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Why is State of California Spending Up to $1.7 Billion for its Own COVID Lab?

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Also… Medicare's New COVID Test Claim Rule!

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 or Not, Lab Market Enters 'Twilight Zone'

OUR HEALTHCARE SYSTEM IS IN A MOST REMARKABLE STATE. Even as all providers—including clinical laboratories and anatomic pathology groups—continue to devote considerable resources to meeting the urgent need for SARS-CoV-2 testing, health insurers and regulators continue to issue new requirements governing all aspects of "normal" lab testing activities.

Today, all clinical labs and pathology groups operate in a strange duality. On one hand, their daily energies are consumed with delivering quality COVID-19 testing services, while dealing with restrictions on how consumers and patients can access hospital and physician services.

On the other hand, most hospitals, office-based physicians, ambulatory surgery centers, nursing homes, and other providers are offering the usual range of services to patients as they get sick or need acute care. All labs in the United States are supporting these care sites with the routine, reference, and esoteric tests that cover the entire span of diseases and health conditions.

In the midst of this weird duality, payers and lab regulators throw unwelcome curve balls at the medical laboratory profession. These curve balls range from downward changes in what labs are paid for testing, to more restrictions on how labs submit test claims. And even a state government now provides COVID-19 tests in competition with hospital labs and independent clinical labs!

This issue of THE DARK REPORT provides examples of each of these changes. We cover Medicare's new requirements and payment rates for COVID-19 tests reported in less than 48 hours and more than 48 hours on pages 18-19. The latest development with **UnitedHealthcare's** requirement that labs must register every test and panel they perform with the payer's new Laboratory Test Registry Protocol if their claims are to be paid after Apr. 1, 2021, is presented on page 6. And on pages 3-5, read how California has built its own COVID-19 testing laboratory and is now diverting lab instruments, supplies, and test kits away from hospital labs and independent labs in the state.

These are reasons why many lab managers and pathologists might feel like they are characters in the old television show, the "Twilight Zone." At the very moment they must urgently deal with a pandemic that is unprecedented in modern medicine, all the usual players (payers and regulators) continue to restrict the ability of labs to bill and be paid for their lab testing services. TDR

Calif. Builds COVID Lab: $25 Million or $1.7 Billion?

In first week of operation, news outlets reported the lab produced inconclusive SARS-CoV-2 results

CEO SUMMARY: California dropped a bomb on the state's existing network of hospital labs and independent clinical labs when, on Oct. 30, it announced it had built and opened a new laboratory facility in Valencia designed to perform 150,000 COVID-19 tests per day. Now, existing labs in the Golden State must compete against their state government for an already inadequate quantity of supplies, COVID-19 test kits, and even clinical laboratory scientists needed to do COVID-19 PCR tests.

CAN GOVERNMENT DO THINGS BETTER THAN PRIVATE ENTERPRISE? That's one question being asked after it was learned that the State of California had built and opened a brand-new clinical laboratory to perform COVID-19 testing.

Less than two weeks after California Gov. Gavin Newsom cut the ribbon for the new COVID-19 testing lab in Valencia, the lab was reporting inconclusive testing results, according to published reports.

It was on Oct. 30 when Newsom announced that the new lab would return COVID-19 test results within 48 hours, and that by March, the lab would run 150,000 tests for the SARS-CoV-2 coronavirus every day. Not only were state officials aiming to increase COVID-19 testing statewide, but also, Newsom said he hoped that by increasing testing, the state could ease off of strict social-distancing rules.

At a time when established clinical laboratories across the United States and throughout the world are scrambling to get enough collection supplies and SARS-CoV-2 tests, somehow the State of California used its power to divert the *in vitro* diagnostics (IVD) supply chain in ways that enabled it to build and equip this large new laboratory facility.

Further, the State of California now competes against hospital and independent laboratories for the limited number of qualified and experienced PhDs and clinical laboratory scientists required to perform the complex COVID-19 tests. This will have major consequences for existing labs in California as they struggle to recruit the additional staff they require to support the increased volumes of SARS-CoV-2 tests needed by hospitals, physicians, and businesses in the Golden State.

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

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Initially, the state had paid $25 million to get the laboratory operating, but *Newsweek* reported that state officials were concerned about the potential for the cost of the new lab to rise to $1.7 billion under the no-bid contract state officials signed with **PerkinElmer**, a diagnostics and life-research company in Waltham, Mass.

PerkinElmer did not respond to a request for comment from THE DARK REPORT in time to be included in this article. *(See sidebar, "Cost for New Calif. Lab May Total $1.7 Billion Under No-Competitive Bid Contract with PerkinElmer," on next page.)*

'Inconclusive Results'

Despite making such a heavy financial commitment, the lab was reporting "a higher number than expected" of bad test results by Nov. 10 and leaving patients waiting days for results, according to reporting in *Newsweek* magazine.

Not only were patients waiting longer than expected for results, but Mark Ghaly, MD, MPH, California's Secretary of Health and Human Services, told reporters last week that the lab was reporting a higher number of inconclusive tests than officials had predicted. The inconclusive test results were the result of a failure of a chemical reaction during some tests, *Newsweek* reported.

As a result of understanding the reason for the inconclusive results, Ghaly said the lab director in Valencia was confident that the staff had identified and corrected the problems behind the number of inconclusive test results, *Newsweek* reported.

Lab's Medical Director

The lab director was reported to be Haleh Farzanmehr, MD, a molecular genetic pathologist and laboratory medical director who previously served a similar role at **GeneX Laboratory PC** in Irvine, Calif. THE DARK REPORT was unable to confirm that Farzanmehr is in fact the medical director at the Valencia lab.

In an Oct. 30 press release about the opening of the new laboratory, state officials said, "the per-test cost would be $30.78 at 150,000 [COVID-19] tests per day. For context, Medicare and Medicaid both reimburse at roughly $100 per test, while the average consumer price for a COVID-19 test ranges from $150 to $200 per test. To support this contract at the lowest cost to taxpayers, the state will enter into a contract for third-party billing services to recoup costs from health insurance companies or other payers." There was no reporting on how much patients were paying for these tests.

Neither the state HHS agency nor Newsom's office responded to requests from *Newsweek* to provide the exact number of COVID tests that were inconclusive, the magazine reported.

KCRA TV news in Sacramento reported that state health officials expect the new clinical laboratory to more than double testing capacity in the state when the lab is running 150,000 tests per day in March. As of one day last week, California's clinical and molecular laboratories were averaging about 134,000 tests per day, *KCRA* reported.

Disrupting Lab Supplies?

California officials did not provide details about how they are obtaining the supplies required for their new lab facility to perform more COVID-19 tests daily than the combined total of all other labs in the state. Officials did recognize that they intended to be disruptive to the existing laboratory supply chain. In the press release, they wrote:

> *This first-of-its-kind agreement aims to disrupt the testing marketplace, help break supply chain logjams, and drive down the costs for tests for every Californian. It will greatly expand California's ability to track and prevent COVID-19 infections across the state and create additional testing capacity that will allow the state to increase testing in communities at high*

Cost for New Calif. Lab May Total $1.7 Billion Under No-Bid Contract with PerkinElmer

ONE ISSUE THAT DOMINATED NEWS COVERAGE IN CALIFORNIA about the state government's new COVID-19 testing lab in Valencia was the cost of the contract state officials signed with PerkinElmer. The Sacramento television station *KCRA* reported that the clinical laboratory and associated costs of COVID-19 testing could total as much as $1.7 billion. "The no-bid contract will cost millions before the first test is even completed," the station reported.

