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Will one or all of these companies be your new primary care provider?

(See pages 10-16.)

CVS Walmart Walgreens Albertsons TARGET Kroger Publix RITE AID

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...

R. Lewis Dark

Founder & Publisher

Major Changes Coming to Primary Care

FOR MORE THAN A DECADE, Medicare officials and healthcare policymakers have told the medical establishment that the primary goal must be to keep people healthy and out of hospitals, and to help patients manage their chronic conditions so as to avoid acute events.

Stated another way, the goal is to shift the U.S. healthcare system into a proactive mode, where the objective of caregivers is to actively engage patients and help them with specific medical issues such as:

- getting necessary screening and diagnostic procedures in a timely fashion,
- quitting smoking, losing weight, exercising, etc., and,
- closely monitoring chronic conditions such as diabetes, hypertension, chronic kidney disease, etc., so as to prevent the need for hospitalizations and similar major interventions.

According to the **Agency for Healthcare Research and Quality**, the U.S. primary care workforce includes approximately 209,000 practicing primary care physicians, 56,000 nurse practitioners (NPs), and 30,000 physician assistants (PAs) practicing primary care, for a total of nearly 295,000 primary care professionals.

Primary care is a huge industry! As you will read in the first intelligence briefing in our new series about changes coming to primary care, some of the nation's largest corporate pharmacy and grocery chains are interested in adding full-service primary care clinics to their retail stores. *(See pages 10-16.)*

This has many implications for clinical laboratories. For example, it means that primary care physicians, NPs, and PAs working in these in-store clinics will probably be employees of those corporations. It also means that big corporations will be the buyers of any lab tests ordered by the primary care providers in their clinics.

THE DARK REPORT will publish at least four installments in this important series to describe why new big players will be ordering large volumes of clinical laboratory tests, why faster time-to-answer for lab results will encourage them to establish in-clinic labs, and why Millennials will be major patrons of in-store primary care clinics. Each installment will help you and your lab's executive team understand this new development so that you can develop appropriate strategies. TDR

MedPAC Advises Congress on Lab-Data Reporting

Suggests other collection methods to produce more accurate data on what insurers pay labs

CEO SUMMARY: For years, the clinical lab industry has sought unsuccessfully to get the federal Centers for Medicare and Medicaid Services to address the inequities in the payment formula CMS adopted after Congress passed the Protecting Access to Medicare Act (PAMA). In April, the lab industry received good news when the Medicare Payment Advisory Commission (MedPAC) reported that its staff found a more equitable and less burdensome method of data reporting for labs.

THERE MAY SOON BE GOOD NEWS ON THE SUBJECT of how Medicare officials require clinical laboratories to report the lab test prices paid by commercial health insurers, as mandated by the Patient Access to Medicare Act (PAMA).

If Congress were to act on the recommendations in the final report by the **Medicare Payment Advisory Commission** (MedPAC), two significant changes could result. One change would be an increase in clinical lab test prices as listed on the Medicare Part B Clinical Fee Schedule (CLFS). The second important change would reduce the reporting burden on labs when they gather private payer lab test prices from all types of labs that currently provide testing to Medicare patients.

This information comes from a preliminary report submitted last April to Congress by the MedPAC, a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice.

MedPAC's report was based on its analysis of how the federal **Centers for Medicare and Medicaid Services** (CMS) implemented PAMA. It determined that a more efficient way of reporting data on what commercial insurers pay for lab tests could lead to increased Medicare payment to labs of 10% to 15% over what CMS currently pays clinical labs for tests. MedPAC is due to issue a final version of the report this month and it could come as early as Tuesday (June 15), according to sources in the clinical lab industry.

MedPAC was required to do the analysis under the Laboratory Access for Beneficiaries (LAB) Act, which went into effect at the end of 2019. The LAB Act addressed two of the most onerous

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requirements of PAMA. First, it delayed the data-reporting requirements under PAMA. Second, it required MedPAC to review the methods Medicare officials used to implement PAMA and to recommend revised data collection and rate-setting processes.

For more than six years, the clinical laboratory industry has tried—but mostly failed—to make progress in its efforts to get CMS to implement a more efficient and equitable way for labs to report data on the lab test prices paid by commercial insurers.

Now that MedPAC is about to issue its final report, as required by the LAB Act, the industry may be about to get a more equitable way to report what insurers pay for lab tests. A more equitable method of assessing how labs are paid would result in higher payment rates for labs, according to lab industry sources who commented on background, meaning they would not be named.

More Types of Labs to Report

In its preliminary report, MedPAC showed that producing accurate estimates of private payer lab test prices from a wide range of laboratories could reduce by as much as 70% the total number of laboratories currently required to report this information. Under the current rule issued by CMS, all applicable labs must comply with a complicated formula to assemble and report the lab test prices they've been paid by private payers. Labs have regularly complained that CMS' data-reporting requirements are onerous, time-consuming, and costly, while excluding data from relevant types of labs.

In its preliminary report, MedPAC noted that, not only would revising the data-collection method improve the efficiency of the data-reporting system that CMS has used, but it also would increase the types of laboratories that would be required to report. Having a wider range of labs report payment rates would help to ensure all labs are represented even though all labs would not need to report, the preliminary report suggested.

In the first round of data-reporting under PAMA, MedPAC's preliminary report showed that independent labs were over-represented. This confirms a major criticism that clinical laboratories have made to CMS since issuance of the first draft rule years ago.

Independent Lab Reporting

In 2016, for example, independent labs ran 48% of all tests on the Clinical Laboratory Fee Schedule (CLFS), MedPAC noted, but that level of tests represented 90% of the payment-rate volume reported to CMS.

