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BREAKING IN THIS ISSUE

- *Explosion in Medicare Genetic Test Claims*
- *DOJ Indicts 345 people in $6 Billion Fraud*
- *UnitedHealthcare's Three Major Billing Changes*

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Finances to Become More Challenging

When you finish reading our story on pages 3-6 about how Medicare spending for molecular and genetic tests jumped by as much as 700% in certain states during 2019, you'll be among the first in the nation to understand why a financial crisis is soon to wash over those clinical laboratories and pathology groups that perform genetic tests.

We thank Bruce Quinn, MD, PhD, principal of **Bruce Quinn Associates LLC**, in Los Angeles, for sharing his early findings with us. After the Medicare program made public the 2019 claims data in September, Quinn accessed it to analyze spending on molecular and genetic tests. He determined that abusive billing for a number of CPT codes is one logical conclusion for why payment for genetic test claims shot up exponentially in 2019, compared to 2018. Quinn also noted that Medicare genetic test payments for 2018 were 100% greater than 2017. You can visit *brucequinn.com* to read his blog on these findings.

There is a simple economic fact: no healthcare system in the world can sustain a spending increase of 700% in one year for some services. Thus, what will be the response of the Medicare program to the flood of molecular and genetic test claims? Particularly when, as Quinn notes in his blog postings, one obvious conclusion from a study of the billing data is that billing fraud is rampant.

Data shows some lab companies bill large volumes of certain genetic CPT codes and a large portion of those claims are being reimbursed by a handful of Medicare Administrative Contractors (MACs) whose test coverage criteria are not as comprehensive as, for example, the MolDx program. It would also be safe to assume that the same lab companies filing large numbers of claims for medically-unnecessary genetic tests are doing the same to private payers.

If true, then the stage is set for government and private payers to have a rational reason to do what they always do when some sector of the clinical lab market taps the fee-for-service piggybank with huge numbers of false claims. They will: a) stop coverage of specific tests; b) slash their reimbursement for those tests to make them unprofitable; c) audit abusive labs and seek huge recoupment; and/or, d) bring legal action against the most egregious offenders.

Unfortunately, as payers take these steps, it is the law-abiding labs and pathology groups that suffer. The market developments described above are the reason why all labs can expect their finances to be more challenging going forward. TDR

Medicare Pays 500% More for Molecular Test Claims

In some states between 2018 and 2019, Medicare paid 500% to 700% more for some genetic tests

CEO SUMMARY: Rapid growth in what Medicare spent for molecular tests in recent years may lead federal investigators to increase scrutiny of fraudulent billing for clinical laboratory and molecular pathology tests, according to a lab consultant who has tracked such spending in recent years. Data show that Medicare spending for these tests rose sharply since 2017, and that in some Medicare jurisdictions, spending on genetic tests in 2019 rose by 500% to 700% over spending levels from 2018, according to a new analysis.

Newly-released Medicare claims data from 2019 show a previously little-known explosion in claims and payment for molecular and genetic testing—by as much as 500% to 700% in some states in just one year: 2018 to 2019.

The Dark Report is first to report this important development based on an analysis that Bruce Quinn, MD, PhD, did on 2019 Medicare claims data. Quinn is the founder and principal of **Bruce Quinn Associates LLC**, in Los Angeles. Using data from Medicare Administrative Contractors (MACs) in all 50 states, Quinn showed that payments for genetic test claims in several states exploded by as much as 700% between 2018 and 2019.

Quinn's analysis has significant implications for all clinical laboratories. Assuming the accuracy of the assessment is true, the clinical laboratory industry may soon find itself responding to two major developments.

First, Medicare and private payers can be expected to become more aggressive in in their efforts to control the utilization of those molecular and genetic tests they believe physicians are ordering that are inappropriate for their patients. These payers may revoke coverage decisions for tests that lack evidence of clinical utility or make deep cuts in payment for genetic tests and implement tougher audits of genetic testing labs in an effort to recoup payment.

Second, federal healthcare investigators may already have launched a national initiative to investigate genetic testing

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labs, similar to that of the LabScam investigation in the 1990s. The objective of the latest probe would be to curb fraud by bringing civil and criminal charges against those labs that have violated their contracting agreements and federal laws.

$6 Billion in Fraudulent Claims

The federal **Department of Justice** announced just such an enforcement action last week. In this latest nationwide crackdown on healthcare fraud, the DOJ brought charges against 345 defendants in states that the department alleged were responsible for more than $6 billion in fraudulent claims.

Many of the multi-jurisdictional cases involve clinical and molecular testing laboratories, the DOJ said when it announced what it called the largest healthcare fraud and opioid enforcement action in department history. *(For more, see pages 7-10.)*

Quinn suggested that his analysis of the 2019 Medicare claims data showed why some clinical laboratories and molecular pathology groups running genetic tests could be at risk of criminal liability for fraudulent and unnecessary testing. Attorneys with extensive knowledge about state and federal healthcare laws confirmed Quinn's suggestion.

Criminal Liability for Labs

"The reason for the increased risk in criminal liability for laboratories and pathology groups is that genetic testing in several states rose dramatically last year," observed Quinn, a health policy and genetics testing consultant who once was a medical director for a MAC. "In some states, the Medicare data show spending on genetic tests last year rose by 500% to 700% over spending levels from fiscal 2018."

Quinn based his assessment on an analysis of Medicare claims data from 2019 that the federal **Centers for Medicare and Medicare Services** (CMS) made public on Sept. 10. That data is on the CMS website under the heading, "2019 Part B Carrier Summary Data File."

