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DOJ To Increase Investigations and Prosecutions of Lab Test Fraud Involving COVID-19 Tests, Opioid Tests
(see pages 10-15.)

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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

Decline in COVID-19 Test Orders Signals a Shift

MIGHT THE FEDERAL HEALTHCARE ESTABLISHMENT BE CLOSE TO DECLARING AN END TO THE SARS-COV-2 PANDEMIC and—given the ongoing decline in the daily number of new cases and deaths—that COVID-19 is expected to become an endemic disease?

The SARS-CoV-2 statistics posted daily by the federal **Centers for Disease Control and Prevention** (CDC) show that, as of March 31, the seven-day moving averages for these factors were:

- 28,670 for new COVID-19 cases.
- 605 for COVID-19 deaths.
- 597,424 for COVID-19 test volume.

The last time all three of these factors were at comparable levels was on July 15, 2021. Another relevant statistic is that the current positivity rate for COVID-19 tests is 2.5%. That compares with a 29.31% positivity rate on Jan. 9 of this year (as the Omicron variant became prevalent) and a 1.74% positivity rate as of June 17, 2021.

Epidemiologists point out that the history of pandemics indicates they can last from 18 to 30 months. One can look at the daily national statistics reported by the CDC to see how they support the assertion that the pandemic is ending and possibly evolving into an endemic disease.

The economics of COVID-19 testing are compelling. Employers, school districts, universities, and colleges will not want to continue to bear the expense of frequent COVID-19 testing if the statistics show that a testing program is not delivering benefits. At the same time, to be fair to public health officials, the number of hospitalized COVID-19 patients remains a concern, as the daily number of COVID-19 deaths have not declined at the same rate as the daily number of new COVID-19 cases.

On page 6, we report on the State of California's decision to cancel its contract with **PerkinElmer** to operate the **Valencia Branch Laboratory**—built in 2020 specifically to do COVID-19 testing. This announcement suggests state officials may recognize that federal funding for such tests is coming to an end. Clinical laboratory administrators and pathologists may want to reassess their own lab's COVID-19 testing programs in light of these developments. TDR

Calif. LFS Agency Problems Deepened Valencia Saga

Effectiveness of Laboratory Field Services unit was previously questioned by California state auditor

CEO SUMMARY: ***Adding a new twist in the ongoing saga of the CLIA compliance failures at the Valencia Branch Laboratory in California are insights from a former clinical laboratory director familiar with the industry in California. He observed that problems at California's Laboratory Field Services (LFS) office are known to the state legislature, following an audit of LFS conducted by the California State Auditor's Office in 2015.***

Is it a conflict of interest when a state-owned COVID-19 testing laboratory is inspected by the same state's department of health, yet is allowed to continue testing patients despite the findings of serious CLIA deficiencies, including deficiencies that expose patients to "immediate jeopardy"?

This is one of the serious questions surrounding the State of California's operation of its **Valencia Branch Laboratory** (VBL), a large clinical lab facility built and operated by **PerkinElmer** to perform COVID-19 tests. It opened in the fall of 2020 and news reporters quickly began publishing stories about serious problems within the lab. Lab whistleblowers were the source of this information, including a whistleblower who was one of the first laboratory directors at VBL. *(See TDR, "Whistleblowers Disclose Issues in Calif.'s Valencia COVID-19 Lab," Mar. 1, 2021.)*

As The Dark Report previously noted, each chapter in this unfolding saga has left many lab administrators curious as to how VBL remained open after inspections turned up deficiencies that put patients in immediate jeopardy. *(See TDR, "Questions Remain about California's Valencia Lab," March 14, 2022.)*

"I believe that the biggest flaw that this project exposed is the idea that the California governor decided that it was necessary for the state government to get into the clinical laboratory business in competition with private enterprise," commented a pathologist and former lab director in California who asked not to be named.

Any discussion about VBL inevitably leads back to California Gov. Gavin Newsom, who proposed the idea for the state-funded laboratory to increase the daily volume of COVID-19 tests. Newsom

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authorized the state to sign a no-bid contract—worth as much as $1.7 billion—with PerkinElmer in Waltham, Mass., to build and operate the clinical laboratory.

"That fact alone emphasizes the problems that can arise when government runs a business enterprise in which it has no experience or expertise," the former lab director told THE DARK REPORT.

State Inspection Questions

Based on his extensive experience in the lab industry in California, the former lab director offered strong opinions about possible weaknesses in the **California Department of Public Health's** (CDPH) Laboratory Field Services (LFS) unit, which inspects clinical laboratories.

The LFS and CDPH have taken heat in the VBL situation because few details have been released about exactly how VBL corrected serious deficiencies after state inspections uncovered them.

"The Valencia Branch Laboratory underwent multiple thorough inspections by both Laboratory Field Services and the **College of American Pathologists**," CDPH's press office told THE DARK REPORT previously. "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."

LFS has a recent history of its effectiveness being questioned. In September 2015, the California State Auditor's Office issued a report that concluded LFS was unable to oversee clinical laboratories effectively but that alternative approaches were available for LFS to take.

14 Recommendations

The auditor's report made 14 recommendations to the state legislature and CDPH as to how to address the problems as LFS. Eleven of those have been fully implemented, while three remain partially complete after years of delays, as follows:

- LFS to address staffing issues by preparing a recruitment and retention proposal and succession plan, and by implementing a planned reorganization.
- LFS to ensure its information technology and data systems have all necessary safeguards, contain accurate and complete data, and support its program needs.
- LFS to ensure it can provide effective oversight of labs by updating its regulations to ensure consistency with existing state law.

The latest deadline for these corrections is winter of 2022, according to a Sept. 2021 update from the state auditor.