Hospital outpatient labs ran 29% of all tests on the CLFS in 2016, but that volume represented only 1% of the payment-rate volume reported to CMS, the report showed.

In that same year, physician-office labs (POLs) ran 28% of all CLFS tests, but that volume represented only 8% of the payment-rate volume reported to CMS, the report added.

In addition, hospital outpatient and POLs reported higher payment rates from commercial insures, on average, MedPAC reported. Relative to what commercial insurers paid independent labs, commercial insurers paid hospital outpatient labs at rates that were 45% higher than what they paid independent labs, MedPAC noted. Also, insurers paid POLs rates that were 53% higher than what they paid independent labs, the report added.

MedPAC's Findings

Since independent labs were over-represented when CMS calculated what commercial insurers paid for lab tests in 2016, the resulting calculations showed independent labs were paid rates that were close to the median payment rates for all labs, the report noted. Although MedPAC's preliminary report did not say so, the report implied that when CMS set payment rates

for lab tests based on these calculations, the rates were lower than they were previously and lower than they would have been if all segments of the lab industry were represented more equitably.

After all changes under PAMA became effective, Medicare payments for tests on the CLFS decreased by an average of 24%, but changes in payment were not uniform and even increased for about 23% of tests, MedPAC reported. Payment for routine, low-cost tests declined by 20% to 30% while newer, more expensive tests had smaller payment rate cuts and even had some increases in payment, the report noted.

CLFS Payments in 2019

In 2019, CMS paid more than $7.5 billion to labs for 428 million assays on the Clinical CLFS, MedPAC reported in April. Most of that $7.5 billion went to three types of laboratories: independent labs such as **Quest Diagnostics**, **Labcorp**, and others; hospital outpatient labs; and physician office labs, the advisory agency reported.

Having all types of labs report payment rates to CMS would make the data-collection method more equitable and would increase what CMS pays for clinical laboratory tests. Basing Medicare payment rates on a representative sample of laboratories would increase Medicare spending on lab tests by 10% to 15%, the preliminary report showed.

A new methodology that is designed to include all segments of the clinical lab industry would mean that CMS would collect data from independent labs, hospital outreach laboratories, and physician-office laboratories.

Sources representing clinical laboratories have said they support the idea that CMS would use survey methods for most tests on the Clinical Laboratory Fee Schedule (CLFS), instead of requiring each laboratory to report all data that they have on what commercial health insurers pay for their clinical lab tests. TDR

PAMA Led to Deep Cuts in Lab Test Payments

AFTER CONGRESS PASSED THE PATIENT ACCESS TO MEDICARE ACT (PAMA) OF 2014, the Centers for Medicare and Medicaid Services used data it collected during the first reporting period in 2017 to cut the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) prices in 2018, 2019, and 2020. *(See TDR, "PAMA Final Rule Issued, CMS Plans to Cut Rates by 5.6%," July 5, 2016; "What Labs Can Expect from PAMA in 2019," May 20, 2019.)*

In 2017, the **American Clinical Laboratory Association** (ACLA) filed a lawsuit against Alex Azar, who, at the time, was the Secretary of the federal **Department of Health and Human Services** (HHS). In that lawsuit, ACLA challenged a rule that HHS issued in 2016 in which HHS defined laboratories that needed to report what commercial health insurers pay under PAMA for lab tests as "applicable laboratories." Under the definition of "applicable laboratories," HHS said labs must report what they get paid if they bill Medicare Part B under their own national provider identification (NPI) number.

In the lawsuit, ACLA charged that the definition of an applicable lab under this standard was arbitrary and capricious and that it excluded significant numbers of hospital labs that provide outreach services to patients from needing to report what health insurers pay them. Most hospital laboratories bill under their hospitals' NPI numbers. By excluding hospital outreach labs, the data-collection method was skewed, the lab industry contended.

By excluding hospital outreach labs, the data tended to over-sample large commercial labs. Private payers tend to pay large commercial labs less than they pay hospital outreach labs. Therefore, the data that CMS collected resulted in lab test prices for all labs that were lower than labs had been getting paid.

Legal Update

Whistleblower Lab Manager Files Response to PerkinElmer Lawsuit

Former manager-turned-whistleblower at troubled California lab challenges claims in legal complaint

In a David-versus-Goliath-like battle, perhaps the most unusual lawsuit in decades involving clinical laboratory operations and compliance is unfolding in a federal courthouse in California. In this case, a multi-billion-dollar *in vitro* diagnostics (IVD) company is suing a laboratory manager who was once in a leadership position at a lab the plaintiff company operated, and who became a whistleblower against the lab company.

That's not the only twist in this story. In the court case (**PerkinElmer Health Sciences** versus **Mahnaz Salem**), the former lab manager is acting as her attorney.

For these and other reasons, every clinical pathologist serving as a medical director at a CLIA-certified laboratory will want to follow the progress of this case. Given that the core issues in the lawsuit involve control of documents and the rights of a whistleblower versus the employer, the well-known proverb "There, but for the grace of God, go I" can apply to medical directors at other labs.

Contempt of Court Charge

In the latest twist in the case, PerkinElmer has asked the court to find the defendant in contempt of court and to order that she pay monetary damages and attorneys' fees. The parties will return to court in July.

The clinical laboratory at the center of this dispute is the **COVID Valencia Branch Laboratory**, which the State of California owns. Under a contract with the **California Department of Public Health** (CDPH), PerkinElmer built and has operated the lab since it was opened in November. *(See TDRs, "State of California's COVID Lab Producing Inconclusive Results," Dec. 7, 2020, and "Whistleblowers Disclose Issues in California's COVID Lab," March 1, 2021.)*

Early Trouble Reported

Since that opening, the Valencia Branch Laboratory experienced numerous problems that California news outlets reported widely. In February, for example, *CBS13 TV* in Sacramento reported that PerkinElmer filed the lawsuit against Salem, claiming she was a whistleblower, along with 25 other unnamed whistleblowers who were not named but who may be named later.