"These spending amounts may be related to massive genetic test fraud that is similar to what federal investigators found in a sting operation in 2019," commented Quinn. Last year, the DOJ charged 35 defendants with fraud related to genetic testing that totaled $2.1 billion. Many of those 35 defendants were affiliated with clinical laboratories and pathology groups under a DOJ program called Operation Double Helix. *(See, "DOJ Charges 35 Individuals in Genetic Testing Scam," TDR, Oct. 19, 2019.)*

Molecular Test Investigations

Justin T. Berger, a partner with the law firm of **Cotchett, Pitre, and McCarthy, LLP**, in San Francisco, commented that lawyers who work with clinical laboratories and molecular pathologists have speculated for more than a year that federal regulators have been looking into molecular test spending. *(See sidebar at right.)*

It's worth noting that Quinn published his analysis on his blog, "Discoveries in Health Policy," on Sept. 22 and Sept. 25. The DOJ announced its crackdown on Sept. 30. "The DOJ's action could be related," Quinn said in an email. "I suspect what the DOJ found is more of the same genetic testing in the poorly-monitored states that my analysis identified, and likely with the same CPT codes that the DOJ acted on last year. In fact, they could be acting on the 2019 claims that I have analyzed."

Quinn's review of 2019 data is significant because it comes after two separate government reports showed that Medicare spending for molecular pathology tests essentially doubled from 2017 to 2018. In one of those reports, the federal **Office of Inspector General** showed

Many Lab Industry Attorneys Expected Action by Federal Prosecuters against Genetic Labs

LAWYERS REPRESENTING CLINICAL LABORATORIES AND MOLECULAR PATHOLOGY COMPANIES have heard rumors for the past several years that criminal investigators are looking closely at how much the Medicare program spends on molecular testing, said Justin T. Berger, a partner with the law firm of Cotchett, Pitre, and McCarthy LLP, in San Francisco. Berger specializes in corporate fraud cases and has represented whistleblowers in clinical lab testing cases.

"For some time, I've heard that scrutiny of these labs and this type of testing has increased," he said in an interview with THE DARK REPORT. "We know about some of this increase because of whistleblower complaints. In addition, increased spending on molecular tests has made these tests an area of focus for the government as we saw last year and again this year."

The press release issued last week by the Department of Justice (DOJ) describing criminal charges against 345 defendants involving fraudulent Medicare claims totaling $6 billion is confirmation that ongoing rumors about active investigations are true.

"Up until recently, it's been almost too early to know exactly how this scrutiny would play out," he added. "Now we see that the DOJ is dead serious about cracking down on fraud.

"One thing that stood out to me in Dr. Quinn's work is that there's a discrepancy between how the different Medicare jurisdictions apply payment rules," he commented. "One Medicare contractor might not pay for a test, while another would pay for that same test."

Labs 'Shop' MACs

When one Medicare Administrative Contractor (MAC) denies coverage for a test, but another MAC pays for that test, labs may then look for ways to bill for their tests through the MAC that pays for them, Berger explained.

"Labs have gotten pretty wise to this method of trying to find the most favorable MAC," he added. "Lawyers have a similar strategy that the legal industry calls forum shopping. You try to bring your case in the friendliest state or where you think the judges are best.

"Basically, labs have adopted an equivalent strategy by trying to find the MAC that will give them a good coverage determination," he said. "That way they can get paid for running a test by setting up shop in states that are sending out those patient specimens to labs in those states. It's a risky strategy, but until we see more uniformity in coverage determinations, it's not likely to end."

that spending on genetic tests rose by $500 million in 2017 and to $1 billion in 2018. The **Medicare Payment Advisory Commission** reported similar numbers.

Quinn's analysis extends this growth pattern from 2018 into 2019. Spending on genetic testing roughly doubled from 2017 to 2018, and now it has been shown to have doubled again from 2018 to 2019. Quinn found the most unusual 2019 spending in states under just two of the seven CMS MACs (the two MACs were **Novitas** and **FCSO**).

"Before spending doubled from 2017 to 2018, spending for molecular pathology tests had been roughly level for several years," noted Quinn. In those years, spending totaled about $500 million and mostly went to a few tests, such as those for BRCA mutations, **Exact Sciences'** Cologuard test, and **Genomic Health's** Oncotype Dx, he added.

Total spending in 2019 for molecular pathology tests was $1.6 billion, an increase of about $600 million over spending levels in 2018, and an increase of $1 billion from 2017, he said. He noted these data do not yet include genetic testing billed to Medicare by hospital outreach labs.

Medicare Spending Levels

In his research, Quinn totaled Medicare spending levels for certain CPT codes from the 28 states. "Basically, I went through more than 50 spreadsheet files state by state," he explained. "For that data, I pulled a sum of spending for CPT codes 811xx, 812xx, 813xx, 814xx, and 815xx."

In addition, Quinn added spending for 0037U in Massachusetts. The 0037U is a CPT code that labs use when billing for a test from **Foundation Medicine**.

In 2019, spending on molecular diagnostics in the 28 states under the CMS MolDx program was $570 million, or 35% of the total that Medicare spent last year on molecular tests. Among those four MACs, **Noridian** accounted for 90% of molecular diagnostic tests in 2019, he reported. MolDx is a formal program under which four of the CMS MACs use the same genetic test policies in 28 states.

$1.07 Billion Spent

In the other 22 states, Quinn reported that $1.07 billion—or 65% of Medicare's total spending last year—was on molecular diagnostic tests. Some of the highlights of Quinn's work include the following:

- In Florida, the total spent on molecular testing was $123 million in 2019, which was seven times more than the $17.5 million that CMS paid for such testing in Florida in 2018.
- In Washington, D.C., Medicare spent $43 million on molecular tests in 2019, and that amount was 5.7 times more than the $7.5 million that CMS spent in that city in 2018.
- In Oklahoma, the total was $123 million in 2019, but Medicare spent only $33 million on these tests in 2018, meaning that what labs in Oklahoma were paid in 2019 was 3.7 times more than what CMS spent in 2018. TDR

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Genetic Labs May Already Have Whistleblowers

IT IS COMMON FOR EMPLOYEES AND INDIVIDUALS associated with a lab company to recognize sales and business practices that violate federal and state healthcare fraud laws. These individuals can often become whistleblowers, particularly after they report the illegal behavior to lab management and nothing changes.