"One of the problems we've seen in California is that the departments that do the inspections of clinical laboratories often are poor-performing bureaucracies," the former lab director said.

Months for LFS to Reply

He also complained that when other clinical lab directors have called LFS with urgent questions, it can take months to get a reply. In addition, LFS can be months behind clinical laboratory license renewals, he added.

"It's been that way for many years," he said. "What that means is that when a lab is cited for being in immediate jeopardy of harming patients, it will still take a long time for that report to get released to the public."

Long waits for responses from CDPH lab staff and for state lab inspection reports about VBL stand in contrast to a renewal of the agreement to operate the state lab. In October 2021, the contract automatically renewed with PerkinElmer for $1.7 billion, according to *CalMatters*, a nonprofit news organization.

"That contract appeared to get renewed almost automatically," the former lab director commented. "Essentially, the CDPH was sweeping its own findings of immediate jeopardy under the rug."

As THE DARK REPORT and other publications have reported over many years, when CMS or state officials issue an inspection report that cites a lab for imme-

diate jeopardy of patient harm, those deficiencies need to be fixed within a matter of days or sometimes weeks. "There's no way a lab with patient safety issues would be allowed to operate for months without addressing those deficiencies," the former lab director noted.

Deficiencies at Theranos

The inspections at ill-fated **Theranos** offer a case in point. In December 2015, CMS conducted a CLIA inspection at the Theranos lab in Newark, Calif. Inspectors found serious deficiencies, including some that put patient safety in jeopardy.

On March 18, 2016, CMS notified Theranos' executives of sanctions that could include revoking the lab's CLIA certificate, imposing fines of $10,000 per day, suspending or canceling the lab's approval to receive Medicare payments, and imposing a two-year ban on the owner and laboratory director. *(See Dark Daily, "CMS Notifies Theranos of CLIA Sanctions That Include Revoking Clinical Laboratory's CLIA License and a Two-Year Ban on Holmes, Balwani, and Dhawan," April 14, 2016.)*

"Theranos was cited for being in immediate jeopardy of patient harm and had to fix the problems that CMS found right away," the former lab director commented. "After Theranos fought those findings and didn't fix the problems in time, CMS shut down the lab."

Valencia Lab Still Operates

VBL was cited for significant deficiencies, but the lab still operates under a contract with the state, he added.

"Somehow the Valencia lab is continuing to operate because CDPH's Laboratory Field Services section decided that the lab had fixed the problems—at least in the view of CDPH," he said. "And those problems were fixed at about the same time as the lab contract renewal. All of that history raises the question of what the state and federal inspectors are doing, if anything, about the Valencia lab."

Was Valencia Branch Lab a Success or Failure?

IT TURNS OUT THAT THE STATE OF CALIFORNIA WAS PAYING PERKINELMER $37.78 per COVID-19 PCR test, according to a study conducted and published by *CalMatters*, which describes itself as a "non-profit, non-partisan newsroom."

CalMatters wrote that California "then charges schools $21 and community organizations $55 per test." For comparision, *CalMatters* noted that an independent lab company in California, **SummerBio**, was charging $12 per COVID-19 test to the **Los Angeles School District**. *CalMatters* also provided useful insights into COVID-19 test pricing in California, as follows:

*According to [L.A. Unified] district documents, 22 companies were evaluated through an expedited bidding process and SummerBio offered the lowest price by far, between $38 and $166 less than other diagnostics companies, including major players like **Curative** and **Fulgent**.*

The state paid PerkinElmer about $740 million for testing in the past year. Most of the cost is recouped through federal funds and health insurance payments, according to the state health department. In contrast, LA Unified is projected to spend $350 million for the entire school year, and tests far more people per week than the Valencia lab. The district will also recoup the costs through federal school reopening grants and federal emergency funds.

It appears that the ongoing cloud over the quality and reliability of the Valencia Branch Laboratory's COVID-19 test results is about to become moot. On March 31, PerkinElmer announced in a filing that the State of California had terminated its contract to run the VBL. Details of this development follow on page 6. TDR

Lab Market Update

PerkinElmer Says California Terminated COVID-19 Contract

Company's tenure operating the controversial Valencia Branch Laboratory will end May 15

According to a new securities filing from **PerkinElmer**, the **State of California** served notice of termination of the company's contract to run the beleaguered **Valencia Branch Laboratory** (VBL).

PerkinElmer, a diagnostics firm based in Waltham, Mass., made the surprising announcement about the early termination on March 31 in a filing to the **U.S. Securities and Exchange Commission**.

"PerkinElmer, Inc. (the Company) has been notified by the **California Department of Public Health** (CDPH) that due to the decrease in COVID cases and the related need for testing, the CDPH intends to end its contract with the Company for the supply and operation of the Valencia Branch Laboratory," PerkinElmer wrote in its filing. "The discontinuation of the Company's operation of the Valencia Branch Laboratory for CDPH will take effect on May 15, 2022."

Contract Is Worth $1.7 Billion

PerkinElmer entered into a $1.7 billion agreement to operate the VBL in October 2020, which was when the new COVID-19 testing laboratory opened. The contract automatically renewed for the same amount in October 2021.

That renewal was mired in controversy, however, after a series of clinical laboratory inspections earlier in the year uncovered dozens of deficiencies, some of which placed patients in immediate jeopardy, according to regulators. (*See the related story on page 3.*) The situation was further muddied because CDPH was slow to publicly release reports about the inspections. Even now, details about how the VBL addressed the deficiencies remain scant.

It is not immediately clear if the State of California will continue to operate the Valencia Branch Lab after May 15. It is also unknown whether the controversy about CLIA deficiencies at the the state-owned clinical laboratory had any influence on the decision to end the contract. As of presstime, the CDPH had not responded to questions from THE DARK REPORT.

