Volume XXX, Number 15 Monday, October 23, 2023

Clinisys CEO

Michael Simpson on... How to Leverage Forces Transforming Healthcare!

(See pages 10-15)

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER

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

Why Many Patients Cannot Pay for Their Lab Tests

IT IS WIDELY RECOGNIZED THAT GOVERNMENT AND PRIVATE PAYERS STEADILY NIBBLE AWAY at what they reimburse clinical laboratories and anatomic pathologists. Lowering the prices paid for tests, excluding labs from networks, and declining to grant coverage for new lab tests are just a few of the tactics used by the health insurance industry to cut what they pay out for lab tests.

But the payer side is only one element in how labs are paid. On the patient side, as recently as 2021, 55% of Americans were enrolled in high-deductible health plans (HDHPs). The **Kaiser Family Foundation** writes that "HSA-qualified HDHPs are legally required to have an annual out-of-pocket maximum of no more than $7,050 for single coverage and $14,100 for family coverage in 2022."

This means that labs providing testing for HDHP-insured patients must often collect 100% of the charges (based on a specific HDHP plan) until the patients meet their deductible—typically late in a calendar year. This is a reason why many clinical labs (along with physicians and hospitals) post a significant increase in patient bad debt on their financial reports. Many patients do not have adequate cash to pay for even a few hundred dollars of lab tests.

How big a problem is patient bad debt? Here is a headline from *CNBC*, dated June 22, 2022: "100 million adults have healthcare debt—and 12% of them owe $10,000 or more!" Using data from the Kaiser Family Foundation, *CNBC* wrote, "Using $2,500 as a base level, 56% who carry medical and/or dental debt owe below that amount and 44% owe that much or more."

This means that about 44 million adults owe more than $2,500 in medical debt. This illustrates why clinical labs and pathology groups are challenged to collect directly from patients.

Last year, **Prudential** surveyed consumers and wrote: "Emergency savings funds are in crisis: 50% of all respondents have less than $500 or no emergency savings fund. Nearly four in 10 (39%) of both millennials and Gen Z report having no emergency savings at all."

Now you know why labs are challenged to successfully collect monies due from patients for their lab tests. They don't have much cash! TDR

Hospitals, Pharmacies Struggle to Be Profitable

Rite Aid files bankruptcy while survey of hospitals in Washington State reveals large operating losses

CEO SUMMARY: Pharmaceutical companies may be posting strong growth in revenue and profits. But that's not true for the nation's largest retail pharmacy chains. Rite Aid's Chapter 11 bankruptcy filing earlier this month put a spotlight on financial stress at all the retail pharmacy chains. This news was matched by the release of a survey which determined that acute care hospitals in the State of Washington reported a collective operating loss of $750 million during the first six months of 2023.

No less a news outlet than *Barron's* is declaring that "the U.S. retail pharmacy business is in big trouble." The trigger for this headline last week was the announcement that national pharmacy chain **Rite Aid** had filed Chapter 11 bankruptcy. But Rite Aid is not the only pharmacy chain with financial woes.

The news of Rite Aid's bankruptcy filing comes just a week after the **Washington State Hospital Association** (WSHA) reported the results of a survey of the financial performance of all the state's hospitals for the first six months of 2023. The survey determined that the state's hospitals suffered collective operating losses of $750 million during that period.

Clinical laboratory administrators and pathologists crafting strategies for their labs can consider both developments as sentinel events for the financial soundness of those two sectors of the U.S. healthcare system. Understanding the forces causing these losses can help lab leaders make better decisions on capital investments and how to position their labs for clinical success.

The financial woes of rural hospitals and many integrated delivery networks (IDNs) have been a national news story in recent years, in part because of the pandemic. But the economic pressures on retail pharmacy chains is less well known.

In its coverage of the bankruptcy filing, *Barron's* wrote that Rite Aid's "problems are emblematic of a struggling industry," further commenting that "**Walgreens**, which owns the Walgreens and **Duane Reade** chains in the U.S., is a perennial underperformer."