However, when Gov. Gavin Newsom announced the new COVID-19 testing center, he said the facility would cost $25 million. "While talk centered around the cost of the facility and increased testing capacity for the state, *KCRA 3 Investigates* has been looking at the contract signed with the lab company and what it could cost in total," the news station reported.

The contract state officials signed in August with PerkinElmer calls for the state to pay the Waltham, Mass., diagnostics and life-science technology company three startup payments. The contract was signed under an order that Newsom issued. "As such, there is no competitive bidding," the news station reported.

"If PerkinElmer meets a series of benchmarks—from ordering equipment, hiring personnel, to getting necessary accreditations through the first reported results of testing—the company can rake in more than $270 million," *KCRA* reported. "Added to that, the state of California will pay for the facilities, electricity, water, storage, refrigeration, and the phone and internet service."

Even so, the state could pay anywhere from $700 million to $1.6 billion by the end of the contract. The maximum cost of the contract is set at $1.7 billion.

The term of the contract is 14 months. At the end, the contract can be renewed annually for two years, *KCRA* reported.

risk for contracting COVID-19, like essential workers, those in congregate settings, and communities of color.

"California is using its market power to combat global supply chain challenges and protect Californians in the fight against COVID-19. Supply chains across the country have slowed as demand for COVID-19 tests has increased, and flu season will only exacerbate the problem," said Governor Newsom. "So, we are building our own laboratory capabilities right here on California soil with a stable supply chain to fight the disease, lower the prices of testing for everyone, and protect Californians most at risk from COVID-19."

Since the state's lab in Valencia has only recently begun performing COVID-19 testing, it is too early to determine how the state's diversion of collection supplies, transport media, primers, COVID-19 tests, and other laboratory products is impacting hospital and independent clinical laboratories throughout the Golden State.

Recruiting Clin Lab Scientists

Another question of interest to the state's existing clinical labs is how the state is recruiting and paying the limited number of pathologists, PhDs, and clinical laboratory scientists who have the training and experience to perform these complex COVID-19 PCR tests. For existing labs to expand their COVID-19 lab test volumes, they need more of these lab professionals.

The pathologists and administrators at existing hospitals and labs in California now must compete against their state government, which is using its power to divert the supply chain and suck skilled lab scientists out of the existing labor pool. TDR

Coding/Billing Update

UnitedHealthcare Delays Its New Test Registry Protocol Until April 1

Clinical laboratories and anatomic pathology groups working to register their tests with **UnitedHealthcare's** (UHC) new Laboratory Test Registry Protocol just got a 90-day reprieve. UHC has delayed the start date to April 1, 2021.

"There is no truth to the rumor that UHC has ended the program before it began," said Leigh Polk, Director of Sales and Marketing for **Change Healthcare**, a lab billing and consulting company. "The only change is that the program has a new start date of April 1."

With more than 40-million beneficiaries, UnitedHealthcare is the nation's largest health insurer. No other health insurance company has attempted to develop the scope and scale of UHC's Laboratory Test Registry Protocol.

UHC is requiring all clinical laboratories and pathology groups to register every test and panel performed before March 1, 2021. Per the new update, effective April 1, UHC will not pay labs for claims if those tests or panels are not registered in UHC's Lab Test Registry Protocol. *(See TDRs, Aug. 3 and Oct. 5, 2020.)*

Some Labs Not Prepared

The new implementation date is the third one that UHC has set since announcing the program. Previously, the deadline to register tests was Sept. 1 for payment that would begin Oct. 1, 2020. The second date to register tests was Dec. 1 for payment that would start on Jan. 1, 2021.

"Not all clinical labs or pathology groups are prepared for UnitedHealthcare's new protocol," noted Polk. "Even some billing companies are not prepared. But we are fully prepared. We continue to talk to our clients to help each lab get its test compendium uploaded to the UHC site.

Avoiding Denials After April 1

"At the same time, UnitedHealthcare is still working out a few items on its end. The instructions from UHC do not say certain fields are required, for example," commented Polk. "So, when a clinical laboratory submits its test to the compendium during this registration period, that test claim will get denied if those fields are not completed correctly."

Also, the instructions from UnitedHealthcare say that the unit of measure (UofM) for what is called Procedure Code 1 are misleading, Polk explained.

"While this is a required field, and UHC provides a list of applicable UofM codes in the appendix, if none are applicable to the test it can select 'None.' Doing so will not affect payment by UnitedHealthcare," she noted.

For reflex testing, UHC said information is required on whether reflex testing is done, and the field needs to be marked as yes or no. "Again, this information is for UHC's purposes only and will not affect payment," she added.

Polk sent a notice to Change Healthcare clients alerting them to the new deadline, called the Test Compendium Upload Date.

"UnitedHealthcare is encouraging all clinical laboratories and pathology groups not to wait, but to submit their lab-test data as soon as possible," she noted. TDR

Contact Leigh Polk at 843-601-0184 or Leigh.Polk@ChangeHealthcare.com.

NY Hospital Lab Succeeds with Pooled COVID Testing

171-bed Saratoga Hospital is in eighth month using pooled tests in ER for inpatient admissions

CEO SUMMARY: Pooled testing helps the clinical lab staff at the hospital in Saratoga Springs, N.Y., do more COVID-19 tests when supplies might otherwise run short. Lab managers estimate this method has saved 5,000 test cartridges since May. Pooled testing also helps the physician staff in the emergency department identify patients who may be positive for COVID-19, so the hospital can cohort patients to different care units as needed. Doing so also helps conserve personal protective equipment for staff.

"To pool or not to pool?" That is the question many clinical laboratory directors are asking to support efforts to perform greater numbers of COVID-19 tests as the pandemic gathers momentum.

At **Saratoga Hospital**, a 171-bed community hospital in Saratoga Springs, N.Y., the lab team answered that question with a "yes." In fact, it is now in its eighth month of using pooled testing.

As a method of testing, pooling has been successful in conserving supplies. It is useful for identifying patients who are positive for COVID-19 and those who are not. This allows treating physicians to segregate patients into COVID and non-COVID units.

In the spring, when supplies became the main obstacle to testing more patients for COVID-19, Saratoga Hospital conducted an assessment of the concept of pooled testing. Validation studies were performed and, once the laboratory found that pooled testing would be feasible, the administrators decided to use pooled testing whenever possible since then.

As of the end of the first week of November, almost 7,000 patients in pools of three to five specimens each were performed at the Saratoga Hospital laboratory. Only 26 of those patients were positive for COVID-19, or less than 1% of all patients tested.

"We have used pooled testing since the spring and continue to do it today because it's been a very successful program for us," Josenia Tan, MD, Chair and Medical Director of the hospital's Department of Pathology, said in an interview with THE DARK REPORT. "Our hospital has been able to test all patients admitted to triage for isolation and use of appropriate PPE."

Enable High Levels of Testing

For Richard Vandell, MS, MT(ASCP) SC, SH, Administrative Director of Laboratory Services, a critical benefit of the pooled approach is that it enables Saratoga Hospital to continue COVID-19 testing at a high level.

"To do all of that testing, we have used a little more than 1,400 test cartridges, meaning we have saved over 5,000 cartridges to date," he commented. "That level of conservation means we were able to sustain testing at the same level

during this entire time. Pooled testing for COVID-19 has allowed us to continue to test because we are maintaining a self-fulfilling ability to do so."

Three Lessons Learned

For Tan, there were three significant lessons learned that other labs would find useful as they start pooled testing for SARS-CoV-2:

- Know the infection rate in your service area,
- Understand the capability of your lab to do pooled testing, and
- Get regulatory approvals to do this form of testing.