Financial Consequences

Any financial repercussions due to the contract ending won't be disclosed until PerkinElmer's second fiscal quarter closes at the end of June. "The Company reiterates that it continues to expect COVID-related revenue of at least $400 million in the aggregate in 2022, and will provide a further update on its first quarter 2022 earnings call," stated PerkinElmer in its SEC filing. It is not clear how much, if any, of the outstanding contract amount will be paid to the company.

Investor site *Seeking Alpha* said the news is a financial blow to the company. "The setback comes at a time [when] PerkinElmer's quarterly earnings beats have gradually dropped from a peak in 3Q 2020. In 2021, the company reported $1.6 billion of COVID-related revenue."

The ongoing decline in the daily number of COVID-19 lab tests performed in the U.S. means other labs are generating less revenue for COVID-19 test claims. TDR

Judge Vacates Provision in No Surprises Act

New court ruling in Texas makes arbitration process easier to manage during payment disputes

Charles Dunham IV

CEO SUMMARY: ***It did not take long for providers to go to court to challenge the new federal No Surprises Act. A district court judge has vacated a provision in the No Surprises Act that emphasized one criterion during arbitration which put the dispute process in conflict with the wording of the Act. The court ruling resulted in a victory for the Texas Medical Association. For clinical labs, the legal development is a reminder to carefully review their own responses to lab test billing disputes covered under the Act.***

THREE MONTHS INTO THE OFFICIAL ROLLOUT OF THE NO SURPRISES ACT, a court ruling has already vacated a provision in the law's arbitration process. Under that process, providers, emergency facilities, and health plans can resolve payment disputes for certain out-of-network (OON) charges.

For clinical laboratory directors and pathologists, two points are worth noting. First, the ruling—in which a federal judge in Texas listed the criteria for payment disputes—may make resolution requests more straightforward for arbitrators to manage under the No Surprises Act. Second, it's yet another example of a court ruling against a federal law that affects laboratories.

Ruling in Another Court

Last year, a district court judge in Hawaii decided that payments of percentage-based sales commissions to clinical lab sales representatives do not violate the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). The fallout of that decision has not been fully determined, as we reported in our last issue. *(See TDR, "Labs Should Be Cautious about 'Surprising' EKRA Ruling." Feb. 22, 2022.)*

The No Surprises Act aims to protect patients covered under group and individual health plans from getting unexpected medical bills when they receive most emergency and non-emergency services, such as lab tests, from out-of-network providers at in-network facilities.

Arbitration Process

Attorneys following the Texas ruling said it is limited and does not vacate the actual arbitration process, but rather one aspect of it. Further, the day-to-day services of many labs don't even fall under the No Surprises Act.

"It doesn't apply if a patient goes to his or her own primary care physician, or another doctor in the community, and that doctor sends that patient to an out-of-network laboratory," stated healthcare attorney Charles Dunham IV, a shareholder at law firm **Greenberg Traurig LLP** in Houston. "In general, it applies to emergency services or a non-emergency service where the patient is in an inpatient or outpatient setting in a hospital that's in network, and they utilize a lab that's out of network."

The No Surprises Act ruling stemmed from a lawsuit filed by the **Texas Medical Association** (TMA) against the **U.S. Department of Health and Human**

Services (HHS). The TMA argued that the HHS approach to resolving disputes under the No Surprises Act was unlawful.

35-Page Ruling

Judge Jeremy Kernodle from the **U.S. District Court for the Eastern District of Texas** agreed with the TMA. In a 35-page ruling on Feb. 23, Kernodle wrote that the resolution process language conflicts with the requirements of the No Surprises Act. He vacated a small portion of the arbitration clause that put more weight behind the qualifying payment amount (QPA), which is a health plan's or issuer's median contracted rate for a service.

The QPA is among a series of criteria listed for arbitrators to consider when resolving disputes. Other criteria include:

- Level of experience and quality of the provider or facility that furnished the service.
- Market share held by the provider, plan, or insurer in the region in which the service was given.
- Acuity of the patient who received the service.
- Scope of services at the facility.
- Demonstration of good-faith efforts by providers, plans, or insurers to enter network agreements on rates.
- Additional information submitted by a party.

However, the dispute resolution wording from HHS stated the arbitrator "must begin with the presumption that the QPA is the appropriate out-of-network rate for the … service under consideration," according to the government's "Requirements Related to Surprise Billing, Part II," as published in the *Federal Register* on Oct. 7, 2021.

Kernodle ruled that the above wording conflicted with the language in the actual No Surprises Act and thus must be vacated as a matter of law. "The Act plainly requires arbitrators to consider all the specified information in determining which offer to select … Nothing in the Act, moreover, instructs arbitrators to weigh any one factor or circumstance more heavily than the others," he wrote.

By contrast, the resolution process wording "places its thumb on the scale for the QPA, requiring arbitrators to presume the correctness of the QPA and then imposing a heightened burden on the remaining statutory factors to overcome that presumption," Kernodle concluded.

In practice, the ruling will make arbitrators look more closely at other criteria beyond just the QPA during resolution disputes, said Robert Charrow, a shareholder at Greenberg Traurig in Washington and former General Counsel at HHS.

"This requires the person who is acting as the arbitrator to actually assess all the factors," he noted.

Appeal Might Be Difficult

"The potential success on appeal of the Texas ruling by the government may not be strong," Charrow observed. "I think the government's case is relatively weak. A government rule cannot give added weight to one factor over the others, and that's what this dispute resolution's wording did. It undermined the vitality of the other factors."

