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YEAR-END SPECIAL REPORT

2020 TOP TEN BIGGEST LAB STORIES

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...

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Managing Labs in Two Dimensions in 2021

EXPECT 2021 TO BE JUST AS CHALLENGING A YEAR for lab management as was 2020. This will be true not only because of the SARS-CoV-2 pandemic. Other important factors will complicate the operation of clinical laboratories and anatomic pathology groups in the new year.

One reason is the lab management duality that I described in the last issue of THE DARK REPORT. Today, lab administrators and pathologists manage their labs to meet dual objectives that often conflict with each other. One objective is to perform COVID-19 tests in growing volumes. The other objective is for the lab to provide all the regular routine, reference, and esoteric testing that is needed by referring hospitals, physicians, and other clients.

All signs indicate that this unique management duality will continue well into 2021. The SARS-CoV-2 coronavirus continues to mutate, and physicians struggle to understand if the new strains are easier to transmit and more virulent when they infect individuals. Clinical labs on the front lines will continue to perform the COVID-19 tests necessary for providers to diagnose and treat infected patients.

Another challenge confronting labs is the ongoing shortage of key instruments, test kits, and essential lab supplies. The supply shortage is acute and hinders the ability of labs to perform both COVID-19 tests and the daily intake of other specimens from patients undergoing care for other conditions.

While all this is happening, labs will continue to provide the daily flow of lab test results needed by the hospitals and physicians they serve. But the daily workflow will not be normal, since providers must diagnosis, treat, and monitor patients for the typical range of diseases and health conditions while also watching those patients for SARS-CoV-2 infections.

One big unknown in 2021 is whether vaccines for COVID-19 will prove to be effective at preventing or greatly reducing the number of infections. Most lab leaders are working with their parent hospitals, health networks, and regional healthcare officials to anticipate the need for serological testing in support of vaccination programs. This requires advance planning while working to lock in adequate supplies of collection materials and test kits.

Collectively, these developments mean that lab administrators and pathologists can expect to be managing in two dimensions well into 2021. TDR

2020's Top 10 Lab Stories Are Without Precedent!

Yes! COVID-19 pandemic was the dominant story, but other events this year are reshaping lab services

CEO SUMMARY: There are several surprises in THE DARK REPORT's list of the Top 10 Lab Stories for 2020. Despite the SARS-CoV-2 pandemic dominating every aspect of clinical care, social life, and economic activities since March, at least one major health insurer pushed ahead with two major policies governing how labs can submit claims. In another big story, for the first time in decades, the federal Anti-Kickback Statute and the Stark Law were revised with new final rules.

WITHOUT QUESTION, THE SINGLE BIGGEST CLINICAL LABORATORY STORY OF 2020 is the COVID-19 pandemic. It is involved in five of THE DARK REPORT's Top 10 Lab Industry Stories for 2020. But lab administrators and pathologists would be well served to recognize the importance of the other five stories on this year's list

That's because the non-COVID-19 stories on the list represent significant events that will influence how medical laboratories are organized, operated, and reimbursed for years to come. For example, federal officials finalized new rules that change the sales and marketing compliance risk for labs and pathology groups.

This is the 24th year that THE DARK REPORT has used the last issue of the year to present its list of the top 10 lab industry stories for the year just passed. Much has happened during those 24 years—and the 26 years since THE DARK REPORT begin publication in 1995. But in no single prior year did the clinical laboratory industry find itself disrupted in every aspect of diagnostics and lab testing as it has throughout 2020 because of the pandemic.

In presenting this year's Top 10 Lab Industry stories, it is essential that the senior leadership of clinical labs, hospital/health network labs, and anatomic pathology groups understand the need to look beyond the COVID-19-related stories and pay attention to the non-COVID-19 stories. That is because the non-COVID-19 stories of 2020 will be shaping the clinical lab market for years into the future.

Of course, the number one story in this year's list is the COVID-19 pandemic. Not only has it changed almost every aspect of healthcare, but federal, state, and

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local governments' responses to the pandemic have been to constrain economic activity and restrict the movement and social interactions of people. *(See page 5.)*

The four other Top 10 Lab Stories in 2020 involving COVID-19 include:

- Actions and directives of federal, state, and local governments to the pandemic, *(page 6)*,
- The $6.8 billion in cash flow lost by clinical labs in the early months of the pandemic because of the collapse in physician referrals of routine lab test specimens, *(page 9)*,
- Disruptions to the clinical laboratory supply chain and new patterns in how labs select vendors, *(page 10)*, and,
- Well-financed, new lab competitors are building lab facilities to do COVID-19 testing—facilities that can be shifted to routine, reference, and esoteric testing once the pandemic subsides. *(Page 9.)*

Top Non-COVID-19 Stories

There are other developments during 2020 that were significant for clinical laboratories and pathology groups, but probably did not get the attention they deserved because lab administrators and pathologists were engaged with the urgent demands to increase their labs' daily production of SARS-CoV-2 tests.

One serious issue with immediate implications for the finances of clinical laboratories is story number five on the 2020 list. It is Medicare's soaring spending on molecular and genetic tests. This story surfaced in September, after the federal **Centers for Medicare and Medicaid Services** (CMS) released Part B payment data for 2019. A nationally-known expert in genetic testing analyzed the data and discovered that, between 2017 and 2018, Medicare spending on molecular and genetic tests roughly doubled. Then, from 2018 to 2019, it doubled again.

More troubling for the lab industry, however, is that Medicare spending for one genetic test CPT code increased by 700% between 2017 and 2018 at just four Medicare Administrative Contractors (MACs). *(See page 7.)* This is relevant to labs and pathology groups for two reasons.

Focus on Genetic Test Claims

First, if Medicare's spending on genetic test claims has doubled in each of the past two years, then the same thing is happening with private payers. It should be expected that government and private payers will take firm steps to reduce what they spend for genetic tests—whether by denying coverage or slashing the prices they pay for genetic tests.

Second, if one genetic test CPT code is being used by a handful of labs billing just four MACs and generating a 700% increase in monies paid for that CPT code, that is strong evidence of potential fraud and abuse.

Another managed care story in the 2020 Top 10 list involves two significant actions by **UnitedHealthcare** (UHC), the nation's largest health insurer, to rein in how much it spends on lab tests. One new policy in 2020 is that a hospital lab cannot submit claims for outreach patients using its hospital's inpatient fee schedule. The second new policy is a requirement that all UHC network labs submit every test and panel for which they bill to UHC's new Laboratory Test Registry Protocol. After Jan. 1, 2022, UHC will not pay for claims of tests and panels that are unregistered. *(See page 7.)*

Strategic Planning at Labs

It is recommended that labs and pathology groups use THE DARK REPORT's list of the Top 10 Lab Stories as the basis for strategic planning. Such planning should acknowledge that COVID-19 will continue into 2021, creating the need to plan for appropriate contingencies. But strategic planning should also address how 2020's other developments in 2020 will affect lab operations and finances in 2021 and beyond. TDR

TOP TEN 2020 LAB STORY 1

Coronavirus Strikes the World, Puts Clinical Lab Testing on Center Stage

FROM THE EARLIEST DAYS OF THE PANDEMIC, clinical laboratory testing has been a national news story. The SARS-CoV-2 outbreak created an opening for the entire clinical laboratory profession to gain widespread awareness and recognition for the essential role it plays in supporting diagnosis, treatment, and patient monitoring.

