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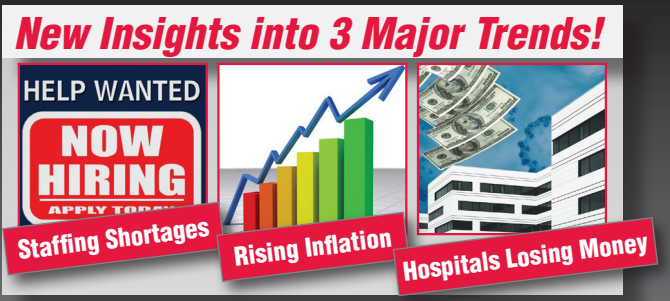
New Insights into 3 Major Trends!



See pages 3-7.

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Labs Face Powerful and Unwelcome Forces

Over the past 25 years, there has been widespread recognition that healthcare in the United States is on an unsustainable path. The obvious argument was that year-over-year increases in healthcare costs would eventually overcome the ability of employers (private health plans) and the government (Medicare and Medicaid) to pay the bill.

Yet, 25 years after HMOs (health management organizations) disrupted the formerly predictable system of fee-for-service, any willing provider, and usual and customary fees, we are still here. Deep and fundamental reforms to the healthcare system have yet to be made.

My guess is that, with healthcare spending in 2021 totaling $4.3 trillion, the most powerful, richest sectors of healthcare always act to protect their profits. Think: hospitals, physicians, pharma companies, medical device companies, for starters. Each of these segments have major players with plenty of money to influence congressional elections, to hire lobbyists to argue against healthcare reforms that would reduce their share of the profit pie, and to publicize their positions to consumers, patients, and voters.

One point to be made here is that, when it is recognized that something is broken and it does not get a timely fix, problems inevitably surface. This issue of The Dark Report illustrates that point. On pages 3-7, you'll read about the three powerful market forces that our editorial team describe as the "gale-force" headwinds now confronting both clinical labs and hospitals industry. They include a severe shortage of staff, inflation during a time of decreasing budgets, and the fact that a substantial number of hospitals and major integrated delivery networks (IDNs) are losing buckets of money each month and each quarter.

It could be argued that the acute shortage of medical technologists (as well as nurses and other key medical professionals) reflects a failure to reform the education system dating back to the 1990s. A problem recognized, but not acted upon. Similarly, our coverage on pages 15-18 about the struggles of labs to obtain coverage and reimbursement decisions for new diagnostic tests illustrates the failure of diagnostic companies, payers, and the medical establishment to craft reforms in how new laboratory tests that incorporate brand-new technologies can be evaluated and cleared for clinical use in a timely, cost-effective manner. These are among the reasons why it will be an uphill fight for labs to survive in coming years. TDR

News and Insights from AACC Meeting in Chicago

17,000 attendees and 786 exhibitors came together at the lab industry's largest live conference in two years

***CEO SUMMARY:** There was plenty of positive energy last month when the 72nd Annual Scientific Meeting and Exhibition of the American Association of Clinical Chemistry (AACC) took place in Chicago. Attendees seemed pleased to be gathering and networking in person. However, there was recognition that the acute staffing shortage, combined with increasing inflation and deteriorating finances at hospitals, were putting clinical labs under intense pressure.*

by Robert L. Michel

In Chicago last month, some 17,000 medical laboratory professionals attended the scientific meeting and exhibition of the **American Association of Clinical Chemistry** (AACC). For those who have missed scientific meetings during the pandemic, the good news is that, in most respects, the event resembled the pre-pandemic annual meetings of the AACC.

But the picture was not entirely rosy for the clinical laboratory industry. During the week, conversations at the meeting with many clinical lab administrators and executives of the *in vitro* diagnostics (IVD) manufacturers confirmed that nearly all clinical laboratories are struggling to deal with three major trends within the U.S. healthcare system. These trends will be covered in the intelligence briefing found on pages 5-7. The three trends include:

- A serious and ongoing shortage of lab staff across all skill sets and positions.
- Extreme budget pressures because of rapid increases in staff compensation, amplified by supply chain shortages and inflation-fueled price increases for lab analyzers, tests, consumables, fuel, etc.
- Deteriorating finances at a substantial number of hospitals and health systems that directly hinders the ability of their clinical labs to sustain the desired high level clinical testing services.

Thus, the success of the AACC meeting itself can be considered a positive development for the House of Laboratory Medicine, while the intelligence gathered from leaders of labs and lab vendors provided useful insights about how the three trends described earlier are creating

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unprecedented stresses and financial challenges for labs across the nation, particularly labs operated by hospitals and health systems.

Positive Energy at AACC

For the good news part of this briefing, in the AACC exhibition hall, vendors had a steady stream of visitors at their booths and stayed busy over the three days of the exhibition. Similarly, there was good attendance at the many scientific sessions.

The number of attendees and their enthusiasm to be networking in person is evidence that a large number of clinical chemists, lab industry vendors, and others would like to get back to business as usual.

Many attendees acknowledged that—in this almost-post-pandemic era—SARS-CoV-2 still lingers and shows signs of continuing as an endemic disease. Yet, this week-long assemblage of scientific presentations and the huge exhibition (with 786 exhibitors) unfolded without incident.

The one reminder that COVID-19 is still present were the two safety protocols required of attendees. These requirements were probably the single major change from the last pre-pandemic AACC annual meeting in 2019.

COVID-19 Safety Protocols

One requirement was that all attendees needed to show proof of vaccination (two shots plus booster) or a negative COVID-19 PCR test within 72 hours of arrival. The second requirement was that masks were to be worn at all times within the McCormick Center, the exhibition hall, and the scientific sessions. Most attendees complied with the "wear a mask at all times" requirement.

Many lab managers attend the AACC annual meeting to shop for new automation and analyzers and to scope out any breakthrough technologies that may be of interest. Feedback from attendees was that most of the newest generation of automation and instruments shown by vendors represent incremental improvements over the prior generation of products.