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • ©The Dark Group, Inc. 2023 • All Rights Reserved

Barron's continued, stating "meanwhile, pharmacists at **CVS Health** (CVS) stores and at Walgreens stores in the U.S. have walked out in recent weeks in protest of what they have called chronic understaffing leading to untenable working conditions."

Too Many Retail Pharmacies?

Overbuilding of retail pharmacy stores is a contributing factor. As part of its bankrupcy reorganization, Rite Aid plans to close 900 of its 2,000 stores.

But it is a similar story at the other national pharmacy chains. CVS closed 244 stores between 2018 and 2020, followed by an announcement in 2021 that it planned to shutter another 900 stores by 2024. At its peak, CVS operated 9,962 stores as of 2020.

In 2019, Walgreens disclosed it would close 200 stores. Last June, it said it would close an additional 150 stores. As of 2022, its website said it operated "almost 9,000 stores."

Financial analysts tracking the retail pharmacy industry generally identify decreasing profitability, particularly because of how PBMs (pharmacy benefit managers) and **Amazon's PillPack** division have increased their share of prescriptions at the expense of retail pharmacies. Other factors include opioid litigation, acquisitions by several pharmacy chains that did not deliver the expected results, and the general overbuilding of retail pharmacy stores that was mentioned earlier.

Poor Hospital Finances

As noted earlier, hospitals are another sector of healthcare that is under relentless financial pressure. The survey conducted by the Washington State Hospital Association (WSHA) is a good bellwether for the hospital industry nationally.

In its report of the survey results, WSHA stated that acute care hospitals in Washington reported a collective $750 million in net operating losses during the first six months of 2023. The survey conducted by WSHA involved all the acute care hospitals in the state. This finding represented 93% of the acute care hospital beds in the state.

If there is good news in the survey findings, it is that during the same six months of 2022, hospitals in Washington State reported a collective net operating loss of $1.1 billion. Thus, the losses reported for the first six months of 2023 are down about one-third from the prior year.

As a point of reference, when WSHA released the hospital survey findings for the full year of 2022 in March of this year, the state's hospitals reported a collective operating loss of $2.2 billion.

The survey was released on Oct. 11 and its findings mirror the financial woes of many hospitals and integrated delivery networks across the nation. The economic pressures on hospitals and IDNs continue to get plenty of news coverage, both locally and nationally.

Hospitals' Operating Losses

In its press release about the survey, the WSHA identified the factors contributing to the operating losses of hospitals within the state. It stated "When comparing the first six months of 2023 to the first six months of 2022, employee compensation increased by an average of 8% per employee. While the cost of agency staff has declined by $300 million, hospitals increased wages and benefits to employees by $700 million and slightly increased the number of employed staff over the first six months in 2023. This is expected to exceed $1.4 billion over the year, with many contracts still in negotiation."

Survey results indicated that only 12 of 81 hospitals surveyed had a positive operating margin in the first six months of the year. WSHA's CFO, Eric Lewis, said during a press conference that 17 of the hospitals disclosed having operating cash in reserve of less than three months. Guidelines recommend hospital have six and a half months of cash in reserve.

Deteriorating Finances Is a Major Reason for Hospital, Health System Mergers, Acquisitions

DURING 2023, THE PACE OF MERGERS AND ACQUISITIONS of hospitals and health systems has equaled that of 2019, the last year before the pandemic.

In its coverage of a report issued in July by **Kaufman Hall**, the healthcare consulting firm, *Chief Healthcare Executive* wrote that "There were 20 announced hospital mergers and acquisitions in the second quarter of 2023, the highest number since the first quarter of 2020 ... That's also around pre-pandemic levels, with 19 mergers in the second quarter of 2019 and 21 in 2018's second quarter."

This confirms that consolidation of hospital ownership continues as a major trend—a trend with implications for those lab administrators and pathologists managing hospital laboratories.

The hospital merger/acquisition trend will result in increasingly larger health systems. This means more laboratory consolidation and the need to service larger regions, including multi-state service areas covered by the parent healthcare system.