"Knowing the infection rate in your community is essential for doing pooled testing successfully," said Tan. "If the rate is too high, your lab will use too many supplies because of the need to do repeat individualized testing. An infection rate of 5% or less is best.

"If the COVID-19 infection rate is higher than 5%, then too many pools of specimens will be positive," she noted. "When that happens, your lab will need to test each specimen in the positive pools again. The need to run those additional tests reduces or eliminates the benefits of pooling."

Since the pandemic began, New York State has had infection rates reach as high as 44% on April 4 and as low as about 1% from the beginning of June through late October. In the first week of November, the positivity rate rose to about 2.4%, according to data from the **New York State Department of Health** (NYSDOH).

Know Lab's Capacity

"The second lesson is that it's necessary to know the capacity of your lab and your staff," she added. "What is the productivity of your lab's testing platform, and what are the capabilities of your lab staff?"

The lab at Saratoga Hospital runs three shifts and about 1.2 million billable tests per year, Vandell noted. Since the pandemic began, the lab has processed 64,000 coronavirus tests. The primary platform for these tests (and the pooled tests) is the **Cepheid** GeneXpert RT-PCR test. In addition, the lab also performs a rapid antigen test. The **Abbott** ID NOW and **Rheonix** platforms are in development, Vandell reported.

The third lesson is to get the regulatory approvals needed for pooled testing. Saratoga Hospital's lab team sought that approval from the NYSDOH public health laboratory at the **Wadsworth Center** in Albany, Tan said. "To help us assess the feasibility of pooled testing, we engaged the staff at the Wadsworth lab almost as a consultant," she added.

Adding Flexibility

"To be able to introduce pooling, we modified the collection method," Vandell explained. "We changed the number of nasopharyngeal swabs placed in each tube of viral transport media from one to up to five, as needed. This gave us the flexibility to meet the emergency department's needs. The testing method for SARS-CoV-2 remained the same."

The lab was testing emergency department patients for SARS-CoV-2 to determine which ones needed to be admitted to the hospital. When assessing these patients, the lab team worked closely with physicians in the emergency department who were assessing patients' symptoms, Tan and Vandell explained.

Ideally, the lab wanted to test five specimens in each pool, but it was not always feasible for the emergency department to collect that number without making some patients wait an inordinately long time. Rather than keep patients waiting in the ER, the lab would run as few as three specimens if needed, Vandell said.

To prove that pooled testing produced an accurate result, the lab compared quantitative data from positive pools against the individual positive patients in the pool. "We saw very little difference in the measured data, and this proved that pooling results were accurate," Vandell said.

"We work very closely with our emergency department to assess patients by their symptoms to determine which specimens to include in the pool," he added.

Pooled testing not only helps conserve supplies, but also allows the ER staff to know which patients are positive so that treating physicians and nurses can segregate positive COVID patients from non-COVID patients. "We want to cohort our patients because doing that allows us to conserve the personal protective equipment for our staff and reduce the level of anxiety among healthcare workers in the hospital," Vandell said. "That has been an institutional goal for us, and the pooling strategy has been a huge part of achieving that goal.

Conserving Supplies

"Of course, with the continuing supply-chain shortages, a significant reason to continue doing pooled testing is to conserve supplies," he explained. "Even now, in November, we do a count every day of our testing supplies because we are continually making decisions about how to conserve supplies.

"Our lab team has done this since the beginning of the pandemic," added Vandell. "Without pooling, we might not be able to continue to do the level of COVID-19 testing we've been doing."

For the lab team, the recent rise in the positivity rate is a new concern. "In the last week in October, we were at 2.4% for symptomatic patients," Vandell commented.

"That's an important distinction because in our pooling technique, we try to screen out symptomatic patients to keep our incidence rate low," he commented. "A few weeks ago, we had a positivity rate of 2.4% in the community. One day during the first week of November, we had seven positives out of a total of 64 symptomatic patients at one of our testing facilities. That's a concern because that's about an 11% positivity rate for COVID-19 in our community." TDR

Lab Team Publishes Study of Pooled Testing Results

SARATOGA HOSPITAL'S IDEA WAS TO USE POOLED TESTING AS A STRATEGY for patients at low risk for SARS-CoV-2 who would be admitted to the hospital, according to, "Pooled Testing for SARS-CoV-2 in Hospitalized Patients," a study published in the *Journal of Hospital Medicine* in September.

In the article, Josenia Tan, MD, Chair and Medical Director of the hospital's Department of Pathology, and colleagues, described how viral testing for SARS-CoV-2 early in the pandemic was limited due to supply shortages—especially reagents.

For the lab's assessment of pooled testing, the team collected nasopharyngeal samples from emergency room patients who were at low risk of SARS-CoV-2 infection in groups of three for the pooled testing. Over three weeks, the lab tested 530 patients in 179 cartridges and had four positive test groups requiring the use of 11 additional cartridges. This level of infection showed an overall positivity rate of 0.8% among those tested.

"This strategy resulted in the use of 340 fewer cartridges than if each test were performed on one patient sample," the authors wrote.

In conclusion, they added, "Pooled testing of low-risk populations allows for continued testing even when supplies are relatively scarce." Once the lab team had validated the process for pooled testing, Tan and other senior lab administrators decided that pooled testing would be useful throughout the pandemic. Since then, the lab has used pooled testing before any patients are admitted.

Contact Josenia Tan, MD, at 518-583-8442 or JTan@saratogahospital.org; Richard Vandell at 518-583-8443 or rvandell@saratogahospital.org.

Palmetto Tells Consultant: Take Down Test Price Data

➤ Molecular data and lab-strategy expert used federal records to inform public about potential fraud

➤➤ CEO SUMMARY: Lawyers for Medicare contractor Palmetto GBA sent a cease and desist letter in September to a respected lab consultant, telling him to delete from his health policy blog a document containing Medicare genetic test price and coding data. In the letter, Quinn was directed to delete the information from his own professional files and to tell all those who downloaded the data from his website to also delete the information.

SHOULD THE AMOUNTS MEDICARE PAYS FOR GENETIC TESTS AND OTHER SERVICES be released to the public simply because Medicare is an agency that spends taxpayer funds? That question surfaced after **Palmetto GBA**, a Medicare Administrative Contractor (MAC), sent a demand letter to a clinical laboratory consultant in September directing the consultant to remove the genetic price data it had earlier provided to him in response to a Freedom of Information Act (FOIA) request he submitted.

The data on what Palmetto paid for molecular tests on behalf of Medicare patients must be removed, Palmetto said in a letter from its law firm to Bruce Quinn, MD, PhD, an expert on health policy, payment, and clinical lab strategies and a former MAC medical director.

➤ Gaming the System

Palmetto's action has attracted attention among clinical laboratory professionals and from news outlets that cover diagnostics. For years, some clinical lab companies have gamed the Medicare program by coding their genetic test claims in ways that result in individual MACs paying these lab companies more for those claims, compared with what other labs billed for the same types of tests using more precise CPT codes.

Lab companies playing this game have benefited because the federal C**enters for Medicare and Medicaid Services** (CMS) never published data that showed the prices that physicians, hospitals, laboratories, and other providers billed Medicare for claims and the prices Medicare actually paid for these claims. In 2014, however, CMS released data on what it paid physicians. That was the first time in the 49-year history of Medicare that it did so. *(See TDR, April 28, 2014.)*

In subsequent years, CMS publicly posted what it paid laboratories. Each year, the data sets CMS released included the:

- Lab's provider number,
- Amount the lab billed Medicare for each CPT code,
- Payment Medicare made for each CPT code, and
- Volume of test claims paid to the lab for each CPT code.