A number of the IVD vendors acknowledged that, because of the pandemic, for the past two years their companies' efforts were focused on manufacturing the instruments, tests, and consumables needed for large volumes of SARS-CoV-2 testing. For this reason, their planned development of breakthrough technologies was interrupted over the past 32 months.

That is why most of the newest generation products unveiled at this meeting represented incremental improvements, not breakthrough innovations. But lab interest in buying was robust, for an obvious reason. Since the onset of the pandemic in March 2020, most clinical laboratories delayed scheduled replacement of their high volume, core lab automation and analyzers.

Overdue for Replacement

Now, with additional years of usage, these lab analyzers are overdue for replacement. The ability to come to this summer's AACC exhibition was the perfect opportunity for lab professionals to shop new solutions. They had plenty of products to see, as this year continued the pre-pandemic trend of new companies appearing as exhibitors, showcasing their brand of lab analyzers and lab tests.

Many of these newer vendors were showing bench-size and point-of-care testing systems. Advances in various technologies are making it possible to design and manufacture smaller analyzers that use reduced volumes of specimen. The miniaturization trend of past years continues through the present.

The intelligence briefing that follows provides more details and insights about the three major trends mentioned earlier. Each of these trends is creating major stresses on most clinical laboratories across the United States. TDR

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Tough Times Ahead for Hospitals and Their Labs

Three market forces now pressure labs, hospitals; ranging from staffing and inflation to poor finances

CEO SUMMARY: These are challenging times for the nation's hospitals, health systems, and clinical labs. A perfect storm involving unprecedented shortages of lab staff, nurses, and other professionals with inflation-fueled cost increases and deteriorating hospital finances was a major topic of discussion by lab leaders and lab vendors at last month's annual meeting of the American Association of Clinical Chemistry (AACC). In many candid conversations, attendees discussed these three developments.

In the world of Wall Street, "headwinds" is the code word used when a company or industry faces difficult challenges going forward. In today's market, it may be more appropriate to use the term "gale-force winds" to describe multiple negative forces confronting the nation's hospitals and their clinical laboratories.

Three gale-force factors are now pushing against hospitals, clinical laboratories, and anatomic pathology groups. Lab administrators and pathologists are acutely aware of two of these factors. One is the severe shortage of lab professionals across all types of positions. The second is the impact of inflation and rising prices on already-shrinking lab budgets.

More Hospitals Losing Money

However, it is the third factor that may have greater long-term consequences for the clinical labs operated by hospitals and health systems throughout the United States. It is the deteriorating finances and operating losses being reported by a growing number of these acute care institutions.

Although The Dark Report has tracked and described these three trends for many months, new insights about the serious impact they are having on clinical labs was front and center in conversations with lab leaders during last month's annual meeting and exhibition of the **American Association of Clinical Chemistry** (AACC) in Chicago.

This intelligence briefing provides more context to each of the three market forces which can be described as "besieging" the nation's laboratories. It is recommended that lab administrators and pathologists use this information to update their lab's strategic plans, as well as to develop solutions to improve staff recruitment and retention and deal with the dual challenges of shrinking lab budgets even as inflation causes the cost of labor, instruments, tests, and lab supplies to increase at the fastest rate in 40 years.

Market Force 1

Acute Shortage of Lab Staff

There has been widespread recognition and reporting about the shortage of workers to staff the nation's clinical laboratories. Conversations with lab leaders at AACC provided more detail as to how the lack of

adequate staff is altering the way affected laboratories operate and deliver lab testing services to physicians and their patients.

For example, in numerous regional markets, the lack of adequate phlebotomists is forcing labs to close patient service centers (PSCs) and shift patients who regularly use those sites to other PSCs in their network.

Similarly, in order to keep more PSCs open, some labs are spreading a lesser number of phlebotomists across all their PSCs. However, when a phlebotomist at one site fails to show up for work in the morning—with a line of fasting patients ready to provide specimens—that PSC remains closed and the lab must swiftly act to redirect patients to open PSCs.

"In our community, we've been offering $20 per hour for phlebotomists," noted one lab administrator. "But we get no response, even at that wage rate. In these times, we are unable to attract and recruit enough people who want to train and work as a phlebotomist. Consequently, we've closed a number of PSCs and have tried to encourage more of our client physicians to provide venipunctures for their patients who need lab tests."

➤ 'Great Resignation'

There are equal challenges in hiring needed numbers of couriers, accessioners, client service reps, and similar operational positions. The "Great Resignation" phenomenon was mentioned often as a reason for the inability to fill open positions.

Much has been reported about the shortages of medical technologists and clinical laboratory scientists. One lab director stated that her lab was understrength by 100 positions, across all job types. She noted that her med techs and other lab scientists were at the stage of burnout because they have worked so much overtime to meet turnaround times and sustain lab operations.

Staffing woes exist everywhere. Another lab manager described how his health system was offering $100 per hour to nurses and getting no takers. One lab leader said his hospital was benefiting by recruiting nurses from an unlikely source. In states where it was mandated that healthcare workers be vaccinated, there were nurses who either were terminated or quit, then took the opportunity to relocate to a state without a vaccine mandate for healthcare workers. In that state, they now make more money, particularly if they are serving through a temp agency.

Is it possible that some med techs relocated to states without the vaccination requirement for the same reason? THE DARK REPORT has not heard of such examples, but would welcome hearing from labs that either lost or gained med techs because of this situation.

➤ Market Force 2

Inflation and Lab Budgets

Since early this year, the annual rate of inflation has climbed steadily with each passing month. The latest numbers for June 2022 showed a year-over-year increase in the Consumer Price Index (CPI) of 9.1%. This is the highest rate of inflation in the United States since 1981.

Lab executives report that prices for most of the products and services they purchase are increasing. Compounding the effect of inflation are continuing supply chain shortages for lab automation, analyzers, test kits, and similar supplies. Sellers, themselves fighting their own supply chain challenges, are pushing increased prices onto their clinical laboratory customers.

