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ALERT TO ALL LABS!
Feds revise both Stark Law and Anti-Kickback Statute
New compliance/fraud issues
(see pages 19-22)

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

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Founder & Publisher

Why Labs Operate in a 'Duality' during Pandemic

HAS IT OCCURRED TO MANY OF YOU THAT YOUR CLINICAL LABORATORIES today must operate in what I will describe as an operational "duality"?

On one side, your lab must deal with COVID-19 testing. This is true whether your lab performs molecular SARS-CoV-2 tests or simply handles specimens that you refer to other labs for testing. The need for your lab to support COVID-19 testing in some way is now a major operational requirement.

On the other side, your lab must continue to provide all regular testing services in support of clinical care, just as it did in pre-pandemic times. In this role, your lab continues to be an indispensable provider of diagnostic services in the communities and regions it serves.

This operational "duality" is without precedent. It means that you must manage a single clinical laboratory operation that now has two primary strategic objectives—each with very different consequences to the ongoing financial stability of your lab. This is why, since the onset of the pandemic last March, it is not business as usual for clinical labs and pathology groups.

This duality, now in its ninth month, continues to put your lab under extreme stress in multiple ways:

- Lab staff has experienced layoffs in the early months of the pandemic and continues working long hours to maintain SARS-CoV-2 testing, along with the regular menu of tests doctors need daily. In many labs, if the tipping point of staff burnout has not been reached, it is probably soon to happen.
- Your lab's supply chain is stretched to the limit and management devotes several hours daily in attempts to secure necessary quantities of tests and other supplies. Cost of supplies have zoomed, exacerbating budget woes.
- Lab analyzers, instruments, and automation are being used past the planned replacement cycle. This lowers the reliability of this vital equipment even as it is more difficult for the vendors' service reps to access labs in hospitals and other facilities to repair malfunctioning instrument systems.

Unfortunately, no crystal ball exists to tell us when the pandemic will pass, returning normality to healthcare and daily life. For that reason, lab executives and pathologists may find it useful to integrate this concept of organizational "duality" into operational plans. Introducing the duality concept to lab staff may also help by triggering their creativity in solving problems. TDR

One Genetic Test CPT Code Earns 'Fraudomatic' Title

Medicare claims paid under this code soared from 5,817 in 2017 to more than 146,000 in 2019

CEO SUMMARY: Several genetic testing companies have noticed that some of the nation's Medicare Administrative Contractors (MAC) pay about $2,000 for test claims billed with CPT code 81408. From 2018 through and 2019, the number of 81408 claims rose dramatically at just two of these federal contractors: Novitas Solutions and First Coast Service Options. This increase led one nationally-known genetic test expert to describe CPT 81408 as the "fraudomatic code."

EVIDENCE SURFACED RECENTLY THAT—when it comes to submitting genetic test claims to the Medicare program—the bonanza CPT code is 81408. The number of claims that Medicare paid for this code increased more than 25-fold in 24 months from 2017 and 2019, totaling $413 million, according to an analysis by Bruce Quinn, MD, PhD, a lab strategy and payment consultant in Los Angeles.

On his blog, *Discoveries in Health Policy*, Quinn reported that certain molecular testing labs have used the billing code 81408 to generate levels of payment that grew by 13 times in one year (2017 to 2018) and by 30 times over three years (2017 to 2019).

In a blog post on Sept. 25, Quinn labeled 81408 as the "fraudomatic" and "most unbelievable" CPT code in terms of increased payment over those three years. For this code, the federal **Centers for Medicare and Medicaid Services** has paid $2,000 per claim since 2017. By contrast, in the past year or more, at least two commercial health insurers (**Cigna** and **UnitedHealthcare**) have said they would not pay for this code.

The **American Medical Association** designates code 81408 as a CPT tier-two level-nine code. As a level-nine molecular pathology procedure, this code is used to analyze more than 50 exons in a single gene by DNA sequence, according to the utilization review company **eviCore**.

Quinn reported the following Medicare payments for 81408:

- In 2017, CMS paid $9.55 million for 5,817 claims filed.
- In 2018, CMS paid $123 million for 62,000 claims.
- Last year (2019), CMS paid $290 million for 146,000 claims.

"Among all genetic codes in Medicare Part B, it's the highest paid code," he said in an interview with THE DARK REPORT. "It's just head-spinning how much CMS pays out for that one code."

In a blog post published on Sept. 16, Quinn reported that CMS had released data in spreadsheet format showing Medicare Part B spending by CPT code for every state. Less than a week later, he published a follow-up blog post after analyzing that data.

"On Sept. 22, I released some deep dive analysis of Medicare's molecular and genetic test spending by state. It showed massive increases in spending for what, in some cases, may be fraudulent test claims," he wrote. Based on his analysis, CMS data showed that spending was concentrated in some states and under certain CPT codes.

'Most Egregious' Case

He also reported that the most egregious cases—meaning "the ones that popped out as being high to the naked eye"—were in the District of Columbia, Florida, and Oklahoma. Only two MACs—**Novitas Solutions** and **First Coast Service Options** (FCSO)—made nearly all of Medicare's payments to labs filing claims for 81408, Quinn noted. Both Novitas and FCSO are affiliated with **Blue Cross and Blue Shield of Florida**.

FCSO serves Medicare providers in Florida, Puerto Rico, and the U.S. Virgin Islands. Novitas is the MAC for Arkansas, Colorado, Delaware, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, Oklahoma, Pennsylvania, Texas, and the Washington D.C. metropolitan area. Also, Novitas serves the **Indian Health Service** and **Department of Veterans Affairs**.

"In my analysis, I found specific codes and specific states that stood out," Quinn said in the interview. "Those states were Florida and Texas, but also some odd places that Novitas serves, such as the District of Columbia and Oklahoma."

For his analysis, Quinn reviewed the Medicare spreadsheet data from all 50 states showing spending for 81408 in 2019 by MAC. Based on his analysis, he explained that the data, "seems to show that some MACs were completely resistant to this rare-gene CPT code and others gushed out money like a firehose.

Apparent 'Fraudulent' Use

"For example," he said, "despite two years of explosive fraudulent use of this code, according to the CMS coverage database, the Novitas MAC still has a billing article (titled A52986) that says, '81408 has no edit codes at this time.' "

Later in the same blog post, Quinn went into more detail about this code. "81408 seems to be the most popular code with fraudsters, based on other analyses I am doing," he wrote. "There are only 24 allowable rare genes listed under 81408. These include 'LAMA2 congenital muscular dystrophy, full sequence,' and 'CEP290, Joubert syndrome, full sequence (a cerebellar malformation that causes gross maldevelopment in infancy with mean age at death age seven).' "

In May 2020, CMS was expected to have released data on payments in 2018 broken down by which physicians and labs CMS had paid. But that data were not released when Quinn wrote this blog post in late September. It could be that CMS did not wish to release that data after the federal **Department of Justice** published information on the $6 billion worth of overpayments in fraud cases it uncovered under Operation Double Helix. *(See, "Medicare Pays 500% More for Molecular Test Claims," TDR, Oct. 5, 2020.)*

"I don't know if CMS will release the 2018 data that showed what it paid individual lab companies or when it will release the 2019 data," he said. "Normally CMS releases provider-level data on what it pays physicians and labs in May. When it's released, that data would be almost 18 months old. So, the 2018 payment data would have come out in May of this year." TDR

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Consultant's Analysis of Medicare Payment Data Provides Insights on Clinical Lab, Pathology Claims

FOR HIS ANALYSIS OF MEDICARE'S PAYMENTS FOR MOLECULAR MICROBIOLOGY IN RECENT YEARS, Bruce Quinn, MD, PhD, reviewed Medicare payment data from all 50 states.