As it turned out, the pandemic did elevate the nation's awareness of the vital role that clinical lab testing plays in managing disease. From the earliest days of the SARS-CoV-2 outbreak, national and local news outlets produced detailed stories about every aspect of diagnostic testing for COVID-19 and how labs operate.

This was the opportunity of a lifetime for the House of Laboratory Medicine. It could take center stage and tell the story about state-of-the-art technologies and dedicated lab professionals that make the U.S. clinical laboratory profession the envy of the world.

Unfortunately, it did not work out that way. Yes, numerous positive news stories were published or broadcast about the remarkable accomplishments of many clinical labs at developing and running COVID-19 tests in volumes unheard of in past epidemics. *(See TDRs, Mar. 30 and Apr. 20, 2020.)*

Negative Press Coverage

But more of the national and local press coverage was negative, focusing on the range of problems bedeviling federal regulators and clinical laboratories awaiting direction from the government. In the earliest months of the pandemic, national news outlets ran a non-stop stream of stories about how long it was taking to get molecular SARS-CoV-2 tests developed and into clinical use.

Then, once the FDA was dealing with a flood of emergency use applications (EUAs) for molecular COVID-19 assays, the press corps turned its focus to other aspects of COVID-19 lab testing. That started a steady stream of news stories about inadequate volumes of SARS-CoV-2 tests and the lengthy delays in reporting these test results. Attention then shifted to the huge problem of inadequate supplies to collect, transport, and test SARS-CoV-2 specimens at the very moment when the need for unprecedented volumes of COVID-19 tests were required to respond to the pandemic.

Issues with Serological Tests

As spring arrived, attention next turned to serological testing for COVID-19. Journalists quickly learned the long-established fact that testing for antigens and antibodies is a complex diagnostic challenge, making the potential for false positives and false negatives much greater in this field of diagnostics than, for example, with basic chemistry tests.

For all the reasons above, few lab professionals would disagree with THE DARK REPORT's choice of the COVID-19 pandemic as the number one story of 2020's Top 10 Lab Industry stories.

It is now nine months since the onset of the pandemic. The continuous news coverage about lab testing raises an interesting question: in what ways will the COVID-19 pandemic permanently alter the clinical laboratory industry?

At least there is good news on one front. What continues to be unquestioned in all the news coverage of clinical laboratories during the pandemic is the dedication of all clinical lab professionals to step up and do everything possible to respond to the nation's needs for COVID-19 tests.

TOP TEN 2020 LAB STORY 2

FDA, CDC, CMS: Fed Agencies Flunk Regulatory Responses to COVID-19

This is the year that President Ronald Reagan's famous statement about government proved accurate as a description of the numerous ways that federal agencies and state officials often took steps that worked against the best intentions of the nation's clinical laboratory scientists and pathologists.

Reagan said, "The most terrifying words in the English language are: 'I'm from the government and I'm here to help.'"

Dealing with Bureaucrats

There are many clinical laboratory professionals who understand the intent of Reagan's wordplay. They have first-hand experience with the bureaucratic mind so aptly described in many of the works of the German author, Franz Kafka (himself a minor bureaucrat during his life). Since the onset of the pandemic, laboratory leaders have been forced to interact with federal, state, county, and city officials.

Reports of inconsistent guidance, confusing directives, and outright obfustication by government officials at all levels have been common anecdotes since the first evidence of a novel coronavirus surfaced in news stories in this country.

Major government missteps started in the earliest days of the pandemic. Guidance from the federal government prohibited the large number of clinical laboratories with molecular testing capabilities from creating their own laboratory-developed test (LDT) for the novel coronavirus, now classified as SARS-CoV-2.

Contemporary with that, the federal **Centers for Disease Control and Prevention** (CDC) delivered a SARS-CoV-2 test kit to public health laboratories which proved to be flawed. That took weeks to sort out.

The federal **Food and Drug Administration** (FDA) has come under criticism for the series of decisions and directives it issued to address diagnostic test kits for the novel coronavirus. Its requirements for how companies were to file emergency use applications (EUAs) for molecular SARS-CoV-2 tests were changed multiple times.

In January and February, as the first news stories about the novel coronavirus were published, FDA actions restricted academic center labs and others from developing and validating laboratory-developed tests (LDTs). During that time, the CDC was the only source for a COVID-19 test. *(See TDR, Mar. 30, 2020.)*

In March, the rules the FDA issued for COVID-19 serological tests had minimal requirements. That triggered a flood of at least 200 serological tests applying for an EUA, and the accuracy of some of these tests was questionable. Thus, on May 4, the FDA issued a more rigorous set of rules for serological COVID-19 tests to obtain an EUA. *(See TDR, May 11, 2020.)*

EUA Requirement Dropped

Months later, on Aug. 19, the **Department of Health and Human Services** (HHS) issued a directive that said clinical labs would no longer be required to obtain EUAs from the FDA for their COVID-19 LDTs. *(See TDR, Sept. 6, 2020.)*

To these examples can be added government control of the supply chain for lab collection supplies, instruments, and COVID-19 test kits. This is an ongoing issue for all labs across the nation. *(See story #7 on page 9.)*

These examples demonstrate how government decisions and control of the lab testing market is often counterproductive to what would be in the public interest.

TOP TEN 2020 LAB STORY 3

Staggering Growth of Molecular Claims Causes Spike in Medicare Spending

ONE IMPORTANT STORY FOR THE ENTIRE CLINICAL LABORATORY INDUSTRY emerged in October, but has not become widely known to many pathologists and lab executives. It involves a dramatic escalation in Medicare payments for molecular and genetic tests in 2018 and 2019.

Using 2019 Medicare data released in September and subsequent months, Bruce Quinn, MD, PhD, an expert on health policy, payment, and clinical lab strategies and a former MAC medical director, determined that Medicare payments for the genetic test claims in several states exploded by as much as 700% between 2018 and 2019.

Digging further, Quinn also determined that genetic test CPT code 81408 was the "fraudomatic" and "most unbelievable" code in terms of increased payment in 2017, 2018, and 2019. Quinn reported these findings:

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

The fact that all the PAMA fee cuts enacted on clinical lab tests are being offset by skyrocketing increases in payments for genetic tests may make this one of 2020's significant lab industry stories. That's because it will have major consequences for all clinical labs in the United States that submit lab test claims to Medicare. *(See TDRs, Oct. 5 and Dec. 17, 2020.)*

TOP TEN 2020 LAB STORY 4

UnitedHealthcare Digs In to Control Spending on Clinical Laboratory Tests

THERE MAY BE NO BETTER EXAMPLE of "business as usual" by a health insurer during the COVID-19 outbreak than the actions taken by **UnitedHealthcare** throughout 2020 to control what it spends on clinical laboratory testing.

During 2020, UnitedHealthcare (UHC) continued its push on several fronts in attempts to attack what it sees as ways that some laboratory testing companies game the system and file claims for tests that the payer considers to be inappropriate, medically unnecessary, or even fraudulent.

One example is the policy UHC implemented to clamp down on hospital laboratories that submit lab test claims for outpatients and outreach patients using their hospital's inpatient fee schedule. That policy became effective on May 1. *(See TDR, Mar. 9, 2020.)*

Contemporary with that policy change, UnitedHealth announced its plans to implement its new Laboratory Test-Registry Protocol. This program requires every in-network clinical laboratory and anatomic pathology group to register almost every type of test and panel before claims can be submitted to the health insurer for payment.