During a news broadcast on Feb. 8, Julie Watts of *CBS13* reported that internal records and quality control reports from the lab—along with interviews of more than half a dozen whistleblowers inside the lab—showed problems ranged from contamination causing inconclusive results and swapped samples to inaccurate results sent to patients.

Also, Watts noted, records indicated that employees handling patient specimens had not been signed off for competency on crucial skills, and that whistleblowers noted some staff were seen sleeping on the job.

In a 12-page complaint PerkinElmer filed in the U.S. District Court for the Central District of California on Feb. 22, the lab company alleged that Mahnaz

Salem, PhD, worked for PerkinElmer for 24 days (Jan. 11 through Feb. 2) as the manager of laboratory services at the company's COVID-19 testing lab in Valencia. During that time, Salem sent proprietary information to herself via email "in violation of her confidentiality agreement," the lawsuit charged.

Breach of Contractual Duty

"Moreover, Salem accepted a job with a different competitor laboratory, **The Testing Co.**, on Jan. 14, breaching her contractual duty of loyalty to PerkinElmer and fraudulently representing to PerkinElmer that she intended to devote all of her business time, attention, skill, and effort to the performance of her duties to PerkinElmer," the company said.

After PerkinElmer named Salem in the lawsuit earlier this year, she decided to represent herself in the case in which PerkinElmer filed six charges in a civil complaint against Salem, including fraud, breach of contract, unauthorized access to computer systems, and negligent misrepresentation.

In Propria Persona

In answering the complaint, Salem used the Latin term, *in pro per*, a shortened version of *in propria persona*, meaning a person who represents herself without a lawyer. In response to a question from THE DARK REPORT, Salem confirmed that she has been representing herself in this case. Keep in mind that PerkinElmer is listed on the S&P 500 and reported $3.8 billion in revenue last year.

Chief among Salem's arguments in her defense are three facts that could serve her well in court. First, she claimed in a 10-page filing that she was wrongfully fired for identifying what she regarded as violations of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Second, she noted that she had a right to report such violations, and third, she explained that during her employ-

Why Would California Open a COVID-19 Lab?

SINCE LAST SUMMER, when California officials announced that it was building its own clinical laboratory facility to perform COVID-19 testing, the project has been subject to criticism.

The facility was designed and built by PerkinElmer, which has operated it since testing operations started in November. Known as the COVID Valencia Branch Laboratory and located in Valencia, Calif., the lab was supposed to perform 150,000 COVID-19 PCR tests per day by March 1 and report results within 48 hours.

Under this contract, PerkinElmer could be paid as much as $1.7 billion. Critics have asked why the state would build a new lab during a pandemic and thus compete against existing clinical laboratories for clinical laboratory scientists, automation, analyzers, test kits, and consumables.

From the launch of testing, consumers, local government agencies, and school districts sending samples to the Valencia Branch Laboratory have complained about delayed and inaccurate results, and a higher-than normal rate of positive test results.

On May 24, *CBS13 TV* of Sacramento reported widespread dissatisfaction with the performance of the lab. "The **El Dorado Union School District** reported a 1,000% increase in their positivity rate when they switched from a private lab to the state lab for testing. The most recent data provided by the state indicated the lab's positivity rate was more than 60% higher than California's overall positivity rate in February and March," *CBS13* said.

Other observers have noted that the California Department of Public Health has been inspecting the lab, which the state government owns, creating a serious conflict of interest.

ment she devoted much of her time to reviewing issues of CLIA noncompliance.

In its lawsuit, PerkinElmer listed six complaints against Salem: breach of contract, conversion, unauthorized access to computer systems, constructive trust, fraud, and negligent misrepresentation. "As a direct consequence of defendants' conduct, PerkinElmer is faced with the substantial risk that defendants will disclose and continue to disclose or use PerkinElmer's proprietary information to PerkinElmer's competitive disadvantage," the company said.

In explaining the complaint of conversion, PerkinElmer said, "defendants wrongfully exerted personal control over PerkinElmer's property," harming its business, finances, and reputation. "PerkinElmer has demanded that defendants return the property they wrongfully converted and, to this day, have refused to return any converted property," the complaint said.

Access to Lab's Computers

Salem and the defendants also "wrongfully and without authorization" accessed PerkinElmer's computer system, devices, and computer network, the complaint noted.

On the issue of "constructive trust," PerkinElmer alleged the defendants wrongfully obtained the company's proprietary information. "Consequently, defendants are involuntary trustees holding PerkinElmer's property," the complaint said.

Finally, Salem and the other defendants "negligently mispresented" that they would not copy or remove proprietary information from the premises except in the pursuit of PerkinElmer's business. Therefore, Salem and the defendants were negligent in using that information and breached their agreement with the company, PerkinElmer noted.

In her response, Salem reported that she did not take any action when she resigned "due to … respect to the CLIA program." She also claimed in her response that she offered to assist PerkinElmer as a consultant or in a modified position. Still, she was wrongfully terminated, she wrote. Also, she added, "It is not true that the amount in controversy for this claim exceeds $75,000 as alleged by plaintiff. Plaintiff's unsubstantiated claim is of a zero-dollar value."

'Claim Is Untrue'

On the first charge in PerkinElmer's complaint (that she emailed proprietary information), Salem responded that this claim is untrue. She said she "emailed herself and several others (including The Testing Company) upon their request, the information available as 'public records,'" and that her employment "… was terminated after announcing her intent to resign."