In a letter dated Sept. 18, B. Craig Killough, a lawyer with the law firm of **Barnwell Whaley Patterson and Helms**, in Charleston, S.C., representing Palmetto

GBA, told Quinn to delete from his "Discoveries in Health Policy" (DHP) blog a document containing Medicare lab test payment and coding data.

In the letter, Killough told Quinn to delete the information from his own files and tell all those who downloaded the data from his website to delete the information as well. Killough also asserted that the information on the DHP blog and in Quinn's file were Palmetto's intellectual property.

CMS Master Edit File

While it may be true that the data are intellectual property, Quinn obtained the information, which was contained in what CMS calls a Master Edit File (MEF), from CMS itself.

"I have a copy of the Palmetto MEF file that CMS released in December 2019," Quinn said in an interview with THE DARK REPORT. "And, I have a newer copy that Palmetto itself released two months ago."

In fact, Quinn obtained the original MEF from Palmetto through a request he submitted under the Freedom of Information Act. Under FOIA, members of the public may request documents that local, state, and federal agencies have not released.

FOIA Law Requirements

Agencies must release those documents unless there is an overriding reason not to do so. The law has nine exemptions and three exclusions that would prohibit agencies from releasing documents. One exemption would exclude the release of information that would be prohibited under a different federal law.

A DARK REPORT review of the exemptions and exclusions showed none that relate to intellectual property.

In his letter to Quinn, Killough said the MolDX program is the intellectual property of Palmetto and that, "possession, use, copying and publication of the file is restricted by intellectual property laws." In addition, Killough said Quinn should ensure that the file "was deleted in all electronic forms." Also, Killough told Quinn, "to provide to us names and contact information for all persons and entities known to you that downloaded the Master Edit File" or transmitted all or part of it.

Lawyer Questions MAC's Claim of Trade Secrets

IN RESPONSE TO A REQUEST FOR AN OUTSIDE LEGAL OPINION, Jeffrey J. Sherrin, a healthcare lawyer with O'Connell and Aronowitz in Albany, N.Y., said he would question whether the Medicare information in question on the "Developments in Health Policy" site could be considered trade secrets.

"I would seriously question whether that information could be considered a trade secret for private commercial lines of business," Sherrin wrote in response to a request from THE DARK REPORT on the letter Palmetto GBA sent to Bruce Quinn, MD, PhD. "I find no legitimacy to such a claim with respect to Medicare payments.

"By definition, if the federal government releases documents pursuant to a valid request under the Freedom of Information Act (FOIA), the presumption must be that they are not confidential trade secrets," he wrote. "The federal government has no authority to release such confidential records under FOIA.

"There is always the possibility that the documents were released by the government in error, but that does not appear to be the case here," he added.

"In addition, I don't see any validity to the claim that how much is paid on behalf of the Medicare program for particular tests is a trade secret," Sherrin noted. "In fact, I find it disturbing that Palmetto would try to prevent disclosure of such information."

This request means that clinical laboratory directors and pathologists could be asked to delete the MolDX information should they have downloaded that data from Quinn's blog site for their own analysis.

CMS Intervenes

While Quinn deleted the link on the DHP blog site to the MolDX data, he did not have access to names of individuals or companies that downloaded the data, and he did not destroy the data, he told THE DARK REPORT. He added, however, that CMS had intervened in the matter and asked him to await further instructions.

"The data in the MolDX MEF that Palmetto is concerned about is the exact same pricing information that CMS releases every year for all physicians, labs, and CPT codes," Quinn said in an email.

"The only difference between what I published on my DHP site and what CMS releases is that CMS imposes a one-year delay on its release. My goal in posting these data was to identify clear-cut payment errors—and I found many of them."

A review of the blog post headlines on Quinn's DPH site may reveal why Palmetto asked him to delete the data. Here are a few:

- "Medicare's Unorthodox Spending on Code 81408 in CY2019: 80% in Red States," Oct. 14.
- "Palmetto's Public DEX Data Shows How Indicted Lab Invades Medicare, Gets Payable Z Codes," Oct. 13.
- "Comparing Medicare Molecular Pathology Spending in the Non-MolDX States," Oct. 7.
- "More Data on the Unbelievable Explosion of 81408 Spending at Medicare: Novitas and FCSO MACs Only, $300M Lost," Oct. 6.

Medicare Spending on Tests

The letter from Killough came one month after the federal **Office of Inspector General** (OIG) reported that the Medicare program spent $7.6 billion for clinical laboratory tests in 2018, a $459 million increase from the $7.1 billion it spent the year earlier.

"Although payment rates for most tests decreased in 2018, savings that resulted from lower rates were overtaken by increased spending on other tests," the OIG said. "Spending on genetic tests increased from $473 million in 2017 to $969 million in 2018 because of new and expensive tests entering the CLFS, as well as an increase in the volume of existing genetic tests."

Price Transparency Final Rule

Meanwhile, even as Palmetto was claiming that certain Medicare price and claims data were proprietary, the federal government was taking steps to increase the transparency of prices paid to hospitals, physicians, clinical laboratories, and other healthcare providers. On Oct. 29, CMS touted the completion of what it called a "historic price transparency initiative."

On that day, CMS and the federal departments of **Labor and Treasury** issued a final rule on price transparency, requiring most commercial health plans—including group health plans and individual health plans sold on the Affordable Care Act Insurance Marketplace—to disclose their prices, including cost-sharing information on what consumers pay.

The rule fulfills a key element of an executive order on price and quality transparency that President Trump issued in June 2019, CMS said.

Earlier this year, CMS issued a similar final rule on price transparency for hospitals and health systems that becomes effective on Jan. 1, 2021.

All clinical labs performing genetic tests have an interest in this dispute, because transparency in prices and claims volume are one way that fraud can be identified, and competitive forces can work to prevent the Medicare program from being overcharged by less-than-ethical testing companies. **TDR**

Contact Bruce Quinn, MD, at bruce@brucequinn.com; Jeffrey J. Sherrin at 518-462-5601 or jsherrin@oalaw.com.

New Twist: HHS Exerts Authority Over FDA on LDTs

In legal memo, Health and Human Services says it is governing agency and intervenes on LDT regulation

CEO SUMMARY: In a recent memo, the federal Department of Health and Human Services' general counsel rendered a legal opinion that FDA would need to issue new regulations to regulate LDTs. By stepping into this years-long dispute and saying that FDA cannot regulate LDTs through guidance documents as it previously did, the HHS legal opinion could benefit clinical labs and IVD companies. HHS seems to be using this memo as a way to assert its authority as the governing agency.

In a significant twist in the federal **Food and Drug Administration's** years-long effort to regulate laboratory-developed tests (LDTs), the federal **Department of Health and Human Services** (HHS) has clarified the process FDA should follow to regulate LDTs.

This is an important development with major implications for any clinical laboratory that performs LDTs. The multi-year effort by the FDA to claim its authority to regulate LDTs by issuing guidance documents has been regularly disputed by many lab companies, national laboratories, and trade groups.

Regulation of LDTs

Since the early 1990s, the FDA has asserted its right to regulate these tests—an effort that many in the clinical laboratory industry oppose. But, in those almost 30 years, the agency did not finalize a plan to regulate LDTs. In 2014, it issued two draft guidance documents for its regulation of LDTs that were later withdrawn. Now the FDA's ability to use guidance documents as the basis of regulating LDTs has been removed under a memo the HHS general counsel issued in June.