The increasing rate of inflation has another insidious effect on clinical laboratories and hospitals. New hires must be offered higher salaries or hourly wages before they will accept job offers. This is a financial double-wammy on labs.

One lab manager at AACC summarized how inflation was distorting her lab's salary base. "First, inflation forces us to spend more on labor over the original budget," she explained. "Second, it creates problems with existing staff doing the same work as the new hires. They know

they are being paid less for doing the same work as the new hire. It's a big morale problem at our lab."

Market Force 3

Deteriorating Hospital Finances

Particularly since the onset of the pandemic in March, 2020, the financial health of many hospitals and health systems in the United States has deteriorated. What was revealing in conversations that took place at AACC last month was how many lab administrators confirmed that their parent hospitals and health systems were failing to cover expenses with current revenue.

The magnitude of the financial losses at hospitals can be stunning. In the July issue of *CAP Today*, Stan Schofield, President, **NorDx**, and Senior Vice President at **MaineHealth**, a 12-hospital system, provided a succinct overview of developments in his region:

> *At a high level in the economics of healthcare, if [your hospital] treated a lot of COVID patients, you lost money. Hospitals and systems make money on joint replacements, high-cost procedures, imaging, and cancer medicine. They need that; government and insurance payments do not cover all typical expenses. At the same time, we've had a massive increase in contract labor costs. They are out of control. People were paying nurses in some cases $200 an hour so they could keep the doors open, or at least the lights on, because they had no other staffing—their nurses left to become travel nurses for the money.*
>
> *Every day I see headlines and get market intelligence—this healthcare system lost $1 billion in the first quarter, another one $870 million. It is clear to me that many healthcare systems are at an inflection point financially, and they are not going to be able to close this gap caused by contract labor. You cannot catch up with enough heart surgeries and joint replacements to make up a billion-dollar loss.*

Hospitals Predicted to Lose Billions in 2022

EARLIER THIS YEAR, A REPORT RELEASED by the **American Hospital Association** (AHA) predicted that the nation's hospitals would lose between $53 billion and $122 billion during 2022.

Issued last February and prepared by **Kaufman Hall** for AHA, the report noted that "under an optimistic scenario, hospitals would lose $53 billion in revenue this year. The loss would primarily come from a $27 billion decline in outpatient revenue and $17 billion for inpatient as well as $9 billion in emergency department revenue." A more pessimistic scenario predicted a loss of $122 billion, attributed to a $64 billion decline in outpatient revenue.

Lab managers should not be surprised to see some hospitals sell their lab outreach programs as a way to raise cash to cover those revenue shortfalls in 2022.

Staffing shortages are a major contributor to poor finances at hospitals. In one conversation at AACC, THE DARK REPORT was told by a pathologist that, in her 10-hospital health system that served both urban and rural areas, 25% of the operating rooms were closed, simply because the hospitals cannot hire enough nurses and staff required to perform operations. This is a remarkable situation, because acute care hospitals need all their operating rooms to operate at capacity in order to remain financially solvent.

What Will the Future Bring?

This intelligence briefing provides more context for the three market forces that will be most impactive on hospital-based labs and pathology groups in coming years, along with their parent organizations. Also, it can be expected that hospitals and health systems experiencing financial losses will be more inclined to sell their lab outreach programs because they badly need the infusion of cash from such sales. TDR

Hospital Lab Outreach Taps On-Demand Testing

Testing program introduces new patients to Bryan Health while also generating a new source of revenue

Christina Nickel

Jayne Ellenwood

CEO SUMMARY: *In this case study, clinical laboratory managers from Bryan Health in Nebraska explain how they expanded their lab outreach program to include direct-to-consumer tests. The project involved researching what tests were most appropriate without the need for a physician's order and enlisting the help of various business departments within the health system.*

Finding new avenues of revenue is imperative, particularly for hospital-based clinical labs. Doing so can help the lab meet its budget targets while adding in-house tests that contribute to better inpatient, outpatient, outreach care.

In the case of the laboratory at **Bryan Health**, a nonprofit healthcare system based in Lincoln, Neb., the lab team did more than generate additional revenue from successfully growing its lab outreach program—including a line of direct-to-consumer (DTC) tests. It also generated thousands of new patients for its parent health system in less than a single year!

These new patients were even more valuable to the health system than the additional lab test orders generated by their physicians. The Bryan Health lab's story showcases three broad lessons that other laboratory leaders can heed:

- Seek the support of ordering physicians ahead of time before making changes to lab test ordering processes.
- Enlist the help of the marketing and IT departments to bear some of the business burdens associated with new testing programs.
- Think creatively when developing outreach strategies and identifying innovative sales and marketing tactics.

When Bryan Health's clinical laboratory leaders were asked to develop a new lab outreach service as part of the system's consumer-focused strategy, they turned to DTC testing to reach people who are uninsured or underinsured.

Serving the New Customer

"We are in a different era, and we had to figure out how to give people what they need," said Christina Nickel, Director of Clinical Laboratory at **Bryan Medical Center**. Nickel spoke at April's *Executive War College Conference on Laboratory and Pathology Management*, presenting a session called, "Establishing the Hospital Lab Outreach Service of On-Demand Testing for Uninsured and Underinsured."

From April 2021 to February 2022, the lab outreach effort attracted 6,173 patients, including 3,519 who were new to Bryan Health. During that time, there were 55,000 billable tests and $335,000 in net revenue.

Bryan Health reaches urban, suburban, and rural communities of Nebraska.

It includes six medical centers, a physician network, and cardiac and telemedicine services. The healthcare system earned $1.2 billion in operating revenue in 2021.

Bryan Health was challenged by a competitor that was penetrating the outpatient imaging market. This motivated Bryan's healthcare leaders to launch low-cost imaging and lab services, starting first with imaging offerings at the new **Bryan Imaging and Diagnostic Center** at the Pine Lake campus in Lincoln.