For this reason, it may be that some of the cases announced by federal prosecutors last Wednesday were based upon *qui tam* lawsuits filed by lab whistleblowers.

It is also possible that a surprising number of whistleblower lawsuits filed against different molecular and genetic testing companies are active and still under seal. That means an unknown number of such genetic testing companies may be under active investigation, but because the lawsuits are still under seal by the court, the lab executives and owners remain unaware of their existence.

For these reasons, the entire clinical lab industry may find itself at the edge of a growing wave of federal fraud and abuse investigations. In the 1990s, the federal Department of Justice initiated "Operation LabScam" as a major effort to prosecute clinical labs for test unbundling and related schemes. During its 10-year run, LabScam snared almost every public lab company (sometimes more than once) and generated about $2 billion in settlements.

DOJ $6B Fraud Crackdown Charges 345 Defendants

Largest enforcement action in department history also ensnares molecular and drug-testing lab firms

CEO SUMMARY: Department of Justice cases involving clinical labs or molecular test claims may represent about half (or about $3 billion) of the total fraudulent claims. Those claims stem from genetic testing, urine-drug and other tests, and healthcare services, the DOJ said. In addition, the DOJ reported that labs were involved in filing fraudulent claims for lab tests while working with telemedicine physicians who allegedly were not following best practices when ordering tests for patients.

ANNOUNCED LAST WEDNESDAY WAS A MASSIVE TAKEDOWN OF MEDICARE FRAUDSTERS by prosecutors at the federal **Department of Justice** (DOJ). Collectively, the DOJ has filed criminal charges against 345 defendants in 51 federal districts and 31 states in what it described as an "historic nationwide enforcement action" involving $6 billion in fraudulent claims.

Certain types of clinical laboratory testing are at the core of many of the cases filed by U.S. attorneys in different states, including pain management testing, drugs-of-abuse testing, and genetic testing. The common elements of the individual cases were described by the DOJ in its press release, as follows:

These defendants have been charged with submitting more than $6 billion in false and fraudulent claims to federal healthcare programs and private insurers, including:

- *more than $4.5 billion connected to telemedicine;*
- *more than $845 million connected to substance abuse treatment facilities, or 'sober homes'; and*
- *more than $806 million connected to other healthcare fraud and illegal opioid distribution schemes across the country.*

This program is described as the 2020 National Health Care Fraud and Opioid Takedown. This development may be significant for the entire clinical laboratory industry, for five reasons.

More Fraud Prosecutions?

First, this may be a sign that federal prosecutors are finally ready to more aggressively prosecutive fraud in the substance abuse sector of healthcare.

If true, this puts a large number of lab companies that sprang up in the past 15 years to offer opioid/pain management and drugs-of-abuse tests—and that were seen by competitors as always willing to offer illegal inducements and kickbacks to referring physicians—at risk of criminal and civil action by federal prosecutors.

Second, DOJ officials filed fraud cases against providers and organizations that submitted false claims to both Medicare and private health insurers. This is evidence that these enforcement actions are

intended to curb illegal billing of both government and private health plans.

Moreover, in this regard, the DOJ is following the lead of private insurers. For more than five years, major health insurance companies have filed lawsuits in many jurisdications around the United States against these same types of providers. The payers sought to recover tens and hundreds of millions of dollars for the identical types of fraud described in the DOJ's press release. *(See TDRs, June 5, 2017, and Jan. 22, 2018.)*

Third, the fact that telemedicine providers are linked to $4.5 billion of the $6 billion in fraudulent claims should be a red flag to pathologists. Fraudsters were using telemedicine as a way to quickly and cheaply authorize high volumes of procedures, including clinical lab tests. If federal investigators will be more closely watching telemedicine claims for fraud, then pathologists will want to fully document any lab test procedures they authorize by telephone, so that they have the necessary information whenever their labs may be audited by Medicare or private payers.

Role of Whistleblowers

Fourth, what remains unknown in these cases involved 345 defendants and $6 billion in fraudulent billings is the role of whistleblowers. How many of these cases involve *qui tam* cases is unknown. Further, there could be a large number of ongoing whistleblower cases that remain under seal. That means the federal government knows about these allegations of fraud, but the providers named as defendants have not been served while federal investigators continue to gather evidence.

Fifth—and what may be most significant for the entire clinical laboratory industry—is how and why the 2020 National Health Care Fraud and Opioid Takedown may be just the opening round of a major enforcement effort against lab companies offering genetic tests.

As explained on pages 3-6, the analysis of Medicare Part B spending on molecular and genetic tests indicates the number of claims for these tests is increasing at both an unprecedented and unsustainable rate. When Bruce Quinn, MD, PhD, looked at at the 2019 data from Medicare Administrative Contractors (MACs) in all 50 states, he determined that payments for genetic test claims in several states exploded by as much as 700% between 2018 and 2019! Quinn is the founder and principal of **Bruce Quinn Associates LLC**, in Los Angeles.

Audits? Recoupments?

Assume that private health insurers, such as **Anthem**, **UnitedHealthcare**, **Aetna**, **Humana**, **Cigna**, and others are experiencing similar increases in genetic test claims that approach 700% in the 12 months of 2019, compared to 2018. If true, then all labs performing molecular and genetic tests can expect greater scrutiny of these claims. This can include tough payer audits that result in demands for recoupment that can financially break the lab company.

This happened to a number of lab companies in recent years that offered proprietary genetic tests. THE DARK REPORT investigated the closure of a number of these lab companies. The common element was either:

- an audit by a Medicare contractor that used sampling and extrapolation to look at a small number of claims and used those findings to justify a recoupment amount in the tens of millions of dollars *(see TDR, Sept. 10, 2017)*; or,
- a decision by a Medicare Administrative Contractor (MAC) to deny coverage for a lab company's proprietary test, with the consequence that the company could not obtain coverage from private payers and thus filed bankruptcy or went out of business *(see TDR, July 8, 2013)*.