Kaufman Hall listed some of the larger hospital acquisitions and mergers announced since the beginning of 2023. They include:

- **Kaiser Permanente** to acquire **Geisinger Health** and place it into the newly-created **Risant Health**.
- **University of Michigan Health** completed its acquisition of **Sparrow Health** in April.
- **Froedtert Health** and **ThedaCare** announced plans to consolidate.
- **UnityPoint Health** and **Presbyterian Healthcare Services** plan to merge.
- **UPMC** plans to acquire **Washington Health System**.

In an interview with *KUOW*, the public radio station in Seattle, WSHA CEO Cassie Sauer commented that losses at this level were unsustainable.

"Over time, these operating losses will result in hospitals reducing high-cost or non-profitable services simply so they can keep the doors open. We've already seen this happen," she said.

Sauer explained that, in several areas of Washington, hospitals have already reduced or closed obstetric services. This lowers access to obstetric care.

Sources of Rising Costs

Sauer listed some of the major sources of rising costs for hospitals in the state. These include:

- Increased cost of labor.
- Increased equipment and supply costs.
- Difficulty discharging patients who remain in hospital beds for long periods of time.
- Low reimbursement rates from governing bodies like Medicaid.

Financial Stresses

The financial pressure on hospitals is not news for most clinical lab administrators and pathologists. They staff the labs in the nation's hospitals and health systems and regularly see their lab budgets squeezed in response to rising costs and inadequate reimbursement at their parent hospitals.

By contrast, economic pressure on the nation's largest retail pharmacy chains is a relatively new development and the retail pharmacy sector is not something closely watched by lab managers. Yet, retail pharmacies may be a useful "canary in the coal mine" about deteriorating finances in other important sectors of the U.S. healthcare system. TDR

Proficiency Testing Ranks High as a CLIA Violation

➤Even an 80% passing mark for PT is a flag that further scrutiny would benefit the lab and patients

Denise Driscoll, MS, MT(ASCP)

➤➤***CEO SUMMARY: Proficiency testing (PT) deficiencies are consistently cited by clinical laboratory accreditors during CLIA inspections. Surveyors and inspectors note that labs may mistakenly believe that an 80% score on a PT event is satisfactory. To the contrary, experts advise labs to scrutinize every PT sample that does not pass muster.***

Kathy Nucifora, MPH, MT(ASCP)

Editor's note: This is the second installment in an occasional series of inspection readiness briefings that focus on how to avoid the most common citations seen during inspections under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

YEAR AFTER YEAR, PROBLEMS WITH PROFICIENCY TESTING (PT) consistently rank among the most common citations issued by CLIA lab assessors during their lab inspections. Over the years, more than one prominent clinical laboratory organization has found itself facing federal sanctions because of violations in the handling, testing, and reporting of proficiency tests.

This insight was shared at the *2023 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*. A panel of CLIA accreditors presented their respective lists of the top 10 deficiencies recorded during CLIA inspections in the prior year. *(See TDR, "CLIA Lab Accreditors Reveal Most Frequent Deficiencies," May 30, 2023.)*

Panelists represented each of the following four major CLIA accrediting groups:

- **The Joint Commission**.
- The **American Association for Laboratory Accreditation** (A2LA).
- **COLA**.
- The **College of American Pathologists** (CAP).

CLIA falls under Section 493 of the Code of Federal Regulations. Several subparts of Section 493 define the requirements for proficiency testing:

- Subpart H outlines the steps labs must take to participate in successful PT testing, including minimum acceptable scores.
- Subpart I covers proficiency testing programs for non-waived testing. Nearly 90 clinical lab tests require PT.
- Subpart M describes the responsibilities of laboratory directors as they pertain to proficiency testing for PT programs, including that all PT reports are reviewed by appropriate staff and that corrective action plans are put in place when testing results are unacceptable.

Most sets of PT samples are sent to participating laboratories on a scheduled basis—usually three times per year, according to the **Centers for Medicare**

and Medicaid Services (CMS). After testing, labs report the sample results back to their PT program. Proficiency testing is not required for any test classified as waived, although some labs choose to conduct PT for waived tests.