Quinn sorted all the pathology and clinical laboratory codes by total payments (meaning allowed amounts), including payments for the technical and professional components and other payments if such were added. The total pathology and clinical lab payments came to $7.1 billion.

$4 Billion for 14 CPT Codes

When Quinn sorted payments by allowed charges, labs received 56% of the total, or $4 billion for 15 codes. It will come as no surprise to pathologists that the highest-paying CPT code was 88305 (surgical biopsy) with 20 million claims filed and $1 billion in allowed charges, Quinn reported.

"The next highest CPT code was 80053 (routine chemistry panel), with 29 million claims and $342 million in allowed charges. "As you can see by eyeball, with around 30 million in services provided and around $300 million in payments, that's in the ballpark of about $10 per service," he noted.

Also, in the top 15 were three molecular pathology codes. One was the aforementioned 81408, and another was 81528 for **Exact Sciences'** Cologuard test at about $500 per case, 482,000 claims, and $245 million in payments, he noted. The next highest code was 81479, an unlisted molecular code. This code is used almost exclusively in MolDx states with 109,555 services and $202 million spent.

When Quinn analyzed the molecular pathology codes, he combined that spending with payments for PLA (or U) codes. Those are codes 81162 through 81599. "For these codes, the allowed charges were a colossal $1.7 billion in 2019, almost double the $1 billion that CMS spent on these codes in 2018," he reported.

The top 15 codes in this category accounted for 78% of payments, or $1.3 billion, he noted. The largest of the payments went for code 81408 due to a rapid rise in payments in three areas (Florida, the District of Columbia, and Oklahoma) from two Medicare Administrative Contractors (Novitas Solutions or First Coast Service Options).

The next largest payment ($245 million) went to Exact Sciences for its Cologuard test, Quinn reported. "Next was an unlisted code, 81479, that has been used only in MolDx states. For this code, labs received $202 million. Third was BRCA testing (meaning BRCA1 and BRCA2 and deletion and duplication analysis), under code 81162. For this code, labs filed 60,000 claims and received $120 million in allowed charges.

The fifth highest payment in this category was for code 81519 for **Genomic Health's** Oncotype Dx test. For this test, CMS paid out $85 million for 22,000 claims.

Most PLA Codes Unused

In conclusion, Quinn reported that for other microbiology MolPath codes (such as 87471 to 87801 and 87900 to 87904), CMS paid $365.8 million. Also, he reported, most PLA codes are unused and that the total amount CMS spent for these codes was $116 million. This amount includes the top two tests in this category, one for **Foundation Medicine** and one for Genomic Health's Oncotype Prostate. Excluding those two tests reduces spending for PLA codes to $16 million, he noted.

Lab Market Update

Surprise! Many Fewer Cases of Flu in US, Canada, Europe

Weeks into the northern hemisphere's flu season, most countries are reporting many fewer flu cases

In North America, the influenza season is now underway. But it is starting off much slower than in past years. What makes this significant is that the number of influenza cases as reported by Europe and countries in the southern hemisphere also has been much lower than in a typical year.

In the United Kingdom, data released by **Public Health England** last Friday "showed there were only 1.2 GP consultations for suspected flu per 100,000 people last week. This time last year—a relatively mild year for flu—the figure was 10.6 per 100,000, so 90% higher."

This seems consistent with how the flu season in the southern hemisphere ended earlier this year. An *NPR* story published in August quoted Kanta Subbarao, MD, Director of the **World Health Organization's** Collaborating Centre for Reference and Research on Influenza in Melbourne, Australia. She said, "Based on what we've seen in the Southern Hemisphere—and I would say this is true of all through the Southern Hemisphere—South America, Africa, Australia, New Zealand, all across this region, there's been very little influenza activity."

Fewer Doctor Visits for Flu

As of last Friday, the federal **Centers for Disease Prevention and Control** (CDC) reported that through "week 48, 1.6% of patient visits reported through ILINet were due to ILI (Influenza-Like Illness). This percentage is below the national baseline of 2.6%." Of equal interest, since Sept. 27, the CDC has reported only about 500 cases of influenza and three deaths.

The situation is similar in Canada. On its website, the federal **Canadian Health Authority** wrote, "In week 48, three laboratory detections of influenza were reported. To date this season, 32 influenza detections have been reported, which is significantly lower than the past six seasons where an average of 2,170 influenza detections were reported between weeks 35-48. All provinces and territories are closely monitoring indicators of influenza activity this season."

Fewer Orders for Flu Tests?

If there is good news in early indications that the influenza season during 2020-21 may be much milder than in recent years, it is that physicians in the United States may be ordering a much lower number of influenza tests from clinical laboratories in coming months.

The number of influenza cases, as reported by the CDC, may also help lab administrators better estimate the number of influenza tests and respiratory virus kits that they need to buy throughout the balance of the 2020-21 influenza season. This would be useful because of budget pressures.

Also, given the serious and ongoing disruptions to the clinical laboratory supply chain caused by the COVID-19 pandemic, fewer flu cases would be a welcome development. TDR

Memphis Path Lab Pivots to COVID, Pooled Testing

Faced with the fall-off in regular tissue referrals, Poplar Healthcare adapted lab to perform COVID tests

CEO SUMMARY: When routine testing volume declined sharply last winter and spring, one of the nation's largest anatomic pathology groups added testing for COVID-19 and boosted revenue significantly. Since then, the laboratory has become the first in the nation to gain an Emergency Use Authorization (EUA) to do pooled testing with 20 samples in one tube. Employers and local and state governments are using pooled testing to reopen schools and businesses.

SINCE THE PANDEMIC BEGAN LAST SPRING, the clinical service mix at **Poplar Healthcare** in Memphis has changed significantly. As a result of the changes the pathology lab made, it now has a strong financial base despite substantial revenue losses in the first months of the SARS-CoV-2 outbreak.

Much like other anatomic pathology groups in the United States, Poplar Healthcare saw the flow of tissue referrals and clinical lab specimens decline by as much as 80% in March and April when patients stopped seeing physicians for regular care because of the COVID-19 pandemic. The fall-off in case referrals and revenue happened just as the pathology lab was deploying a new digital pathology (DP) and whole slide imaging (WSI) system throughout its facilities.

Confronted with the collapse of specimen referrals and cash flow, the pathology group and its 25 pathologists made radical business decisions to stave off financial collapse in March and April. Then, they took steps to use the lab's molecular testing instruments to run assays for COVID-19.

Nine months later, specimen referrals and cash flow from regular patient care are nearly back to pre-pandemic levels, easing the cash flow crisis. Also, despite the interruptions caused by the pandemic, Poplar Health's implementation of digital pathology and whole slide imaging is now complete.