It should be noted that the claims data used in Quinn's analysis originated in 2018 and 2019, before the SARS-

Attorney Says Prior Justice Department Actions Showed More Federal Charges Were Coming

ONE HEALTHCARE ATTORNEY WHO WORKS CLOSELY with clinical laboratory companies and with labs doing molecular testing was not surprised to learn about the federal Department of Justice's national crackdown on healthcare fraud cases last week.

"All of the cases cited by the DOJ in its crackdown last week were not unexpected," said Danielle Holley Tangorre, a partner in the law firm of **O'Connell and Aronowitz** in Albany, N.Y.

"Given last year's DOJ action known as Operation Double Helix, and then recent fraud alerts about genetic and other forms of testing, we knew that labs were an area of concern for the DOJ," she said. "Plus, we've seen a rapid increase in billing for genetic testing. As a result, there has been higher amounts of reimbursement paid over the last year or so.

"We've seen Medicare come out and say that labs and all healthcare providers need to be cognizant that only certain laboratory tests are covered and that other tests are not covered" explained Tangorre. "Also, Medicare has warned providers that it will pay only if the lab tests are medically necessary.

"This is also true of health insurance companies that made similar statements about how labs need to follow new guidelines when submitting claims for genetic testing and for any tests that have higher reimbursement levels," Tangorre added.

"All lab directors should know that any laboratory that has a huge and sudden spike in billing for certain tests is probably going to trigger some form of analytics from payers," she commented. "The insurance companies want to know your lab is only doing testing that's medically necessary and that your lab follows all the rules.

"Insurers also want to know how your lab markets its tests and whether it is developing relationships with physicians who have good relationships with their patients," she noted.

"Telemedicine is one of the tricky areas that can cause a lot of concern for clinical laboratories, and that's why the DOJ cited so many telemedicine companies," she commented. "Once a physician works with patients via telemedicine, then insurers want to know if any tests that doctor ordered are medically necessary.

"If no recent history exists between the patient and the telemedicine physician, then there might not be a legitimate reason to order lab tests for that patient," warned Tangorre. "If there's no medical necessity to order lab tests, then labs need to be aware of that fact before they submit claims that payers may challenge or deny when auditing the lab."

CoV-2 outbreak began in this country last February. Molecular and genetic test claims for COVID-19 in 2020 will be a huge number.

Review Lab Compliance

For the reasons presented above, the DOJ's announced plans to intensify its prosecution of healthcare fraud would make it timely for all clinical laboratories and anatomic pathology groups to review their organizations' compliance with federal and state laws and regulations. It is also recommended that labs assess their documentation of physician orders for lab tests, including ICD-10 codes and other needed documentation. This is the information Medicare and private payer audits want to see in support of the lab test claims being audited.

In general, the clinical lab profession will welcome tougher enforcement of federal anti-kickback and other statutes. For more than a decade, many in the clinical

laboratory industry have watched widespread fraud and abuse by certain lab companies offering drugs-of-abuse, pain management, and genetic tests and wondered when federal prosecutors would take action to curb this activity.

Federal Lab Prosecutions

These lab professionals will support additional federal cases filed against lab operators alleged to have violated federal and state laws. In the list of cases announced last Wednesday, federal prosecutors said charges were brought against clinical laboratories and molecular pathology groups, pharmacies, telemedicine providers, and operators of sober homes. The 345 defendants cited in 191 cases include more than 100 doctors, nurses, and other licensed medical professionals.

A review of the cases showed that fraud charges involving clinical labs or molecular test claims may represent about $3 billion worth of the total the DOJ reported for fraudulent billing.

In addition, the DOJ reported that laboratories were involved in filing fraudulent claims as a result of working with telemedicine physicians who allegedly did not follow best practices when ordering diagnostic tests for patients, the DOJ said.

More Federal Prosecutions?

The DOJ investigations and prosecutions are happening in the midst of the ongoing COVID-19 pandemic. DOJ officials are already on record with their statement that they intend to prosecute fraud involving COVID-19 healthcare services—including lab tests—on a priority basis.

It should also be no surprise if, during the COVID-19 pandemic, a growing number of whistleblowers file *qui tam* lawsuits. Taken together, these factors may mean that clinical labs will see federal prosecutors file a record number of criminal and civil cases involving healthcare fraud in the future. TDR

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One Large N.J. Case Involved $1.2 Billion

ONE OF THE LARGEST FRAUD CASES DESCRIBED BY THE FEDERAL DEPARTMENT OF JUSTICE involved multiple defendants in New Jersey who were charged for their alleged roles in schemes to defraud insurers of more than $1.2 billion.

The owners and operators of three diagnostic testing laboratories and one marketer were charged for alleged healthcare fraud and kickback schemes under the Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA). The case involves $522 million in fraudulent claims billed to Medicare, Medicaid, and commercial health insurers, the DOJ reported. Of that amount, some $84 million was paid for diagnostic tests, the department added. In this case, the three defendants are:

- Reyad Salahaldeen
- Mohamad Mustafa
- Travores Wills

The entities are:

- **Allergy Solutions System, LLC**, Ala.
- **Express Diagnostics, LLC**, N.J.
- **BioConfirm Laboratory, LLC**, Ga.
- **Tox Management, LLC** (dba **Accurate DX**), Texas
- **Tri-State Toxicology, LLC** (dba **Definitive DX**), Texas
- **Brothers Consulting, LLC**, Ga.

The defendants were charged with paying kickbacks to a network of marketers to procure DNA samples for genetic testing that they knew were medically unnecessary and that would not be paid under the patients' healthcare benefit programs, the DOJ noted. Medical professionals approved the tests, including doctors using telemedicine who had not previously treated the patients and who had little or no contact with the patients in connection with prescribing the tests, the DOJ said.