The Texas Medical Association applauded the ruling. "This decision is an important step toward restoring the fair and balanced process that Congress enacted to resolve disputes between health insurers and physicians over appropriate out-of-network payment rates," said Diana Fite, MD, immediate past president of the Texas Medical Association, in a statement.

Clinical lab directors and pathologists should consult with their legal teams about No Surprises Act developments given how new the law is written. A similar suit filed by the **American Medical Association** and the **American Hospital Association** in December 2021 also challenges the reliance on the QPA during disputes. That case is awaiting a hearing in the **U.S. District Court for the District of Columbia**,

No Surprises Act Likely to Create Headaches for Pathologists and Billing Companies

PATHOLOGISTS AND BILLING COMPANIES navigating good faith estimates, new payment dispute rules, and changes to contracted payment amounts are being challenged by the federal No Surprises Act, which took effect Jan. 1, 2022.

The Act is designed to protect consumers from surprise medical bills from out-of-network (OON) providers that they did not choose—in other words, hospital-based OON physicians, such as pathologists, working at a hospital that is in network. Specifically, the law requires that private health plans pay their average in-network rate to OON providers.

The law also prohibits physicians, hospitals, and other providers, including clinical laboratories, from billing patients more than the in-network cost sharing amount for unexpected medical bills. In addition, the No Surprises Act establishes a process for determining the payment amount for unanticipated OON medical bills, starting with negotiations between plan and providers and, if negotiations do not succeed, an independent dispute resolution (IDR) process.

"The initial pain point created by the No Surprises Act centers on lowered payments to providers," said Jim O'Neill, Laboratory Services Business Development Manager at **Advanced Data Systems** (ADS) in Paramus, N.J. ADS develops billing software for healthcare providers and revenue management firms.

Since the law requires OON providers to be paid the same rate as in-network providers, many payers are reducing the amount they pay to in-network providers, bringing down payment rates for all hospital-based physicians.

The law also creates more up-front administrative work, as pathologists now need to provide information to patients about what fees they will be responsible for. The act requires healthcare providers to furnish uninsured and self-pay patients a good-faith estimate of total out-of-pocket costs for services upon request.

Estimates Lead to Changes

The need for good-faith estimates also creates challenges for billing companies as they receive data on the back end of an encounter. It will be important for providers and their billing companies to ensure the good-faith estimate is consistent with what is actually being billed, said Mick Raich, president of RCM consulting at **Lighthouse Lab Services** in Charlotte, N.C., and **Vachette Pathology** in Toledo, Ohio.

"The No Surprises Act is likely to cause some billing and collection issues," Raich said. "Like changing any process, there will be a cost as the old way of doing business is adjusted."

These new administrative burdens—especially the dispute resolution process—are likely to increase overall billing costs, he added, noting that the billing companies he's spoken with say fighting for payment is labor intensive.

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although it's not clear how the Texas ruling will affect this upcoming case.

It would be timely for clinical labs and pathology groups to review their own understanding of the dispute resolution process under the No Surprises Act, including the nuances presented by the recent Texas ruling. TDR

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COVID-19 Testing, Opioid Treatment Con

Federal Healthca Fraud Enforceme Turns to Emergin

➤➤ CEO SUMMARY: Healthcare compliance attorn Department of Justice (DOJ) is turning its focus to fr related to COVID-19 testing. But that's not the only greater scrutiny by the DOJ. Fraud stemming from opioid treatment has snared clinical laboratory ordered medically-unnecessary diagnostic tests. F tors have been ordered to investigate the illegal act als at providers and laboratory companies accused

FEDERAL PROSECUTORS ARE RAMPING UP INVESTIGATIONS of fraud and abuse involving SARS-CoV-2 testing and other COVID-19 related healthcare services, such as telehealth claims. Attorneys familiar with these efforts say investigators are prioritizing the actions of individuals alleged to have violated federal laws.

Clinical laboratory directors and pathologists involved with COVID-19 testing should be aware of this heightened federal enforcement. Further, lab owners and managers who engaged in fraudulent activities may find themselves at greater risk of being charged personally. That's because government fraud investigators are putting more emphasis on individual accountability for these and other fraud cases.

This is one reason why legal experts recommend that lab leaders should review how their organizations process COVID-19-related activities. These audits should review coding, billing, and collection of COVID-19 claims, as well as the sales practices that involved the referral of patient specimens for COVID-19 testing.

Speaking during a Feb. 16 healthcare enforcement webinar, attorneys from Boston-based law firm **Mintz** noted that the government is aggressively pursuing fraud related to COVID-19, including

Come Under DOJ Fire

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ttorneys say the U.S. s to fraudulent activity e only area attracting from telehealth and tory companies that sts. Further, prosecu- al actions of individu- cused of wrongdoing.

improper billing for COVID-19 testing. The webinar was based on the recent report by Mintz firm, "Healthcare Enforcement Year in Review and 2022 Outlook."

COVID-19 Fraud

Through its Consumer Protection Branch, the **U.S. Department of Justice** (DOJ) is particularly active in COVID-19 fraud enforcement, said Samantha Kingsbury, an attorney in Mintz's healthcare enforcement defense practice.

"DOJ has indicated in public comments that it plans to expand its COVID-19 enforcement as COVID-19 related fraud continues to evolve," Kingsbury noted.

Another new enforcement tool is the COVID-19 Fraud Enforcement Task Force, which is comprised of a variety of entities within DOJ that also work with the **Federal Bureau of Investigation** (FBI) and other agencies. This task force was involved in several major investigations in 2021.

That year, the task force brought charges in a scheme involving the provision of COVID-19 testing to Medicare beneficiaries at senior living facilities, at drive-through COVID-19 testing sites, and at medical offices. Defendants were accused of taking the Medicare data and specimens they collected for purported COVID-19 testing and using them, instead, to bill Medicare for unrelated and medically unnecessary testing, including cancer genetic testing, allergy testing, and respiratory pathogen panels—the results of which were often not provided to patients. In addition, when defendants did provide COVID-19 test results to Medicare beneficiaries, these results were often unreliable or not timely.