"We were losing imaging clients to a freestanding site, and we needed to come up with an imaging and diagnostics center to provide quality for low cost," Nickel noted. "We had to capture people who are underinsured and uninsured. Hospital administration asked me, 'How long will it take to build a lab and how much will it cost?'"

Expanding Lab Test Services

The idea for the diagnostic center aligned with the lab's growth goal to expand services and better meet the community's needs. However, launching the services fast and during the SARS-CoV-2 outbreak was an unexpected challenge.

"I brought my team together to consider timeline, budget, space needed, staffing, the test menu, and test pricing," Nickel said.

From the get-go, it was clear test orders from physicians, albeit important, would not be enough to achieve an annual goal of 41,600 tests at the new location. DTC tests, the team decided, could serve the target market while propelling the lab to meet the test volume objective. The team came up with three project phases:

- Phase one: DTC tests.
- Phase two: Pre-employment drug screening tests.
- Phase three: Rapid point-of-care COVID-19 testing offered as DTC.

These new laboratory services debuted in spring 2021 at a patient service center operating under a separate Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver. Specimens collected at the patient center go to the Bryan Medical Center lab for testing and reporting.

Nickel said Bryan Health consulted with in-house attorneys and a local CLIA inspector before introducing its DTC testing menu. Such tests, regulated at fed-

Bryan Health's On-Demand Lab Tests

BELOW IS A RUNDOWN of the some of the laboratory tests and pricing that Bryan Health offers directly to patients without a physician order:

Popular test panels

- Blood chemistry panel: complete metabolic panel (CMP), lipid, TSH, $38
- Thyroid panel: TSH and Free T4, $22
- Women's health panel: CMP, complete blood count (CBC), lipid panel, TSH, and HbA1c, $55
- Men's health panel: CMP, CBC, lipid panel, TSH, HbA1c, PSA, $65
- Immunization status panel; varicella zoster, mumps, rubeola, rubella, hepatitis B, $50

COVID-19 tests

- RT-PCR COVID-19 (for travelers and people with no symptoms), $50
- COVID-19 antibody, $30
- Rapid COVID-19 antigen test, $25

Tests performed individually

- A1c hemoglobin, $7
- Blood type, $7
- CBC, $10
- CMP, $15
- Cortisol, $20
- C-reactive protein, $13
- Free T4, $10
- Glucose, $5
- Hemoglobin and hematocrit, $6
- Pregnancy blood test, $12
- Prostate specific antigen, $10
- Urine drug screening, $67
- Vitamin D, $15

eral and state levels, permit consumers to order them directly from labs without consulting a healthcare provider, according to an **American Association for Clinical Chemistry** statement, which added that 40 states give consumers direct access to clinical testing. THE DARK REPORT has predicted an expansion of consumer-initiated testing options. *(See TDR, "Quest and Walmart to Expand Consumer-Initiated Test Options," Feb. 22, 2022.)*

Still another challenge was educating the public about tests they could order themselves. Bryan Health decided to refer to the offerings as "on-demand tests," a term people are more familiar with as compared to "direct-to-consumer tests."

"We had to help the public understand what direct-to-consumer testing was. Marketing staff advised us not to call them DTC tests but to call them on-demand tests, which people know about," said Jayne Ellenwood, Laboratory Client Services Manager at Bryan Medical Center. Ellenwood also spoke at the *Executive War College* presentation.

Lab Test Development

"Test development became an important part of the project because that is how we attract consumers. We developed a test menu with over 30 tests available for consumers to order," Ellenwood added. *(See the sidebar on p. 9 for more details.)*

The lab team reviewed reference labs' DTC test offerings and aimed for tests the Bryan's laboratory could report on fast.

"We wanted to walk the fine line and keep it to routine lab tests rather than diagnostic. We didn't want to include tests to the menu that require provider interpretation," Ellenwood explained. "We want people to take charge of their own health and know they could talk to a doctor about test results if they choose to share those results."

COVID-19 molecular, antibody, and rapid antigen tests are on the on-demand test menu. "We offered a COVID-19 antibody test because many people wanted to know if they had antibodies after they had COVID-19," Ellenwood noted. "And a later offering of pre-employment drug screening tests allowed us to capture more new clients and be a collection site for the **Department of Transportation**."

Garnering Doctors' Support

Importantly, an outreach specialist from the Bryan Health lab sought input from physicians: What did doctors want to see on the test menu? How did they envision the patient center serving people?

Bryan's physician network includes 148 providers in 24 offices. In the Lincoln market, about 70% of them are self-employed and own 20 clinics.

"We would not be successful unless we had physician support," Nickel said, adding that many of the doctors were focused on COVID-19 patients as the outreach service was in the planning stage.

"They wanted to offer more affordable clinical lab testing to patients, especially those who did not have insurance or who had high-deductible health plans," Ellenwood added.

Lab results with critical values are shared with patients via Bryan's telemedicine network. "That helped us bolster support of physicians, because they knew that a provider would address critical values with that consumer. The doctors didn't have to act on something they didn't order in an emergent manner," she observed.

Physicians have Bryan Health forms which allow them to recommend tests to patients without insurance coverage. In those cases, the lab staff confer with patients about forwarding results to physicians.

Online Payment Integration

In addition to physicians, the lab leaders reached out to finance, IT, facilities, and marketing colleagues.

Working with finance, they developed a document that defined expectations. As it turned out, the first year's annual goal of 41,600 tests was surpassed with 46,961 tests in December 2021. Also, with finance and

IT's help, the online payment system for the tests integrates with **Epic** Beaker, a lab information system, to capture test revenue.

Consumers register online, choose lab tests, and pay with a credit or debit card. No appointment is needed for specimen collection. Results are posted within four to 12 hours to Epic's MyChart (a website and application that offers patients access to health information) and the Bryan Health electronic medical record system.

"We wanted this to be a quick experience for people," Ellenwood said. "We had phlebotomists running this without registration employees to handle cash and balance a drawer at end of the day. We also had an **Apple** iPad touch screen available for people to use if they walked in. And they could pay right there in person."

