided the harsh sanctions that would shut down most other labs in the country.

Lab professionals immediately recognized the conflict of interest in the fact that officials from the California Department of Health Services were inspecting VBL, the lab owned by the State of California.

➤14-Month Investigation

Even before state inspectors issued their reports, Julie Watts, an investigative reporter for *CBS13* in Sacramento, had reported on failures at the lab shortly after it opened in October 2020. On Feb. 8, 2021, Watts broke her story: *"Asleep at Lab: Whistleblower Allegations from Inside CA's Billion-Dollar COVID Lab."*

On Dec. 30, 2021, *CBS13* broadcast a 30-minute special report that was the culmination of a 14-month investigation by the station into the COVID 19 lab's operations that prompted state and federal investigations.

The report resulted in two new state laws and put a spotlight on some of what Watts called the "public health failures" at the lab. She also reported that regulators allegedly tried to hide those failures. *(See sidebar, "TV News Reports Show Extent of VBL's Problems," page 9.)*

Despite the findings that Watts uncovered in her reporting, and the deficiencies that state and federal inspectors found, the lab has remained open even as state officials have downplayed the inspection findings and allegedly misconstrued some of the allegations from whistleblowers, *CBS13* and other local media organizations reported.

Perhaps even more surprising is the fact that shortly after the CDPH issued its first two reports last year, officials renewed the state's $1.7 billion contract with **PerkinElmer** to run Valencia Branch Laboratory under automatic renewal provisions in the contract, according to *CalMatters*, a nonprofit news organization.

'Immediate Jeopardy' Found

On Nov. 22, 2021, when CDPH issued a report on the lab's inspections, Watts noted in a broadcast that inspectors from CDPH confirmed the allegations from whistleblowers at VBL.

Watts based her reporting on interviews she'd done earlier with laboratory staff members, she explained. *(See "Major CLIA Deficiencies Found at California's COVID-19 Lab Facility," TDR, Nov. 29, 2021, and "Whistleblowers Disclose Issues in California's COVID Lab," March 1, 2021.)*

The CDPH's Nov. 22 report included a letter dated April 23, 2021, from CDPH director and state public health officer Tomás Aragón, MD, DrPH, to pathologist Adam Rosendorff, MD, the CLIA laboratory director at VBL.

The letter explained that inspectors from CDPH's **Laboratory Field Services** (LFS) division conducted a complaint inspection at the lab on Feb. 7, 2021, during which state officials identified deficiencies putting patient safety in immediate jeopardy.

Inspection Reports Cite Deficiencies at VBL

IN TWO REPORTS CALIFORNIA STATE OFFICIALS ISSUED ON THE VALENCIA BRANCH LABORATORY, and in a report from the federal Centers for Medicare and Medicaid Services (CMS), inspectors cited failures in administration of the clinical laboratory as well as in the three analytical processes that all clinical labs conduct: pre-analytical, analytical, and post-analytical.

On Feb. 17, 2021, the Laboratory Field Services division of the California Department of Public Health (CDPH) issued a 123-page report on the lab in which it reported finding 37 deficiencies at the COVID-specific testing lab.

Just two months later, state inspectors identified 14 deficiencies in a 43-page report issued April 22. In that report, 10 of the 14 deficiencies were identical to the ones found during the state's February inspection. Then, just two weeks later, CMS inspectors identified 12 deficiencies, seven of which were violations that state inspectors had found.

As defined under California regulations, the term "immediate jeopardy" means that "the laboratory's non-compliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."

Statement of Deficiencies

CDPH's LFS division concluded its inspection on April 22 when it issued a "Form 2567: Statement of Deficiencies" letter. The report identified deficiencies in five areas: lab administration, lab leadership, and three analytical processes found in every lab: pre-analytical, analytical, and post-analytical.

So serious were the deficiencies, the lab could have faced civil money penalties for

each day of noncompliance or per violation, exclusion from ownership or operation of such labs, and revocation or suspension of the lab's public health certificate. Those penalties could have been imposed within 21 days of the date of the letter.

Any sanctions or enforcement actions could only be rescinded when state inspectors had verified compliance, the letter noted.

Rosendorff, VBL's CLIA director, had 10 calendar days to "provide this office with a credible allegation of compliance and acceptable evidence documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the condition-level deficiencies in question," the Form 2567: Statement of Deficiencies letter stated.

On the CDPH website, however, the agency includes statements saying the laboratory now complies with state standards. But as of March 2022, those statements do not explain how the lab became compliant with state inspection requirements.

The statements also make clear the immediate jeopardy status is no longer in place, but they do not explain how the lab reversed that status.

In response to questions from THE DARK REPORT, the CDPH did not provide details on how VBL responded to the deficiencies, but did reiterate that the lab meets state and accreditation standards.