Clinical Lab Owner Indicted

DOJ also indicted a diagnostic laboratory owner, Billy Joe Taylor of Arkansas, in November on charges of healthcare fraud and money laundering. Taylor allegedly used his access to beneficiary and provider information contained in test orders to submit fraudulent Medicare claims amounting to more than $100 million. *(See sidebar "Lab Owner Allegedly Contacted His Victims," on page 15.)*

In September 2021, another investigation targeted 138 defendants, including multiple providers, for alleged healthcare fraud schemes that resulted in approximately $1.4 billion in losses to the government, about $29 million of which was attributed to COVID-19 related fraud. DOJ charged nine defendants with engaging in COVID-19 related schemes to exploit relaxed telehealth policies and misuse of patient information to submit claims to Medicare for medically unnecessary and expensive testing, including cancer genetic testing.

"These takedowns covered a variety of arrangements, but there were a couple of COVID areas of enforcement focus, such as COVID-related healthcare services—specifically COVID lab testing," Kingsbury said. In some cases, beneficiaries did not receive the promised COVID-19 testing, or test results were inaccurate. In other cases, defendants were accused of performing testing completely unrelated to COVID-19, such as allergy or genetic testing.

Kingsbury said she expects to see continued DOJ enforcement in this area, especially given a federal report released at the end of 2021 detailing how COVID-19 testing drove a huge increase in Medicare Part B laboratory spending for 2020. While overall spending went up, from $7.7 billion in 2019 to $8 billion in 2020, non-COVID testing went down. *(See TDR, "Non-COVID Part B Lab Spend Declined by 15.9% in 2020," Jan. 31, 2022.)*

"Given this, we expect more attention to be paid to clinical laboratories going forward," said Kingsbury, noting that there likely will be an increase in 2022 of civil enforcement actions under both the COVID-19 Consumer Protection Act and the FCA.

Test Fraud via Telehealth

Healthcare fraud enforcement is also shifting to address the increasing importance of technology in healthcare, Kingsbury said. The use of telehealth grew exponentially during the COVID-19 pandemic, and its broad use is expected to continue, along with the potential for fraud and abuse.

Telehealth visits for Medicare beneficiaries increased in 2020 by 63-fold—from 840,000 in 2019 to 52.7 million, federal health officials reported in December.

Sham Telehealth Consults

"DOJ historically has prioritized enforcement against outright telefraud, but we have begun to see enforcement evolve toward investigations and False Claims Act cases involving billing for sham telehealth consults," said Kingsbury, who noted that enforcement will continue to follow the massive growth of telehealth during the pandemic.

There is a distinction between "telefraud" and "telehealth fraud." The former involves fraudulent telemarking schemes to falsely bill for genetic and other diagnostic tests, durable medical equipment, and prescription drugs. The latter involves falsely submitting claims for sham or inadequate telehealth visits.

Samantha Kingsbury

➤ "Given this, we expect more attention to be paid to clinical laboratories going forward," said Kingsbury, noting that there likely will be an increase in 2022 of civil enforcement actions under both the COVID-19 Consumer Protection Act and the FCA.

Fraudulent Cancer Tests

In May 2021, the DOJ announced indictments of three telemarketing company owners in an alleged telefraud scheme involving the referrals of medically unnecessary cancer genetic testing to medical laboratories through a chain of kickbacks. Two of the individuals allegedly conducted a telemarketing campaign to convince Medicare beneficiaries to accept genetic tests that these beneficiaries did not need.

According to the indictment, the telemarketing company owners paid kickbacks to telemedicine companies, who contracted with physicians in exchange for physician orders for the expensive genetic tests. The physicians, however, had no prior relationship with and were not treating the beneficiaries for cancer or cancer symptoms, and they did not conduct proper telemedicine visits with these beneficiaries.

Federal Prosecutors Ready to Hold Individuals Accountable for Healthcare Fraud and Abuse

IN 2021, U.S. DEPUTY ATTORNEY GENERAL LISA MONACO issued a memo that renewed the DOJ's focus on individual accountability in cases of healthcare fraud and abuse, including clinical laboratory testing. The Biden Administration has said that white collar crime is a priority and that it will prosecute individuals as well as corporations.

"Monaco urged prosecutors to be bold in prosecuting individual corporate executives, even if it means they might lose the cases," observed Randy Jones, an attorney with Boston-based law firm Mintz. Jones is a former federal prosecutor and has a healthcare enforcement defense practice. He was speaking during the Mintz webinar last February, "Healthcare Enforcement Year in Review and 2022 Outlook."

The DOJ also is increasing the resources dedicated to prosecuting individuals. This includes embedding a team of FBI agents to work full time within the DOJ criminal fraud section. The agents are using data analytics to identify corporate wrongdoing. Because of the large volume of clinical laboratory test claims submitted daily, an effective data analytics tool might help federal fraud investigators detect lab test fraud earlier and with more accuracy.

Past Misdeeds Are a Factor

Monaco also directed federal prosecutors to consider the criminal, civil and regulatory records of a company that is subject to a criminal investigation when deciding the appropriate resolution.

"This renewed focus on individual accountability is going to cause companies under investigation by the DOJ to be prepared to conduct more fulsome internal investigations, to identify all wrong doers and to provide the government with all non-privileged information about individual wrongdoing," Jones explained. "There is no partial credit for incomplete disclosures."