Press coverage of the issue made it appear that the FDA was feuding with HHS, but that's incorrect, according to Roger D. Klein, MD, JD, a former adviser to the FDA and a Faculty Fellow at the **Center for Law, Science, and Innovation** at the **Sandra Day O'Connor School of Law**.

The HHS has the right to assert its authority over the FDA on this issue because FDA is an agency within the Department of Health and Human services and its commissioner derives his or her legal authority through the HHS secretary, Klein explained. *(See "HHS 'Stands Down' FDA on Its Oversight of LDTs," TDR, Aug. 24, 2020.)*

"The FDA's authority stems from the secretary of HHS. Therefore, FDA would need to issue new regulations through 'notice and comment rulemaking' in order to regulate LDTs," said Klein in an interview with The Dark Report.

In a memo dated June 22, HHS General Counsel Robert Charrow explained that the department's legal staff reviewed the FDA's legal authorities and regulatory processes so that it could advise HHS, the FDA, and all policymakers on the issue. The legal team reviewed that authority,

"especially in light of COVID-19," the memo noted.

The FDA has come under fire during the coronavirus pandemic for requiring clinical laboratories to request emergency use authorizations for any LDT that labs would use to identify patients infected with the SARS-CoV-2 coronavirus causing the COVID-19 illness. *(See "Regulators Acted Slowly as Labs Developed Tests for Coronavirus," TDR, March 30, 2020.)*

Rulemaking Procedures

On Aug. 19, HHS issued a directive saying the FDA could not regulate LDTs without issuing new regulations under official rulemaking procedures. New reporting on that issue reveals that the August directive was based on Charrow's legal review from June. *(See, "FDA Will Have No Authority Over Laboratory-Developed Tests, HHS Says," TDR, Aug. 24, 2020.)*

Specifically, Charrow's June 22 legal memo addressed three issues:

- Whether LDTs are medical devices;
- If LDTs are medical devices, under what circumstances the FDA has jurisdiction to regulate them; and
- Whether the FDA can regulate LDTs without notice/comment rulemaking.

On the first two issues, the memo showed that LDTs are medical devices and that circumstances may exist in which the FDA has regulatory jurisdiction. On the last issue, the memo stated that the agency can regulate LDTs, but when doing so, it must use HHS' notice-and-comment-rulemaking procedures as outlined in the Administrative Procedures Act, Klein explained. This last issue, therefore, forms the basis for HHS' Aug. 19 announcement, he added.

In October 2014, the FDA issued draft guidance documents for clinical labs on LDTs. One of those documents was titled, "Framework for Regulatory Oversight of Laboratory-Developed Tests (LDTs)." That guidance was issued for comment only, but was highly controversial among clinical laboratories. *(See "FDA Official Makes Case in Favor of LDT Guidance," TDR, Dec. 28, 2015.)*

"But now, if the FDA wants to regulate laboratory-developed tests, the agency will need to issue new regulations and it will need to do this through the notice-and-comment procedures," Klein said. "The FDA can't just issue guidance documents as it did in 2014.

"For many years, the FDA has been notorious for regulating through guidance documents," he added. "But many in the legal and policy arenas have objected to the use of explanatory guidance documents to set forth what they argue are actually policy determinations. Fundamentally, that's the issue—that even if the FDA has the authority to regulate LDTs, it cannot do so through guidance documents.

"What that means in practice is that the agency must take all the necessary steps required for notice and comment rulemaking," he commented. "That's a more difficult and more time-consuming process. This is an obstacle for the FDA, because now the agency would need to publish the rules in the *Federal Register,* after which the agency must respond to stakeholder comments."

More Laborious Process

While that process is more laborious than issuing guidance documents, it is also less arbitrary and potentially even more equitable for clinical labs, *in vitro* diagnostics (IVD) manufacturers, physicians, patient groups, and the public, Klein observed.

With notice and comment rulemaking, those stakeholders would get a chance to explain why any proposed regulations would affect them before the regulations became final. For example, the proposed regulations could cause costs to rise or result in patient harm.

"Then, the FDA would need to review those comments and perhaps adjust the regulations accordingly or withdraw them if necessary," Klein explained. TDR

Contact Roger Klein, MD, JD, at roger@rogerdklein.com or 203-927-0257.

IVD Update

IVD Firms Report Robust Growth In Third Quarter Financial Reports

Demand for COVID-19 molecular tests exceeds ability of companies to manufacture enough tests

FOR THE BIGGER *IN VITRO* DIAGNOSTIC (IVD) COMPANIES, the third quarter (Q3) ending Sept. 30 was a time when diagnostic sales rose—molecular testing is skyrocketing, actually—while other corporate divisions continued to lag amid the COVID-19 pandemic.

Here are recaps of Q3 earnings reports and investor calls from leading companies serving clinical laboratories with instrument platforms, diagnostic tests, reagents, supplies, and more. During the conference calls, executives often provided insights about how long they believe the demand for COVID-19 tests will continue into 2021. This information will be helpful to clinical lab administrators and pathologists as they do strategic planning for their own laboratories and group practices.

Roche

ROCHE: Diagnostics Division Grews 18% during Third Quarter

Continuing demand for diagnostic instruments and test kits used for SARS-CoV-2 testing fueled sales growth at **Roche Holdings'** diagnostics division. For the first nine months of 2020, global sales at its diagnostics division were US$10.6 billion, an increase of 18% compared to the same period in 2019.

Overall, Roche Holdings, based in Basel, Switzerland, reported revenue of US$48.2 billion in the first nine months of 2020, which was 1% growth at constant exchange rates over the first nine months of 2019.

During the company's earnings call on Oct. 15, Roche CEO Severin Schwan made an interesting observation about the ability of the IVD industry to manufacture unlimited quantities of COVID-19 molecular tests. Roche is about to "bring an antigen test to the market for the clinical lab ... and we will do this by the end of the year. And that is very meaningful, because ... as you know, [there are] constraints on the PCR tests ... I mean, we as an industry will never be able to provide a PCR test for the masses, it's just not possible. But antigen tests can be scaled up."

Thomas Schinecker, CEO of Roche Diagnostics, predicted that demand for COVID-19 tests will continue. "Now with regards to demand, I would say it's pretty clear that—at least until the middle of next year—the demand is still going to be significantly higher than supply," he said. "This is not a Roche-specific phenomenon but this is an industrywide phenomenon."

In answer to an analyst's question, Schinecker said, "Now, if I look into 2021 ... it's very difficult to exactly predict. But it's pretty safe to say that we will not see any downturn in testing until—for certain—in the middle of next year. Potentially, we'll see testing over the next years to come (maybe at low amounts) because this virus is now endemic. This virus is not going to go away anymore.

"That's also why we believe that antigen tests are extremely important," continued Shinecker, "because they can complement the PCR testing. First, if a person is positive and the specificity is

really high, then it's clear that this person is positive. Second, you will definitely identify the people who are having a higher viral load and are really infectious. So, you need to use the combination. And this is what a lot of governments are going for at the moment."

In its earnings release, Roche disclosed that, for the first nine months of 2020, "sales in molecular diagnostics increased 77%, with 88% growth in the underlying molecular business. Growth was driven by virology (predominantly SARS-CoV-2), Quantitative PCR (to detect molecular/genetic targets) and Nucleic Acid Purification (to isolate and purify genetic material), Molecular Diagnostics systems, and Molecular Point-of-Care (influenza viruses)."