High-Complexity Mobile Labs for COVID-19 Testing

Company offers on-site testing with fast results for employers, sporting events, concerts, and more

CEO SUMMARY: Demand for high-complexity mobile coronavirus testing facilities is high, according to the CEO of a start-up company building 25 clinical labs in mobile trailers that can do hundreds of tests per eight-hour day. Employers, schools, event organizers, and other entities all have high interest in contracting with this California company for mobile on-site testing that can deliver rapid results in minutes and molecular test results in hours. The company also offers antigen tests in its mobile labs.

NOW OPERATING IN THE CLINICAL LABORATORY MARKET is a California company with mobile laboratories in trailers that semi-tractors move to any client in the 48 contiguous states to do SARS-CoV-2 testing.

The company is **SafeSite**, a start-up company in Calabasas, Calif., that now operates five high-complexity mobile clinical laboratories that will be CLIA-certified. It launched its first testing operations last month.

New Competitor in Lab Tests

Not only is the clinical lab industry getting a new competitor, but this competitor offers a flexible, competitively-priced COVID-19 testing solution to clients of all types. In addition the five labs already built, it is building 20 more mobile testing laboratories.

"Inside these mobile clinical laboratories, medical technologists (MTs) will offer tests for employers, job sites, schools, concerts, sporting events, and any entity or event needing on-site testing," commented Lauren Rogen Sexton, RD, CDE, CEO of SafeSite.

"Inside these labs, SafeSite will use three tests for each worker or event participant. Sexton said that the three tests being used are:

- **Bio-Rad Laboratories'** CFX Real-Time PCR (qPCR) Detection System;
- **Quidel Corporation's** Sofia SARS Antigen FIA test;
- **Abbott Laboratories'** ID Now COVID-19 point-of-care test.

This strategy of building CLIA-certified, high-complexity mobile testing labs that can go wherever they are needed is something any clinical laboratory could do as long as it is willing to invest the time and money. "Among employers, public and private schools, colleges and universities, large-event planners, and sporting venues there's strong interest for on-site testing," observed Sexton.

Background in Wellness

The owners of SafeSite have a background in wellness testing and working with other organizations serving consumer healthcare needs. At present, SafeSite is not affiliated with any clinical laboratories, hospitals, or health systems.

For some assignments, SafeSite's mobile labs will be needed for no more than a few hours or a day, said Sexton, a registered dietitian, certified diabetes educator, and nutritionist. For others, the mobile labs may be needed every day for weeks or months, depending on clients' needs.

Using these mobile clinical laboratories, SafeSite began SARS-CoV-2 testing for its first three clients last month. One was a sporting event and the other two were movie-production lots.

COVID Testing in Calif., Penn.

"One movie lot job was in Los Angeles where 200 movie studio employees were tested, and the other was in Pennsylvania where 40 employees were tested," Sexton noted. "The movie production clients needed testing done onsite to screen the crews so that filming could begin.

"We started testing for COVID-19 during the last week of September and will go anywhere our clients need us," commented Sexton. "We have a protocol-based testing module that we will use to establish a baseline for our clients to identify workers and students who are either positive or negative for the coronavirus.

"We use a combination of tests—including PCR assays, which are the gold standard—for patients exposed to the coronavirus," she continued. "We also have an antigen test and a rapid test. We run those tests onsite from the first day and then each day thereafter that testing is needed onsite."

Can Serve Different Entities

From its headquarters in Calabasas outside Los Angeles, SafeSite expects that many of its clients will be in the entertainment business, either movie or television studios, she added. SafeSite is also prepared to do testing at schools, concert sites, sporting events, and for employers—particularly manufacturing companies—that typically require staff to work in close proximity to each other, such as meat-packing plants, she said.

"Depending on the timeframe in which a client would need everyone tested, we will determine how many mobile labs we'll have onsite," Sexton explained. "Some of our entertainment clients will want us to start early in the morning so that we can spread out testing throughout the day. Other clients might want us for red-carpet events where they would need to test everyone within a few hours. In that case, we'll have multiple mobile clinical labs onsite."

SafeSite's testing protocol calls for employees or event-attendees to be scheduled for testing according to each client's needs. Some employees arriving for work may be asked to arrive early so that technicians can use nasopharyngeal swabs to collect specimens for the PCR and antigen tests.

Results Reported on Phones

Those who test negative with the rapid PCR test will get a wristband with a quick-response (QR) code and a text message on their mobile phones indicating they are safe to report for work. The text message will include a link to a QR code that the employer can scan to allow workers and event attendees to enter the workplace or venue.

Those who test positive with the rapid test would wait until the results of the Bio-Rad test are reported. The antigen test will be used for screening patients every day for the presence of the virus in their systems, Sexton said.

In May, when the FDA approved the Quidel Sofia antigen test for use in the United States, it said that such assays are specific for the presence of the virus but are not as sensitive as PCR tests. "This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection," the agency added.

Mobile Trailers Can Be Configured to Handle Any Volume of On-Site COVID-19 Testing

Laboratory Configurations

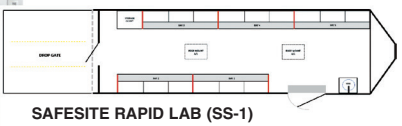
Based on its experience in supporting production of movies and films with services based in trailers and other mobile facilities, SafeSite designed clinical laboratories to fit inside trailers.

These labs will meet CLIA high-complexity laboratory requirements and can be configured to handle any volume of specimens.

At right, from top to bottom:

- Lab testing trailer.
- Interior of lab space.
- SS-1 shows small lab configuration.
- SL-21 shows configuration for rapid testing and high-complexity PCR lab.