Joint Commission: 80% Scores

The Joint Commission's number one citation in 2022 centered on accredited laboratories not performing required corrective action for unacceptable PT results.

"PT deficiencies often stem from a combination of process and people issues," said Amy Null, MBA, MT (ASCP) SBB, Associate Director for the Standards Interpretation Group, Laboratory Accreditation at The Joint Commission.

"For instance, if a robust process for management of PT events is not in place within a laboratory, then if that lab has any breaks in staffing—for example, say they lose a staff member responsible for PT management, a technical consultant, technical supervisor, or general supervisor—there is a high potential that some type of breakdown will occur during the PT process," Null told THE DARK REPORT.

"PT is not something the lab is responsible for on a daily basis, like quality control, instrument maintenance, or recording temperatures," she added. "If the lab does not have a well-defined process for managing the entire PT process, then a breakdown can easily occur."

PT Program Slipups

She has noticed various slipups with a laboratory's proficiency testing program:

- Trainees who are not educated about PT processes.
- Lack of documentation for ungradable or challenged PT results (such documentation should indicate those results have been reviewed and compared to peer results, if necessary).
- Investigations and corrective actions are not performed for individual, unacceptable PT results.

Regarding the last bullet, a common misunderstanding occurs when a clinical laboratory receives an 80% score on a PT submission. Even though that score may appear to be satisfactory, laboratories must still document an investigation and corrective action for those samples that did not pass.

"Generally, there are five samples in a regulated PT event, so if the lab misses one, they are then down to 80%," Null explained. "A score of less than 100% always requires documented investigation and corrective action."

The missed 20% of a PT event should be viewed through the lens of continuous improvement. "When I worked on the bench, I treated the tubes of blood as people—somebody's family member or best friend. Those specimens truly matter," she said. "Proficiency testing can ensure that labs provide the best test result every time, for every patient. So, 80% is just not good enough."

Carlyn Mathews

"A2LA has seen labs that use a calendar system or use some sort of internal tracking to remind them when to submit PT results."

CMS backs up this thinking. "If you receive an 80% score, you should investigate why one of the five samples was outside the acceptable range of results," the federal agency noted in "Proficiency Testing and PT Referral Dos and Don'ts," an online guidebook.

"Document your investigation and what you did to correct the problem that caused the challenge failure," CMS continued. "If you discover the issues which led to the 80% score, it could prevent more serious failures in the future."

Null suggested that labs consider using the "five whys" approach to root cause analysis that was pioneered by **Toyota**. "When faced with a problem,

you ask yourself 'Why?' five times to get to the root cause," she said. "Why was our PT result off? If it was because we did not educate the staff well enough, why didn't they get that training? If it was because the procedure did not provide enough detailed instructions, why were those instructions incomplete. And so on.

"CLIA surveyors often discuss this concept with testing personnel in the laboratory because it is a process that labs can use when they're investigating corrective action for proficiency testing results," Null noted.

COLA: Get Money's Worth

Building on the idea of investigating 80% scores, clinical laboratories should take such actions in the spirit of getting the most out of what they paid for when enrolling in PT programs, said Kathy Nucifora, MPH, MT(ASCP), Chief Operating Officer at COLA.

"Laboratories need to get their money's worth and pay attention to all the scores, including 80% passing scores and even 100% scores," Nucifora noted. "If all five PT challenges are within the acceptable range, giving the lab a 100% score, but several are at the limit of the acceptable range, this should be investigated to prevent the situation from getting worse and affecting patient care. I encourage laboratories to use PT to help them improve. Such improvement is among the things for which they are paying."

Appropriate Staff Review

CLIA requires lab directors to ensure that the appropriate staff review PT results. "One of the top problems that COLA sees with proficiency testing is that the laboratory director doesn't take the time to review the results with the testing personnel or supervisory staff," Nucifora observed. "That's an opportunity to learn from proficiency testing and get your money's worth from it."