UHC initially scheduled the Laboratory Test-Registry Protocol to begin on Oct. 1, 2020. But because of disruptions caused by the COVID-19 pandemic, UHC moved that date back several times. The current implementation date is Jan. 1, 2022. *(See TDRs, Aug. 3, Oct. 5, and Nov. 16, 2020.)*

TOP TEN 2020 LAB STORY 5

OIG, CMS Issue New Rules That Revise Anti-Kickback Statute, Stark Law

For decades, the federal Anti-Kickback Statute and the Stark Law have loomed large over all clinical labs and anatomic pathology groups. Now, in the final weeks of 2020, federal regulators have issued new rules to change both laws.

On Dec. 2, the federal **Office of the 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."

The same day, the federal **Centers for Medicare and Medicaid Services** (CMS) issued the final rule, "Modernizing and Clarifying the Physician Self-Referral Regulations." The physician-self-referral law is commonly known as the Stark Law.

Issuance of these two new federal rules will create new compliance headaches for clinical laboratories, particularly in the way they market and sell their services. For example, the OIG excluded clinical laboratories from the safe harbors in the rule it published. But labs can qualify for the safe harbors in the new Stark Law rule issued by CMS. *(See TDR, Dec. 7, 2020.)*

The new rules were issued by the two federal agencies because the Anti-Kickback Statute and the Stark Law, as written and interpreted, were impeding efforts of federal health officials and providers to implement new care models with new forms of reimbursement. All labs and pathology groups are advised to review the new rules with their legal and compliance advisors.

TOP TEN 2020 LAB STORY 6

In 10 Weeks, Labs Lose Revenue Equal to Full Year of Medicare Payments

What would happen if the Medicare Part B program simply stopped paying for clinical lab tests? That would deprive labs in this nation of about $7 billion per year in cash flow. The resulting red ink would put many labs into dire financial straits.

Something like that happened during the first 10 to 12 weeks of the pandemic. During that time, routine specimen referrals fell off by 60% to 70%, causing a comparable collapse in cash flow to labs. The Dark Report was the only source to publish a credible figure for the drop in specimens and claims—and then quantify those lost revenues.

Working with multiple lab industry vendors, the TDR team used its data to estimate that between Mar. 8 and May 28, the cumulative cash flow lost to the nation's labs was $6.8 billion. By comparison, the Medicare Part B spend in clinical laboratory testing was $7.1 billion in 2017. *(See TDRs, Apr. 20 and June 1, 2020.)*

Most of the clinical laboratories performing molecular COVID-19 tests have been able to offset the loss of revenue from routine testing. Also, by the summer, routine specimen referrals were almost back to pre-pandemic levels.

But for many clinical labs—particularly those not directly performing molecular COVID-19 tests—that 10-week collapse in routine specimen referrals, and the cash flow normally generated by those tests, has left them in a precarious financial position.

TOP TEN 2020 LAB STORY 7

COVID-19 Causing Major Changes in How Labs Buy Instruments, Supplies

If the SARS-CoV-2 pandemic leaves one lasting change to the clinical laboratory industry, it will be that lab managers have a new attitude toward buying supplies and cozying up to a single primary *in vitro* diagnostics (IVD) vendor that provides from half to 80% of a lab's instrumentation, automation, and tests.

Starting in March, as the number of COVID-19 infections ramped up, nearly every lab in this country found it impossible to get needed supplies, instruments, kits, and more. Not surprisingly, the major IVD manufacturers were themselves overwhelmed.

Adding to the chaos was how federal and state officials commandeered supplies and redirected them away from labs expecting shipments—generally without much notice. Suddenly, having one major IVD manufacturer provide half or more of a lab's supply chain went from a cost-saving benefit to a major liability. *(See TDRs, Jun. 1 and 22, Jul. 13, Aug. 3, and Oct. 26, 2020.)*

For the past nine months, the leadership of most clinical laboratories and pathology groups have spent much of their time locating adequate quantities of the supplies, instruments, and tests they need to perform COVID-19 tests, while maintaining standard laboratory testing for their parent hospitals and physician-clients.

Equally significant, the pandemic is causing global IVD companies to rethink their own manufacturing sites and supply chain arrangements.

TOP TEN 2020 LAB STORY 8

Coronavirus Pandemic Is Opportunity for New Clinical Lab Competitors

Like bees to the honeypot, newcomers are flocking into the clinical laboratory market to get their share of the tens of billions of dollars that federal and state governments are paying for COVID-19 tests. Certainly some of the new entrants will want to direct their clinical lab facilities toward regular clinical lab tests whenever the pandemic passes.

The Dark Report considers **Amazon** to be among the most credible of the new players in clinical laboratory testing. In the spring, it announced plans to build and operate its own labs to provide SARS-CoV-2 testing for its 1.1 million employees. It is unlikely that Amazon would close those expensive laboratory facilities once the pandemic ends. *(See TDR, Aug. 3, 2020.)*

Since the outbreak of SARS-CoV-2, The Dark Report has identified and described other new entrants into the lab testing marketplace. These include **eTrue North** of Mansfield, Texas, and **SafeSite** of Calabasas, Calif. *(See TDRs, Sept. 14, and Oct. 5, 2020.)*

Even governments are getting into the COVID-19 testing business. The Dark Report was first to report that the State of California had built a lab facility in Newhall, Calif., and that it planned to perform 150,000 molecular SARS-CoV-2 tests per day by April. *(See TDR, Nov. 16, 2020.)*

Expect that a number of these competitors will want to redirect their fully-equipped laboratories toward routine and reference testing once the COVID-19 pandemic subsides.

TOP TEN 2020 LAB STORY 9

Digital Pathology Gets Major Boost from Pathologists Working at Home

When the pandemic exploded in the United States in March, who could predict that many, many pathologists—restricted by state and local directives to work only from home—would quickly recognize the benefits of using digital pathology (DP) and whole-slide imaging (WSI)?

As lockdown orders were issued in cities and states across the nation, private practice pathology groups with digital pathology systems already installed simply fed the digital images to pathologists working from home.

This helped to maintain diagnostic workflow. Of equal importance, it helped to generate revenue in March and April when the volume of tissue referrals (and associated cash flow) dropped by 60% to 90%. Not surprisingly, during these early months of the pandemic, even the many baby boomer pathologists who had been reluctant to abandon their light microscopes quickly appreciated the clinical, operational, and financial benefits of using digital pathology and WSI. *(See TDRs, Mar. 30, and Dec. 7, 2020.)*

Probably the biggest boost to digital pathology adoption is the project at the federal **Joint Pathology Center**. The JPC just signed an agreement with **Proscia** to digitize the world's largest archive of pathology glass slides. *(See TDR, Oct. 26, 2020.)*

In these unexpected ways, the pandemic is accelerating adoption of digital pathology for use in primary diagnosis. This will trigger fundamental changes to pathology as it has been practiced for decades.

TOP TEN 2020 LAB STORY 10

Federal Judge Schedules Trial for Ex-Theranos CEO Elizabeth Holmes

Any news about Elizabeth Holmes, the discredited founder and former CEO of **Theranos, Inc.**, is of continuing interest to many clinical laboratory professionals. In 2020, the big story involving Holmes is that the judge handling the federal case against against her and Ramesh "Sunny" Balwani, former COO of Theranos and Holmes' former boyfriend, has ruled against most of the defendants' motions. The judge ended the year setting a trial date for 2021.