The unexpected factor in the business fortunes of Poplar Health is that their laboratory now has a COVID-19 testing business that generated revenue at an annualized rate of $40 million in just five months. Poplar Healthcare's lab executives expect this segment of the business to continue to grow into the first half of 2021, and they say it gives the pathology lab a solid financial base going forward.

'Normal' Went Out the Door

"When COVID-19 happened, all of healthcare turned on a dime," commented Poplar Healthcare's Chief Executive Officer James P. Sweeney during a presentation at THE DARK REPORT'S *Executive War College* in September. "'Normal' immediately went out the door and, like other pathology laboratories throughout the United States, we found ourselves with a fully staffed lab, but few tissue referrals and inadequate cash flow.

"We were uncertain about what would happen next with the pandemic and had to decide whether to continue to implement our new digital pathology system," he added.

Throughout March and April, medical clinics were closing, and hospitals were postponing elective surgeries. It was on March 19 when Tennessee Gov. Bill Lee banned elective surgeries and dental procedures to conserve medical supplies.

"We watched cash flow dry up, forcing us to cut salaries by as much as 50% for our 375 employees," noted Sweeney. "The lab also cut the number of hours employees worked each week from 40 to 30 and asked 50 employees to accept furloughs. We also suspended sales commissions, bonuses, and the company's 401(k) match."

The lab used internal funds and applied to the federal **Small Business Administration's** Paycheck Protection Program to survive the drop in cash flow.

➤Responding to the Pandemic

Fortunately for Poplar Healthcare, Sweeney had extensive experience in a variety of executive positions over more than 30 years in healthcare diagnostic and information technology businesses. Before getting into healthcare, Sweeney served five years as an officer in the **U.S. Army Corps of Engineers**. The leadership and management skills acquired in those years served Poplar well.

"That third week in March was very interesting—in part because everything I remember from the military came back to me," he said. "In those early days, we had to make many quick, hard decisions in a matter of hours. Then, we had to implement those decisions in a day or two, and in each case, we did so successfully."

Last month, *The Daily Memphian* newspaper reported that in March, the demand for Poplar Healthcare's specialized diagnostic testing services dropped by about one third, bringing with it a corresponding revenue decline. Those specialized services include testing for cancer and sexually transmitted diseases. The 25 members of its physician staff specialize in anatomic pathology and genetic testing, including gastrointestinal, dermatopathology, oncology, and women's health.

➤Existing Molecular Testing

Seeing the drop in specimen volume, Sweeney and the lab team decided to use the lab's existing instruments and clinical expertise in molecular diagnostics and genetics testing. Much of these molecular testing capabilities came to the pathology lab starting in 2011. Since then, the lab continued to expand that capability through the early months of this year.

"We recognized that the demand for rapid molecular COVID-19 testing could be a significant financial benefit for us," recalled Sweeney. "In a matter of weeks, our genetics and management team collaborated to pivot our existing molecular laboratory to perform SARS-COV-2 tests.

"We had to be nimble to do two things on an accelerated timeline," he continued. "First, our lab team needed to validate the COVID-19 tests and the instrument platforms to support this testing. Second, at the same time that this was happening, our sales team had to put the word out that we had supplies and kits to do COVID-19 tests."

➤COVID-19 Testing Business

In a matter of weeks, Sweeney's team built a multi-million-dollar COVID-19 testing business. Since then, the lab has added pooled testing to support schools, workplaces, state and city employees, and other locations that Poplar's pathologists serve nationwide. Sweeney also noted that Poplar has added antibody testing and continues to implement the digital pathology and WSI systems.

"There is a saying that 'fortune favors the prepared mind," said Sweeney. "Yes, we did have the equipment, the manpower, and—more importantly—the technical know-how to do COVID-19 molecular testing.

In Memphis, Poplar Healthcare Currently Performs 7,000 COVID Tests per Day; Does Pooled Testing

NOW THAT POPLAR HEALTHCARE HAS ADDED TESTING FOR THE NOVEL CORONAVIRUS, it has the capacity to do more than 7,000 COVID-19 tests a day, said CEO James P. Sweeney. The lab is approved to run COVID-19 PCR tests on four different testing platforms.

"In August, we became one of the first labs to gain an Emergency Use Authorization (EUA) from the Food and Drug Administration to do pooled testing," he said. "That was for our **Hologic** platform. Since then, we have submitted a request for an EUA to do pooled testing on the **Roche** cobas equipment.

"For our pooled testing, we began running seven specimens in each pool as part of our initiative to support testing for the City of Memphis," he commented. "We've become a close partner with the city to test first responders and teachers.

"For many of the schools that have tried to reopen, we've expanded our capability to do pooling," Sweeney noted. "We're now doing up to 20 specimens in each tube because the cost savings this generates could allow some public schools to open more classrooms. Also, we added antibody testing in August."

Manoj Jain, MD, MPH, a Hospital Epidemiologist and infectious disease consultant in Memphis, commented that the testing Poplar Healthcare is doing is significant. "Everything they're doing is a potential game changer," he said.

In September, Jain, Sweeney, and other members of the Poplar Healthcare lab team met with officials from the FDA, the city of Memphis, the Shelby County school system, and the Chamber of Commerce to discuss how to increase pooled testing, which is called assurance testing.

The *Daily Memphian* newspaper reported that Poplar Healthcare was the first lab to submit an EUA for pooled testing of 20 samples at a time and clearance to use specimens from 20 patient swabs in one tube. The lab also is developing saliva tests for COVID-19. The goal is to reduce the cost of COVID-19 testing from about $100 per test to $5 per test, Sweeney told the newspaper. Poplar Healthcare has since validated all of these testing protocols under **College of American Pathologists** and CLIA validation guidelines.

Memphis Mayor Jim Strickland had high praise for Poplar Healthcare's efforts. "They built a testing program from scratch right when we needed it," he said. "And they were among the first labs in the country to get approval for pooling, which will be crucial in our efforts to reopen schools. We could not have done any of this without Poplar Healthcare."

"In that regard, our lab was prepared," he added. "But the other reason this strategy succeeded is that our team understood both the clinical and financial opportunity. They were willing to support investing scarce cashflow into SARS-CoV-2 testing, despite the uncertainties of how long the pandemic might last.

"I couldn't be prouder of our lab team," noted Sweeny. "For example, one group of people worked for 72 hours over one weekend to bring up a genetic testing platform for COVID-19. In turn, that allowed us to submit to the **Food and Drug Administration** (FDA) a request for an emergency use authorization (EUA) for COVID-19 testing. Once we submitted the EUA for approval, we were in the game and off to the races with COVID-19 testing."

At the end of March, Poplar Healthcare announced it was processing COVID-19 PCR tests in its 113,000-square-foot high-complexity CLIA-certified and CAP-accredited laboratory using **Roche's** cobas SARS-CoV-2 test on the cobas 6800 System. Roche got its EUA for that test on March 13. In addition, Poplar has been running its own EUA-submitted PCR test on the Roche cobas z480 analyzer and gained EUA approval for pooled testing on the **Hologic** instrument in early August.

Poplar's 90-Degree Pivot

"I describe what we did to start testing for COVID-19 as pivoting the company, but not pivoting 180 degrees," he added. "It was more like a 90-degree turn.