"The Valencia Branch Lab underwent multiple thorough inspections by both Laboratory Field Services and the **College of American Pathologists**," the CDPH's press office told THE DARK REPORT. "After multiple visits to the laboratory and numerous correspondences, these inspections have both been closed with no sanctions imposed and with full accreditation by CAP."

CDPH updated the public about the VBL situation through online questions and answers. The first question was whether state officials would close the lab due to the LFS inspection report. In response, the update said, "PerkinElmer is confident these deficiencies will be quickly remedied to avoid any impact on the laboratory's license … and the laboratory … has worked to make numerous improvements since the onsite inspection."

Another question in the update addressed whether the immediate jeopardy designation meant LFS would revoke the license. In response, CDPH said, "PerkinElmer is confident these deficiencies will be quickly remedied to avoid any impact on the laboratory's license."

Public Access to Report

A third question asked when the final report would be available to the public. In response, CDPH said, "The report will be made available mid-March [of 2021] once PerkinElmer has had a chance to respond to the deficiencies and LFS has had the opportunity to review the responses."

There does not appear to be a report on the website that shows how PerkinElmer responded to the deficiency reports.

CDPH's online updates also noted the first inspection of the lab was done on Dec. 8 and 9, 2020, meaning it was completed within the first few weeks of the lab's opening.

In addition, the update noted that the CDPH's Laboratory Field Services wrote a report and had an exit conference with lab leaders on Feb. 17, 2021, and had asked those lab managers to respond to the written report two days later.

The update also noted that PerkinElmer had sought accreditation from the College of American Pathologists "so that Californians have no doubt about the quality of the services at the laboratory."

The Valencia Branch Laboratory had its initial accreditation inspection on Feb. 19, 2021, and state officials announced that the CAP inspected the lab one month later. After those inspections, the lab received full accreditation, CDPH announced.

The CAP did not respond to requests for comment from THE DARK REPORT.

The question of whether politics played any role in determining the lab's

compliance with the CLIA regulations is worth asking for several reasons.

First, as Watts reported on Nov. 22, "CDPH issued a summary that downplayed the findings and misconstrued some whistleblower allegations." When *CBS13* broadcast its report, Watts noted that the actual inspection records told a different story from the one CDPH noted in its summary.

Unanswered Questions

Second, the California state inspection reports raise questions about VBL that have gone unanswered. One of the most significant unanswered questions is how VBL staff brought the lab into compliance after the initial state report noted the lab's severe deficiencies. Another is whether the inspectors confirmed the whistleblower allegations that Watts reported.

Third, why have state officials never publicly revealed that a team of inspectors from CMS inspected the lab in May 2021?

Fourth, most lab directors know that the official title of the CMS 2567 report is "Statement of Deficiencies and Plan of Correction (POC)" because these reports list the deficiencies on the left side of each page and require lab officials to provide a plan to correct each failure on the right side. The two CDPH reports use the same format, raising the question of why there has been no public record to date that the VBL officials have provided plans of correction for the 61 deficiencies inspectors identified in the two state reports.

CMS said it inspected the lab in May 2021. In response to a question from THE DARK REPORT, a CMS spokesperson sent a copy of the 21-page CLIA inspection report dated May 6, 2021, showing 12 deficiencies.

When asked if CMS received a response from the VBL about the deficiencies that the agency's CLIA inspectors cited in the May 6, 2021 report, a spokesperson told THE DARK REPORT on Feb. 4, 2022, "Yes, CMS received a response. However, CMS has not made a determination regarding the approval of the CDPH VBL's allegation of compliance and is not able to release additional details at this time."

CDPH told THE DARK REPORT that CMS certified the Valencia Branch Laboratory as fully compliant on Feb. 28, 2022. TDR

TV News Reports Show Extent of VBL's Problems

DURING A 30-MINUTE SPECIAL REPORT on Dec. 30, 2021, Julie Watts, an investigative reporter for television station *CBS13* in Sacramento, Calif., broadcast a full run-down of her coverage of the state's COVID-19 testing site, Valencia Branch Laboratory (VBL). The title of the report was "The COVID Lab: State Secrets Exposed."

"Over the past year, this investigation gave a voice to brave whistleblowers who risked their careers in the interest of public health, and it shined a spotlight on shocking public health failures, which it appeared the California Department of Public Health [CDPH] tried to hide," Watts noted.

"CBS Sacramento conducted dozens of interviews with whistleblowers and lab experts, submitted hundreds of public records requests, and reviewed thousands of pages of internal lab documents," she said. "Still, public health officials tried to discredit the reporting, and whistleblower complaints, even after their own inspectors confirmed the findings."

In addition, regulators concluded that the lab posed immediate jeopardy to patient health and safety likely to cause serious injury, harm, or death, "but CDPH didn't warn the public, or even pause testing, as problems continued for nearly a year," she added.

It should be noted that the term "immediate jeopardy" does not appear in the two Form 2567 reports that state inspectors issued, or in the federal CLIA inspection report.