Abbott
A Promise for Life

ABBOTT LABORATORIES: 38.8% Organic Growth in Diagnostics in Response to COVID-19 Pandemic

Abbott Laboratories, which in August, received a $760 million federal contract for 150 million rapid antigen tests to detect COVID-19, had a strong third quarter. The diagnostics business segment grew nearly 40%, said Robert Ford, Abbott President and CEO, during the company's earnings call.

Total worldwide sales were $8.9 billion for Abbott, an increase of 9.6% compared to Q3-2020. "We've sold more than 100 million COVID tests across our diagnostic platforms," said Ford. Abbott CFO Robert Funck added that "global COVID testing-related sales were approximately $880 million in the quarter."

When asked a question about how long the pandemic would last, Ford said, "... COVID-19 sustainability ... is a key topic here ... I've talked about the testing demand over four different phases:

- the pandemic phase,
- the recovery phase,
- the vaccine phase, and,
- a post-vaccine phase.

"... my view is that a lot of the volume was still going to be in the pandemic recovery phase," he continued. "Even with a vaccine, you'd still get more of a steady state, but a lot of the [COVID-19 test] volume was going to be coming during this pandemic and recovery phase. I still think we're in this phase right now—depending on the country and whether it is in a pandemic or in a recovery, and I expect that to last definitely all next year."

Abbott Laboratories is making a big bet on SARS-CoV-2 antibody testing. When asked a question on this topic, Ford replied "Do I think there's an opportunity for antibody testing as the vaccine gets rolled out? Yes, I do. I see the opportunity for [both] core lab-based and rapid lateral flow [COVID-19] testing.

"We've seen some governments already mandate [that] on every blood draw, other tests [are performed] to check for antibodies," he explained. "I think that's going to get more intense when the vaccines get rolled out."

Early in the SARS-CoV-2 outbreak, Abbott's ID NOW platform made national headlines as a way to generate fast results. Ford discussed Abbott's success with the ID NOW and why he believes that this instrument system will be a foundation for further growth.

"When we started the year, we had over 20,000, ID NOWs placed in the US alone," commented Ford. In just "four months, we've already doubled that placement rate by adding more physician offices, retail channels, universities, and a variety of other channels.

"So, what we're building here with the COVID test [run on an ID NOW] is an installed base that will then be able to run different kinds of assays and different tests," added Ford. "And if they're digital, if they're affordable, then, [given] the consumer behavior today in COVID testing, we believe [it will also] be there for all the other assays that we will build on [by using the ID NOW platform]."

DANAHER–BECKMAN COULTER, CEPHEID: COVID-19 Test Planned

Danaher—with a Diagnostics Division that includes **Beckman Coulter**, **Cepheid**, **Leica Biosystems**, and **Radiometer**—announced Q3 net earnings of $883.5 million, a 38% year-over-year increase.

"We generated $5.9 billion of sales with 14% core (business) revenue growth. COVID-related revenue tailwinds contributed approximately 1,000 basis points (or about 10%) to third quarter core revenue growth, while our underlying base business was up approximately 4%," said Rainer Blair, President and CEO, during an earnings call.

Blair also reported these Q3 data during the call:

- Diagnostics revenue was up 18%.
- Cepheid had core growth of 100% due to COVID-19 testing volumes and GeneXpert installs.
- Radiometer and Leica Biosystems had mid-single digit core revenue growth.
- Beckman Coulter Diagnostics saw declines moderating as elective procedures resumed in Q3.

"Moving over to diagnostics," continued Blair, "reported revenue was up 18% and core revenue was up 17.5% led by more than 100% core growth at Cepheid as a result of COVID-19 testing volumes and record GeneXpert System placements. Radiometer and Leica Biosystems, our acute care and pathology businesses, delivered mid single-digit core revenue growth. Declines at Beckman Coulter Diagnostics moderated as elective procedures and wellness checks continue to resume throughout the quarter."

Cepheid is one of Danaher's diagnostic products that is enjoying high demand because of the pandemic. Cepheid introduced its 4-in-1 respiratory virus test. Blair said, "it will be priced right around $55 to $60 per test, and that compares to the COVID-only of about $20 to $40. Once again, [this] depends on the type of customer and volumes and so forth."

During the conference call, the Danaher executives discussed the supply chain issues of meeting the "extraordinary demand" for COVID-19 tests. In the case of Cepheid, they said that in Q2, Cephied had shipped six million tests; in Q3, seven million tests shipped; and expectations are that eight million tests will be shipped in Q4. These production numbers will help labs using the Cepheid system understand how demand overwhelmed supply, even as production was increasing.

BIO-RAD LABORATORIES: Imaging Sales Make Up for Sales Decline in Diagnostics Division

Bio-Rad Laboratories of Hercules, Calif., experienced a Q3 boost in revenue of 15.5% as compared to Q3-2019. Revenue for the period ending Sept. 30 were $647.3 million as compared to $560.6 million in Q3-2019. Other data reported by Bio-Rad for the period are:

- Life Science Segment net sales of $324 million, an increase of 50.2% from Q3 2019.
- Clinical Diagnostics net sales of $322.2 million, a decrease of 5.7% from $341.8 million in Q3 2019.

"Although clinical labs have seen a significant negative impact by the pandemic, we are now experiencing a gradual recovery from the trough of Q2 and expect incremental recovery until the end of the year," said Norman Schwartz, President and CEO, in an earnings call.

During the call, executives said the majority of the year-over-year growth in the third quarter was driven by Bio-Rad's core PCR products: Droplet Digital PCR and Process Media. Both core PCR and Droplet Digital PCR product revenue increases were largely COVID-19-related. TDR

Compliance Update

Medicare COVID Test Coding May Become a 'Logistical Nightmare'

CMS adds more billing codes to implement new 48-hour payment rule for COVID-19 tests

Starting Jan. 1, 2021, clinical laboratories performing COVID-19 tests using high-throughput systems for Medicare patients must comply with a complex new coding rule when submitting claims for these tests.

The federal **Centers for Medicare and Medicaid Services** (CMS) will pay $100 for COVID-19 test claims if labs can document that the tests were completed within 48 hours and that most of the previous month's COVID-19 tests were completed within that same turnaround time.

Fail to meet these two 48-hour TAT requirements and CMS will pay only $75 per COVID-19 test. *(See, "Medicare to Cut Payment for COVID Tests Starting Jan. 1," TDR, Oct. 26, 2020.)*

'Logistical Nightmare'

The new Medicare rule is expected to be "a logistical nightmare for clinical labs, pathology groups, and billing companies," predicted Leigh Polk, Sales and Marketing Director for **Change Healthcare**, a billing and consulting company.

Associations representing clinical laboratories said CMS' use of a TAT standard for cutting payment may be a first for clinical laboratories and anatomic pathologists.

Thus, lab and pathology groups using high-throughput systems for SARS-CoV-2 testing must assess their work processes to ensure that they can complete COVID-19 tests within Medicare's 48-hour TAT requirement.

"What makes this a challenge is that often a lab codes test claims based on which tests physicians order and not on the test turnaround time," explained Polk. "Now, both labs and their billing service companies need to have procedures in place to identify those tests that meet the 48-hour standard and those that do not."

CMS amended an administrative ruling (CMS 2020-1-R2) to lower the reimbursement rate for codes U0003 and U0004 to $75. CMS also said it would pay an additional $25 to laboratories that complete testing within two calendar days and use HCPCS code U0005 for that purpose.