Business from people who prefer to pay with cash or by check may have been lost, she noted. Nickel next acknowledged some of the encounters were made by patients previously seen at a Bryan Medical Center campus. But that was a good thing, she said, because the emergency department was caring for an unprecedented volume of patients during the pandemic.

Gaining New Patients

"We did see a shift, but we also saw many more patients at our Pine Lake campus than we ever would have—a lot of people new to Bryan Health, uninsured patients, or those with high deductibles. That is why we went low on pricing the lab tests," Nickel observed.

Marketing strategies also were key to attracting new customers. They included a website, electronic and print media interviews, and email and postal promotions.

"Purchase your lab test online and walk in at your convenience," the website states. Outdoor billboards helped spread the message, with one near the local airport promoting COVID-19 testing: "Am I Cleared for Takeoff? COVID-19 Travel Test, Airline Approved, $50."

Another billboard on a highway focused on some of the low-priced wellness tests: "On-Demand Lab Tests. No Doctor Order Needed: $7 A1c, $11 Cholesterol, $15 Vitamin D."

Also, a campaign on **Facebook** reached 10,700 people (mostly women between age 25 and 44) and produced 48 leads for a cost of $802, Ellenwood said.

Plans for Expansion

Looking ahead, lab leaders plan to extend hours at the patient center to include weekends and expand the test menu. They are considering drive-up testing and streamlining the MyChart sign-up experience. TDR

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Lab Processes Tiger Tests for a Zoo

ONE OF THE STRANGER ASSIGNMENTS that Bryan Health's laboratory tackled during the pandemic was to perform SARS-CoV-2 tests for a pair of tigers from **Lincoln Children's Zoo** in Lincoln, Neb.

In October 2021, the zoo had an event planned that was to feature two tigers amid human guests. However, one of the tigers was showing symptoms of COVID-19, said Christina Nickel, Director of Clinical Laboratory at Bryan Medical Center.

Because COVID-19 can pass between humans and big cats, the zoo wanted to be sure about the animals' conditions and asked Bryan Health if it could help. The zoo told the lab that a local veterinary school wouldn't perform the tests, Nickel said.

The zoo collected the specimens and sent them to Bryan's lab, which processed the samples quickly. It turned out the tigers did have COVID-19; they later recovered from the illness.

"The zoo actually trained these tigers to have the nasopharyngeal collection," Nickel noted. "I really wished we could have seen that."

PAMA Cuts Might Be Reduced to Zero for 2023

➤New legislation aims to overhaul how Medicare calculates the Clinical Laboratory Fee Schedule

Erin Will Morton

➤➤CEO SUMMARY: Congress may soon vote on a new bill that permanently reduces the amount of price cuts to Medicare Part B lab test prices, as specified under the Protecting Access to Medicare Act of 2014 (PAMA). The Saving Access to Laboratory Services Act (SALSA) eliminates a 15% payment cut for hundreds of lab tests that would otherwise take effect on Jan. 1. 2023.

NEW BIPARTISAN LEGISLATION before both bodies of Congress aims to halt the scheduled price cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) that otherwise could hit labs hard on Jan. 1.

Under the existing Protecting Access to Medicare Act of 2014 (PAMA), during 2023, medical labs and pathology groups face payment cuts of up to 15% for 800 lab tests on the Medicare CLFS.

However, the new proposal before federal lawmakers—called the Saving Access to Laboratory Services Act (SALSA)—seeks to accomplish three things:

- Eliminate the scheduled Jan. 1 price cuts,
- Reduce future payment decreases to the Medicare CLFS, and,
- Reconfigure how HHS/CMS calculate lab test payments for the CLFS.

"Under the proposed bill, clinical laboratories would be in a much better situation because this bill caps payment reductions at 5% by 2025. That's huge in and of itself," stated Erin Will Morton, Senior Vice President at **CRD Associates** in Washington, D.C., in an exclusive interview with THE DARK REPORT. Morton represents the **National Independent Laboratory Association** (NILA) in matters pending before Congress.

"To have those caps built in permanently is really important," she said, adding, "That's a stark difference between this bill and the existing PAMA statute, which caps price cuts at 10% and 15% depending on the year."

➤Working with Lawmakers

NILA and other laboratory industry groups have been working with members of the **Senate** and **House of Representatives** to bring SALSA forward.

"Over the past several years, we have achieved strong bipartisan and bicameral support to delay these anticipated cuts, but it is time to permanently fix this problem," Susan Van Meter, President of the **American Clinical Laboratory Association** (ACLA), said in a statement.

PAMA has been a burr in the side of clinical laboratories since its inception in 2014. Beginning in 2018, the law triggered significant changes to how the Medicare program paid for lab tests. Under the CLFS, certain laboratories were required to report the lab test prices they were paid by private health insurers to the **Centers for Medicare and Medicaid Services** (CMS).

The PAMA statute directs CMS to use that private payer price data to set prices for the CLFS. PAMA specified that CMS could not cut the price of a specific lab test by more than 10% in each of the years 2017, 2018, and 2019, nor by more than 15% in each of 2020, 2021, and 2022. Notably, the PAMA statute is silent about any limits to price cuts to the Medicare CLFS for the years following 2022.

Congress delayed the cuts in 2021 and 2022, owing largely to the pandemic and the resulting feeling that clinical laboratories had raised their public perception. The next round of payment cuts is set for Jan. 1, 2023, unless other action stops it. *(See TDR, "PAMA Test Price Cuts Deferred: It's a 'Huge Win' for Labs," Dec. 20, 2021.)*

Laboratory observers have noted that going to Congress each year seeking action to delay the PAMA cuts is a piecemeal effort, whereas SALSA would attempt to permanently limit the severity of future payment reductions.

Data Collection Questioned

The language in the SALSA bill focuses on "statistically representative samples" for affected clinical labs. Because of how the **U.S. Department of Health and Human Services** (HHS) implemented PAMA, some observers believed that data collection for private payer rates skewed towards larger, independent laboratories—to the detriment of all labs subject to the new, lower rates, Morton noted.