Clinical laboratories are not immune from this focus on individual accountability, noted Karen Lovitch, an attorney at Mintz. Executives must be aware that if their laboratory is investigated, the government is going to expect the clinical laboratory to provide information about anyone who was involved in the conduct at issue, she warned.

10 Texas Doctors Settle

As if to underscore this focus on individual accountability, the DOJ on March 22 announced that 10 Texas doctors and a healthcare executive who ran medical clinics in Florida agreed to pay back $1.68 million to resolve allegations involving illegal kickbacks related to clinical laboratory testing. *(See the related story on p. 16 for more details.)*

"There is nothing more paramount to justice than holding all individuals accountable for committing and profiting from healthcare fraud, no matter their station in life," said U.S. Attorney Brit Featherston about the settlement with the Texas physicians and the hospital CEO.

Should the DOJ increase the frequency with which it files criminal charges for healthcare fraud and abuse against individuals, many in the clinical laboratory industry would welcome this step. It would increase the consequences for those owners, executives, and sales reps of labs—along with the physicians who accepted illegal bribes and other forms of remuneration—to be criminally indicted and face substantial penalties, including prison time and restitution.

All three indicted individuals then sold the orders to laboratories, one of which allegedly submitted $46 million in claims to Medicare and received $27 million in reimbursements. The unnamed laboratory allegedly paid the telemarketing company $14 million in kickbacks for those test orders.

New Type of Enforcement

Meanwhile, a new type of enforcement involving telehealth emerged in mid-2021. DOJ announced charges against individuals engaged in various healthcare fraud schemes—including telehealth fraud—that caused more than $143 million in false billings.

Kevin McGinty

➤ "In trying to mitigate your risk of *qui tam* [whistleblower] litigation, it's important to focus not only on compliance, but also the environment of reporting on compliance and letting employees know that their complaints are being acted upon and sent to HR."

The announcement marked a significant change in telehealth enforcement because certain defendants billed for sham telehealth consults that did not occur, in contrast to the telefraud schemes involving fraudulent orders for ancillary services ordered through telehealth.

"A continued shift in enforcement activity toward fraud involving telehealth consults seems inevitable given the marked increase in telemedicine users among Medicare beneficiaries during the pandemic," Kingsbury said.

The False Claims Act continues to be one of the government's most potent enforcement tools. Healthcare cases continue a 25-year trend of driving total volume, with close to 500 cases filed in 2021, according to Kevin McGinty, Chair of Mintz's class action practice. The number of healthcare cases initiated by DOJ has trended up significantly since 2015.

More Fraud Investigations

"In 2012, there was relatively low volume, and that has substantially increased over the past 10 years," he said. "This is a bipartisan trend. What we're seeing is that healthcare cost containment is a bipartisan issue."

In regard to whistleblower cases, former employees brought more than 70% of the cases, with current employees making up for another 20%.

"In trying to mitigate your risk of *qui tam* [whistleblower] litigation, it's important to focus not only on compliance, but also the environment of reporting on compliance and letting employees know that their complaints are being acted upon and then sent to HR," McGinty explained.

Given that overdose deaths remain high, the government's focus on opioid-related enforcement is expected to continue in 2022 and beyond. Therefore, the activities of toxicology laboratories are likely to remain in the government spotlight, said Karen Lovitch, Chair of Mintz's health law and healthcare enforcement defense practices.

'National Fraud Crackdown'

In October 2020, the DOJ filed criminal charges against 245 defendants in what it called a "national healthcare fraud and opioid takedown." Included in those charges were $845 million in false and fraudulent claims related to substance abuse treatment facilities and more than $806 million to other healthcare fraud and illegal opioid distribution schemes across the country. *(See TDR, "DOJ $6B Fraud Crackdown Charges 345 Defendants," Oct. 5, 2020.)*

As recently as March 2022, **Redwood Toxicology Laboratory** in Santa Rosa, Calif., paid nearly $4.8 million to settle allegations that it overcharged the Connecticut Medicaid programs for drug testing services for substance abuse patients.

Meanwhile, back in September, a Michigan pain management physician was convicted of healthcare fraud for a scheme to defraud Medicare of over $100 million. Francisco Patino of Wayne County billed for expensive and medically unnecessary spinal injections to certain patients in exchange for Patino prescribing high doses of opioids for these patients. The Eliminating Kickbacks in Recovery Act (EKRA) is a criminal law that prosecutors can use to charge laboratories with testing fraud related to opioid prescriptions.

Kickback Scheme with Lab

Patino also participated in a kickback scheme with an unnamed diagnostic laboratory through which he received payments in exchange for referrals to the laboratory, and he used those funds to promote a fad diet and wellness book.

Ultimately, 2022 is shaping up to be an active year for healthcare enforcement, Lovitch said. To mitigate risk, clinical laboratories and pathology groups must invest in their compliance program, regularly evaluate the effectiveness of the program through proactive auditing and monitoring, and ensure that they have a strong human resources department.

"Employees, former and current, are the biggest group of relators out there," stressed Karen Lovitch, an attorney at Mintz. "It's important to treat your employees with respect, especially employees who are on their way out the door who may not be happy. You need to give them ample opportunities to report compliance-related concerns and make them feel heard and seen."

DOJ Warning to Providers

One consequence of the DOJ's policy of bringing more cases against the individuals involved in healthcare fraud is that it may encourage more whistleblowers to file *qui tam* actions going forward. If this proves true, that would increase the risk for those clinical laboratory companies willing to push their interpretation of the federal Anti-Kickback Statute, EKRA, and the Stark Law because employees are often first to recognize violations of federal law. TDR

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Lab Owner Allegedly Contacted His Victims

BILLY JOE TAYLOR OF LAVACA, ARK., A LABORATORY OWNER who allegedly used fraudulent lab reimbursement to fund colorful purchases, had his bond revoked for allegedly violating conditions of his release.