"After we got involved in PCR testing for COVID-19, we began calling area hospitals and Memphis city officials because there was much concern about how COVID-19 would affect the community," he noted. "We felt it was our civic duty to make the investment to get heavily involved in COVID-19 testing.

"Looking back on it, I think from a civic pride and a financial perspective, we made a smart decision to do that testing," Sweeney commented.

Digital Pathology Launched

"But at the same time, we did not want to stop or derail the launch of our digital pathology system," he added. "So, while we were doing COVID-19 testing, we were also working with our anatomic pathologists and with **Gestalt Diagnostics** to build the digital pathology capability and get the scanners and systems in place, validated, and into full operation.

"For our lab, the COVID-19 testing has been a godsend," Sweeney commented.

The $40 million that Poplar Healthcare generated in run-rate revenue from such testing through August allowed the lab to return all of the funds it received under the Paycheck Protection Program to the federal Small Business Administration.

City of Memphis Uses Pooled COVID-19 Tests

IN NOVEMBER, THE CITY OF MEMPHIS started a new program of COVID-19 testing. It describes the program as "pod testing" and Poplar Health is one of the the labs that performs the tests for this effort.

City councilman Jeff Warren, MD, (a family practice physician) set up his own pod test site. *Fox13 News* reported that, "Dr. Warren set up in his Midtown neighborhood earlier this month, as neighbors walked up to get tested. He says 76 people were tested in two days, with all results coming back negative."

As described in news reports, each individual does their own nasopharyngeal swab, while being watched in person or remotely by a healthcare professional. Specimens are sent to Poplar Healthcare Labs and the results are reported in 24 hours. The goal is to allow neighbors to be confident that there are no COVID-19 cases.

The term "pod testing" describes a pooled testing arrangement for COVID-19. *Fox13 News* noted that Dr. Warren said, "There are 20 tests in each pod kit for $100. He said the conversation now is about possibly introducing this method outside of individual neighborhoods."

"Unlike some labs, we were very fortnate to be able to give that money back," Sweeney said.

"In closing, I'll just say that we learned a variety of business lessons from COVID-19," he said. "I'm very proud of the team here. Everybody that worked on it taught me a lot about what you can do when your back is against the wall. We had to learn quickly how to implement new testing when it is needed. Those skills will help us continue to grow and support our efforts to launch digital pathology systems as we go forward." TDR

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Lab Market Update

State of California's COVID Lab Producing Inconclusive Results

In its first full month of operation, state's new lab struggles with inconclusive results, slow turnaround times

INCONCLUSIVE COVID-19 TEST RESULTS and delays in reporting results continue to plague the State of California's brand new clinical laboratory, located in Valencia. That's according to reports by several news outlets in the Golden State.

On Nov. 20, *CBS13* reported that the "state's new billion-dollar **PerkinElmer** lab is returning a high number of inconclusive test results which may be skewing the testing turnaround times provided by the state." *CBS13* also said that, as of late November, the Valencia lab had returned only 35% of results in two days or less, which is the turnaround-time target for the lab.

Disruptive to Other Labs?

There are legitimate questions as to why the state government would decide to build its own clinical laboratory to perform high volumes of COVID-19 tests, and thus be a direct competitor to existing clinical labs in California. The Valencia lab immediately puts the state in competition with existing labs for test kits, supplies, and the limited number of qualified genetic PhDs and clinical laboratory scientists. This potential of the state's lab to disrupt the operation of other labs has not yet been addressed by journalists in California. *(See TDR, Nov. 16, 2020.)*

The State of California signed a no-bid contract with **PerkinElmer** to build and operate the laboratory. The contract will be worth as much as $1.7 billion to PerkinElmer. The initial cost for the state to get the lab in operation was $25 million.

The clinical lab opened around Oct. 30. By the end of the first month, California reported that the lab had processed 100,000 COVID-19 tests, while disclosing that one out of every 29 were inconclusive (a rate of 3.5%).

Issues with Validation Step

California's health secretary, Mark Ghaly, MD, told *CBS13* that one source of the inconclusive results had been identified. He said, "One of the validation steps that confirms the necessary chemical reaction to run the test didn't occur for some of those inconclusive tests. We've identified some of the issues with why they didn't occur and have since corrected them."

CBS13 asked Sacramento County for statistics on COVID-19 tests within its boundaries. It said, "While the state did not provide us [*CBS13*] with the number of inconclusive tests coming from all other labs for a comparison, Sacramento County did. They received 95 times more inconclusive [COVID-19 test] results from the PerkinElmer lab than all other labs combined during the first two weeks of November."

The State of California plans for the clinical lab in Valencia to perform 150,000 COVID-19 tests per day. PerkinElmer's agreement with the state government calls for the lab to be fully operational and achieve a 48-hour turnaround on those test results by March. TDR

Lessons from the 2009 H1N1 outbreak cause lab to swiftly build COVID-19 LDT

NorDx Lab Started to Prepare for COVID-19 Testing in 2019

CEO SUMMARY: In a remarkable example of presience, informed by decades-long experience in clinical lab testing and past epidemics, the president of NorDx Laboratories in Maine saw the December news accounts of a widespread outbreak of a new respiratory disease in China. He warned his lab team to assume the worst and energized them to start work on a test for the novel coronavirus. Before the end of January, NorDx had obtained SARS-CoV-2 specimens from a source in Germany, had acquired probes and primers, and was developing its in-house molecular test for COVID-19 as an LDT.

For clinical laboratory professionals with years of experience, the appearance of any new respiratory virus can be a déjà vu event. That experience was useful to Stan Schofield, President of **NorDx Laboratories** in Scarborough, Maine, after he saw news reports late last year about an outbreak of a zoonotic virus transmitted from animals to humans in China. That news led him to alert the lab staff to prepare for what he feared could be a virulent strain of a new virus.

By responding swiftly to these early reports of a novel coronavirus, Schofield's lab was able to obtain samples of this new infectious agent in January! The lab team then used these samples to develop their own rapid molecular laboratory-developed test (LDT) for SARS-CoV-2. In early March, that enabled the lab to be one of the first in the nation to get an emergency use authorization (EUA) from the federal **Food and Drug Administration** (FDA). NorDx was also one of the first labs in the United States to obtain an FDA EUA for pooled COVID-19 testing.

Hospital Labs as Resource

The early and effective responses of NorDx Laboratories—the laboratory division of **Maine Health**—to the COVID-19 pandemic demonstrate why locally-based laboratories in hospitals and health networks are perfectly positioned to deliver speedy, accurate lab testing, particularly during a crisis like the current pandemic. These are facts that governors and federal health officials continue to overlook or ignore.

Moreover, the actions taken by the lab team at NorDx following the earliest news of the widespread outbreak in China attributed to the novel coronavirus will inspire all clinical pathologists and lab administrators who lead hospital and health network laboratories.

Open Market Supply Chain

Another important aspect of NorDx's speedy response to the outbreak is that the laboratory's response incorporated the knowledge and experience gained from three previous global outbreaks of a novel respiratory virus:

- First was the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 that appeared in China, then showed up in Hong Kong and Toronto, Canada.
- Second was the outbreak of Influenza A (H1N1), which was first recognized in Mexico in 2009. It spread across the United States and throughout the world.
- Third was the Middle East Respiratory Syndrome (MERS), a novel coronovirus believed to have developed in camels. Identified in 2012, infections have primarly been to individuals living or traveling in the Middle East.