Labs Use IoT Tools for Specimen Logistics

For Interpath Laboratory, tech improves tracking of specimens and offers new quality measures

Brad Ruffkess

CEO SUMMARY: Internet of Things (IoT) devices have proven adept at managing logistics, and BoxLock uses the technology to help clinical labs and pathology groups monitor pre-analytic specimen collections. Interpath Laboratory also has found IoT tools to be beneficial in providing greater accountability during specimen pickup and improving customer service.

THERE MAY BE NO GREATER RISK TO CLINICAL LABORATORY CUSTOMER SERVICE than a specimen that goes missing on the way to a lab. The problem raises questions about ineffective processes, inconvenienced patients, and delays getting test results to the referring physicians.

To prevent these problems in the pre-analytic phase, some medical laboratories and anatomic pathology groups are turning to Internet of Things (IoT) devices to collect and track data on lab-bound blood and tissue samples.

IoT refers to the idea of interconnected tools that use the internet to stay in touch with each other in real time. The technology has proven useful in logistics environments, such as lab specimen collection, because it uses data to fill in areas of uncertainty along a supply chain.

"The space between taking a specimen and the point it arrives at the lab is often like a black box," said Brad Ruffkess, CEO and founder of **BoxLock**. "The loss of lab specimens correlates with increased healthcare costs and timeliness in receiving the specimens at the lab." Ruffkess was speaking at the 2021 *Executive War College*, in the session "Internet of Things Comes to Clinical Laboratories: Using a Smart Lockbox to Improve the Integrity of Specimens from Client to Lab, While Documenting Time, Temperature, and Other Factors."

IoT Tracks Specimen Data

BoxLock, an Atlanta-based company founded in 2017, offers supply chain access and control devices to healthcare, aviation, and other industries. It serves clinical laboratories with a pre-analytical specimen logistics solution using IoT devices that connect to each other and with systems over the web to provide data.

The company is named for its bright yellow smart locks, which labs can attach to any brand of specimen container. As IoT devices, the locks are embedded with barcode scanners and use cellular connectivity to exchange data with other systems and devices.

Additionally, the BoxLock platform offers access control, inventory information, and route management. Integration over cellular networks for environmental conditions in the specimen container during transport is accomplished via Bluetooth sensors. Related data is available to labs in real time in the cloud.

The idea behind this specific IoT technology is to keep blood and tissue specimens secure and monitored from the time they are placed in the container and picked up by a professional driver to when they arrive at the lab for accession, test performance, and reporting. "In healthcare, there is a huge focus on specimen control," Ruffkess said.

With BoxLock and similar IoT platforms, lab staff can review the full chain of custody of a specimen, from the time it is placed in a collection box to when the specimen is accepted by the lab.

"It's detailed and quality information," Ruffkess noted. "The lab gets a robust picture of the quality of specimens."

These statistics suggest more reasons why labs may want to consider a specimen logistics solution, according to BoxLock:

- More than 13 billion specimens are collected annually in the U.S., according to pre-pandemic data from the **American Association for Clinical Chemistry**.
- Pre-analytic errors may account for up to 87% of lab errors, as documented in a 2017 case study published by the **U.S. Agency for Healthcare Research and Quality**.
- The loss of just one specimen costs a lab an average of $548, according to a 2016 study done by **Northwell Health** in New Hyde Park, N.Y., as reported by *Medscape Medical News*.
- More than 30% of lab pick-ups by drivers have no specimens in the containers, increasing costs, according to BoxLock customer and partner data.

Lab-Bound Specimens

Those numbers illustrate the direct and indirect costs that can occur during the transport of specimens to the laboratory. "There is substantial risk during that pre-analytic time, even if the number of errors or mishaps is not high. It's where errors can and do occur," Ruffkess added.

"The BoxLock product records the time specimens were placed inside a container, notes how many specimens are present, and alerts drivers if no specimens are to be picked up," he explained. "Use of this type of data benefits labs through escalated customer service, improved test turnaround time, and potential decreases in logistics costs of up to 30% if previously wasted stops are eliminated."

Interpath Lab's Success

Interpath Laboratory in Pendleton, Ore. has been using BoxLock for about one year with goals of tracking processes better and gaining more insights and data about its extensive routes and specimen transport. The privately-owned clinical and anatomic pathology lab has a fleet of more than 100 vehicles covering more than 10,000 miles daily.

Interpath has a wide network of patient service centers and testing facilities in addition to its main lab in Pendleton. It also works with physician offices, hospitals, and other providers.

"My task is to make sure we do not lose samples," said Tyler Kennedy, Logistics Manager at Interpath and its sister consulting company **Adaugeo Healthcare Solutions**. "We're good about picking up samples from our locations because we know what samples are produced at that location. But when it comes to going to a client's office, if we don't interact with them before the pick-up, we're pulling specimens out of the box and hoping for the best with the samples.