On Dec. 20, U.S. District Court Judge Edward J. Davila, established July 2021, as the date when the trial will begin. It will start with selection of the jury. Judge Davila further described the specific precautions that will be taken during the trial in response to the SARS-CoV-2 pandemic, including wearing of masks and an air filtration system over the witness stand.

Several weeks earlier, federal prosecutors filed a third superseding criminal indictment. The newest charge involves claims associated with a patient's blood test. Holmes now faces 12 criminal counts.

Holmes and Balwani entered "not guilty" pleas to all charges. If convicted, they could each face maximum penalties of 20 years in prison, a $2.75 million fine and possible restitution, the **Department of Justice** said. *(See TDR, Feb. 17, 2020.)*

The fate of Theranos and its disgraced founder, Elizabeth Holmes, continues to be of high interest to many in the clinical laboratory industry. TDR

Lab Market Update

UK Postpones Mass COVID Testing Plan Due to Questions of Accuracy

In the United Kingdom, a mass COVID-19 testing plan called "Operation Moonshot" is on hold until at least the end of January. Under the plan, health ministers sought to increase daily SARS-CoV-2 testing from 430,000 to 10 million Englanders per day.

Inaccurate early results from a newly-launched, same-day, at-home COVID-19 lateral-flow test caused officials to postpone that plan, according to published reports. Called the **Innova** SARS-CoV-2 Antigen Rapid Qualitative Test, the self-administered assay provides results in 30 minutes. However, a pilot test program among university students showed that the test missed 30% of cases among those who had a high viral load, according to *The Guardian* newspaper.

On Dec. 23, the UK's **Medicines and Healthcare products Regulatory Agency** (MHRA) authorized the **Department of Health and Social Care** (DHSC) to use the antigen test for detecting COVID-19 infections in asymptomatic individuals.

Just two days earlier, health experts had questioned the accuracy of the test. Jon Deeks, PhD, CStat, Professor of Biostatistics at the **Institute of Applied Health Research** at the **University of Birmingham**, said his researchers used polymerase chain reaction testing to retest 10% (710 of the 7,189 university students) who had tested negative with the Innova test.

The PCR tests found six false-negative cases, raising the rate to 60 per 100,000, the *British Medical Journal* (*BMJ*) reported. Deeks leads the institute's Biostatistics, Evidence Synthesis and Test Evaluation Research Group.

"We found two positives in 7,189 students, which scales up to 30 per 100,000 and was shocking in itself, as Birmingham has a rate of 250 cases per 100,000," Deeks said. "The government should not be proceeding with plans for schools testing until they have a proper evaluation of the test."

Universities in Bath, Birmingham, Bristol, Durham, Leeds, Leicester, and other cities used the assay to test students for SARS-CoV-2 ahead of the Christmas break, the newspaper added. From his assessment, Deeks estimated that 58% of the antigen tests produced false positives. Also, he said, the test has a low sensitivity level of about 3%, leading to false negatives.

'Not Fit for Purpose'

About the lateral flow tests, *The Tab*, a London newspaper for students, quoted Deeks saying, "They're not ready. They're not fit for purpose. I'd rather hang these tests on a Christmas tree in Trafalgar Square. That would be better."

The Guardian wrote, "The development is a blow to the UK government's 100 billion pound 'Operation Moonshot' mass-testing plan, which aims to increase the number of COVID-19 tests done each day from 430,000 to 10 million."

A DHSC spokeswoman called the antigen tests accurate and reliable for identifying asymptomatic individuals who have COVID-19. "The country's leading scientists rigorously evaluated the lateral flow test and confirmed the accuracy of the tests using a sample of over 8,500. Latest figures for similar settings [are] showing sensitivity of 57.5% generally and 84.3% in people with high viral loads," she stated. TDR

CEO SUMMARY: Newly-released data indicates that Medicare officials are falling far short of their goal to decrease the total amount of money spent annually on Part B clinical laboratory tests. That is one finding by the federal Office of the Inspector General in its report of Medicare lab test spending during 2019. Despite deep cuts to the prices for many high-volume tests, the OIG found that Part B lab test spending totaled $7.68 billion in 2019, which is an increase of $93 million, or 12.1% from 2018. More genetic test claims helped increase total spending.

Savings from PAMA Price Cuts Exceeded by More Spending on Genetic Tests

OIG Says Medicare Spending On Testing Increased in 2019

EARLIER THIS MONTH, THE FEDERAL OFFICE OF INSPECTOR GENERAL (OIG) finally issued its report on Medicare Part B clinical laboratory spending for 2019. The OIG's findings are unwelcome news for both the Medicare program and the clinical laboratory industry.

For Medicare officials, the bad news is that, yes, the deep price cuts to many high-volume, highly-automated lab tests did reduce spending for those tests. But sizeable increases in spending for molecular and genetic tests caused overall spending for Medicare Part B clinical lab tests to increase to $7.68 billion in 2019, an increase of $93 million or 12.1%, compared to 2018.

For the clinical laboratory industry, the bad news is that officials at the federal **Centers for Medicare and Medicaid Services** (CMS) are failing in their goal to reduce total spending on Part B clinical lab tests from one year to the next. Thus, CMS officials will be motivated to look for additional fee cuts to the prices the Medicare program pays for clinical lab tests.

The OIG's report is titled, "Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests." This annual report is mandated by the Protecting Access to Medicare Act (PAMA) of 2014.

This year's OIG report was not as comprehensive as its earlier annual reports on Medicare CLFS spending. These reports analyze how each year's PAMA fee cuts (which are based on CMS' market study of the prices paid by private health insurers for lab tests) have influenced CLFS spending for that year.

The OIG's annual report on Medicare spending for lab tests is useful in two ways. First, it provides details about what Medicare spends each year on clinical laboratory testing—details that were not easily accessible in the years before the OIG began publishing this report.

Second, the data and commentary in the OIG's annual report is one of the few places where federal officials publicly comment on events and trends in spending by the Medicare program for clinical laboratory tests.

Despite Cuts, More Spending

The 2019 spending report revealed that, although the PAMA fee cuts on high-volume, routine tests did reduce Medicare spending for those tests, overall spending rose by 12.1% in 2019 because some high-priced genetic and molecular tests drove up overall spending. On those tests, PAMA had no effect, the OIG reported.

"Because this group of [molecular and genetic] tests had relatively high payment rates, the increased spending for this group overtook the savings achieved by the PAMA rate reductions in 2019," the report noted. The report was dated December 2020 and was released on Dec. 18.

High-Priced Tests a Factor

"In the second year [2019] of the new payment system, reduced payment rates for many lab tests resulted in savings for the Medicare program," the Inspector General wrote. "However, total Medicare spending increased slightly because of increased utilization and spending on certain high-priced tests, such as genetic tests."

The report showed that—despite payment rate reductions on 73% of lab tests on Medicare's Clinical Laboratory Fee Schedule (CLFS)—Medicare Part B spending jumped by 12.1% between 2018 and 2019, for a total of $7.68 billion.