While she was employed, Salem devoted most of her time at the request of the lab's management to reviewing "various out-of-compliance records," she added. Also, she noted, "Plaintiff fraudulently informed Mahnaz Salem that the laboratory was in compliance with all of the applicable laws despite the fact that it had complete knowledge of its non-compliance conditional situation as one of its records entitled: 'CDPH Branch Laboratory: Pending list, questions and reminders' clearly showed its non-compliance.'"

Salem also refuted a charge that PerkinElmer alleged she was an agent or employee of the other codefendants and that they conspired and agreed to deprive PerkinElmer of its rights and to cause damages the company described in the complaint. "This is not true," she wrote. Instead, Salem said she was "informed" that PerkinElmer and others "harassed and retaliated against her."

Research Lab vs. CLIA Lab

On the issue of proprietary information, Salem made a distinction between the work a lab does as "research-use only" and a lab running tests under CLIA. For example, she noted that PerkinElmer defines its

proprietary information as research activities. "Plaintiff was reminded by Mahnaz Salem who upon review and identification of non-compliance issues … documented such issues to draw a line between its research-use-only activities in its [California] state-registered CLIA certified clinical laboratory (provided to plaintiff conditionally) where plaintiff was performing experimental studies at the same time it was reporting patient test results to troubleshoot its 'Condition Non-Compliance' situation."

On this point, she noted that she had a right, "to report the above to governmental agencies, including providing records which are not part of public records."

She also made a distinction between a lab that PerkinElmer owned and a lab that the state of California owns. "Mahnaz Salem is informed and hereby alleges that the Valencia COVID-19 Testing Laboratory is owned by CDPH according to the disclosure of ownership filed by plaintiff," she wrote.

'Efforts to Circumvent'

"Indeed, plaintiff was exercising efforts to circumvent when it was notified about its non-compliance situation upon resignation of CDPH laboratory director who resigned from being the CLIA director," she noted. When Salem and other defendants reported issues of non-compliance, PerkinElmer "started making threats and published defamatory information" about the whistleblowers, she wrote.

As the case continued in court on June 10, the federal judge heard arguments from PerkinElmer that Salem should be held in contempt of court for what PerkinElmer said was failure to comply with court's preliminary injunction order, a request for monetary sanctions, and a request for $9,464 in attorneys' fees.

PerkinElmer's attorneys said a notice of motion for contempt was sent to Salem via e-mail and bounced back due to an unknown address error and that "the primary e-mail address associated with the party record has been deleted." The judge in the case granted a motion to allow Salem to be served in the standard manner. The parties will return to court on July 9. TDR

Contact Mahnaz Salem, PhD, at 424-354-6899 or salemmahnaz20@gmail.com.

Lawyer for Whistleblowers Comments on Court Case

ONE QUESTION THAT CLINICAL LABORATORY DIRECTORS MIGHT WANT ANSWERED is how common are cases such as the one PerkinElmer has brought against Mahnaz Salem, PhD, and other unnamed whistleblowers in the case involving California's Valencia Branch Laboratory.

For an answer, THE DARK REPORT reached out to Justin T. Berger, a partner with the law firm **Cotchett, Pitre, and McCarthy**. He often represents whistleblowers in *qui tam* actions under the federal and California False Claims acts.

Berger told *The Dark Report* that he has not been involved in the dispute between Salem and PerkinElmer and could not comment on the facts of the case. "I can say that it is extremely common for legitimate whistleblowers to be attacked by their former employers for purported violations of confidentiality provisions," he wrote in an e-mail.

"It is an age-old tactic of intimidation, used to drive up whistleblowers' legal costs, and send a message to other potential whistleblowers," he added. "If that is what is happening here, it is especially disappointing, given that we are not just talking about COVID test results, but a massive public contract." *(See TDR, "California Builds Its Own COVID Lab: $25 Million or $1.7 Billion?" Nov. 16, 2020.)*

"Moreover, in most situations, there is a public policy exception that allows employees to take confidential documents for purposes of reporting fraud being committed against the government, even if doing so violates a confidentiality provision," he added.

➤➤ ***CEO SUMMARY: This first installment in our series describes why market forces are at work to create a new player in healthcare that will transform the lab testing marketplace as we know it today in two ways. First, a new category of primary care providers has the potential to eventually order as many lab tests per year as are reimbursed by the Medicare program. Second, if the first prediction comes true, these new primary care clinics will also become the nation's biggest buyers of lab analyzers and lab tests. That would be both a threat and an opportunity for today's largest IVD companies.***

Might Walmart Buy Large Volumes of Lab Tests?

This is an example of the full-service primary care clinics Walmart is building in several states. The sign at the front of the clinic advertises clinical lab testing and imaging, among other services. It was reported that Walmart's board of directors approved a plan in November 2018 to build 4,000 of these primary care clinics by 2029.

Three distinct trends represent new sources of disruption to clinical labs

New Players May Alter Who Buys & Who Orders Lab Tests

FIRST IN A SERIES

By: Robert L. Michel

IN THE NEAR FUTURE—EVEN WITHIN AS FEW AS FIVE YEARS—the clinical laboratory industry can expect to be confronted by a very different marketplace than it currently serves.

This will happen because at least three primary forces now becoming visible will bring about a radical restructuring of today's clinical laboratory market, which currently operates along the same principles as during the 1970s and 1980s. In those decades, two factors revolutionized the clinical laboratory industry.

One factor was the automation of routine lab testing. The second factor was the emergence of public corporations that launched or acquired clinical labs and began a five-decade long process of lab consolidation that continues even today.