SAFESITE™



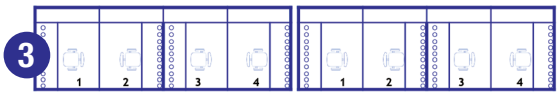
SAFESITE RAPID LAB (SS-1)

SAFESITE SUPER LAB (SL-21)

On-Site Collection and COVID Testing

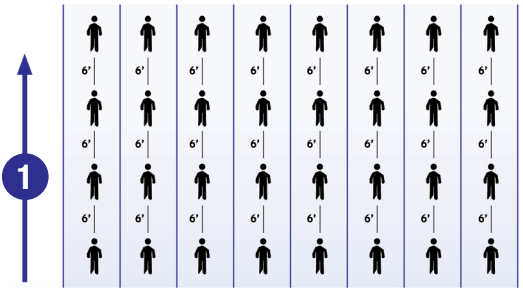
At right is SafeSite's flow during an on-site test program. From bottom to top:

1) Specimen collection done under tents, with lines feeding each collection station.
2) Specimen collection stations.
3) Specimens immediately flow to the testing bays in the mobile, CLIA-certified, high-complexity clinical laboratory.



SAFESITE CUSTOM-BUILT MOBILE LABS

TENTED TESTING AREA



TENTED QUEUE LINES (8X4=32)

"One key to success in testing for COVID-19 is administering tests where they are needed, which is onsite," Sexton commented. "The other key is producing rapid test results onsite, which we can do anywhere and at any time with our high-complexity mobile clinical labs.

"Any testing site that does not provide results immediately or at least in a few minutes or hours is not a viable solution if we want to stop the spread of the virus," she added. For accommodating large numbers of individuals needing testing, SafeSite also can set up sample collection bays in tents, the company said.

Innovators Target Lab Testing

Clinical laboratory administrators and pathologists looking at the marketplace strategically will want to watch how companies like SafeSite are innovating in response to the urgent demand for greater numbers of COVID-19 tests. Because of how it was serving the entertainment industry and organizers of special events, SafeSite had unique experience in using trailers as a way to deliver a service at one time and place, and then moving that trailer to the next event or project site.

THE DARK REPORT wrote about another company that is developing laboratories in shipping containers that can be certified as high-complexity CLIA labs. **Clarity Lab Solutions** in Boca Raton, Fla., is partnering with **SG Blocks Inc.**, of New York on this effort. In response to the demand for COVID-19 tests, their business plan is to speedily build and deliver shipping container-based labs to clients that are cheaper than traditional construction. *(See TDR, "New York Firm to Build CLIA Laboratories in Shipping Containers," Sept. 14, 2020.)*

These are just two examples of how the COVID-19 pandemic is motivating outsiders to enter the clinical laboratory market with solutions they believe will be disruptive and allow them to profit. TDR

Contact Lauren Rogen Sexton at lauren@safesitescreening.com.

Safesite's Labs on Wheels Can Be Different Lengths

SAFESITE'S MOBILE CLINICAL LABORATORIES come in three different configurations that range in size from 20-foot-long to 50-foot-long trailers.

The longer mobile laboratories can accommodate 10 bays for clinicians to meet with patients and collect specimens.

The shorter mobile labs contain five to eight patient bays. There's also room for testing instruments, an entrance door on one side, and an exit door on the back.

The patient bays line the walls on each side of the trailers, separated by a corridor down the middle. Patients would enter at one end, show their appointment codes on their mobile phones, get tested, and then exit out the rear door.

The number of tests SafeSite can run per day would depend on each client's needs and what testing protocol SafeSite would recommend to meet those needs, company officials said.

Some COVID-19 tests will take about 15 minutes to produce a result. Therefore, a mobile lab in a trailer that has five bays producing a test result every 15 minutes could produce 200 tests in a 10-hour day.

Theoretically, an eight-bay trailer could produce 320 tests in 10 hours, and a 10-bay trailer could produce 400 tests in 10 hours.

An RT-PCR instrument in the mobile lab could run 96 samples on a 96-well plate in about 75 minutes, company officials added.

Over the course of a day, one mobile lab could run 768 tests in a 10-hour day. A second trailer configured in the same way could double that number of tests, company officials said.

LIS Update

LIS and Lab Informatics Vendors, Report Second Quarter Earnings

During one earnings conference call, a CEO described labs' growing interest in moving their LIS to the Cloud

It's been a challenging year for companies that sell laboratory information systems (LIS) to the nation's clinical laboratories. Because of the SARS-CoV-2 outbreak, labs have delayed decisions to acquire or upgrade their existing LIS systems, as well as previously-scheduled installs of new or upgraded systems.

Two major sellers of LIS products in the United States are **Cerner Corporation** and **Roper Technologies' Sunquest Information Systems**. Both are public companies and report their quarterly earnings. However, at each company, revenue from LIS sales makes up a relatively small part of total revenue. For that reason, the quarterly earnings reports for each company may not always provide significant information about LIS sales activity in the quarter.

What follows are some basic insights about each company's LIS sales activity in their respective second quarter earnings reports. This information can help clinical lab administrators and pathologists who may be ready to upgrade their LIS or purchase a new LIS.

Roper: Data Innovations, CliniSys, Sunquest Information Systems: 'PERFORM NICELY,' FLAT EXPECTATIONS FOR REST OF YEAR

Roper Technologies' financial results for Q2 2020 included information about the financial performance of its three laboratory IT companies:

- **Sunquest Information Systems**, Tucson, Ariz., which offers the Sunquest Laboratory laboratory information system (LIS) and other diagnostic and laboratory informatics solutions;
- **Data Innovations**, Burlington, Vt., the provider of Instrument Manager and EP Evaluator for lab connectivity and autoverification; and,
- United Kingdom-based **CliniSys Group**, supplier of laboratory management systems to labs worldwide.

During its earnings call with Wall Street investors, Roper President and CEO Neil Hunn said Q2 revenue fell 2% to $1.3 billion while the company's Application Software segment revenues were $398 million, up 1%.