A 12.1% rise in spending is significant. This could be a bad sign for clinical laboratories in the coming year if it leads Medicare administrators to scrutinize more closely what the agency spends on high-priced genetic tests and advanced diagnostic laboratory tests (ADLTs). In particular, the OIG cited two tests that could get more attention in the coming year.

In the report, the OIG explained that what Medicare spent on the top 25 tests increased slightly in 2019 over what the agency spent in 2018. The analysis of spending on these tests showed two trends:

- "First, 17 of the top 25 tests had payment rate reductions required under PAMA," the OIG said, adding, "For this group, overall Medicare spending decreased in 2019 compared to 2018."
- Second, payment rates for the remaining eight tests among the top 25 did not change in 2019, and overall Medicare spending for this group increased compared with spending in 2018 because the nation's clinical labs submitted more claims of these tests, the OIG reported.

PAMA Law's Mandates

When Congress passed PAMA in 2014, the law changed the way Medicare pays for lab tests by requiring CMS to conduct a market study of lab test prices paid by commercial health insurers. CMS then used that data to set market-based prices for the Medicare Part B CLFS. Congress also required the OIG to report annually on what effect, if any, the law is having on Medicare Part B spending for clinical lab tests.

In addition, the law requires the OIG to review the top 25 tests based on Medicare spending and report on that analysis each year. Under PAMA, CMS is allowed to cut the price of a lab test by no more than 10% in each of the first three years (2018, 2019, and 2020) and by no more than 15% in each of the next three years. (Because of the COVID-19 pandemic, fee cuts scheduled for Jan. 1, 2020, were delayed by one year.)

"Prior to PAMA, the OIG found that Medicare was paying significantly more than other [private] payers for many lab tests," the inspector general noted.

In the report, the OIG said, "Our analysis of Medicare Part B spending on lab tests demonstrates that—as expected—the payment rate adjustments required by PAMA achieved savings for some lab tests that had payment rate reductions in 2019." But this statement obscures the fact that Medicare spending for lab tests continued to rise. *(See exhibit 1 in sidebar on page 15.)*

Medicare's overall spend on clinical lab tests continues to increase—despite the price cuts—because of rising expenditures for genetic tests. "Medicare spending on genetic tests reached $1.36 billion in 2019, an increase of about $390 million from 2018," the report showed. The report does not say this, but $390 million is 29% of $1.36 billion. *(See exhibit 2 in sidebar on page 15.)*

"Medicare paid for about 2.22 million units of genetic tests in 2019, up from about 1.76 million units in 2018," the report showed. That spending for genetic tests came in three categories:

- Molecular pathology,
- Multianalyte algorithmic assays (MAAAs), and,
- Genomic sequencing procedures.

Exhibits that show Medicare spending for these three categories were included in the OIG report. These exhibits are reproduced in the sidebar on page 17.

The Top 25 Tests

Another factor contributing to increased Medicare spending on lab tests 2019 was the effect the top 25 tests had on total spending. "Medicare spent $4.64 billion on the top 25 tests in 2019, up from $4.57 billion in 2018," the OIG noted. While payment rates were cut for 17 of the top 25 tests, rates were not cut in 2019 for the remaining eight tests in the top 25. For all but one of the 17 tests, the rates Medicare paid in 2019 dropped by 10%, as PAMA prescribed.

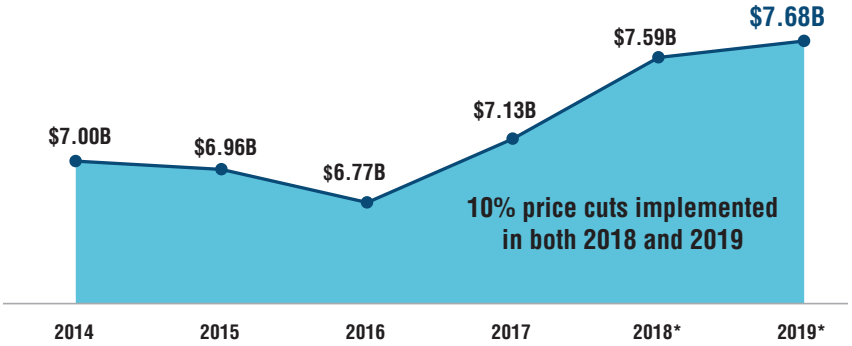
"Because of these rate changes, total spending for the group of 17 tests decreased by $175 million in 2019, illustrating that—as expected—the lab payment rate changes required by PAMA achieved savings for some lab tests," the OIG commented. "Notably, savings for some of these tests occurred despite increased utilization in 2019 compared with 2018."

On example presented in the OIG was for the comprehensive blood chemistry

OIG Reports Rise in Overall Medicare Part B Test Spending, Despite PAMA Price Cuts to High-Volume Lab Assays

TWO CHARTS PRESENTED BELOW were published by the federal Office of the Inspector General in its report on spending for Medicare Part B clinical laboratory tests during 2019. Exhibit 1 below shows total Medicare spending. Despite the 10% price cuts enacted to many lab tests in both 2018 and 2019, Medicare spending continued to increase in each year by a significant amount.

Exhibit 1: Medicare spending for lab tests continued an upward trend 2019.



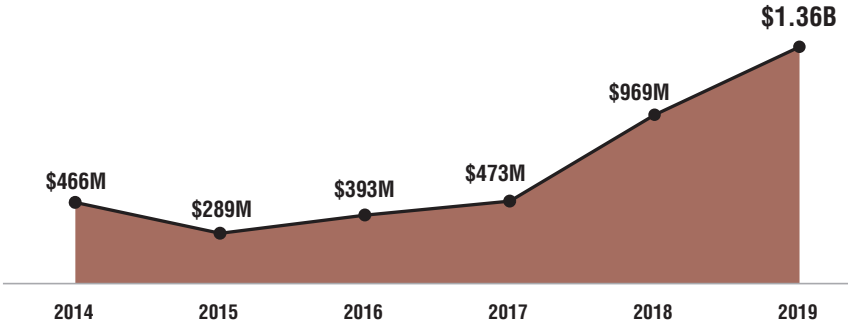
*In 2018 and 2019, lab payment rates were subject to the rate reductions required by PAMA.

Note: Medicare spending dollar values are rounded.

Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, in billions, 2020.

EXHIBIT 2 BELOW presents what the Medicare program spent for genetic tests in the years from 2014 to 2019. Between 2017 and 2018, spending almost doubled and between 2018 and 2019 it grew by another 50%.

Exhibit 2: Medicare spending on genetic tests increased for the fourth year in a row and reached its highest point of $1.36 billion in 2019.



Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, 2020.

(CBC) test. The OIG wrote that Medicare spending for this test dropped by about $45 million in 2019, despite an increase in utilization of about 500,000 such tests.

Unchanged Payment Rates

For Medicare, spending on the 17 tests was mostly good news, but spending on the remaining eight tests in the top 25 told a different story. "For the group of eight tests with payment rates that did not change, total spending increased in 2019," noted the OIG.

For six of those eight tests, payment rates did not change from 2018 to 2019 because they had already reached the rate that PAMA required under the law's volume-weighted median calculations from lab-reported data. "The volume-weighted median is calculated by taking the median value of all private payer rates, weighted by test volume," the report explained. Among those six tests, four were drug assays and two were genetic tests.

Before Congress passed PAMA in 2014, the OIG said its research and other reports showed that Medicare was paying significantly more than private payers for many lab tests. "In the coming years, payment rate reductions for many lab tests that are on the CLFS are expected to result in further savings for the Medicare program," the OIG predicted without providing any support for this contention.