When using code U0005, the lab would be designating that it was detecting an infectious agent by nucleic acid (either DNA or RNA) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using an amplified probe technique and high-throughput machines, CMS said.

Those tests need to be completed within two calendar days from the date and time of specimen collection, the agency added.

The U0005 code would need to be listed separately in addition to either HCPCS code U0003 or U0004. This change would be effective for a date of service collection on or after Jan. 1, CMS said.

Quick Turn-around Time

One challenge for clinical labs and pathology practices will be accomplishing these tests within two calendar days.

"That TAT includes the date and time from specimen collection to the date the specimen result is completed, which CMS

ACLA Says CMS Change to COVID-19 Payment 'Raises Red Flag for a Number of Reasons'

EARLIER THIS YEAR, the federal Centers for Medicare and Medicaid Services (CMS) increased payment for COVID-19 molecular tests to $100. But last month, CMS cut that rate to $75, creating problems for clinical labs seeking to boost capacity, said the **American Clinical Laboratory Association** (ACLA).

"The latest change in payment from CMS raises red flags for a number of reasons. Primarily that payment cuts don't actually address the root causes of delayed turnaround times," said ACLA President Julie Khani.

"Turnaround times are driven largely by fluctuations in demand and labs' access to critical supplies," she added. "Instead of addressing those core issues, the new Medicare framework penalizes laboratories for factors often outside their control.

"Adequate, predictable reimbursement allows labs to make investments and increase capacity for COVID-19 testing." Khani noted. "At a time when the country faces a rise in infections, we are concerned about the potential domino effect of this policy.

"There is no question that unsustainable reimbursement has an impact on efforts to expand COVID-19 test capacity, and CMS acknowledged that reality when the agency increased the payment for high-throughput COVID-19 testing back in the spring," she reported.

"But now, CMS cutting payment and insurance companies continue to deny claims for COVID-19 testing—even in cases when the patient is suspected of having or been exposed to the coronavirus—creates problems for labs," she added.

"Increasing the payment per test to $100 allowed labs doing COVID-19 testing to expand capacity, and also allowed labs that were not doing these tests to begin doing so," she added.

"Now that CMS has cut payment, ACLA encourages all healthcare professionals both inside and outside the lab community to contact members of Congress to make sure that we are closing the persistent coverage gaps that make it harder to obtain testing," she concluded.

says is when the results of the test are final and ready for release to the ordering physician," she said.

Once a lab has run these molecular COVID tests using high-throughput machines, then they can bill for the $25 add-on payment using HCPCS code U0005 as long as they meet these two conditions:

- First, the tests must be completed within two calendar days from the date of specimen collection, and
- Second, most (51%) of a lab or pathology group's COVID-19 tests must be completed using high-throughput technology in the previous calendar month within two calendar days for all of their patients, and not just a lab or group's Medicare patients.

CMS Audit of U0005 Claims

"There is a strong likelihood that CMS will audit practices that bill using U0005," Polk commented.

"Therefore, we urge our lab clients to have processes in place to monitor and document turnaround time for both individual tests and the tests run in the previous month." TDR

Contact Leigh Polk at 843-601-0184 or Leigh.Polk@ChangeHealthcare.com; Julie Khani at 202-569-9715.

Lab Regulatory Update

CLIA Lab Inspections Different Because of COVID-19 Pandemic

CAP, COLA, The Joint Commission provide updates during session at last month's Executive War College

With the onset of the COVID-19 pandemic in March, three of the major organizations deemed to have CLIA status suspended inspections of clinical laboratories for several months. Inspections and assessments of laboratories have restarted, but with significant changes because of the SARS-CoV-2 outbreak.

These changes to the CLIA lab assessment and accreditation process were the subject of an important virtual session at the *Executive War College* last month. The panel chair was Nora Hess, a senior consultant with **Accumen**, a healthcare consulting firm. The panelists represented:

- **College of American Pathologists**,
- **COLA**, and,
- **The Joint Commission**.

One key message shared by all the panelists is that, because of the ongoing pandemic, clinical laboratory managers should prepare themselves for more virtual inspections and a slow return to business as usual.

Hess opened the panel by noting that travel restrictions and stay-at-home orders across the country disrupted clinical lab inspections and changed the way the accrediting agencies operate while complying with the requirements of CLIA.

Following is an overview of the comments from each of the three panelists representing the three major laboratory accrediting agencies. They provide insights and information about how the pandemic affected their ability to conduct surveys of clinical labs and pathology labs.

The Joint Commission

The Joint Commission: TJC IS CATCHING UP ON CLIA LAB SURVEYS

The Joint Commission (TJC) paused surveys in March but resumed in June, offering both virtual and on-site surveys, stated Heather Hurley, Executive Director.

When determining where to travel for surveys, The Joint Commission considers COVID-19 positivity rates in communities where clinical laboratories are located, as well as the number of COVID-19 patients currently being treated in a particular hospital.

"We are in communication with each healthcare organization due for a CLIA lab survey to understand how it has been impacted by the pandemic and whether the facility is able to sustain a survey in its current condition," said Hurley. "These factors determine whether or not we will complete an on-site survey. Based on our system, we determine 'no go' zones which indicate the surveys in those areas will be done virtually."

The organization has expanded its driving radius, though surveyors do continue to fly to clinical laboratories for inspections. All surveyors are employed by The Joint Commission.

"For clinical laboratory organizations that are past due, CLIA has put out a requirement that surveyors need to catch up by the end of the year. So if your laboratory is past due, you can expect that we will be reaching out to you soon," she stated.

To limit contact, Joint Commission surveyors typically travel alone or in small groups, noted Hurley. TJC surveyors are not entering areas where there are COVID-19 positive patients.

"Our surveyors practice social distancing, wear personal protective equipment, and limit the number of staff in the room with our surveyors," continued Hurley. "In regions designated 'no go' zones—and that changes daily and weekly—we expect virtual CLIA laboratory surveys to continue."

COLLEGE of AMERICAN PATHOLOGISTS

College of American Pathologists: CAP CUSTOMIZING CLIA INSPECTIONS

The College of American Pathologists (CAP) also stopped performing inspections in mid-March and resumed them in June, explained Denise Driscoll, CAP's Senior Director of Laboratory Accreditation and Regulatory Affairs. Initially upon resuming inspections, the CAP performed a limited number, primarily in response to complaints, to investigate immediate jeopardy concerns, or to follow up instances of noncompliance.

CAP's next priority was completing initial CLIA inspections for laboratories, followed by addressing overdue routine inspections in regions where the community spread of COVID-19 allowed such activity. Routine inspections were next on the priority list, Driscoll explains.

"We're trying to optimize the process for the future," said Driscoll. "The scope of the inspection has not really changed. We will conduct a complete inspection of all disciplines and subdisciplines prior to an accreditation decision, with a slight change in how we go about doing that."

Specifically, CAP inspectors are being encouraged to perform online document review prior to the on-site inspection, thus allowing for a smaller group of inspectors to go onsite at a clinical laboratory. The goal is to reduce potential exposure to the virus.

The federal **Centers for Medicare and Medicaid Services** (CMS) does require an on-site component of CLIA inspections, but currently allows remote document review.

"We are working to manage this balance as best fits the laboratory being examined," explained Driscoll. "Some clinical labs are not comfortable providing online access to the inspectors ahead of time, or they may want only a few documents to be shared with the team ahead of time. There's a lot of customization of inspections based on the laboratory's needs."