As a lab executive with more than 30 years of experience Stan Schofield, President of NorDx Laboratories in Scarborough, Maine, has vivid memories of these outbreaks of novel respiratory viruses. Thus, when he read news stories in December 2019 of a novel coronavirus responsible for large numbers of infections in China, he was aware of how quickly a new virus could travel across the globe.

In particular, the December news reports reminded Schofield of 2009, when the novel Influenza A H1N1 virus emerged. It was first identified and reported internationally by Mexico on April 12. Just three days later, on April 15, the first case in this country was reported in California. H1N1 quickly spread across the United States.

In December, Schofield recognized that it was reasonable to assume that this novel respiratory virus could quickly spread worldwide. "Based on my experience with H1N1 in 2009, I knew that could be a problem," he said.

2009's Demand for H1N1 Tests

"Here in the United States, public health labs got overwhelmed with specimens and couldn't handle the demand for respiratory and H1N1 testing in 2009 coming from physicians and hospitals," he recalled. "The emergency departments were full of people, and labs could not report test results because the the public health system was structured so that hospital labs like us could

not get the probes and primers necessary to build a test specific for H1N1."

Based on those recollections, Schofield told the lab staff at NorDx to prepare for the worst from COVID-19. "I didn't want to go through that again and so, I asked the staff to get the genetic sequence of the SARS-CoV-2 virus," he recounted. "At the time, half my staff thought I was a nutcase. They asked me, 'What are you talking about? We don't need to do that.'

Stan Schofield

➤"We acquired the genetic sequence of SARS-CoV-2 from Germany. We then set about to add the probes and primers and had everything needed to develop our COVID-19 LDT by the end of January."

"My CFO said I would be wasting the money at the very moment that we are struggling to respond to the PAMA cuts to Medicare Part B lab test fees. 'Are you sure about this?'" he asked.

"But I knew what might happen, so I insisted," affirmed Schofield. "We got to work on acquiring the genetic sequence of SARS-CoV-2. That material came from a source in Germany. We then set about to add the probes and primers and had everything needed to develop our COVID-19 LDT by the end of January."

➤Assembling Needed Supplies

The NorDx molecular staff were busy the entire month of February building the test and assembling the supplies needed to test for SARS-CoV-2. "This is why, when COVID-19 infections started to rise in March, our lab had enough reagents to test 3,000 patients. Even at that level, I thought the lab might end up wasting money," he noted.

By early March, NorDx became one of the first clinical laboratories in the United States to earn an emergency use authorization (EUA) for its own laboratory-developed assay for SARS-CoV-2, the virus that causes the COVID-19 illness. In April, NorDx earned a second EUA, this time to pool four COVID-19 samples in each tube.

"Since earning that first EUA, NorDx has run 300,000 PCR COVID-19 tests," noted Schofield. "About 60% of those tests were in pools of two to four samples in each tube.

"When we started running COVID-19 PCR tests, we could do about 200 tests a day," he said. "Now, we do 3,000 COVID-19 tests a day. Even though the lab runs seven days a week, 24 hours a day, we're not quite at full capacity. Later this week, we expect to move up to 4,000 tests a day."

The pooled testing strategy proved to be so successful that by early May, **MaineHealth**, NorDx's parent health system, reopened all 12 of its hospitals that serve much of Maine and six counties in neighboring New Hampshire, Schofield said in an interview with The Dark Report last week.

➤No Elective Surgeries

Those 12 hospitals were unable to do elective surgeries or ambulatory visits after Maine's Gov. Janet Mills postponed all non-urgent medical procedures, elective surgeries, and appointments at hospitals and healthcare providers across the state under an emergency order on March 15.

"When the hospitals reduced operations, there was no elective surgery or procedures," Schofield noted. "But by May 1—and because of our FDA EUA for pooled testing—our lab could begin pooled testing for COVID-19. Because our lab could pool, all of our hospitals could open up again for elective cases.

"Beginning in early May, we had patients come in for a PCR COVID-19 test 72 hours before an MRI, a surgery, or any other procedure," he said. "If the patient had a negative result on the PCR COVID-19 test, that patient could have that procedure," he explained. "This test-

Ability to Start COVID-19 Pooled Testing Early Helped NorDx Extend Limited Quantity of Supplies

IN APRIL, NORDX LABORATORIES IN SCARBOROUGH, MAINE, became one of the first labs in the United States to earn a second emergency use authorization (EUA) from the Food and Drug Administration, this time for pooled testing for COVID-19.

The ability to do pooled testing was significant for two reasons. First, it allowed the lab to support its parent company, MaineHealth, in reopening 12 hospitals for elective surgeries and other care after being shut down under state order. Second, it allowed the lab to conserve testing COVID-19 supplies.

"Pooling is the only reason we've been able to stay in business during the times when we couldn't consistently get reagents," said NorDx President Stan Schofield. "When we got this EUA, our lab started pooling four COVID-19 samples in each tube. By the third week in April, we were doing most of our PCR COVID-19 testing by pooling specimens. That was for asymptomatic patients.

"We had to pool specimens because we needed to conserve the reagents and the supplies that we had. Running short was a possibility every day," he noted.

"Not only was it useful in reopening our hospitals, but doing pooled COVID-19 testing has utility in the field for schools, nursing homes, or businesses," he added.

Seven months later, NorDx continues to pool specimens from asymptomatic patients but has done so with two specimens at a time instead of four because the positivity rate in Maine has started to climb, as it has in every state.

"When our positivity rate climbed in the last couple of weeks, we started pooling two specimens at a time," noted Schofield. "We are concerned because we see that the COVID-19 positivity rate in other regions can be 8% to 10% or more. When it gets that high, pooling is a lot more work than it's worth because the lab must do too much retesting.

"When a pool is positive after the first test, the lab must retest each specimen in the pool," he said. "At four-to-one, that's five tests. At two-to-one, that's three tests.

"For symptomatic patients, we don't pool specimens," he said. "But with the spike in the last two weeks, we're testing asymptomatic patients two at time in each pool. In the first week in December, our positivity rate for symptomatic patients was running about 4% to 5%. And our asymptomatic patients were under 1%."

For now, Schofield does not expect to return to pooling four specimens any time soon. "We're not going to make any changes until after Christmas, because I think we'll get slammed next week, which will be two weeks after Thanksgiving," he warned.

"At the moment we have the reagents we need, and we are pooling two specimens at a time," he explained. "If we go back to four-to-one and have a spike in COVID-19 infections, that will create more work for the staff and could cause a shortage of reagents."

ing protocol and our lab's fast turnaround time for a COVID-19 test result was the key to allow all 12 hospitals to reopen for full services last spring."

Schofield said that this protocol of pre-procedure testing continues today. "Currently, of the 3,000 PCR COVID-19 tests we run every day, between 1,200 and 1,400 tests are for asymptomatic patients who need to get tested before elective surgery or a procedure such as a CAT scan or MRI," he reported. "Our lab does those tests so that our 12 hospitals can remain as COVID-free zones.