A2LA surveyors have not seen long-term patterns with proficiency testing problems, but they have noticed simple steps that labs successfully incorporate to ease PT efforts, said Carlyn Mathews, Clinical Program Manager at A2LA.

"A2LA has seen laboratories that use a calendar system or use some sort of internal tracking to remind them when to submit PT results," Mathews noted. "Otherwise, labs can miss the turn-in time window, which can result in a failed PT submission."

A2LA accredits laboratories under CLIA and standard ISO 15189—Medical Laboratories: Requirements for Quality and Competence. ISO 15189 promotes quality within the lab environment, and that approach can feed into how labs monitor PT-related workflows.

Amy Null, MBA, MT(ASCP)

➤"If the lab does not have a well-defined process for managing the entire PT process, then a process breakdown can easily occur."

"Some labs audit their reminder systems throughout the proficiency testing process," Mathews noted. "Does the system keep track of not only when they're supposed to get PT kits, but also when PT is supposed to be submitted? When do you have to get approvals if there's a multi-step process for your lab's proficiency testing procedures?

"Labs can break those moments down into specific chunks, so it doesn't seem as daunting," she added. "Maybe the lab will have a reminder go out on Friday saying the staff needs to have a portion of the PT submitted because the due date is Monday. By doing so, the lab hits its target, and on Monday staff members don't have to worry about PT on the very last day it's supposed to be submitted."

CAP noted PT deficiencies concerning laboratory director duties and corrective actions for unacceptable results, but those

Accreditors' Standards Cited for Proficiency Testing

THE FOLLOWING STANDARDS are frequently cited by CLIA inspectors for poor proficiency testing (PT) assessments:

CAP

- COM.01400 (All Common Checklist, PT Attestation Statement)—The proficiency testing/external quality assessment attestation statement is signed by the lab director or designee and all individuals involved in the testing process.
- COM.01700 (All Common Checklist, PT and Alternative Assessment Result Evaluation)—Ongoing evaluation of proficiency testing/external quality assessment and alternative assessment results with appropriate corrective action are taken for each unacceptable result.

The Joint Commission

- QSA.01.02.01 (Quality System Assessment for Nonwaived Testing), Element of Performance (EP) 2—The lab investigates causes, provides evidence of review, and performs corrective action for the following: unacceptable PT results, late submission of PT results, and nonparticipation in a PT event.

COLA

- LDR 4—(Lab Director Responsibilities)—Lab director fulfills the proficiency testing responsibilities of the position.
- PT 16—Laboratory director reviews PT results with supervisory staff and test personnel.
- PT 9—All unsatisfactory PT scores and any scores less than 100% are evaluated and corrective action documented.
- PT 15—PT records include attestations signed by the lab director and testing personnel.
- PT 10—Lab verifies the accuracy of any analyte, specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the lab's actual test performance.

citations were not a surprise. "Overall, for the CAP, our PT citations during the public health emergency didn't change significantly from before that period," said Denise Driscoll, MS, MT(ASCP) SBB, Senior Director for Laboratory Accreditation and Regulatory Affairs at CAP.

"We added proficiency testing, of course, for COVID-19 tests and different methods for those tests," Driscoll continued. "But the overall test performance of the laboratories that we accredit was stable."

Driscoll had previously noted to THE DARK REPORT that clinical laboratory scientists who rotated among sites could create difficult situations in terms of measuring staff competency. *(See TDR, "Competency Assessments Prove to Be a Nagging CLIA Deficiency," July 31, 2023.)*

She cautioned about similar effects on PT. "PT helps provide stability and confidence of a lab's performance. When labs hire traveling clinical scientists or employ younger staff, that can sometimes affect overall test quality," Driscoll explained.

Closing Thoughts

During these times when many labs struggle to operate with full staff, it is easy to understand why clinical laboratory managers and testing personnel might be satisfied with 80% scores on PT. However, it is clear from the accreditation experts at these four organizations that clinical laboratories need to concentrate more effort on their proficiency testing activities to avoid potential citations.