Reductions to Test Prices

However, not all tests on the CLFS had payment rate reductions in 2019. This occurred for one of two reasons:

1. Tests with payment rates that had already reached the rate required by PAMA did not require further reductions, or
2. Tests that were new to the CLFS as of 2018 were not affected by the 2019 rate reductions required by PAMA.

In the report, the OIG noted that COVID-19 may affect spending for clinical lab tests. "Looking ahead, we anticipate that Medicare spending for lab tests in 2020 will be significantly affected by the COVID-19 pandemic, especially diagnostic testing for the novel coronavirus and other respiratory illnesses," the report noted.

"OIG has a body of oversight activities underway regarding COVID-19-related lab testing. Additionally, OIG will continue to monitor the effect of the PAMA changes on Medicare spending."

Since it launched in 1995, THE DARK REPORT has closely watched the officials in charge of the Medicare program as they regularly and repeatedly proposed different ways to rein in spending for Medicare Part B clinical laboratory tests.

These efforts started in the early 1980s, when the federal agency managing the Medicare Program was called the **Health Care Financial Administration** (HCFA). That name was changed in 2001 to the Centers for Medicare and Medicaid Services (CMS).

Studies to Reduce Spending

As early as 1981, HCFA was spending money on consultants to study the Part B Clinical Laboratory Fee Schedule and identify different methods to reduce spending. In 1988, Congress cut lab fees significantly, but, as an offset to labs, dropped the requirement that labs collect a 20% copayment from Medicare beneficiaries.

In the 1990s, HCFA issued several reports and published studies advocating competitive bidding for lab testing. Eventually, Congress authorized a demonstration project. CMS attempted to launch its first demonstration project in 2008 in San Diego County, Calif. Several labs filed a lawsuit in federal court and successfully stopped that demonstration project for competitive bidding of lab tests.

Then, a few years later in 2014, language was included in the PAMA statute mandating CMS to conduct a market study of the prices paid by private payers for lab tests and to use this data to set prices on the CLFS. TDR

Three Charts Illustrate How Molecular, Genetic Tests Fuel Most of Medicare's Increased Spending on Testing

DESPITE TWO CONSECUTIVE YEARS OF 10% PRICE CUTS FOR MOST CLINICAL LABORATORY TESTS, overall Medicare spending on Part B clinical laboratory tests increased in 2018 and 2019. The federal Office of the Inspector General (OIG) reported that a major factor in this increased spending was the dramatic increase in claims for molecular and genetic tests. The OIG presented the three charts below to illustrate that finding.

Chart A: Medicare Spending on Molecular Pathology Tests

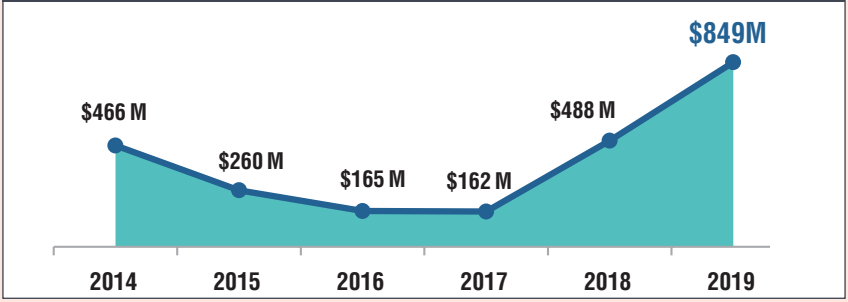


Chart B: Medicare Spending on Multianalyte Algorithmic Assays

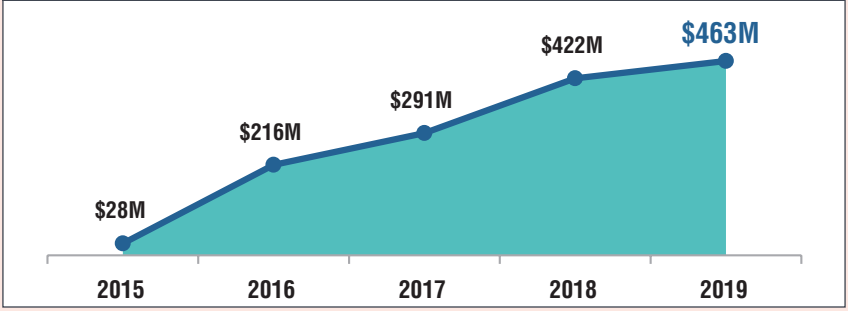
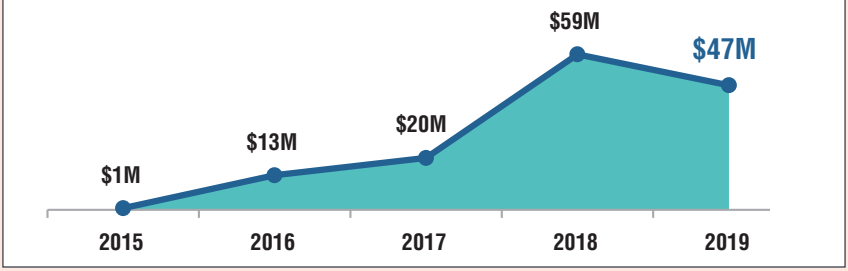


Chart C: Genomic Sequencing Procedures



Source: Office of the Inspector General, Data Brief: Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests; OEI-09-20-00450.

IVD Update

THE DARK REPORT'S Ranking of 2019's Top 10 IVD Companies

Each year's rankings show how acquisitions are a major way the biggest firms get bigger

One trend continues to reshape the *in vitro* diagnostics (IVD) industry year after year: acquisitions.

Since the 1990s, the biggest IVD companies have frequently used acquisitions to boost their revenue and keep shareholders happy. But acquisitions have another consequence. The clinical laboratories and anatomic pathology groups buying instruments, automation, and test kits from one IVD firm might suddenly find that IVD company acquired by a competitor. Now these lab customers must deal with a new corporate entity.

Disruptive Acquisitions

They see their long-standing relationships with service reps and sales people end, as the acquiring company integrates its acquisition and cuts back the sales and service teams of the acquired company. This is one way that IVD acquisitions can be disruptive to the lab customers of the acquired firm.

There is a useful way to track how the market shares of the major IVD companies shift from one year to the next because of acquisitions and other developments. That is to rank the top IVD companies by revenue and compare their individual revenues to each other and to the total global sales of IVD products.

Until now, it has been difficult for most clinical laboratory administrators and pathologists to see a ranked list of the largest IVD corporations. Such lists have not been published in the lab trade press.

These rankings generally have only been available by spending several hundred or several thousand dollars on an IVD industry report prepared by one of the many financial analysts who sell this information to professional investors.

First Top 10 IVD Ranking

This year, THE DARK REPORT is commencing coverage of the IVD industry as a complement to our regular coverage of clinical laboratories and anatomic pathology groups. To the right is THE DARK REPORT's ranking of the Top 10 Global IVD Companies for 2019.

The number one ranking is no surprise. The diagnostics business of **Roche Holdings** has been the world's largest IVD company for decades. Similarly, **Abbott Laboratories** has held the number two slot for many years.