"We also do about 600 to 900 COVID-19 tests each day for symptomatic patients who visit our doctors' offices and emergency departments," he added. "Those tests are for people who have colds, sniffles, fevers, or family members who have been exposed to someone who has COVID-19, such as when a college student returns home, for example."

Low Demand

In addition, NorDx implemented a COVID-19 antibody test. However, since launching it on June 1, demand for this assay has been low, running at about 100 tests per month. "COVID-19 antibody tests will not be a player until the vaccine comes out," Schofield predicted. "Then people will want to know if they've developed antibodies. At that point, we will need a quantified antibody test for COVID-19."

One reason NorDx has been successful with its COVID-19 testing program is that its PCR LDT for SARS-CoV-2 does not require test kits and supplies from any particular diagnostic test manufacturer. "Even though it's difficult to get the supplies we need, we can perform adequate numbers of tests because we have an open-channel, lab-developed assay," Schofield explained. "That means our lab is not dependent on any one diagnostic company for either the testing platform or the test kits.

Open Market Supply Chain

"Also, we can get reagents, master mix, and pipette tips on the open market," he added. "Sometimes we have to pay more on the open market than if we were buying these supplies from diagnostic testing companies. But for months now, those companies have been unable to ship adequate quantities of these supplies to us.

"Neither the federal government nor the diagnostic testing companies have been reliable sources of supplies because the government diverts those supplies to the hotspot cities," noted Schofield. "Therefore, our lab must get universal transport media directly from South Korea. We get pipette tips directly from Germany.

"We've also been able to get most of the master mix, probes, primers, extraction units, and similar supplies we need from **Thermo Fisher**," he added. "Being in Maine, we're very low on the priority list for COVID-19 testing supplies. Out of the 50 states, Maine is at something like 48."

In the first week of December, data on state-level positivity rates showed that only two states were not in the red zone: Hawaii and Maine, he reported.

Stan Schofield

➤"Even though it's difficult to get the supplies we need, we can perform adequate numbers of tests because we have an open-channel, lab-developed assay. It means our lab is not dependent on any one diagnostic company for either the testing platform or the test kits."

Despite being in the most rural state in the nation, NorDx is no small operation. In the core lab in Scarborough, the laboratory team churns out more than five million billable tests every year. Collectively, the 12 hospital laboratories run about three million tests annually. The core lab staff totals 175 full-timers, and the total staff in the core lab and the hospital labs combined total more than 700 workers, Schofield said. Most of the 12 hospitals are small (25 beds) to mid-size facilities, and one, the **Maine Medical Center**, has 650 beds.

"Being a rural state has helped to keep our infection rate low," he noted. "But it's hurt our ability to respond to the COVID-19 testing needs in the communities we serve. When we've ordered big lab systems, some of those shipments were diverted by diagnostic companies to large city hotspots. The thinking of the U.S. government and the diagnostic companies was to send that equipment to other places.

For Self-Directed Asymptomatic COVID-19 Testing, NorDx Requires Consumers to Pay $105 in Cash

IN OCTOBER, NORDX LABORATORIES IN MAINE STARTED OFFERING PCR COVID-19 TESTING to asymptomatic Mainers willing to pay $105 for the test. NorDx calls this strategy community testing.

"We average between 50 and 100 of those tests each day, which are perfect for self-directed asymptomatic testing in the community," said NorDx President Stan Schofield. "Given that health insurers won't pay for testing asymptomatic patients, consumers need to pay out of pocket.

"We do not advertise this testing or promote it because reagents are limited and we need to conserve those reagents for our hospitals and for sick patients," he noted.

"Still, this strategy provides a service to the community because most people can't get tested unless they go to a national pharmacy chain store, such as **CVS** or **Walgreens**," he explained. "But then it takes a week to get the PCR COVID-19 test results back. We produce our test results in eight to 12 hours.

"The other problem for patients is that health insurance companies don't pay for surveillance screening of asymptomatic cases," noted Schofield. "So, when we do community testing, consumers must pay on their own because they are self-requesting this test and can't use insurance because they're asymptomatic.

"This strategy has been very successful and financially rewarding for us because the $105 helps to offset all the extra overtime in our laboratory since last spring," Schofield commented. "It also helps us to cover the cost of reagents, which have been higher than they were when the pandemic broke out.

"Community testing works for people who want a COVID-19 test before they travel, or if grandma is coming to visit or somebody is coming home from college, and they want to get tested to be sure they're negative," he said.

"Every day has been a scavenger hunt because some days we get short on extraction kits. Other days, it's the supply of pipette tips that gets low," he commented. "We have to bend all the normal supply chains into pretzels trying to get the supplies we need. In April and May, our lab got master mix from the research divisions at pharmaceutical companies because we couldn't get anything from the *in vitro* diagnostic (IVD) manufacturers. Those IVD firms took all the master mix off the market to build more kits."

Leveraging the Value of LDTs

Using a metaphor, Schofield describe how a clinical lab is similar to running a bakery. "Just as bakeries gather the ingredients they need and then bake cakes, labs collect the ingredients they need to run tests," he said. "Most labs aren't like NorDx, where we use the flour, the eggs, the sugar, and the salt, and then produce our own birthday cake—our LDT COVID-19 test result. Most labs have to go buy $50 birthday cakes from the bakery—their IVD manufacturer—to produce their results."

As mentioned earlier, the innovations of the NorDx Laboratory team show how and why the laboratory of a hospital or health network can be an invaluable community resource for local COVID-19 testing. "NorDx is well-positioned because we have PhDs and molecular-trained lab scientists who have the skills, instrument systems, and supplies they need to perform the COVID-19 tests needed by hospitals, physicians, and patients in our communities," concluded Schofield. TDR

—Joseph Burns

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Lab Compliance

CMS Sends Cease/Desist Letters to Labs Lacking CLIA Certificates

Clinical laboratories doing COVID-19 testing and lacking the proper CLIA certificates to do so are receiving cease-and-desist letters from the federal **Centers for Medicare and Medicaid Services** (CMS).

The first letters were sent on Aug. 12 and letters have been sent to other labs each month.

Recently, CMS reported it had sent cease-and-desist letters to 195 companies that include a mix of clinical laboratories, hospitals, physicians' offices, wellness centers, chiropractors' offices, urgent care centers, and other entities. By far, most of the letters went to physicians' offices. In the letters, CMS alleged one of two violations:

- Testing without a CLIA certificate, or
- Testing under the incorrect CLIA certification.

In each CMS letter, the allegedly offending organization was told to cease testing. The letters to the different organizations were similar, but those sent to labs that were testing without holding a CLIA certificate of any type, read, "Laboratory is required to cease all testing immediately."

In the letters to labs testing without the appropriate certificate, CMS wrote, "You are required to cease any non-waived and/or high-complexity testing immediately."

All but 45 of the companies told to cease testing did so. Of those 45, 28 obtained the correct CLIA certificates, 12 corrected their CLIA certificates, and five did not respond, according to CMS.

In an announcement of the action on Oct. 9, CMS said it conducted a check of CLIA certifications. "Every facility that conducts COVID-19 testing is considered a 'laboratory' and must be certified under CLIA," CMS said.