"Our laboratory software businesses—Sunquest, Data Innovations, and CliniSys—all grew and performed nicely aided by the global demand to deploy diagnostic testing software interfaces and laboratory software associated with combatting COVID-19. Specific to Sunquest, we received the termination fee payment for the Queensland project (**Queensland Health**) that opted to terminate implementation due to COVID challenges," said Hunn said during the call.

During the call, Hundley confirmed that a growing number of clinical laboratories are interested in having their LIS hosted remotely. This confirms a trend where labs see the benefits of using an LIS that is hosted remotely.

"Broadly across this segment [of clinical lab software solutions], we see

an increased desire from our customers to migrate [their LIS functions] to our cloud or SaaS (software-as-a-service) offerings," explained Hunn. "[This is] one of several trends that COVID appears to be accelerating."

The shift to cloud-based LIS "should be a long-term growth driver for our business, as we have a large installed base of [lab] customers who will—over time—migrate [their LIS services] to the cloud," he continued. "And turning to the outlook for this segment, we expect to be roughly flat for the second half of the year."

Hunn disclosed that the Q2 financial results were "aided by sales pipelines" launched prior to COVID-19, while the second half of the year is affected by the pandemic shutdown. "As a result, we expect our prospects' decision timeframes may extend longer than our historical experience," Hunn said.

Cerner Corporation: SOFTWARE REVENUE DOWN, BOOKINGS NICELY SURPRISE, DEALS DELAYED

For **Cerner Corporation**, Q2 revenue of $1.33 billon was down 7% from $1.43 billion in Q2 2019. This was attributed to the pandemic and the end of a large contract in Q4 2019, according to a news release.

"Revenue was $10 million below our guidance range, with the impact of COVID contributing to lower levels of technology resale and reimbursed travel," said Marc Naughton, Cerner's Chief Financial Officer, during an earnings call

Also, Cerner's licensed software revenue in Q2 was $152 million, down 23% from a record high of $197 million in Q2 of 2019, according to Naughton.

"While we expected licensed software would be down this quarter, it did come in a bit lower than expected," he noted. "Technology resale of $42 million in Q2 was down 31% year-over-year, primarily driven by a few anticipated new business deals pushing out of the quarter amid the pandemic. Subscription revenue grew 3% in Q2 to $92 million."

In addition to subscription revenue, managed services was the other Cerner revenue line that grow during Q2, increasing 3% to $307 million, *Healthcare Dive* reported.

For the full year 2020, revenue may now be in the range of $5.4 billion to $5.5 billion, down from $5.5 to $5.7 billion, Cerner said. TDR

Epic Systems Sells Beaker LIS to Labs

ONE COMPETITOR IN THE **LIS** (LABORATORY INFORMATION SYSTEMS) MARKET is **Epic Systems Corporation**, of Verona, Wis. Privately held, it is not required to disclose financial information. It offers the Epic Beaker Clinical Pathology LIS in addition to the Epic EHR and other solutions. Epic's annual revenue for 2018 was reportedly $2.9 billion.

Because Epic frequently offers a free license for the Beaker LIS to hospitals purchasing its electronic health record system, it has grabbed marketshare from the established LIS vendors.

Enlyft is a business-to-business marketing development company that provides marketing data bases to its clients. In its data base, it shows this information about five LIS vendors:

- Sunquest: 1,204 customers–57.14%
- Epic Beaker: 498 customers–23.47%
- Care360: 270 customers–12.24%
- Cerner CoPathPlus: 138 customers–6.12%
- Aspyra: 29 customers–1.02%

It is important to note that this is an incomplete list of LIS vendors in the United States, which would include long-established companies such as **CCA**, **LigoLab**, **McKesson**, **Meditech**, **NetLims**, **Orchard Software**, and **SCC Soft Computer**.

Lab Regulatory Update

UnitedHealth Sets More Billing Rules for Labs, Pathologists

UHC seeks refunds for some prostate biopsies and requires member consent for out-of-network referrals

SUBMITTING CLINICAL LABORATORY AND PATHOLOGY TEST CLAIMS to **UnitedHealthcare** (UHC) will be more complex after the nation's largest health insurer announced three significant changes in its claims processing procedures.

The three changes involve:

- Requests for refunds from anatomic pathology (AP) groups that UHC says may have submitted incorrect claims for biopsies,
- Rules for out-of-network referrals, and
- More tests needing prior approval.

This first change could be the most troubling of the new rules. Anatomic pathology (AP) groups may need to pay refunds on prostate biopsy cases billed for members in UHC's Medicare Advantage plans with the CPT code 88305 (level IV surgical pathology, gross and microscopic examination) instead of HCPCS code G0416, said Leigh Polk, PathLab Marketing Specialist at **Change Healthcare**.

Out-of-Network Consent

The second change was made this summer, when UHC instituted a new rule requiring clinical laboratories, AP groups, and other providers to get UHC's members to sign consent forms for out-of-network referrals. The third change came when UHC added more codes to the list of services requiring prior authorization. Each of the new changes is discussed below.

On top of these challenges, clinical laboratories and AP groups must understand and comply with UHC's new Laboratory Test Registry Protocol that goes into effect on Jan. 1, 2021 *(see TDR, Aug. 3, 2020)*.

UHC's new policy for CPT code 88305 affects the most common of all billing codes in anatomic pathology.

"It's been UHC policy since 2015 to align its policies with guidance from the federal **Centers for Medicare and Medicaid Services**," said Polk. "Under this guidance, prostate biopsy claims must be submitted with HCPCS code G0416 with one unit.

88305 versus G0416

"However, UHC's Medicare Advantage plans have not denied cases sent with 88305 versus G0416," she advised. "When coding, AP groups may not be aware of the payer associated with the case.

"For our client AP groups, Change Healthcare implemented processes that identify all prostate biopsy cases for UHC's Medicare Advantage members," said Polk. "These cases are converted from 88305 to G0416 before Change Healthcare submits those claims to UHC."