What may surprise many lab managers is the position of **Danaher Corporation** as the number three biggest IVD company in the world. In recent years, it has been an active acquirer. Its biggest IVD division is **Beckman Coulter**. It also owns **Cepheid**, **Leica Biosystems**, and **Radiometer**. The other companies on the list are familiar to most lab professionals.

The next annual ranking will be for 2020. That ranking will be compiled after the publicly-traded IVD corporations report their fourth quarter 2020 and full-year 2020 earnings next year. TDR

THE DARK REPORT'S Top 10 IVD Companies By Global Revenue in 2019

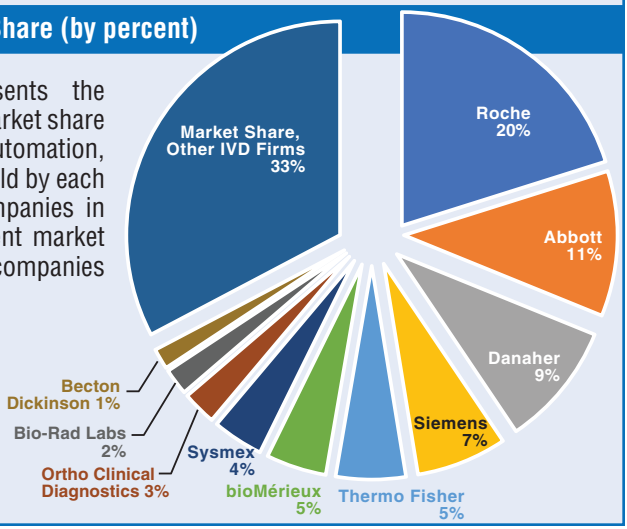
IVD Corporation (Revenue in Billions)	2109 revenue	Cumulative revenue	percent	Cumulative percent
1. **Roche Holdings** *Basel, Switzerland, founded 1896*	$14.1	$14.1	20.4%	20.4%
2. **Abbott Laboratories** *Abbott Park, Ill., founded 1888*	$7.7	$21.8	11.2%	31.6%
3. **Danaher Corporation** *Washington, D.C., founded in 1969*	$6.6	$28.4	9.6%	41.2%
4. **Siemens Healthineers** *Erlangen, Germany, founded 1896*	$4.8	$33.2	7.0%	48.1%
5. **Thermo Fisher Scientific** *Waltham, Mass., founded 1956*	$3.7	$36.9	5.4%	53.5%
6. **bioMérieux** *Marcy-l'Étoile, France, founded 1963*	$3.2	$40.1	4.6%	58.1%
7. **Sysmex Corporation** *Hyogo Japan, founded 1968;*	$2.7	$42.8	3.9%	62.0%
8. **Ortho Clinical Diagnostics** *Raritan, N.J., founded 1939 2018 revenue*	$1.8	$44.6	2.6%	64.6%
9. **Bio-Rad Laboratories** *Hercules, Calif., founded 1952*	$1.4	$46.0	2.0%	66.7%
10. **Becton Dickinson** *Franklin Lakes, N.J. founded 1897*	$1.1	$47.1	1.6%	68.3%
Total Revenue Share, Top 10 IVD Firms	$47.1	$47.1	68.3%	68.3%
Remaining Revenue Share, Other IVD Firms	$22.9	$22.9	31.7%	31.7%
Total Global IVD Revenue in 2019 (est.)	**$70.0**	**$70.0**	**100.0%**	**100.0%**

Source: Company documents, news reports, financial analysts' reports.

TABLE ABOVE: Shows how the global market for *in vitro* diagnostic (IVD) products is dominated by only 10 companies that generate almost 70% of all IVD sales. Just four companies account for almost half of all global IVD sales.

2019 Global IVD Market Share (by percent)

CHART AT RIGHT: Presents the percent of the worldwide market share for IVD instruments, automation, tests, and other products held by each of the 10 biggest IVD companies in 2019, along with the percent market share of all remaining IVD companies combined.



Lab Regulatory Update

Congress Passes Bill to Ban Surprise Medical Bills

Starting Jan. 1, 2022, out-of-network clinical laboratories may no longer be allowed to bill patients for lab tests performed in certain settings under a law both houses of Congress passed on Dec. 21.

The COVID relief bill includes a ban on unexpected medical bills from some out-of-network providers, such as clinical laboratories, anatomic pathologists, anesthesiologists, and emergency room physicians. Included in the legislation is The No Surprises Act, which would ban balance billing from out-of-network medical providers for amounts those patients' insurers do not cover.

Designed to stimulate the economy, this comprehensive bill also includes short-term unemployment benefits and $600 direct payments to individuals. However, the president had conditions he wanted met before he agreed to sign the bill into law, *The Washington Post* reported on Dec. 26.

"Starting in 2022, when the law goes into effect, consumers won't get balance bills when they seek emergency care, when they are transported by an air ambulance, or when they receive nonemergency care at an in-network hospital but are unknowingly treated by an out-of-network physician or laboratory," *Kaiser Health News* (*KHN*) reported.

Instead, patients would pay only the deductibles and copayment amounts that they would normally pay for in-network care under their health plan. "Medical providers won't be allowed to hold patients responsible for the difference between those amounts and the higher fees they might like to charge," *KHN* wrote.

Clinical labs and AP groups that still have payment disputes with consumers would need to negotiate acceptable terms with insurers. For those who are uninsured or get all of their care out of network, the bill requires the federal **Department of Health and Human Services** to establish a provider-patient bill dispute resolution process, *KHN* reported.

Most patients may not know when they get a lab test or AP procedure from an out-of-network provider, especially if they get care at an in-network hospital. When seeking emergency or urgent care, patients have little choice and may assume they are getting in-network care.

"The legislative agreement also applies to nonemergency care provided at in-network facilities, where patients receive care and services from out-of-network providers, such as anesthesiologists and laboratories," *KHN* noted.

Patient Consent

In some situations, physicians, but not all providers, would be allowed to balance-bill patients if they get patient consent in advance. Providers would need to provide a cost estimate and get consent at least 72 hours before treatment. For shorter-turnaround times, the new law says patients should get the consent information when they make the appointment, *KHN* reported.

Clinical laboratories, pathologists, radiologists, neonatologists, and assistant surgeons, however, would not be allowed to seek consent to balance-bill for their services. What's more, the legislation allows the consent-seeking process only in nonemergency circumstances. TDR

Non-Physician Providers Can Supervise Testing

Medicare's interim rule first issued in May because of COVID-19 now published as a final rule

CEO SUMMARY: It's the latest example of how interim rules issued earlier this year in response to the pandemic are being made permanent by the federal Centers for Medicare and Medicaid Services. Issued on Dec. 2, this new final rule allows certain non-physician practitioners—including nurse practitioners and physician assistants—to supervise diagnostic testing. Clinical labs will want to review the new rule with their legal advisors to ensure their compliance with the final rule.

One of Medicare's newest rules has the potential to create a new set of regulatory headaches for pathologists and clinical laboratory managers. The new rule now allows certain non-physicians to supervise diagnostic testing.

This is a change to Medicare rules that has been proposed in previous years and generally met with opposition from most pathology and laboratory associations. However, in the era of COVID-19, for example, many things in healthcare are changing, particularly with federal and state laws that govern medical scope of practice. Thus, the SARS-CoV-2 pandemic played a role in how this new rule was drafted, posted for public comment, and issued in final form earlier this month.