"If a client says, 'We put out five specimens at 5 p.m.' and we come by at 5:30 p.m., we expect to pick up five samples. If there's discrepancy, we have to figure out why the sample is missing," he added.

Working with BoxLock allows Interpath to provide more accountability in specimen collection processes, including any gaps in service. "The majority of time when five samples go in a box, five samples come out," Kennedy observed. "Sometimes a sample remains inside, and

How IoT Connectivity Helps Clinical Laboratories Monitor and Streamline Logistical Workflows

CONNECTIVITY PROVIDED BY IOT DEVICES can be used by labs to monitor lab environments, instruments, and inventory as well as streamline workflows, and "provide assurance that equipment and processes are running smoothly," according to *Labcompare*, an online buyers guide for lab equipment.

"IoT devices collect data about the physical world and make [this] data available in the cloud," said Brad Ruffkess, CEO at BoxLock. "When a driver walks up to the box, BoxLock enables scanning of the specimens. The driver will already know how many specimens are expected inside the box," he explained.

Here's how the IoT devices operate:

- Devices: Locks are integrated with barcode scanners and include real-time connectivity to protect and track assets worldwide. They work with Wi-Fi, cellular connectivity, and Bluetooth for environmental sensors. No software application download is required.
- Platform: Software features include access control, audit logs, and inventory management.
- Tools: Cloud-based application programming interface (API), real-time notifications, and software development kits (SDKs) that support a lab's workflow are among the options labs can use.

Access to the data is possible from a hand-held device, employee badge, or barcode on the specimen label. Also, route management features from BoxLock can integrate with a laboratory information system.

"We can do an automated pick-up request at the time a specimen is scanned in. BoxLock can also send notifications to a clinic or practitioner to inform them that the lab's cut-off time is approaching.

"So, for example, if the lab hasn't seen a specimen by 2 p.m., and the cut-off time is 3 p.m., the clinic will receive a one-hour warning to prevent them from missing the opportunity to have the lab pick-up within the confines of that day," Ruffkess explained.

when that happens, we know we have corrective actions we can take. Our clients have more trust in us knowing we are able to grab that data. It gives us better service to roll out. We can say to clients, 'We have quality measures that we're working on.'"

Environmental Monitoring

For environmental monitoring of specimens, BoxLock partners with **Parsyl**, a Denver-based insurer of supply chains and provider of single-use temperature trackers and long-lasting multi-sensors. The single-use trackers help monitor critical specimens, Ruffkess noted.

IoT devices from BoxLock and Parsyl integrate to monitor and protect specimens from decreasing in quality due adverse weather conditions, for example.

"We use cellular connectivity on locks and Bluetooth sensors to read environmental conditions within the specimen box. The devices capture the current environment and log each time that box or specimen has crossed thresholds. From the time the box was opened until the courier picked it up and it arrived back to the lab, we know what the conditions of shipment were like," he said.

Clinical laboratories looking to gain an edge on competitors while also protecting their clients should consider IoT and other data-rich technologies that improve security and monitoring of specimens during collection and transit. TDR

Contact Brad Ruffkess at 678-800-1269 or bar@getboxlock.com; Tyler Kennedy at tylerkennedy@adaugeohealthcare.com.

Seven Doctors Settle Lab Test Fraud Case

In Texas, seven doctors and a hospital CEO will pay a total of $1.1 million in lab fraud case

CEO SUMMARY: In January, a U.S. Attorney from East Texas announced that seven physicians and a hospital CEO had agreed to settle allegations of fraud involving the payment of bribes in exchange for lab test orders. This is a positive development for the clinical laboratory profession because it demonstrates that the federal Department of Justice is willing to prosecute doctors who accept bribes and illegal inducements in exchange for ordering clinical laboratory tests.

It takes two parties to violate the federal Anti-Kickback Statute (AKS): one party to pay the illegal inducement and one party to accept it. Yet the majority of actions federal prosecutors bring against lab companies for violating the AKS seldom include charges against the physicians who accepted the illegal bribes.

Seven Doctors Were Indicted

However, that is not what happened in a recent federal court case involving laboratory testing and illegal kickbacks. Seven physicians faced charges for accepting illegal inducements and agreed to pay restitution. A notable element in this case is the role of management service organizations (MSOs) as a vehicle for the alleged fraud.

The case, filed in federal court in Texas, involved the CEO of a multi-hospital health system and the seven physicians. Collectively, the defendants agreed to repay $1.1 million to the federal government to settle allegations of kickbacks related to clinical laboratory test orders, the **U.S. Department of Justice** (DOJ) announced on Jan. 20.