Hospital outpatient laboratories and physician office labs were underrepresented in the data, resulting in Medicare payment rates being artificially lowered.

"In the data collection process specified by PAMA, CMS defined an 'applicable laboratory' in such a way that excluded the major of hospital laboratories from reporting their private payer lab test prices," Morton explained. "The bulk of the data came from independent labs and specifically from the two large national, independent labs.

Lawmakers Supporting the SALSA Bill

MEMBERS OF CONGRESS who have sponsored the Senate and House of Representatives versions of the Saving Access to Laboratory Services Act (SALSA) include: Senator Richard Burr (R-NC), Senator Sherrod Brown (D-OH), Representative Bill Pascrell (D-NJ), Representative Scott Peters (D-CA), Representative Richard Hudson (R-NC), Representative Gus Bilirakis (R-FL), and Representative Kurt Schrader (D-OR).

The bill version numbers are:

- Senate version: S.4449
- House version: H.R.8188

"Those private payer rates are significantly lower than the rates paid to hospital labs and other independent laboratories in the private sector. So, by moving to a statistical sampling methodology as defined in the proposed SALSA bill, we hope the agency will more accurately capture the makeup of the market."

Data from All Types of Labs

That market includes not only independent and hospital labs, but also hospital outpatient labs and physician office laboratories, according to SALSA's wording.

The ACLA filed a lawsuit against HHS in 2017 over PAMA, and after several twists and turns, an appeals court recently ruled in the ACLA's favor. *(Watch for full analysis about this court decision in the next issue of THE DARK REPORT.)*

While SALSA defines goals for data collection, it remains to be seen how HHS and CMS will gather the payment data.

Some research has already been done on this matter, as called for in 2019's Laboratory Access for Beneficiaries (LAB) Act. Under that Act, the **Medicare Payment Advisory Commission** (MedPAC) researched how test payment data was collected. MedPAC concluded in 2019 that PAMA's methodology captured far more Medicare payments made to

Comparing Payment Reductions in PAMA and SALSA

ONE MAJOR MOTIVATION behind the proposed Saving Access to Laboratory Services Act (SALSA) is to reduce the severity of clinical laboratory test payment cuts currently in effect under the Protecting Access to Medicare Act of 2014 (PAMA).

PAMA does not explicitly state what cuts are in effect beyond 2025, which leaves the language open for any amount of reduction or increase, observers have noted. SALSA, on the other hand, caps the reduction amount to no more than 5% in 2025 and beyond. The table below compares the payment reductions in PAMA, and proposed cuts under SALSA, for 2023 through 2025:

Year	Cut in PAMA	Proposed cut in SALSA
2023	No more than 15%	0
2024	No more than 15%	No more than 2.5%
2025 and subsequent years	No more than 15%	No more than 5%

independent labs compared to payments made to hospital labs and physician office labs. *(See TDR, "MedPAC Advises Congress on Lab Data Reporting," June 14, 2021.)*

MedPAC hired an external statistic consultant to look at the best way to collect the data. The consultant used two methodologies, one of them is known as "Maximal Brewer Selection," Morton said. Language in the SALSA bill refers to Maximal Brewer Selection.

"Because the bill points to Maximal Brewer Selection and it's established in the MedPAC study, CMS should lean on that methodology when implementing the rules for collecting this data as called for in the proposed legislation," she explained.

A related provision in the new bill would delay a reporting requirement from 2023 to 2026 and decrease the frequency of reporting from every three years to every four.

LAB Act Was a Precursor

SALSA's roots stretch back to the LAB Act, which also took aim at aspects of PAMA, including instituting a delay in reporting requirements for labs. *(See TDR, "33 Groups Cooperated to Get PAMA-Related LAB Act Passed," Jan. 27, 2020.)* Clinical laboratory industry groups have pushed lawmakers for more action since the LAB Act.

"When the industry supported the LAB Act a couple of years ago, we were clear that it was a starting point to get the MedPAC report, but there would need to be additional legislation to implement permanent changes to PAMA," Morton recalled.

Congress passed PAMA in 2014 because of the need to find funds to avoid a 24% cut to Medicare physician fees, as required by the "Sustainable Growth Rate" (SGR) formula in a Medicare funding bill passed by Congress in 1997.

This was described as the "doc fix". Lawmakers estimated that the new rules for lab test pricing would reduce the money paid to labs by $2.4 billion over a 10-year period. *(See TDR, "New Federal Law Changes How CMS Sets Lab Prices," April 7, 2014.)*

PAMA has led to nearly $4 billion in cuts to laboratories since 2018, far greater than the original estimate, according to figures published by the ACLA.

Morton said NILA's goal is to have SALSA attached to must-pass legislation that Congress typically votes on at the end of each year.

Not only should clinical laboratory administrators and pathologists closely watch the progress of SALSA over the next several months, they may want to contact members of Congress if they feel strongly about the proposal. TDR

Contact Erin Will Morton at emorton@dc-crd.com.

Coverage, Reimbursement Still Difficult for New Tests

When considering new tests, health insurers want adequate data on test accuracy and clinical value

Steve Stonecypher

CEO SUMMARY: Bringing a new proprietary diagnostic test to market is an arduous process. It takes patience and planning to complete the journey from test development to payer reimbursement. This slow process stems from the fact that the healthcare reimbursement system is fragmented, with the three main segments being Medicare, Medicaid, and private payers, each with its own set of coverage requirements.

Obtaining favorable payer coverage and reimbursement decisions for new diagnostic assays requires patience, long-term planning, and realistic assessments of their technologies by the lab companies bringing these tests to market.

That was the key message from Steve Stonecypher, Managing Partner at **Shipwright Healthcare Group** in Greensboro, N.C., during a presentation at April's *Executive War College Conference on Laboratory and Pathology Management*. He later spoke exclusively to The Dark Report.