All 10 regional offices of CMS sent letters to labs in their service areas. By far, the Dallas regional office sent the most letters (120), Chicago was second with 20, followed by Philadelphia 17, Atlanta and San Francisco 11 each, New York six, Kansas five, Seattle three, and Boston one.

Expedited Review Process

To expedite testing when the FDA declared a public health emergency on Jan. 27, CMS implemented an expedited review process for labs applying for CLIA certificates.

Labs must operate within the scope of those certificates, "to prevent false results that could adversely alter diagnosis, treatments, and contribute to the further spread of COVID-19," CMS added.

The companies were required to provide CMS an attestation within 10 days of receiving the letter certifying they had ceased testing.

"Given that so many of these letters went to physician practices, I'd have to assume that these were physician office labs," said Jim Flanigan, CAE, Executive Vice President of the **American Society for Clinical Laboratory Science**. "Typically, those tests would be waived.

"It's likely that someone sold these physicians some COVID-19 tests and told them no approvals were needed," he added. "In all the other cases, the situation might be similar, but it's difficult to tell from what CMS has said about these cases." TDR

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Feds Revise Stark Law, Anti-Kickback Statute

New rules are intended to support providers in value-based or coordinated-care arrangements

CEO SUMMARY: It is essential that all clinical laboratories and anatomic pathology groups understand major changes in two new federal rules that take effect next month. Revisions to the Physician Self-Referral Law (also known as the Stark Law) and the Anti-Kickback Statue will have wide-ranging effects on how clinical labs engage in value-based and care-coordination contracts—as well as how they sell their services. Lab executives are advised to discuss these rules with their attorneys.

For many years, the federal Anti-Kickback Statute and the Stark Law have been the primary laws governing fraud in the Medicare and Medicaid programs. Last month, federal health officials issued new final rules for both laws that all clinical laboratories and pathology groups would be advised to study and understand.

One rule involves how labs can comply with the Anti-Kickback Statute (AKS) and one addresses how to comply with the Stark Law, also known as the Physician Self-Referral Law.

Coordinated-Care Programs

Both rules seek to reduce the burden laboratories and other providers face when engaging in value-based or coordinated-care arrangements by lowering the barriers that labs face when contracting with health insurers and physician groups in care-coordination arrangements, said the federal **Department of Health and Human Services** (HHS) in a press release. The two new rules will be effective on Jan. 19, although certain provisions will become effective on Jan. 21.

One important, unanswered question is whether and how these revised new rules may be positive or negative for clinical laboratories and pathology groups. The new rules also affect how labs sell their services. In an interview with The Dark Report, one attorney commented that the new AKS regulations raise the potential for criminal fraud risk for clinical laboratories and pathology groups.

"When participating in some value-based arrangements, clinical labs may not be fully protected from criminal fraud risk," commented Danielle Holley Tangorre, a partner with the law firm of **O'Connell and Aronowitz** in Albany, N.Y. "The problem is that the HHS **Office of Inspector General** (OIG) did not extend the protection of all of the safe harbors to laboratories because the OIG sees labs as potentially exploiting the new safe harbors and were concerned about the potential of fraud and abuse.

"But overall, the new rules provide more flexibility for innovation when clinical laboratories and other providers contract with health plans and providers," she added.

Two HHS departments issued the final rules:

- The OIG issued, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements."
- The **Centers for Medicare and Medicaid Services** (CMS) issued, "Modernizing and Clarifying the Physician Self-Referral Regulations." Commonly known as the Stark Law, the physician self-referral law aims to protect patients from receiving lower quality or more costly services from physicians' with a financial self-interest.

Clinical Labs Excluded

For lawyers working with clinical laboratories, the new rules may generate increased legal work, in part because the rules depart from the current practices under the Stark Law and the AKS, Tangorre said. For example, regarding care-coordination regulations, CMS took a different approach in the new Stark rule, compared to the approach used by the OIG as it revised the Anti-Kickback Statute.

"The new anti-kickback regulations from OIG specifically exclude clinical laboratories from being able to access many of the new safe harbors built into the rules on value-based arrangements," she explained. "Under the Stark final rule, however, CMS choose not to specifically exclude clinical laboratories. Therefore, labs can potentially participate in value-based arrangements under the Stark final rule, but have to consider the implications of the AKS final rule.

"In fact, the CMS rule makes clear that laboratories may play a beneficial role in the delivery of value-based healthcare services," added Tangorre.

For each rule, Tangorre focused on the three most important sections of the AKS and the Stark rules. Here are the top three issues for clinical laboratories as written into the OIG's new anti-kick rules.

"First, it should be noted that the OIG said labs would still no longer be allowed to participate in the safe harbor involving electronic health record (EHR) systems," Tangorre explained.

Under laws passed along with the Affordable Care Act in 2010, clinical labs were allowed to assist client physicians and other providers in establishing systems to send clinical lab test requisitions to labs electronically and to receive lab test results in the same way.

Clinical Labs Excluded

"Those federal rules were sunsetting and this new rule reaffirms that labs are not allowed to participate in the safe harbor for EHR systems," she commented. "Some labs still operate under the theory that they can provide EHR systems to physicians, but this new rule makes it clear that they are no longer protected when they do so."

A second important aspect of the OIG AKS rule involves whether clinical laboratories can participate in outcomes-based payments under a safe harbor regarding personal service management. "The final role specifically excludes laboratories from that particular provision," Tangorre said.

"Laboratories can still use the old safe harbor regarding personal service management, which labs use frequently for the consulting and other arrangements they have with independent contractors for some marketing activities," she noted. "But clinical labs will not be able to use the new provision that relates to outcomes-based payments."

Safe Harbors in AKS Rule

A third point involves the impetus behind issuing the final rules and how those issues relate to coordinated-care arrangements. "The new anti-kickback rule sets out a whole set of safe harbors relating to value-based payment arrangements.

Federal Government's Changes to AKS, Stark Rules Are Intended to Encourage More Value-Based Care

TWO NEW FINAL RULES GOVERNING VALUE-BASED AND CARE-COORDINATION ARRANGEMENTS are designed to accelerate the transformation of the healthcare system from one that pays providers to deliver volume under fee-for-service payments, to one that pays for value under capitated payment, according to the federal Department of Health and Human Services (HHS).

By shifting away from volume-based payment, HHS seeks to give labs and other providers more flexibility in contracting, while protecting patients and federal healthcare programs from fraud, the agency said.

On Nov. 20, the HHS Office of Inspector General (OIG) issued the final rule, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," and the federal Centers for Medicare and Medicaid Services (CMS) issued the final rule, "Modernizing and Clarifying the Physician Self-Referral Regulations."

The new rules are part of what HHS calls its Regulatory Sprint to Coordinated Care. This is an effort to revise those federal regulations that could impede healthcare providers' efforts to advance the transition to value-based care, HHS said.

Danielle Holley Tangorre, a partner with the law firm of O'Connell and Aronowitz in Albany, N.Y., commented on how HHS set an effective date of Jan. 19 for both new rules. That date is a departure from an earlier plan to make these two rules effective in August, she added.

In response to publication of the draft rules, healthcare provider groups submitted comments that urged HHS to issue the long-awaited final rules, in part, based on speculation that a Biden administration might be less likely to finalize the rules, Tangorre explained.