Another fact that makes this case noteworthy is it includes several types of healthcare fraud schemes involving clinical lab test orders that sprouted during the decade of the 2010s and continue into the present. One example is the pass-through lab billing scheme that uses a rural or small hospital to bill for substantial volumes of lab tests originated in multiple states outside that hospital's community. *(See TDR, "Mississippi Blue Cross Sues Hospital, Tox Labs," June 5, 2017, and "Why Lab Companies Buy Broke Rural Hospitals," May 29, 2018.)*

MSOs as Vehicles for Fraud

Another example is the use of Management Service Organizations by some lab companies. The labs recruit physicians to be owners and members of the MSO who earn payments or dividends paid through the MSO that are directly linked to the volume of lab tests they referred to the participating labs. *(See TDR, "Lab Fraudsters Recruit Hospitals to Bill as In-Network Providers," Oct. 30, 2017.)*

All of these elements are present in the federal case in Texas that was settled

in January. The doctors received tens of thousands of dollars from 2015 through 2018 from eight management service organizations in exchange for ordering clinical laboratory tests from **Little River Healthcare**, which ran several hospitals and clinics in southeast Texas. Little River closed in 2018.

Volume-Based Commissions

Little River funded the illegal remuneration to the doctors in the form of volume-based commissions paid to independent contractor recruiters, who then used MSOs to pay numerous physicians for their referrals, according to the **U.S. Attorney's Office of the Eastern District of Texas**. The accused agreed to pay back about $1 million to settle the allegations.

In a related investigation, Richard DeFoore, the former CEO at **Stamford Memorial Hospital** in Stamford, Texas, will pay back $50,000 for his role in an alleged scheme with **True Health Diagnostics** in Frisco, Texas, and **Boston Heart Diagnostics** in Framingham, Mass. True Health filed for bankruptcy in 2019. *(See TDR, "After Two-Year Battle with CMS, True Health Diagnostics on Verge of Collapse," August 12, 2019.)*

Illicit Lab Test Billing Scheme

Prosecutors said DeFoore and the two companies entered into arrangements in 2015 and 2016 for the hospital to profit from illicit billing of diagnostic lab tests. In addition to the monetary settlement, DeFoore is barred from participation in federal healthcare programs for three years.

The Dark Report previously detailed some of the legal issues behind these cases, revealing that a lab company paying for packaging and handling of patients' specimens could be liable for filing false claims. *(See TDR, "Federal Judge Rules 'Pull-Through' Is Illegal Inducement in Boston Heart Case," Oct. 1, 2018.)*

The DOJ settlements with the seven Texas doctors who agreed to settle "False Claims Act allegations involving illegal remuneration in violation of the Anti-Kickback Statute and Stark Law" can be useful to lab administrators, pathologists, and lab sales representatives.

For example, when visiting their client physicians, sales reps for hospital laboratory outreach programs often hear the physicians tell them about various forms of inducements and remuneration that sales reps from certain labs will offer them—forms of remuneration that are clearly illegal.

When told that those inducements potentially violate federal laws—such as the Anti-Kickback Statute—there are physicians who will answer, "I don't believe it and I don't have any colleagues who have been prosecuted by the federal government for accepting money in exchange for ordering lab tests."

DOJ Will Charge Doctors

In such situations, the hospital lab outreach sales reps would find it helpful to show those doctors this and similar stories in The Dark Report which describe federal prosecutors winning criminal convictions and civil settlements from physicians who accepted illegal bribes in exchange for referring lab tests.

Criminal prosecutions of physicians who violate state and federal laws are intended not just to punish the lawbreaker, but to deter others from commiting similar criminal acts. That is why it can benefit sales reps from law-abiding clinical laboratories to educate physicians in their communities that federal prosecutors are indicting doctors for accepting bribes from labs.

News stories about these indictments are powerful evidence that physicians who take these illegal payments from labs can find themselves indicted by the DOJ.

In the following story on pages 16-18, we provide the names of the seven Texas physicians and the Department of Justice description of their alleged acts that violate the AKS. TDR

Why the Management Services Organization May Be Healthcare's "Scam of All Scams"

DURING THE DECADE OF THE 2010S, AN INTERESTING HEALTHCARE FRAUD MODEL EMERGED and became surprisingly widespread, particularly in certain states, including Texas. This fraudulent scheme used the MSO—management service organization—as the vehicle that enabled organizers to enlist willing physicians to refer them a healthcare service, such as lab tests, in exchange for inducements that violated the federal Anti-Kickback Statute and the Stark Law.

THE DARK REPORT picked up this scheme by the second half of the 2010s. The story of how MSOs turned into a useful vehicle for healthcare fraud starts after passage of the Affordable Care Act of 2010 (ACA, also called Obamacare). Just as the ACA required health insurers to include mental health benefits and drug rehabilitation services in their health plans (thus creating the huge fraud and abuse seen in the pain management and drug rehab sector in the following years), the law also created a new fraud opportunity that was quickly spotted by scamsters.