"It's really about being open, transparent, and honest about your company's diagnostic technology and where it fits," said Stonecypher, a consultant who assists healthcare companies in navigating the payer marketplace. "Should a lab company fail to set unrealistic timelines and guidelines, the potential for a pitfall is great."

Lab companies might wait longer than a year before their test even appears on the **Medicare** Part B Clinical Laboratory Fee Schedule (CLFS). And Medicare is just step one of a potentially lengthy process. Getting subsequent decisions from commercial health insurers and **Medicaid** can add another 12 to 24 months to the timeline at a minimum, and that's if everything goes right, he added.

"I know organizations that are in their sixth and seventh year of seeking coverage for their lab test, and they're just starting to get the payers to come on board," Stonecypher warned. The process to introduce a new diagnostic test must have an eye toward a technology's likely fit in patient care and how it's going to be coded, he added.

Does a New Test Fit In?

Lab companies should perform a technical assessment that reflects how payers will ultimately make coverage decisions involving their new diagnostic test, he said.

One key question that Stonecypher focuses on: "Is the test a 'nice to have' or a 'need to have'? The payer might look at the technology, and say, 'Why do patients need it? You're using a code that somebody else is already using.' That's just nice

to have, versus a need to have. On the other hand, is the test filling a void? Is the test solving a problem for this payer and for the patient population?"

Contemplate Three Areas

Here are other considerations:

- **Competing tests.** Don't discount the benefit of not being first to market. "Sometimes it's great to follow a lab company that's already been there," Stonecypher said. "Maybe your lab company's new test will be more sensitive and more specific. But the first test blazed a trail, so the payers might have already made positive determinations."
- **Cost-benefit analysis.** Lab companies must determine how the test drives cost savings or appropriate patient care. Another aspect: Does the test impact the financial bottom line for the payer?
- **Support from key influencers.** "It's very important to have big organizations behind you," Stonecypher explained. This includes medical specialty societies where the test might fit into a clinical guideline, as well as key opinion leaders who may be using the technology. "Can these advocates demonstrate current utilization to the payer and thus market adoption?" he asked.

Many payers will want to see a dossier that documents the validity and utility of the diagnostic test. "But the clinical dossier needs to very concise," Stonecypher advised. "I've seen 100-page dossiers, but what medical director is going to read that? So, get it down to something more like a 20-page term paper with a succinct executive summary: What is the test? What patient care problem does it solve? What is the intended use?"

Determining the Code

Navigating the **American Medical Association's** (AMA) Current Procedural Terminology (CPT) codes can be challenging when it comes to a new diagnostics test. "One key question is: Does the lab get a new code or is there an existing code?" Stonecypher said. "That's a very important determination because it drives next steps."

If an existing CPT code accurately describes the test, that's the path of least resistance. "Pricing is already set, and some determinations are already set. The lab doesn't have to do anything other than go chase contracts," he said. "On the other hand, the established rate may not be ideal, or there may be negative determinations that have to be addressed."

A second option is to use an unlisted CPT code. These codes are set aside for broad categories of procedures, usually new ones, for which a specific code is not available. The AMA currently has three CPT codes for unlisted laboratory procedures:

- Chemistry procedures (code 84999).
- Miscellaneous pathology tests (code 89240).
- Molecular pathology procedures (code 81479).

The downside is payers don't have established rates for unlisted codes, requiring extra documentation for favorable reimbursement decisions, Stonecypher noted.

Obtaining a New Code

A third option for a new lab test is to apply for a new CPT code from the AMA. Doing so will ultimately facilitate pricing and claims processing. But it also creates another set of hurdles to jump through.

"The application process can be time sensitive and resource intensive," Stonecypher said. "It can take a minimum of 12 to 18 months from submission to coverage determination. To obtain a new code, labs are best served to provide documented evidence of clinical validity and clinical utility."

Yet another obstacle is getting the new code on the Medicare CLFS. That process depends on whether the test is considered a crosswalk or a gapfill.

"Crosswalk means there's a code that's comparable, but it's not a perfect match,"

With 175,000 Genetic Tests Available, Payers Struggle to Manage Utilization

ANY DISCUSSION ABOUT HOW TO SEEK REIMBURSEMENT FOR NEW DIAGNOSTIC TESTS must also acknowledge the pressures that private payers face as tens of thousands of new diagnostic assays are introduced each year.

One database of genetic tests maintained by **Concert Genetics** of Nashville, Tenn., currently catalogs more than 175,000 genetic tests offered by hundreds of U.S. laboratory companies.

For context, back in 2000, a complete lab test catalog offered by major national reference lab companies listed only 2,000 diagnostic assays.

Exponential Growth

Seen from this perspective, growth over the past decade in the number of different genetic tests has been exponential. Payers were unprepared for the sheer volume of genetic test claims, often billed with between 10 and 40 Current Procedural Terminology (CPT) codes.

"Declining cost of sequencing, inflow of investment capital, heightened public interest, and the relatively permissive regulatory framework around laboratory-developed tests have all contributed to the rise in the number of available tests," Rob Metcalf, CEO at Concert Genetics, told THE DARK REPORT. The company develops solutions that help providers and health plans manage genetic test selection, coverage criteria, coding, and payments.

THE DARK REPORT has noted in the past that a significant consequence from the tidal wave of new genetic tests is that the Medicare program and private payers are overwhelmed with claims for these novel tests. *(See TDR, "Genetic Tests Grow in Number, Complexity," July 26, 2021.)*

Many genetic testing companies performing these new lab tests do not have sufficient evidence of analytic validity and clinical utility. Consequently, insurers must deal with large volumes of claims for genetic tests that may have little clinical value.