Under the new rule, non-physician practitioners (NPPs)—defined as nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs)—now will be allowed to supervise diagnostic testing, but only within their scope of practice.

This potentially places an additional burden on clinical laboratories to ensure that test orders are submitted in accordance with state and federal laws.

Prior to the COVID-19 public health emergency, physicians and certain NPPs could order diagnostic tests when they used the results of the tests to manage a Medicare beneficiary's specific medical problem and, in some cases, perform the tests without physician supervision. However, only physicians were permitted to supervise diagnostic tests.

Interim and Final Rules

In an interim rule issued May 8, 2020, the **Centers for Medicare and Medicaid Services** (CMS) authorized—on a temporary basis—PAs, NPs and certain other NPPs to order, furnish directly, and supervise the performance of diagnostic tests, subject to state law and scope of practice, during the COVID-19 public health emergency.

In its 2021 final Physician Fee Schedule Final Rule, announced Dec. 2, 2020, CMS made permanent those relaxed supervision requirements. Notably, PAs, NPs,

and other NPPs (e.g., CRNAs and CNMs) may provide supervision of diagnostic tests only to the extent that they are authorized to do so under the scope of their practice and applicable state law.

Primary Risk for a Laboratory

"The primary risk for a laboratory is that a practitioner orders a test outside of his or her scope of practice as defined by state law," noted Karen Lovitch, an attorney and Chair of the Health Law Practice at **Mintz** (Washington, D.C.). "Even though Medicare rules might permit it, that doesn't necessarily mean that the state does so. Each state can be different, so the lab should be sure to check the rules for each state from which it receives specimens.

"It could be considered a false claim under the False Claims Act if a lab performs and bills for testing ordered by an unauthorized provider," Lovitch continues. "Laboratories should also keep in mind that these rules, as currently written, are time-limited. Laboratories should be sure to follow CMS developments, so they are aware of any changes when the public health emergency ends."

Isabelle Bibet-Kalinyak, a partner with **McDonald Hopkins**, believes the change will provide more flexibility for test supervision, particularly in physician practices or hospitals where there may be a shortage of physicians, such as in rural areas or settings strained by the pandemic.

Benefits in Rural Areas

"Mid-level providers or physician extenders fill a lot of gaps in rural areas and underserved communities," she says.

"There obviously is a need for this because CMS tried it during the COVID-19 pandemic and it has worked. This was essentially a demonstration that showed there was no increased risk in giving more independence to certain mid-level providers."

Currently, there is a patchwork of laws and regulations in each state regarding physician extenders, notes Bibet-Kalinyak. In nearly half the states, nurse practitioners can practice without any physician supervision or collaboration and are already doing much the same work as physicians, including ordering and performing some diagnostic testing (e.g., psychiatric).

"In other states, such as Ohio, nurse practitioners must—at least contractually—collaborate with a physician. Vicarious liability also varies state to state and provider to provider," noted Bibet-Kalinyak. "For example, under Ohio law, physicians are statutorily liable for all acts and omissions of PAs under their supervision, but not for NPs.

"It's really all over the place, which creates some difficulties in administering this efficiently," she continued. "This really must be determined on a case-by-case basis, relative to the scope of practice and the training required for each physician extender."

High-Complexity Testing

For high-complexity testing, this change is not significant, she says, since those tests require a higher level of supervision. "There is no pathology specialty for nurse practitioners," said Bibet-Kalinyak. "But in the future, that could be possible."

Bibet-Kalinyak also recommends that clinical laboratories—including physician office laboratories—check their malpractice insurance policies to ensure that supervision of diagnostic testing by NPPs is covered appropriately.

"Some lab organizations may find that their existing malpractice policies have a gap in coverage that needs to be addressed in response to this new Medicare rule that allows certain non-physicians to supervise diagnostic testing," she stated. "It would thus be a good time to review current coverage." TDR

Contact Karen Lovitch at 202-434-7324 or KSLovitch@mintz.com; Isabelle Bibet-Kalinyak at 216-348-5736 or ibk@mcdonaldhopkins.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Seattle is the latest city to open walk-up kiosks for COVID-19 testing that allow individuals to collect their own saliva, then hand the specimen to a worker in the booth for overnight testing. Three such kiosks are now in operation. **Curative**, based in San Dimas, Calif., performs the testing using a molecular SARS-CoV-2 test that has an FDA EUA. The walk-up kiosks are part of a COVID-19 testing program run by the City of Seattle. A statement on the city's website says, "COVID-19 tests are free. Insurance is not required. If you have insurance, Medicare or Medicaid, you must provide this information and **UW Medicine** will bill them. You will not be charged."

LABCORP ACQUIRES ANALYTICS FIRM VISIUN, INC.

In a little-noticed transaction, **LabCorp** acquired **Visiun Inc.**, of Ann Arbor, Mich., one of the largest providers of an analytics middleware solution for clinical laboratory operations and workflow. The parties did not respond to THE DARK REPORT's requests for comment as of press time, but a notice on the Visiun website says the acquisition was completed on Dec. 1. This is an interesting development that could have significant ramifications. Visiun provides near-real-time analytics to hundreds of hospital and health system laboratories.

MORE ON: *LabCorp's Acquisition of Visiun*

Among Visiun's clients are some of the nation's best lab operations. Visiun has developed benchmarking and best-practices based on the performances of hundreds of its lab clients. As Visiun's new owner, LabCorp now has access to that performance data. Lab administrators should keep in mind that LabCorp had business reasons for acquiring Visiun and the performance information it gathers. Might LabCorp believe it now has a potentially game-changing advantage, particularly in markets where a hospital or health system has a highly-effective laboratory outreach business?

TRANSITIONS

- Pathologist Ana K. Stankovic, MD, PhD, MSPH, was appointed to the Board of Directors by **Fluidigm Corporation** of San Francisco. She is currently Managing Director at **Koliada Consulting** and previously held positions with **Becton Dickinson**, **University of Vanderbilt School of Medicine**, **Quest Diagnostics**, and the Division of Laboratory Services at the **Centers for Disease Control and Prevention**.

- **Rhinostics** of Cambridge, Mass., announced that Cheri Walker is its new President and CEO. Walker earlier held executive positions at **Abcam**, **Kailos Genetics**, **Charles River Laboratories**, **Qiagen**, **Invitrogen**, and **Deutsche Bank**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 18, 2021.

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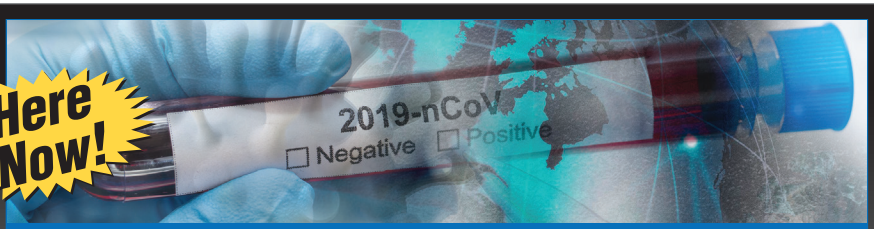

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UPCOMING...

- ***When will 'normal' return to healthcare and lab medicine? Experts weigh in on what to expect during 2021.***
- ***One pathology group's implementation of digital pathology during the pandemic, including use of self-certification.***
- ***Understanding fundamental changes to the IVD industry and the clinical laboratory and pathology supply chain.***

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