Fabulously Profitable

This fraud centered around orthopedic implants and similar medical devices. It was fabulously profitable to the organizers. The scheme was simple and followed these steps:

- Organizers would create an MSO, primarily using an LLC.
- Doctors would buy shares in the MSO, typically $15,000 to $25,000. There would be no more than 10 to 20 doctors in each MSO, and the paid-in capital enabled them to share in the MSO's profits.
- MSOs could buy orthopedic appliances directly from the manufacturers at wholesale prices. The MSO could then sell the appliances to the MSO's physicians at retail prices (which were reimbursed by the health plans).
- The fraudsters, in their roles as the MSO's general partner, would then pay "dividends" to the physicians, proportionate to the volume of service referrals they generated.

This fraud was so rampant that by about 2014, Office of Inspector General opinion letters and changes in state laws shut down the "MSO as orthopedic device wholesaler" scheme. That caused the fraudsters to look around at another healthcare service that could be run through an MSO. Lab testing fit the bill.

Many MSOs in Texas

In Texas, THE DARK REPORT became aware of a number of MSOs handling lab tests that had the referring physicians as shareholders. Also, by the second half of the 2010s, health insurers like **Aetna** were filing lawsuits in Texas against some of the most egregious schemes, and the court documents described these illegal arrangements in great detail.

In fact, these MSOs were cash generating machines for the scamsters. First, the organizers would sell shares to, say, 10 doctors, who each invested $20,000. That gave the fraudsters $200,000 in cash, with no upfront costs! Lawsuits filed by health insurers described defendants who organized as many as 30 of these MSOs. That put $6 million in their pockets before they even ran lab tests through the MSOs!

The MSOs would commonly pass the tests referred by their shareholder doctors to a rural hospital that would bill under its contracts with payers. Because rural hospitals were allowed to charge health plans more for lab tests, the pass-through billing arrangement allowed the fraudsters and physician shareholders in the MSO to reap huge profits.

Lab Legal Update

Federal Prosecutors Describe Illegal Lab Bribes to Physicians

Pathologists and clinical lab managers should welcome every federal prosecution of a physician who accepts illegal bribes and inducements in exchange for laboratory test referrals. If physicians understood that federal prosecutors would file criminal charges against them for this behavior, fewer doctors would engage in fraudulent schemes involving lab test referrals.

As explained in the previous story on pages 13-15, federal prosecutors filed criminal charges against seven physicians and a hospital CEO in Texas for receipt of bribes and illegal inducements based on the physicians' referral of clinical laboratory tests, which violated the False Claims Act and the Anti-Kickback Statute.

The fact that physicians who accepted bribes from clinical laboratory companies in exchange for test referrals were prosecuted by the federal **Department of Justice** (DOJ) is a positive development for the clinical lab industry.

Bribe Requires Two Parties

Every scheme to induce the referral of a clinical lab test in return for a bribe or illegal inducement requires two parties: a lab to offer the bribe and a physician willing to accept the bribe.

Unfortunately, the prosecutors from the DOJ have a long-established track record of filing criminal charges against the lab companies paying these illegal inducements, while seldom taking the additional step of filing charges against the doctors who accept the illegal bribes.

For this reason, many physicians believe they have little risk of federal prosecution. More importantly, these same physicians can become "serial participants" in the inducement schemes offered by multiple labs.

A good example of this is cardiologists who accepted illegal inducements from now-defunct **Health Diagnostic Laboratories** (HDL) of Richmond, Va. Once HDL went out of business, many of these cardiologists followed some of the same lab managers and lab sales reps to **True Health Diagnostics** of Frisco, Texas, and continued to accept allegedly illegal inducements from True Health until it filed bankruptcy in 2019.

Restitution of $1.1 Million

In the Texas case, a total of $1.1 million in restitution will be paid by seven doctors and a hospital CEO. Details of the settlements with the doctors in this case are presented below.

Laboratory sales reps will find this information useful for sharing with their client physicians to demonstrate that there truly is a risk of criminal and civil charges for physicians willing to refer large volumes of often medically-unnecessary laboratory tests in exchange for an illegal payment or bribe.

In a press release datelined Jan. 20, 2022, Sherman, Texas, the federal Department of Justice announced settlements in a criminal case that centered on "False Claims Act allegations involving illegal remuneration in violation of the Anti-Kickback Statute and Stark Law."

Reproduced below is the DOJ's description of the settlements with the physicians who were charged in this case:

The settlements announced today resolve allegations that seven Texas doctors received thousands of dollars in illegal remuneration from eight management service organizations (MSOs) in exchange for ordering laboratory tests from ***Rockdale Hospital d/b/a Little River Healthcare*** *(Little River),* ***True Health Diagnostics LLC*** *(True Health), and* ***Boston Heart Diagnostics Corporation*** *(Boston Heart).*

Little River allegedly funded the illegal remuneration to the doctors, in the form of volume-based commissions paid to independent contractor recruiters, who used MSOs to pay numerous doctors for their referrals. The MSO payments to the doctors were allegedly disguised as investment returns but in fact were based on, and offered in exchange for, the doctors' referrals.