The two new federal rules themselves, however, are not political in nature, she added. "These rules show a bipartisan approach to address problems in the healthcare system as it evolves to support value-base care," she added.

These safe harbors allow for innovation in how physicians and other healthcare providers coordinate patient care," commented Tangorre.

"The OIG specifically excluded clinical laboratories from these safe harbors because OIG found there could be too much risk of fraud based on the OIG's historical enforcement experience with clinical laboratories," she added. "The OIG may consider that laboratories could misuse the value-based safe harbors when marketing tests and services."

Laboratory directors interested in providing clinical lab test results to assist physician groups, accountable care organizations (ACOs), and health plans in coordinated-care arrangements will need to understand when the safe harbor applies. "Depending on the arrangement, those contracts could now be protected under value-based, coordinated-care arrangements for other entities, but not for laboratories," Tangorre explained.

Business for Lab Lawyers

Unlike the OIG's AKS rule, CMS' rule on the Stark Law allows clinical laboratories to participate in value-based, coordinated care arrangements. In this way, the two new rules are likely to drive new lab business to health law attorneys.

"The big takeaway in how CMS addressed value-based care is that the agency deviated from the OIG's approach in that CMS did not specifically exclude

clinical laboratories as a group," explained Tangorre. "That's important, for at least two reasons.

"First, under the Stark Law, a laboratory can participate in a value-based arrangement. In fact, CMS found that laboratories may play a beneficial role in the delivery of value-based healthcare," she said. "It will be interesting to see how that plays out because value-based contracts are allowed under Stark, but laboratories may run afoul of the AKS depending on the type of arrangement they have.

"It's important to understand that the Stark Law is known as a strict interpretation or strict liability law," she added. "That means you either comply with the safe harbors or you don't. If you don't, then you could suffer penalties.

"On the other hand, the anti-kickback statute is a criminal law, which means guilt or innocence could turn on intent," Tangorre noted. "If your lab can comply with the Stark statute, you will have to assess the risk of whether your lab is knowingly, willfully, or blatantly violating the AKS.

➤Requests for OIG Opinions

"For these reasons, we can expect that more clinical laboratories may seek OIG opinions on whether their value-based arrangements are protected under a safe harbor or whether they run afoul of the AKS for enforcement purposes," predicted Tangorre. "This will be true, even if a lab requesting the opinion is complying with the Stark Law."

Another important issue for labs to understand is how the Stark rule could affect physician office labs and large group practices. "The new rule changed parts of the definition of the term 'group practice' under the Stark Law," she said.

"When a physician office has a laboratory, it must meet the exceptions for group practices and for in-office ancillary work," she explained. "Meeting those exceptions will affect how profits can be distributed among the participating physicians."

Coordination of Care Between Providers

HEALTHCARE OFFICIALS WITHIN THE FEDERAL GOVERNMENT are working to implement two major goals. One goal is transition providers away from fee-for-service payment by using new payment models that reward providers for improving patient care and reducing the cost of care.

The second goal is to encourage healthcare providers to keep patients healthy and to provide clinical care that helps prevent acute episodes, thus avoiding expensive hospitalizations.

But to accomplish this second goal, hospitals, physicians, nursing homes, labs, and other providers need to better integrate their services. In turn, tighter integration of different providers creates the need for funding and reimbursement arrangements that encourage quality care, while discouraging the many types of fraud and abuse that are associated with fee-for-service payments to providers.

The new revisions to the Stark Law and the Anti-Kickback Statute are intended to help providers achieve both goals described above.

In making her comments on these two rules, Tangorre addressed how the new rules apply to clinical laboratories participating in value-based or coordinated-care arrangements.

"My advice to lab managers is that they meet with their lawyers before Jan. 19 to understand what they need to do to comply with these new final rules," she commented. "For these meetings, labs should review their current contracting arrangements with health plans and physician groups and go over all innovative collaborative or technology arrangements they have or are negotiating with health plans and physician groups." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Supply chain issues associated with the SARS-CoV-2 pandemic are about to disrupt testing for other infectious diseases, ranging from strep throat and pneumonia to sexually-transmitted diseases (STDs). That was one important finding from the **American Society for Microbiology's** (ASM) November survey of 134 microbiology labs around the country. More than half of the responding labs report shortages of supplies used in the microbiology lab for non-COVID-19 infections.

MORE ON: *Shortage of Microbiology Test Supplies*

ASM's survey responses from the week of Nov. 20-27, 2020, were summarized as follows:

- 70.0% of labs are short of supplies for the molecular detection of sexually transmitted infections.
- 39.1% of labs are short of supplies for detection of routine bacteria (including the bacteria causing strep throat, pneumonia, bronchitis, and urinary tract infections).
- 35.3% of labs are short of supplies for mycobacteria testing (including supplies for tuberculosis (TB), Buruli ulcer, and pulmonary non-tuberculous mycobacterial disease testing).
- 17.6% of labs are short of supplies for routine fungal testing, ranging from superficial, localized skin conditions to deeper tissue infections to serious lung, blood (septicemia) or systemic diseases.

ASCP AND CLMA TO PARTNER WITH SERVICES, MEETINGS

Last month, the **American Society of Clinical Pathology** (ASCP) and the **Clinical Laboratory Management Association** (CLMA) announced a partnership. In that agreement, CLMA members will receive ASCP benefits. When CLMA's virtual KnowledgeLab convenes in 2021, it will be "co-hosted" by CLMA and ASCP. All members of the two organizations will receive free registration. This collaboration is evidence that the pandemic, travel bans, and other factors are disrupting the normal educational conferences and workshops that laboratory professionals regularly attended prior to the pandemic.

TRANSITIONS

- Mark McDonough was appointed as CEO of **PierianDx** of Creve Coeur, Missouri. He has held executive positions at **CombiMatrix Molecular Diagnostics**, **Pathwork Diagnostics**, **DIANON Systems**, **US Labs**, and **Ventana Medical Systems**.

- **NDA Partners**, of Rochelle, Va., said that Julie Ballard had joined the firm as an Expert Consultant. She previously held positions at **Seer**, **Grail**, **Guardant Health**, and **TOMA Biosciences**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 28, 2020.

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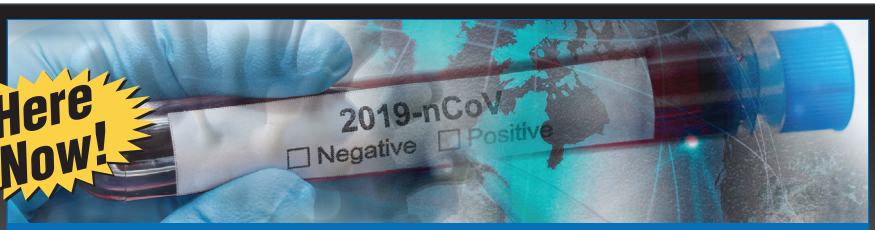

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UPCOMING...

- ***What some of the smartest people in lab medicine predict about the course of the pandemic in 2021.***
- ***Major changes happening in CLIA lab certification as major health systems select new accrediting bodies.***
- ***The Dark Report's list of the world's 10 Largest IVD Firms: Surprising changes because of COVID-19, acquisitions.***

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