Taylor was indicted in November for allegedly filing claims for diagnostic tests that were not ordered by physicians and had not been performed. Taylor's labs sent in Medicare claims worth more than $100 million.

"Taylor allegedly then used the proceeds of the fraud to live a lavish lifestyle, including purchasing numerous luxury automobiles, including a Rolls Royce Wraith, as well as real estate, jewelry, guitars, and other luxury clothing and items," according to the U.S. Department of Justice.

Taylor pleaded not guilty at his arraignment on Nov. 23. He was released on $100,000 bond, but the **U.S. District Court for the Western District of Arkansas** revoked that bond on Dec. 20, according to TV station *KNWA*.

In arguing for the revocation, prosecutors said Taylor engaged in criminal activity while on pretrial release; made unauthorized overnight stays at an out-of-state casino; and contacted victims or witnesses in the investigation, *KNWA* reported.

He was taken into custody after his bond was revoked. His trial is scheduled to start on Sept. 12.

Legal Update

Another 10 Doctors Settle Lab Kickback Cases, Pay Back $1.68m

FALLOUT CONTINUES FROM A LARGE LABORATORY BILLING INVESTIGATION IN TEXAS, as another 10 physicians and one healthcare executive agreed to settle with the government and pay back $1.68 million.

Clinical lab sales teams throughout the United States will be interested in this news. Account representatives can take copies of these settlements to prospective customers as evidence that the federal **Department of Justice** (DOJ) is seeking out doctors who engage in possible fraudulent lab billing activity.

The latest settlements were announced on March 22 by the **U.S. Attorney's Office of the Eastern District of Texas**. In January, this same office settled with an initial seven Texas physicians and a hospital executive for $1.1 million. *(See TDR, "Seven Doctors Settle Lab Test Fraud Case," March 14, 2022.)*

Latest Settlements of Fraud

The latest settlements resolved allegations that the 10 Texas doctors violated the Anti-Kickback Statute by receiving paybacks from eight management service organizations (MSOs).

The renumeration was in exchange for ordering laboratory tests from **Little River Healthcare**, which ran several hospitals and clinics in Texas and closed in 2018; **True Health Diagnostics** in Frisco, Texas, which filed for bankruptcy in 2018; and/or **Boston Heart Diagnostics** in Framingham, Mass., which paid back nearly $27 million in 2019 to resolve False Claims Act allegations.

The following doctors were accused of receiving kickbacks and have settled:

- Tamar Brionez, MD, of Spring, Texas (who agreed to pay back $85,006).
- Gary Goff, MD, of Dallas, and two affiliated entities, Gary Goff, MD, PA, and **DFW Primary Medical Alliance, LLC** ($454,088).
- John Hierholzer, MD, of San Antonio ($24,850).
- Bruce Maniet, DO, of Bells, Texas ($175,436).
- Huy Chi Nguyen, MD, of Arlington, Texas ($211,821).
- Dung Chi Nguyen, MD, of Arlington, Texas ($211,721).
- Rakesh Patel, DO, of Houston ($174,539).
- Cuong Trinh, MD, of Houston ($45,056).
- Randall Walker, MD, of Magnolia, Texas ($60,898).
- Michael Whiteley, DO, of Tomball, Texas ($52,015).

Also, the DOJ settled with Brett Markowitz, founder and CEO at **Florida Rejuvenation Holdings**, which operates medical practices in Tampa, Fla., under the name **Tampa Practices**.

Disguised as Handling Fees

From 2016 through 2018, True Health representatives allegedly paid for each patient that physicians at Tampa Practices referred to True Health for clinical laboratory services. True Health and Markowitz allegedly disguised the payments as processing and handling fees. Markowitz agreed to repay $185,000.

All defendants that settled also agreed to cooperate with the DOJ on investigations involving other parties. TDR

COLA Re-enters CLIA Accreditation for Pathology

COLA announced that CMS granted it deeming authority for pathology specialty, effective March 7

Nancy Stratton

CEO SUMMARY: ***COLA again has deemed authority by the Centers for Medicare and Medicaid Services to accredit clinical labs and pathology groups for the pathology specialty. The organization's CEO says the move will help meet current and future lab customer needs. It's a reversal from 12 years earlier when COLA bowed out of pathology accreditation due to low lab enrollment in the program.***

CLINICAL LABORATORIES SEEKING PATHOLOGY ACCREDITATION HAVE A NEW OPTION, as **COLA** recently received deeming authority for that specialty.

The change became official on March 7, when the **U.S. Centers for Medicare and Medicaid Services** (CMS) awarded COLA deemed status for the specialty of pathology.

The deemed status, which falls under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), lasts through March 7, 2024. Clearly, COLA sees new business opportunities in today's pathology market.

"We knew that the addition of pathology to COLA's laboratory accreditation program would allow us to support a wider variety of laboratories," CEO Nancy Stratton, MBA, told THE DARK REPORT in a written response to questions. "The bottom line is that we are now better positioned to meet the needs of our current and prospective customers," Stratton added.

Veteran lab administrators and pathologists will recall that COLA previously had deemed status for pathology from 2007 to 2010. In June 2010, COLA informed its members and CMS that it was voluntarily dropping its pathology accreditation program.

At that time, COLA noted that the decision was financially motivated. Only 3% of the organization's labs were accredited for pathology back then, and it was too expensive to maintain the program given the low number of labs being accredited for the specialty.

"The cost to maintain the highest levels of quality and patient care for this small number of laboratories has become prohibitive," then CEO Douglas Beigel wrote to COLA's members.