Another change is that the CAP team is not personally observing testing performed in patient care areas because of potential exposure of inspection team members and patients, noted Driscoll. CAP also has reduced inspection team size. In many cases, both CAP staff surveyors and local peer inspectors—who can drive rather than fly to the sites—are conducting inspections. "We continue to make modifications as needed," she added.

CAP suspended international inspections. It has plans underway to begin virtual options for non-CLIA laboratories and to follow domestic plans for CLIA-licensed labs outside the United States; however, travel restrictions will impede on-site visits for all international laboratories in CAP accreditation programs.

COLA Accreditation. Education. Innovation.

COLA: COLA OFFERS THREE-STEP CLIA SURVEY PROCESS

COLA suspended routine CLIA clinical lab surveys in mid-March, but has since resumed surveys in areas deemed safe, stated Kathy Nucifora, Chief Operating Officer.

"We do that by looking at the incidence of new COVID-19 cases in a given area, as well as the positivity rate," she said. "Each week, we go into several credible websites and maps and drill down to the state and county level and make a decision as to whether or not we will go into that area the following week. And then the next week, we do it again. We have had areas where we have paused CLIA lab surveys, maybe resumed a few,

and then paused again. We do this in near-real time to protect our surveyors, the clinical laboratories being assessed, and their staffs."

Currently, COLA surveyors only drive to sites and do not fly. Initially, surveyors would do day trips, but now they may do extended trips, coming home at the end of the week. "COLA is assessing the safety of air travel and hopes to be able to have surveyors fly to sites in the not-too-distant future," she said. "COLA surveyors practice social distancing, wear PPE, and follow other guidelines recommended by the federal **Centers for Disease Control and Prevention**."

Remote CLIA Surveys

CMS announced in May that accrediting organizations would be given the flexibility to define a process for remote surveys. COLA received approval for its remote process in July and has since implemented virtual CLIA surveys for clinical laboratories that are due or overdue for surveys and are located in areas that surveyors cannot get to by driving, or that have not been deemed to be safe.

The process is not 100% virtual, explains Nucifora. There are three components to COLA's virtual surveys:

1. **Documentation Review.** Clinical laboratories are asked to upload documents to COLA's customer portal, including current CLIA certificate, qualifications for any personnel that have not yet been reviewed, competency assessments, all proficiency testing records, as well as a representative sampling of quality assurance and quality control records.
2. **Video Conference.** Once documents are reviewed, surveyors hold a video conference with the clinical laboratory director and staff to follow up on document reviews and do spot checks to ensure ongoing compliance. The date of the video conference is recorded as the official survey date.
3. **On-site Visit.** Once the clinical laboratory is deemed safe, surveyors perform an on-site visit. This serves as a confirmation of lab operations and allows additional follow-up on issues identified during the first two components of the inspection.

Not all COLA clinical labs are eligible for remote surveys. New labs and large labs are prioritized for on-site surveys. Laboratories are encouraged to contact COLA to discuss the possibility of a virtual survey.

"When surveyors are onsite, they practice physical distancing," stated Nucifora. "We ask that laboratories give our surveyors the space to work so they can maintain six feet of distance from others. This has been a significant challenge. Our surveyors report that it's hard to break habits that have been solidified over years and years."

COLA surveyors will not observe certain processes in patient care areas, such as transfusions. Surveyors will comply with all facility requirements in place to protect patients and staff, such as taking temperatures, answering questionnaires, and limiting the areas of the hospital or clinical lab where they are working.

Though COLA is not yet caught up on surveys, it is trying to get back to a regular biennial schedule, explained Nucifora. For example, if a clinical laboratory was due for its CLIA survey in March 2020, but because of the pandemic it was not surveyed until July 2020, the next biennial survey will be in March 2022.

Future Impact on Inspections

All the representatives from the accrediting agencies believe the changes to the CLIA survey process made due to COVID-19 will continue to impact inspections. Nucifora believes virtual surveys will likely continue to some extent for the foreseeable future.

Surveyors also will be enforcing a relatively new CLIA requirement that all clinical laboratories report results of SARS-CoV-2 to their state health agency. **TDR**

Contact Kathy Nucifora at knucifora@cola.org; Heather Hurley at hhurley@jointcommission.org; Denise Driscoll at ddrisco@cap.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It appears that the onset of the influenza season in North America is bringing with it a sizeable increase in the daily number of new COVID-19 cases. In the second week of November, the United States saw daily new cases push towards 200,000—which is more than double the mid-July peak of about 70,000 cases per day. In turn, that larger number of daily new infections increases the need for larger daily volumes of SARS-CoV-2 tests. The **American Clinical Laboratory Association** (ACLA) responded to these developments with a press release on Nov. 12 warning that the nation's labs are running at full capacity and will be challenged to maintain the desired turnaround time of 48 hours for a COVID-19 test result.

MORE ON: *Upsurge of COVID-19 Cases*

ACLA said that its member laboratories performed 495,000 COVID-19 PCR tests on Nov. 11, which was "an all-time high" for ACLA-member labs. ACLA also said, "the surge in demand for testing will mean that some members could reach or exceed their current testing capacities in the coming days. In cases where the number of specimens received exceeds an individual laboratory's testing capacity, there could be an increase in their average time to deliver results. "

ELAN MUSK: 'EXTREMELY BOGUS' COVID-19 TESTS

One Silicon Valley billionaire is learning about the complexities of a clinical laboratory test. Days ago, *Bloomberg* reported that **Tesla** CEO Elon Musk went on Twitter and posted, "Something extremely bogus is going on. Was tested for COVID four times today. Two tests came back negative, two came back positive. Same machine, same test, same nurse. Rapid antigen test." That got noticed by the news media. On Nov. 15, Musk posted a tweet that said, "Doing tests from several different labs, same time of day, administered by RN & am requesting N1 gene PCR cycle threshold. There is no official standard for PCR testing. Not sure people realize this."

TRANSITIONS

- Jeffrey Field, MS, MBA, is the new Chief Commercial Officer at **Clear Labs** of San Carlos, Calif. Field previously worked at **IDbyDNA**, **GenePeeks**, **Foundation Medicine**, **Caris Life Sciences**, **CVS Health**, **AstraZeneca**, and **Merck and Company**.
- **The American Academy of Dermatology**, with headquarters in Rosemont, Ill., announced the selection of Elizabeth K. Usher, MBA, as its new Executive Director and CEO. Usher previously held executive positions with the **College of American Pathologists**, **GE Healthcare**, and **Amersham Health**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 7, 2020.

Publisher: Robert L. Michel *rmichel@darkreport.com*

Executive Publisher: Bob Croce *bcroce@darkreport.com*

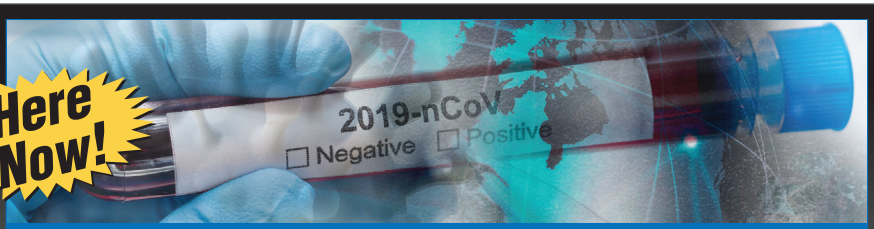
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*

Managing Editor: Michael McBride *me@michaelmcbride.com*

Senior Editor: Joseph Burns *joeburns@capecod.net*

IVD Reporter: Donna Marie Pocius *donna11019@att.net*

Legal/Compliance Reporter: Kim Scott *kmscott2@verizon.net*



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