- *Jaspaul Bhangoo, MD [internal medicine], of Denton, Texas, agreed to pay $125,625 to settle allegations that (a) True Health paid him kickbacks from January 1, 2015 to December 1, 2015; and (b) True Health referred him to an MSO, established by Little River marketers, which paid him MSO kickbacks from June 14, 2016 to September 16, 2016.*
- *Robert Megna, DO [clinical lipidologist], of Ferris, Texas, agreed to pay $232,000 to settle allegations that from February 2, 2016, to December 31, 2017, he received kickbacks from (a) one MSO,* ***Ascend MSO of TX, LLC****, in exchange for ordering Boston Heart laboratory tests from Little River; and (b) another MSO,* ***Geminorium MG LLC****, in exchange for ordering laboratory tests from Boston Heart.*
- *Baxter Montgomery, MD [cardiology], of Houston, Texas, and his professional association B-Saz, P.A., agreed to pay $60,000 to settle allegations that from December 29, 2015, to February 3, 2018, he received kickbacks from (a) one MSO, Ascend MSO of TX, LLC, in exchange for ordering True Health laboratory tests from Little River; and (b) another MSO,* ***Indus MG LLC****, in exchange for ordering laboratory tests from True Health.*
- *Murtaza Mussaji, [internal medicine], of Houston, Texas, agreed to pay $215,000 to settle allegations that from August 7, 2015, to November 14, 2017, he received kickbacks from (a) one MSO,* ***SYNRG Partners LLC****, in exchange for ordering True Health laboratory tests from Little River; and (b) another MSO,* ***Catalyst Health Partners LP****, in exchange for ordering laboratory tests from True Health.*
- *David Sneed, DO [family medicine], of Austin, Texas, agreed to pay $200,000 to settle allegations that from September 30, 2015, to December 23, 2016, he received kickbacks from an MSO,* ***Alpha Rise Health LLC****, in exchange for ordering True Health and Boston Heart laboratory tests from Little River.*
- *Kevin Lewis, DO [family medicine], of Houston, Texas, agreed to pay $57,324 to settle allegations that from June 24, 2015, to April 20, 2016, he received kickbacks from an MSO, Alpha Rise Health, LLC, in exchange for ordering Little River and Boston Heart laboratory tests.*
- *Angela Mosley-Nunnery, MD [family medicine], of Kingwood, Texas, agreed to pay $166,500 to settle allegations that from April 12, 2016, to June 14, 2018, she received kickbacks from one MSO,* ***North Houston MSO Group, Inc.*** *and another MSO,* ***Tomball Medical Management****, in exchange for ordering laboratory tests from Little River and True Health.*

Hospital CEO's Settlement

Along with settlements with these seven doctors, the U.S. Attorney also settled with a former CEO of a small hospital in Texas.

Details in the court documents indicate that the alleged fraud used a pass-through billing arrangement whereby lab tests originated elsewhere were billed by the hospital using the higher lab test prices it had with various health plans.

In the Jan. 20 press release issued by the U.S. Attorney, titled, "Seven Texas Doctors and a Hospital CEO Agree to Pay over $1.1 Million to Settle Kickback Allegations," the DOJ described its agreement with the ex-hospital CEO:

> *...the United States announced a settlement with Richard DeFoore of Anson, Texas, the former Chief Executive Officer of* ***Jones County Regional Healthcare*** *d/b/a* ***Stamford Memorial Hospital*** *(Stamford), which was a small hospital [of 25 beds] in Stamford, Texas. In late 2015 and early 2016, DeFoore allegedly was approached by representatives of True Health and a partner company, who proposed an arrangement by which Stamford could profit by billing for diagnostic laboratory tests. Under the arrangement, which expanded to include Boston Heart tests, Stamford allegedly coordinated with True Health and Boston Heart representatives and paid volume-based commissions to independent contractor recruiters, who used MSOs to make payments to doctors that were disguised as investment returns but in fact were based on, and offered in exchange for, the doctors' referrals.*
>
> *Pursuant to the alleged arrangement, Stamford billed the resulting claims to commercial insurers and True Health and Boston Heart billed the resulting claims to Medicare and other federal healthcare programs. Under the terms of the settlement agreement, DeFoore agreed to pay $50,000, to cooperate with the Department's investigations of and litigation against other parties, and to be excluded from participation in federal healthcare programs for three years.*

Doctors at Risk of Charges

This federal case shows why physicians who accept inducements in violation of the federal Anti-Kickback Statute and the Stark Law are at of risk criminal indictments and civil settlements. Calling the attention of the physician community to the outcomes of these federal prosecutions and settlements may help individual doctors understand the true level of risk they face, should they participate in such arrangements. TDR

Dozens of Doctors Guilty in BDL Case

RECENT SETTLEMENTS IN TEXAS aren't the only examples of physicians indicted by federal prosecutors for fraud involving lab test claims.