Today, 50 years later, the consequences on the lab testing marketplace of these two factors is easy to see. Labs of almost any size have lots of automation and nationally, the duopoly of publicly-traded **Labcorp** and **Quest Diagnostics** dominates the scene.

But today's clinical lab marketplace will be upended by three powerful forces that are already visible to keen observers. The three forces are:

- The emergence of a new class of buyers for clinical laboratory tests that will grow to become dominant.
- A flood of ever-smaller and faster lab analyzers and test kits that incorporate new and transformative diagnostic, digital, and AI technologies. These are specifically engineered for use in near-patient settings and to produce low-cost, speedy results at a competitive price per test.
- The new preferences of Millennials who—as patients—demand access to medical services and health information in radically different ways than earlier generations.

THE DARK REPORT is first to recognize these developments and present them to our clients and regular readers. Clinical laboratory administrators and pathologists can use the information that follows to guide strategic planning in their respective labs and pathology groups.

This series of intelligence briefings will describe each of the three new market forces in detail. In this first installment, we address the pending arrival of a major new class of buyers of clinical lab tests. Typically, payment for the biggest proportion of lab tests have been government and private health insurers. However, that will change as these new buyers establish their

clinical operations in every region of the United States.

The next installment in this series will deal with the second market force we predict to be transformational. That market force will be propelled by a new class of *in vitro* diagnostics (IVD) companies that offer smaller and cheaper analyzers that can deliver lab test results of comparable accuracy to today's centralized clinical laboratories.

As noted earlier, these new diagnostic tests and analyzers will be designed for use in near-patient and point-of-care settings, will use much smaller sample volumes, will deliver results in minutes, and—in many cases—will do these tests cheaper than if they were performed in a large regional core lab.

The third installment of this series will take up how the different needs, interests, and preferences of Millennials, as well as the Gen Z generation now entering the workplace, are in the earliest stages of reshaping how healthcare is delivered and how individual patients access medical services.

As they age, a large proportion of Millennials will prefer seeing their primary care physicians virtually. They will monitor their exercise and biomarkers with wearable devices. They will use smartphones and the Internet to access their patient health records and research their health conditions.

➤Lab Sample Collections

Those clinical labs and pathology groups that adapt to these different needs and preferences of Millennials and Gen Z will thrive. But to do so, they will need to develop different ways to collect lab samples from patients who used virtual exams to consult with their physicians.

Millennials will also value clinical laboratories that digitally deliver not just lab test results, but also provide their patients with the full clinical and health implications of their lab test results.

The possibility exists that a fourth powerful force for change—**Amazon**—can disrupt today's clinical lab marketplace all by itself. Since the onset of the pandemic, it has built its own network of CLIA-certified complex laboratories for COVID-19 testing of its one million employees.

THE DARK REPORT will use the fourth installment of this series to assess Amazon's clinical lab testing activities and the different ways it can be expected to leverage the clinical laboratory facilities it built and operates today. Because of Amazon's track record at disrupting several different industries in the past 25-years, we must consider its potential to upend the lab testing marketplace as we know it today.

➤TREND ONE: New Clinical Lab Test Buyers

The new class of buyers for clinical laboratory tests will be include the large national and regional corporations that operate primary care clinics and medical care "hubs" in their retail stores.

Three types of national retailers will be prominent in this trend. One will be the pharmacy chains, including **CVS**, **Walgreens**, **RiteAid**, and others.

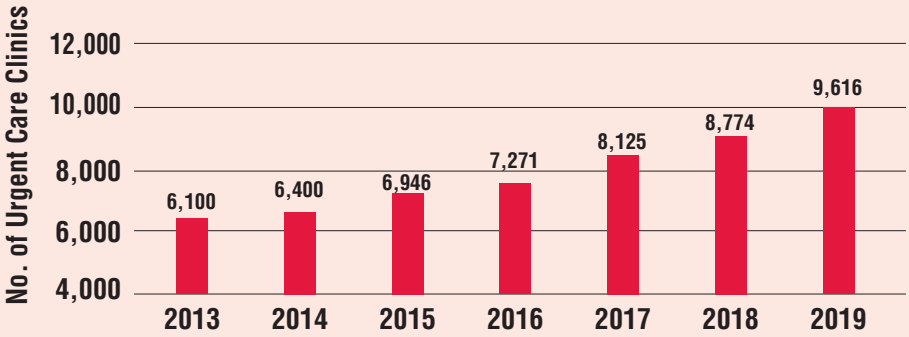
The second will be national retailers, particularly **Walmart** and **Target**. Third will be national and regional grocery stores that include pharmacies. The biggest of these supermarket chains include **Kroger, Albertsons,** and **Publix**.

Each of these corporations have plans to incorporate full-service primary care clinics in some of their retail stores and may already be building and operating their first such clinics. Typically, the primary care clinic is located next to the pharmacy counter. In some cases, retail chains are building stand-alone primary care clinics located on the same properties as their retail stores.