Health insurance plans face three fundamental problems in managing genetic testing, as outlined by Metcalf:

- **Test identification.** "Most billing codes align to individual genes rather than tests, yet the majority of testing volume and claims comes from multi-gene panels represented by multiple codes," he noted. Variability in how tests are represented in coding compounds the problem for health insurers.
- **Rapidly changing evidence.** It is challenging to track proof of analytic validity and clinical utility of new assays. "The evidence and clinical guidelines for testing change rapidly—often much faster than health plans update their medical policies," Metcalf explained. "The plan often finds itself in a position where its understanding of the test and the evidence are both out of date."
- **Lack of coordination.** Accurate reimbursement requires synchronization among groups that handle network contracting, medical management, and claims. However, achieving this is difficult without a unified view of tests, policy, coding, and pricing.

Managing Test Utilization

Carriers are seeking ways to better manage test utilization.

"Prior authorization is costly and burdensome, especially in genetic testing where multiple codes may reference multiple policies for one test," Metcalf said. "Most utilization management programs do not deliver a cohesive test ID system or coding standards, which means payment integrity remains a challenge."

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Stonecypher noted. Finalizing a crosswalk can take about a year from initial submission to placement on the fee schedule.

Labs should expect an additional year if a test is a gapfill, meaning "there's nothing comparable," he said.

Getting on the CLFS "is going to be the easiest thing a lab can do out of all this," he added. "The documentation that's required for Medicare is significantly different from what the commercial payers are requiring. And it's different from what a state Medicaid program requires."

Medicare Advantage Plans

Even getting coverage from Medicare Advantage plans may be a challenge, Stonecypher cautioned. Federal regulations typically require these plans to follow Medicare rules and determinations, but they "aren't always going to follow them, or you have to remind them they have to follow."

Success in this effort can also depend on which company is offering the Medicare Advantage plan and the specifics of the contract.

State Medicaid plans are supposed to follow Medicare determinations, but that does not always happen due to budget constraints and the delegation of contracting capabilities on the state's part, he said.

Further complicating the matter, each state has its own rules, and in some states, such as Tennessee, policies and their determination are delegated to the Medicaid HMOs. Tennessee is divided into three regions managed by three different Medicaid HMOs.

"So, in one state, you could have one plan covering the test and another not covering it," he observed. "Subsequently, payers may bring their own unique requirements into the process." *(See sidebar on this page for more details.)*

"This is a long-term process to bring a test and a technology to market," Stonecypher advised. "It's about mapping out the process and creating a timeline." TDR

Payers Use Different Policies in Test Reviews

AMONG COMMERCIAL PAYERS, **Aetna**, **Elevance Health** (formerly **Anthem**), **UnitedHealthcare**, and **Cigna** implement and manage their own medical policies or have a subsidiary company that manages their policies.

Some plans delegate medical policy decisions and can opt in or out of specific decisions, said Steve Stonecypher, Managing Partner at Shipwright Healthcare Group. For example, **Blue Cross Blue Shield** plans may subscribe to a third-party company for medical policies, but the plans can opt out of a particular determination if they are so inclined.

Technology assessment organizations such as **ECRI**, **InformedDNA**, and others also influence coverage policies even though they don't enforce them. "So, plans can opt into using those organizations," he said.

Lab benefit management companies—such as **Avalon Healthcare Solutions**, **eviCore Healthcare**, and **AIM Specialty Health**—are also playing a bigger role.

"That's good and bad," he said. "You can have a dialog with some of these companies, whereas you can't with some of the payers. But if a test gets a negative decision, it may be for multiple plans. On the other side, if everything's in order, a test may get a positive decision and suddenly go from zero plans to 20 overnight."

To deal with inevitable setbacks when introducing a new test, labs should think strongly about how to respond to denials and prepare to go through multiple levels of appeal if a plan initially declines to cover the test.

"This is key to building attention in the marketplace for your new test technology," Stonecypher said.

Contact Steven Stonecypher at sstonecypher@shipwrighthg.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One of the biggest health insurers in the United States has changed its name. As of June 28, **Anthem** in Indianapolis, Ind., is now known as **Elevance Health**. The new name is a combination of "elevate" and "advance," noted *Modern Health Executive* on June 16. Elevance also announced **Carelon** as its new healthcare services brand and the return of **Wellpoint** for certain health insurance products, *Forbes* said on June 16. Prior to 2014, Anthem was called *Wellpoint*. The Anthem moniker will continue to be used for the company's **Blue Cross Blue Shield** health plans.

MORE ON: *Rebranding*

Northwest Pathology in Bellingham, Wash., announced that with the December 2021 acquisition of **Avero Diagnostics** in Irving, Texas, the combined company will go by the Avero Diagnostics brand. Avero now employs 20 pathologists and offers services in Texas, Washington, and Alaska.

NIST OFFERS FREE MONKEYPOX TEST CONTROL

As part of the federal effort to expand monkeypox testing capabilities in the country, the **U.S. National Institute of Standards and Technology** (NIST) has developed a material to help ensure the positive accuracy of diagnostic tests for the disease. NIST is making the material available for free to test manufacturers and testing labs. For more information, go to www.nist.gov.

LABCORP TO SEPARATE CLINICAL DEV BUSINESS

Labcorp in Burlington, N.C., plans to spin off its clinical development business into a new, publicly traded company that offers clinical trial management and related technology to pharmaceutical and biotech companies. Labcorp is hoping to complete the spinoff by the second half of 2023.

TRANSITIONS

• Anthony Guidi, MD, has been announced as the new Chief of Pathology at **Brigham and Women's Faulkner Hospital** in Boston. Guidi will also continue to serve as the Chair of the Department of Pathology at **Newton-Wellesley Hospital,** an affiliated medical center in nearby Newton, Mass., where he has worked for 12 years.

• **Cornerstone Diagnostics** in Jamestown, Ky., named J. Dean Reed as the new Vice President of Sales and Business Development. Previously, Reed worked at **Mayo Clinic Laboratories** and **Miraca Life Sciences**.

• Thomas Schinecker, PhD, CEO at **Roche Diagnostics Division** in Basel, Switzerland, will become the CEO of parent company **Roche** in March. He will succeed current chief executive Severin Schwan, who has been CEO at Roche since 2008. Schinecker has held several leadership roles at Roche since 2003.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 29, 2022.

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