AP groups that use other billing companies may want to determine if those billers are using the proper code when billing for CPT 88305, Polk recommended.

On July 1, UHC began requiring clinical labs, AP groups, and all other providers serving members in commercial plans to sign consent forms for out-of-network referrals for non-emergency care.

"UHC said labs and anatomic pathologists can have UHC members in com-

mercial plans sign a 'Member Consent for Referring Out-of-Network Form,'" explained Polk. "The form tells UHC members that they may have to pay more out-of-pocket or the entire cost of the out-of-network care depending on each member's out-of-network benefits. As an alternative, UHC said providers can get prior approval for the out-of-network referral by calling the phone number on the back of the UHC member's healthcare identification card.

"If a lab is out-of-network, it can get a UHC member's consent by downloading the 'non-preferred' laboratory consent form at UHCprovider.com," she added. "Once the member signs the form, the provider can upload the signed form to UHC. It might, however, be difficult or impossible for labs to know if a UHC member is in a commercial plan without seeing the patient's insurance card.

Could Face Penalties

"While UHC is not saying they'll deny out-of-network claims if there's no signed consent form, they are saying that the out-of-network provider could face penalties," commented Polk.

On its member-consent form, UHC explained that out-of-network care means the patient may pay more out of pocket, even if the member has out-of-network benefits, or may need to pay for the full cost for the referred service if the member lacks out-of-network benefits.

The UnitedHealthcare form also requires providers to explain to patients why they are being referred for out-of-network care and to disclose any financial interest the provider may have in the out-of-network care provider.

"If, upon seeing this information, you're okay with your doctor's choice to involve an out-of-network healthcare provider in your care, please give your consent below," the form states. "This consent will only be valid for the service(s) your doctor refers on the date you sign this consent." TDR

UHC Adds Lab Tests Needing Prior Approval

PRIOR APPROVAL IS NOW REQUIRED FOR SOME 40 NEW CPT CODES that clinical laboratories and anatomic pathology groups would use when billing UnitedHealthcare (UHC). If clinical labs and AP groups do not get prior approval for these new codes, the health insurer will not pay for these tests or procedures, noted Leigh Polk, PathLab Marketing Specialist at Change Healthcare.

The new codes include those for proprietary laboratory analyses (PLA) test codes between 0172U and 0201U, and for the following CPT codes: 87480, 87481, 87482, 87510, 87511, 87512, 87623, 87660, 87661, 87797, 87798, 87799, 87800, 87801, Change Healthcare reported.

"Although pathologists and clinical labs have 90 days from the date of service to receive prior authorization, labs and AP groups should keep in mind that claims submitted without prior authorization will be denied and cannot be resubmitted," warned Polk.

Diana Richard, Director of the Anatomic Pathology Program at **XIFIN**, recommended that AP groups appeal these denials if the prior authorization can be acquired, even if the group is unlikely to get paid. "If the services rendered were medically necessary, and the prior authorization was acquired within 90 days of the date of service, pathology groups need to express to the payer, through this formal process, that they should be paid for the work completed," she asserted. "When future discussions happen with the payer, these 'push-back' events provide AP groups with the critical documentation they will need to support justification for change."

Contact Leigh Polk at 800-832-5270 x2941 or Leigh.Polk@changehealthcare.com; Diana Richard at 843-319-2409 or drichard@xifin.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Guess who will be partnering with the **US Department of Veterans Affairs** to support its wider use of digital pathology? It's **Google**! Last month, it was announced that the Defense Innovation Unit (DIU) of the **Department of Defense** (DoD) had selected Google Cloud "to prototype an artificial intelligence-enabled digital pathology solution to help detect cancer on multiple disease areas." This relationship can be expected to encourage acceptance and wider use of digital pathology by pathologists throughout the United States.

MORE ON: *VA and Digital Pathology*

In the joint press release, the two partners wrote that the digital pathology project "includes the delivery of augmented reality microscopes to DoD's medical facilities and access to artificial intelligence (AI) models that can help military doctors with cancer detection tasks on multiple disease areas. The early access to the digital pathology platform is for research use only ... The initial rollout will take place at select Defense Health Agency treatment facilities and Veteran's Affairs hospitals in the United States, with future plans to expand across the broader U.S. Military Health System."

CALIF. GOVERNOR VETOS GENETIC BILL

California's "Genetic Information Privacy Act" (SB 980) will not become law. It was vetoed on September 25, 2020, by Governor Gavin Newsom. The bill was intended to define requirements for how entities, including direct-to-consumer (DTC) genetic testing companies, collect, handle, and share genetic information. California's legislature is often first to propose and pass legislation that is then used as a model for other states when developing their own bills on the same subject.

TRANSITIONS

- Rick Panning retired from his position as Senior Administrative Director of Laboratory Services at **HealthPartners/ Park Nicollet** in Minneapolis. He previously served at **Fairview Health Services**, **Allina**, and **American Red Cross**. He is a past president of the **American Society of Clinical Laboratory Sciences**.
- **Biofidelity** of Cambridge, England, announced the selection of Stephen Miller as Chief Commercial Officer. Miller formerly held positions at **Precipio**, **Transgenomic**, **BG Medicine**, and **Athena Diagnostics**.
- **Neogenomics, Inc.**, of Fort Meyers, Fla., selected Madhushree Ghosh as its new Vice President, Strategic Alliances and Projects, Pharma Services. She previously served at **Thermo Fisher Scientific**, **AltheaDx**, and **Qiagen**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 26, 2020.

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Resources and Help for Labs During SARS-CoV-2 Pandemic

STAT INTELLIGENCE BRIEFINGS

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UPCOMING...

- ***Why are brand-new lab companies with no operating history winning big government contracts for COVID-19 testing?***
- ***Important updates on UnitedHealthcare's requirement that laboratories must register their tests and panels for payment.***
- ***How some clinical labs are succeeding and profiting from COVID-19 employee and student screening programs.***

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