The interest of retail chains in adding primary care services to existing retail stores did not happen overnight. It grew

Why Companies Like CVS, Walmart, Target, and Kroger Want to Put Full-Service Primary Clinics in Their Stores

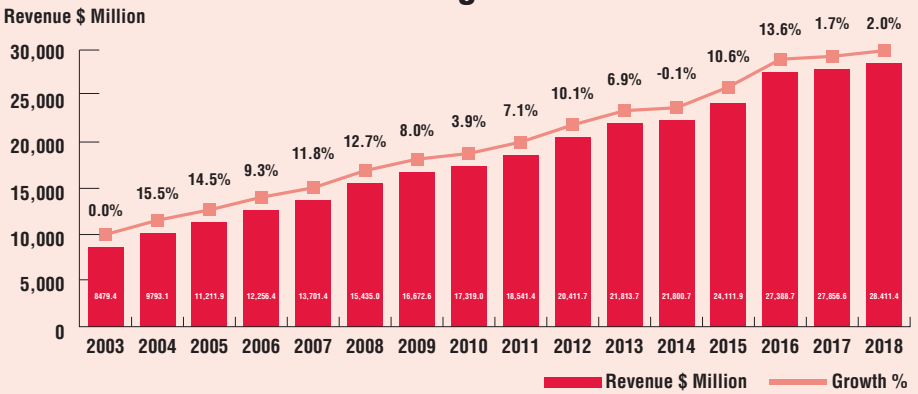
Number of Urgent Care Centers in the United States



Source: Urgent Care Association 2019 Benchmarking Report

HAVING WATCHED THE EXPLOSIVE GROWTH OF URGENT CARE CENTERS IN THE UNITED STATES SINCE 2005, major retail pharmacy and grocery chains see opportunity in providing the full range of primary care services, including ancillary services like clinical laboratory testing and imaging. The chart above shows how the number of urgent care centers increased by 58%, from 6,100 to 9,616, in just six years. During this same period, retailers were expanding their walk-in clinics at a similar pace.

Growth of the Urgent Care Sector



**July 2018 IBIS report re: the urgent care industry*

SHOWN ABOVE IS A CHART THAT TRACKS BOTH THE TOTAL ANNUAL REVENUE AND PER ANNUM GROWTH PERCENT of urgent care centers in the years 2003 to 2019. IBIS created the chart and reports that urgent care centers generated revenue of $28.4 billion in 2019. Revenue increased annually at high single-digit rates or better. For retail chains, this is attractive growth with good profit margins. They would like to capture market share in this healthcare segment.

out of the 15-years experience these corporations gained from operating "walk-in clinics" (sometimes called "rapid clinics") within their network of retail stores.

In fact, one way to characterize and describe this coming new class of buyers for clinical laboratory tests is to review how the novel concept of the walk-in clinic was created about 15 years ago. Owners and operators of this unique, new type of medical service provider are the direct evolutionary precursors—and will be part of the coming new class of clinical laboratory test buyers.

MinuteClinics Was First

Long-time clients and regular readers of THE DARK REPORT will remember how **MinuteClinics** (originally launched in 2000 in Minneapolis-St. Paul as **QuickMedx**) began an expansion in 2004 that introduced the walk-in clinic as a novel category of healthcare provider.

Today, it is estimated that more than 11,000 walk-in clinics are in operation throughout the United States. During the past decade-and-a-half, this new type of medical provider moved past the proof-of-concept stage.

Widespread consumer acceptance of walk-in clinics now makes them the launching pad for retailers to expand them into full service primary care clinics. These national retail chains will begin operating full-service primary clinics in their retail pharmacies and stores.

As developed by QuickMedx/MinuteClinics in 2000, the walk-in clinic concept was simple. It was often described as the "nurse practitioner (NP) in the box." The walk-in clinic typically was located next to the pharmacy counter in drug stores, grocery stores, and chains like Target and Walmart. It was a walk-up service.

Walk-in clinics would generally diagnose and treat about 40 common medical conditions, most of which would require a prescription that the NP could provide. These conditions ranged from ear infections and strep throat to colds, flu, and the administration of immunizations.

The price for the visit was cheap—typically as low as $40—and was generally paid in cash by the consumer. Wait times to see the NP were short and if consumers could not immediately see the nurse practioner, they were given pagers. That allowed them to shop in the store until the NP was available. (Incidentally, retailers who hosted these walk-in clinics liked that consumers would shop while waiting to see the nurse practictioner. This boosted sales at the store.)

The concept of the walk-in clinic was an immediate success with retailers. MinuteClinic quickly placed its rapid clinics in a number of Target stores and CVS pharmacies. CVS was so impressed with the performance of these walk-in clinics that it acquired MinuteClinic in 2005 for a price of about $170 million.

Currently, CVS operates almost 10,000 retail pharmacies in the United States. Between its retail pharmacies and the pharmacies it operates in Target stores, it has about 1,100 walk-in clinics.

Competitors to MinuteClinic appeared almost immediately. For example, Walgreens quickly introduced what it calls the **Healthcare Clinic** and currently operates 413 such walk-in clinics in its stores in the United States.

Customer Acceptance

By watching how consumers used the medical services of walk-in clinics, and experiencing a worthwhile increase in associated sales in those retail stores—not just in filling more prescriptions (a lucrative business line in its own right)—but in sales of other products, these national and regional corporations recognized the opportunity to move into clinical care in a bigger way.

A related trend that reinforces consumer acceptance of walk-in clinics is the explosive growth of urgent care centers. This care concept first emerged in the 1970s. As recently as 2005, there were

How Retail Chains' Purchasing Clout May Position Them as Major Buyers of Clinical Lab Tests in Coming Years

SHOULD THE NATION'S BIGGEST PHARMACY AND GROCERY CHAINS push to open full-service primary care clinics in coming years, they would quickly become a large buyer of clinical laboratory tests. This would be a major disruption to the clinical laboratory industry as it exists today. It also would be disruptive to *in vitro* diagnostics (IVD) manufacturers, because they would be selling to multi-billion dollar retail corporations that want to standardize instruments, tests, and test methodologies across hundreds and thousands of sites throughout the United States.