One major prosecution of physicians accused of accepting illegal inducements in return for lab test orders was the **Biodiagnostic Laboratory** (BDL) case, filed by federal prosecutors in 2014. Nearly 100 people were charged in the case over the following years, which involved bribes connected to a long-running lab test referral scheme at BDL, based in Parsippany, N.J.

According to details previously released by the U.S. Department of Justice (DOJ), 39 people—including 26 physicians—eventually pleaded guilty to charges in the BDL case. Those convicted admitted to taking millions of dollars in bribes, and the scheme resulted in payments to BDL of more than $100 million from **Medicare** and private insurance companies.

As part of the convictions, the goverment collected $12 million in forfeitures, DOJ previously noted. Health insurer **Aetna** also filed a civil suit against BDL for allegedly submitting false claims for tests. *(See TDR, Sept. 22, 2014.)* This case remains active.

On Oct. 7, 2021, the **New Jersey State Appeals Court** reinstated the case after parts of it had been dismissed by a lower court. Recent arguments have focused on whether Aetna properly stated its legal arguments.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Telehealth proved to be popular with Medicare patients during the SARS-CoV-2 pandemic. The federal **U.S. Department of Health and Human Services** (HHS) reported telehealth visits for Medicare beneficiaries increased in 2020 by an incredible 63 times—from approximately 840,000 in 2019 to 52.7 million! Federal health officials said in a news release that these figures will guide policymaking at HHS as the U.S. enters what appears to be a post-pandemic phase of COVID-19. Lab managers should develop a strategy for their lab to respond to the increased use of telehealth by patients, particularly a 63-time increase in telehealth usage by Medicare beneficiaries.

MORE ON: *Concerns of Post-Pandemic Phase*

Laboratory information systems (LIS) are not meeting the expectations of a sizable amount of lab professionals, and that could have implications as the pandemic winds down, according to results from a new survey by **XIFIN**. For example, more than 30% of respondents said their LIS had gaps in its ability to meet testing needs. XIFIN categorized this finding as "a significant problem, considering the nation is moving to an endemic approach to infectious disease."

ONE-THIRD OF PATHOLOGISTS ARE BURNED OUT

In sobering news, approximately one-third of pathologists describe being burned out on the job. The figures come from a report released by online publisher *Medscape*. Career fatigue seems to be more serious for women in pathology, as 46% of female pathologists reported burnout compared to one-quarter of male colleagues. The most frequent factors for burnout cited by pathologists were too many hours at work (62%), lack of respect from colleagues (49%), and lack of control in life (44%), according to *Medscape*.

ELIZABETH HOLMES SUBJECT OF HULU SERIAL TV SHOW

It seems Elizabeth Holmes, former CEO of **Theranos**, is getting as much attention in disgrace as she did when news media hailed her as a genius entrepreneur comparable to Steve Jobs of **Apple**. Hulu is streaming fresh new episodes of "the compelling drama series 'The Dropout.'" Holmes is portrayed by Amanda Seyfried. For clinical laboratory managers who like to binge watch, four episodes have aired and more are scheduled.

TRANSITIONS

• John Martinson has joined **StatLab Medical Products** in McKinney, Texas, as its new Chief Operating Officer. Martinson was most recently Senior Vice President and Head of Global Operations at **Ascensia Diabetes Care** in Parsippany, N.J. Before that, he was Vice President of Global Product Supply at **Bayer**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 4, 2022.

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*
Senior Editor: Joseph Burns *joeburns@capecod.net*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*
Legal/Compliance Reporter: Kim Scott *kmscott2@verizon.net*

SPECIAL SESSION

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Private Payer Trends in Handling and Payment of Lab Test Claims

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Robert E. Mazer
Senior Counsel, Baker Donelson, Baltimore

Cures Act Payment Issues, Waiver of Coinsurance, Medical Necessity, EKRA, and More

Probably no area of clinical laboratory testing changes more frequently than the requirements used by private health insurers to process lab test claims. That's particularly true for claims involving COVID-19 and genetic test claims. This session provides insights and answers labs need to improve the number of clean claims they submit to generate speedy payment.

It's equally true that the coding, billing, collection departments of labs must understand the multiplicity of federal and state regulations governing how patients are to be billed for lab tests. During this session, attendees will learn key issues associated with waiver of coinsurance, medical necessity, and how to work with payers consistent with Cures Act requirements.

This knowledge means extra dollars for your lab, as well as improved compliance with appropriate federal and state laws. Bring your team and ensure your place by registering today at *www.ExecutiveWarCollege.com*!

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UPCOMING...

- ***Federal judge streamlines arbitration in early No Surprises Act court challenge.***
- ***Intriguing new technologies designed to disrupt phlebotomy and specimen collection.***
- ***Hospital lab outreach program hits home run with services targeting uninsured, under-insured.***