Rare Move from CMS

It is rare for CMS to grant new deemed status to an accrediting organization. The last similar decision by CMS occurred in 2014 when it approved deeming authority to the **American Association for Laboratory Accreditation** (A2LA). *(See TDR, "CMS Gives Deemed Status to A2LA Under CLIA Law," April 7, 2014.)*

Prior to that announcement, it had been seven years since COLA had deemed status for pathology, as noted earlier.

CMS can grant authority to approved third-party organizations to conduct CLIA inspections on the federal agen-

cy's behalf. Those organizations' laboratory surveys must meet or exceed CLIA requirements.

COLA joins other well-known groups in inspecting for pathology under deeming authority, including **The Joint Commission**, **College of American Pathologists**, and A2LA.

The addition of COLA as a deeming authority for pathology gives laboratory directors a new choice when it comes time for their lab to meet pathology-related CLIA requirements.

In-house Influence?

COLA's move comes as many office-based physicians continue to offer their own pathology services rather than referring patients elsewhere for those activities. Doing so brings additional revenue into the physicians' practice and offers patients convenient options for testing.

As far back as 2004, THE DARK REPORT noted a shift by physician groups to offer in-house anatomic pathology. *(See TDR, "Pathology Consultants See In-House AP Trend Unfolding," Aug. 9, 2004.)*

An example of this arrangement would be a gastroenterology physician group practice establishing an in-house histology laboratory and employing a pathologist to handle the professional component of diagnosing the tissue.

Pathology Accreditation

For its part, COLA said its move to pathology accreditation was not in response to this scenario. "COLA recognizes that in-house histology laboratories established by physician groups is one type of pathology laboratory setting," said the organization's new Chief Medical Officer, David Chhieng, MD. "We do not have any information about the percentage of pathology laboratories that fall into this category or any ongoing trend."

As noted, earlier, since the early 2000s, one major trend in the urology and gastroenterology specialties has been for physician groups to set up an in-house histology laboratory to perform and bill for the technical component (TC). The groups would then either hire a pathologists or contract with a pathology group for the professional component (PC).

Because it is known that COLA provides CLIA accreditation services to many physician office laboratories (POLs), regaining its CLIA deeming authority for pathology positions COLA to serve these types of laboratories as well. TDR

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COLA Adds Pathology Muscle To Its CLIA Team

IN GRANTING COLA DEEMED STATUS FOR PATHOLOGY ACCREDITATION, the U.S. Centers for Medicare and Medicaid Services (CMS) said COLA's pathology specialty includes histopathology, cytology, and oral pathology.

In preparation for the added status, COLA assembled a pathology team, including new Chief Medical Officer, David Chhieng, MD. He will lead the organization's pathology accreditation program.

Chhieng joined COLA in November 2021 after more than four years as Director of Anatomic Pathology, Vice Chair of Clinical Affairs, and Professor in the Department of Pathology at the **University of Washington's School of Medicine** in Seattle.

Prior to that, he had stints at **Mt. Sinai Health System** in New York, **Yale University School of Medicine** in New Haven, Conn., and the **University of Alabama** at Birmingham.

He has more than 20 years' experience participating in accreditation services.

Also as of March, COLA named Kathy Wilson, HT(ASCP)QLS, as Director of Pathology Accreditation. Wilson was hired by COLA as an executive in December 2021 and previously served as Operations Manager of Anatomic Pathology at **Clinical Pathology Laboratories** in Austin, Texas.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

On March 22, the **U.S. Health Resources and Services Administration** (HRSA) announced that its COVID-19 Uninsured Program had stopped accepting claims for related laboratory testing due to lack of sufficient funds. This development potentially affects 8.6% of the nation's population which doesn't have medical insurance, according to the **U.S. Census Bureau**. Clinical labs may face delayed payments from HRSA for COVID-19 tests performed on uninsured patients.

MORE ON: *Testing for the Uninsured*

The HRSA money dried up because it was cut from a bill before Congress that is funding other parts of the government and U.S. aid to Ukraine. It's possible funding for COVID-19 testing for uninsured patients could be restored. The uninsured program has provided more than $20 billion in reimbursements to medical laboratories, hospitals, physician offices, pharmacies, and clinics since spring 2020, the *Washington Post* reported. "Clinical labs will continue to do COVID-19 testing and will continue to bill for these tests, and there may be some retroactive payment for those tests done for uninsured patients," said Mick Raich, President of Revenue Cycle Management Consulting at **Lighthouse Lab Services**.

PATHOLOGY BLISS: CHOCOLATE, ROSES, TISSUE SAMPLES?

Wedded bliss is the real deal for pathologists, as a large majority of pathologists recently surveyed reported being in a happy marriage. According to results from the **Medscape** survey, "Physician Lifestyle and Happiness Report 2022," 81% of pathologists described their matrimony as "very good" or "good." While that percentage sounds like love is in the air, it was actually on the lower third based on rankings for all physician specialties included in the survey. The physician specialties that had the highest number of happy marriages were otolaryngologists and immunologists, both at 91%. Medscape conducts this survey annually.

TRANSITIONS

- San Diego-based **XIFIN** named Harley Ross the company's first Chief Commercial Officer on March 10. Prior to joining XIFIN, he served at **StoveGuard** and **Quadax**.

- Michaela Hart is the new Vice President of Regulatory, Quality, and Lab Operations for **Delfi Diagnostics** of Baltimore, Maryland. Previous positions were with **Roche Sequencing USA**, **Veracyte**, and **Vaxart**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 25, 2022.

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UPCOMING...

- ***The Dark Report's annual list of global ranking of Top IVD Companies shows changes.***
- ***Decline in demand for COVID-19 tests has many COVID-only testing companies looking to sell.***
- ***What's hot in precision medicine: a new generation of lab tests for earlier, more accurate diagnosis.***