THE DARK REPORT did a "back of the envelope" calculation to illustrate the potential buying power of these retail chains as they expanded the number of primary care clinics they operate. The estimate is below:

Assumptions:

1. 34,000 retail pharmacy and grocery stores
2. 25% of these locations open a primary care clinic
3. 40 patients per day per clinic (40 x 8,500)
4. 30 patients per day get lab test orders from doctor
5. 3.5 lab tests per patient (3.5 x 255,000)
6. Clinics operate six days/week (255,000 x 312 days)

34,000	total retail stores
8,500	stores with PC clinics
342,000	patients treated/day
255,000	patients/day with lab orders
892,500	number of lab tests/day
278,304,000	**number of lab tests/year**

One way to give context to the lab test buying power represented by the above example is to compare the numbers above with the number of clinical lab tests reimbursed by the Medicare Part B program.

The **Office of the Inspector General's** 2020 PAMA Report includes a table of the top 25 tests which shows price, volume, and total spent by the Medicare program. For the top 25 clinical lab tests by volume, Medicare reimbursed 321,170,000 tests in fiscal 2020.

These calculations demonstrate that the potential volume of lab test orders from the primary care clinics operated by the major retail pharmacy and grocery chains could reasonably grow to just about equal the yearly number of clinical laboratory tests reimbursed by Medicare.

National Retailers Keep Building New Stores

To understand why the national retail chains could grow into major buyers of clinical lab tests in coming years, it is necessary to understand the number of stores they operate. These numbers are taken from corporate websites and public sources.

	#Stores
CVS	9,957
Walgreens	9,021
Rite Aid	1,932
Walmart	4,743
Target	1,868
Kroger	2,742
Albertsons	2,252
Publix	1,239
Total	**33,754**

under 1,000 urgent care centers in the United States. However, according to data provided by *FierceHealthcare*, that number grew rapidly over the past 15 years and there were 9,616 urgent care centers operating in 2020. *(See sidebar on page 13.)*

Urgent care centers differ from walk-in clinics in important ways. They are typically located in stand-alone facilities. They offer extended hours and are open on weekends. They are staffed with physicians and physician assistants and usually

CVS Opens New 'HealthHUBS' Every Month, Expected to Have 1,500 in Operation by 2022

WITH ALMOST 10,000 PHARMACIES IN THE UNITED STATES, CVS IS POSITIONED TO BE A SIGNIFICANT FACTOR ONCE IT DECIDES PRIMARY CARE CLINICS SHOULD GO INTO ITS STORES. It currently operates 1,100 MinuteClinic sites that feature low-acuity services like colds and immunizations. However, CVS has learned that half of the patients who visit MinuteClinics do not have primary care providers. In its HealthHUBs, CVS wants to focus on chronic disease management and will provide services like blood draws and sleep apnea assessments. A MinuteClinic typically has one to two exam rooms, while HealthHUBs will have three to four exam rooms. In the photo above, the reception desk is marked "care concierge" and is the focal point for customers and patients seeking information.

provide a full range of clinical services that include on-site imaging and laboratory testing. Urgent care centers typically accept insurance and charge standard prices for office visits and other services.

Powerful Economics

It is important to understand that the impressive growth in the revenue generated by both walk-in clinics and urgent care centers over the past 15 years is why national retail chains now want to put full-service primary care clinics into their retail stores.

If these national chains make a big push into primary care, they have the potential to originate large volumes of lab tests and they could become the nation's biggest buyers of lab analyzers and lab tests. THE DARK REPORT did a "back of the envelope" estimate of just how big the test demand could be, shown in the sidebar on page 15.

Using reasonable assumptions, our analysis showed that if major retail chains put a primary care clinic in just 25% of their stores, and these clinics ordered tests for just 30 patients per day, collectively they would need 278 million lab tests per year. That would approach the 428 million tests reimbursed by Medicare in 2019. Coming installments in this series will assess other factors THE DARK REPORT predicts will drive primary care in retail stores. **TDR**

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Managed Care Update

Getting Payer Coverage for New Tests Continues to Be Difficult

One secret to winning coverage is to provide extensive data on the test's accuracy, clinical value

EVERY YEAR, IT BECOMES TOUGHER FOR CLINICAL LABORATORIES WITH NEW GENETIC AND OTHER TESTS to obtain favorable coverage decisions by government and private payers.

Not only does it take longer to get a decision from a payer, but payers today want to see more complete data on the analytical and clinical validity of the test before making a coverage decision.

Another change in recent years is that private payers often move faster than the Medicare program to make a coverage decision for a lab test. Historically, private health plans would wait until Medicare agreed to cover a test.

Flood of New Lab Tests

But the flood of new genetic and molecular entering the market assays—with most being laboratory-developed tests (LDTs)—is causing private payers to make faster coverage decisions, often long in advance of Medicare's determination for the same assay.

Soaring utilization of new assays and the corresponding increase in money paid for test claims motivates payers to act. "Private payers tend to examine their coverage requirements where they see significant growth of new technology or utilization of services," said Deborah Godes, Senior Director of **McDermott+Consulting**.

"A payer will not necessarily establish a new coverage policy for a diagnostic assay simply because there is a new assay," she continued. "There must be a reason why they evaluate coverage and usually it's because there has been a significant increase in volume or cost. Not every lab-developed test will go through a coverage review—payers simply don't have the resources for that."

Lab Benefit Managers

As has been regularly reported by THE DARK REPORT, payers increasingly are turning to third-party benefit administrators to manage laboratory test utilization. **United Healthcare**, **Anthem**, and **Blue Cross Blue Shield** plans all use laboratory benefit managers (LBMs) to manage utilization of laboratory testing.

Clinical labs can improve their chances of getting a laboratory-developed test covered by providing payers with extensive data showing the clinical utility of an assay.

While federal programs such as Medicare like to see preliminary data from pilot studies, Godes observed that private payers and LBMs prefer to see studies that have already been published in a peer-reviewed journal or that have resulted in approval by the **Food and Drug Administration**.

"Medicare also does not establish coverage policies for every test," Godes explained. "Depending on codes for the tests, claims will either be processed or reviewed on a claim-by-claim basis. When Medicare—in particular a local Medicare Administrative Contractor (MAC)—determines a need, it will review to determine whether a local coverage determination is needed."

Types of testing ripe for review include expensive tests such as molecular diagnos-

tics or assays that have more cost-effective counterparts. While coverage determinations are made on the basis of clinical utility, cost may factor into the decisions.

"We can't make an across-the-board statement about the role that cost plays in payers' coverage decisions," Godes noted. "For some payers, the economic analysis may be a bigger factor. But all payers want to see evidence of improved outcomes when the provider uses the diagnostic test in decision making.

Proving Clinical Utility

"Key to getting a positive coverage decision from payers is making a solid case through good quality evidence," Godes advised. "Clinical laboratories need to demonstrate that a particular assay actually works as it is intended and also that it is used by clinicians to make decisions regarding patient care. Essentially, clinical utility of a test is related to the added value it has for patient management.

"I think to some extent clinical laboratories may underestimate the impact of showing that the test has an effect on decision making and on outcomes," Godes stated. "We hear from payers over and over again that they want proof of clinical utility that shows the test has a positive effect on patient outcomes.

"Payers have a relatively small group of people that make these coverage decisions, and they may not necessarily have the depth of knowledge into specific nuances of the testing, especially around novel testing, that clinical laboratories have," she explained. "That's why showing evidence is so important. Payers tend to give more gravitas to published evidence."

When does a clinical laboratory know that they need to provide evidence that their assay has a positive effect on patient outcomes? Laboratories should focus on demonstrating evidence of clinical utility throughout the development process, Godes said. Timing for engagement with payers will vary depending on how the laboratories are reporting their assay (i.e., an existing code or a new code), the resources of the lab, and the timeline for reimbursement planned, she added.

"At a minimum, laboratories should begin engagement if or when they start to see payers denying claims for a particular test or when the payer publishes a negative coverage policy that covers the lab's assay," Godes advised. "However, developers of novel diagnostic technologies with the resources to do so should seek engagement before the test is on the market, potentially even when studies that can demonstrate clinical utility are being planned."

Additionally, for tests that will be billed under codes for which payers have not previously seen much utilization, proactive engagement with payers to make them aware of a potential rise in utilization, and the medical necessity of the underlying service, may help to minimize the chance of a misunderstanding in the future about the cause of that utilization increase.

"If that happens, labs should start compiling all their evidence—not only on analytical and clinical validity—but also on clinical utility," Godes said. "Pull together a clinical dossier that can be used to have a discussion with payers.

Address Payer Concerns

"If it is a test that historically has been covered but now is not being covered, labs need to have a conversation with payers to understand what has changed," she noted. "Labs need to be able to address the concerns that payers have."

Godes added that each payer has its own coverage determination process and that clinical laboratories should be prepared to deal with each one individually. "Not all payers will be persuaded by the same arguments," she said. "You need to determine what drives that payer's the denials and then present evidence to address those concerns." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Is it possible to use a genetic test to predict an individual's risk of severe infection requiring hospitalization or death from SARS-CoV-2? That is the claim of Australian-based molecular diagnostics company **Genetic Technologies Limited**. It recently announced an agreement with U.S.-based **Infinity BiologiX LLC** (IBX) to sell its "COVID-19 Severe Disease Risk Test" to consumers in the U.S. Consumers can purchase the test for $175, which uses a sample of the consumer's saliva. The Infinity website advertises the test as follows: "Estimate your personal risk of severe disease requiring hospitalization if you were to be infected with SARS-CoV-2 (the virus that causes COVID-19)."

MORE ON: *SARS-CoV-2 Genetic Test for Risk*

This genetic test was developed from research described on the Infinity website as follows: "The COVID-19 Risk Test uses clinical risk models as well as patient-specific genetic risk markers to better identify a person's risk of developing severe COVID-19, if ever infected with SARS-CoV-2." However, several scientists responded to this news with criticism. *Science* quoted Priya Duggal, PhD, a professor of genetic epidemiology at **Johns Hopkins Bloomberg School of Public Health**, who stated, "I think it's premature to use a genetic test to predict a person's likely COVID-19 severity. We don't understand exactly what these genetic variants mean or how they affect disease." The two companies have introduced this test into the United States without review by the federal **Food and Drug Administration**.

DEMAND FOR COVID-19 TEST FALLS ACROSS U.S.

Pathologists and clinical lab managers have watched the demand for molecular COVID-19 tests fall in most regions of the United States. As of last Thursday, the **CDC** reported 242,822 SARS-CoV-2 tests were performed on that date. This is a 90% decline from the daily peak in the number of COVID-19 tests recorded on Jan. 6, 2021, when 2.3 million tests were performed. Of equal significance, on June 4 the 7-day moving average percent of positivity for new tests performed fell below 2% for the first time since the onset of the pandemic. These developments are attributed to less demand for testing, including vaccinations, immunity from individuals previously infected, and even the arrival of warmer temperatures as summer approaches.

TRANSITIONS

- **Resolve Biosciences** of San Jose, Calif. and Monheim am Rhein, Germany, appointed Chris Barbazette to be its new Chief Commercial Officer. He previously worked at **EAB Consulting**, **GenapSys**, **Agendia**, **Affymetrix**, and **ASYST Technologies**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, July 6, 2021.

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