In the next installment of our inspection readiness series, THE DARK REPORT will examine deficiencies related to clinical laboratory directors not meeting their required duties. **TDR**

Contact Contact Denise Driscoll, MS, MT(ASCP), at ddrisco@cap.org, Carlyn Mathews at cmathews@a2la.org, Kathy Nucifora, MPH, MT(ASCP) at knucifora@cola.org, and Amy Null, MBA, MT(ASCP), SBB at ANull@jointcommission.org.

NEWSM INTE

Michael Simpson

Clinisys CEO Di Changes Labs

"Today, we predict that the next storm is about ready to happen, and it will involve clinical laboratories and anatomic pathology practices."
—Michael Simpson

CEO SUMMARY: In this exclusive Q&A with THE DARK REPORT, Clinisys CEO Michael Simpson describes the main forces transforming healthcare here in the United States and abroad. He connects these trends with advances in cloud-based technology, artificial intelligence, and machine learning.

EDITOR'S NOTE: Michael Simpson became CEO and President at lab informatics provider **Clinisys** in 2017. Since then, he has steered the Tucson, Arizona-based company through acquisitions of **HORIZON Lab Systems**, **ApolloLIMS**, and **Promium** while also merging with **Sunquest Information Systems**. These moves further consolidated the laboratory information system (LIS) and lab information management system (LIMS) markets. Prior to his arrival at Clinisys, Simpson had executive roles at **Amazon Web Services**, **GE Healthcare**, and **McKesson**, giving him a first-hand perspective on how emerging innovations were influencing the way businesses operated. In the first of a two-part interview, Simpson gauges strategic trends facing clinical laboratories and how technology fits into that discussion.

FIRST OF TWO PARTS

EDITOR: Given your background in healthcare and at big tech companies, what do you see changing in healthcare and the delivery of care these days?

SIMPSON: The single biggest story in healthcare across all developed countries is the continuing increase in healthcare costs. We are familiar with the demo-

MAKER RVIEW

iscusses Strategic Need to Make

graphics of aging populations, demand for medical services that exceeds supply, and the introduction of expensive new diagnostic services and prescription drugs.

EDITOR: Have the advances in computer hardware and digital technologies been a contributor to higher healthcare costs?

SIMPSON: Going back 10 or 15 years, literally billions of dollars have been spent to implement electronic medical records (EMRs). Today, we have plenty of data in those EMRs. Yet, workflows are not optimal. Sadly, the cost of these EMRs has been passed on directly to the patient. In the United States healthcare system, rising costs are not because doctors are making too much money. Rather, it is because the infrastructure holding this all together is not where it needs to be.

EDITOR: Can you explain that further?

SIMPSON: Today, across all of healthcare, there is lots of data that sits in data silos. All healthcare providers—medical laboratories in particular—need to begin getting value from this data.

EDITOR: Wasn't the adoption of electronic health records (EHRs) intended to unlock the value of data in support of patient care?

SIMPSON: In 2004, those of us in healthcare informatics were uncertain how the digitization of healthcare would evolve. Then came that storm of adoption from 2004 into the 2010s. In the United States, part of that storm was the federal government's HITECH Act, which provided billions of dollars in incentives to hospitals and physician groups to adopt EMRs. All this change happened on the healthcare side. Today, we predict that the next storm is about ready to happen and it will involve clinical laboratories and anatomic pathology practices.

EDITOR: Where do you see this happening for medical laboratories?

SIMPSON: There is not much of this happening yet in the United States. But overseas, there are medical laboratory networks that are very much independent from the hospital. They are absolutely driving technology at a faster rate than laboratories do now in the United States.

EDITOR: What is different about lab services overseas?

SIMPSON: These lab networks are not trying to be a cost center or a profit cen-

ter for a hospital with an emphasis on billing for lab tests. To the contrary, what differentiates the lab networks in the UK and Belgium, for example, is that they are driving a change in diagnostics and laboratory testing services. It is extremely useful to have the perspective of what they are doing, knowing that this is what will begin to unfold here in the United States over the next couple of years.

EDITOR: Are there other healthcare trends that you are tracking?

SIMPSON: I think every lab manager and pathologist should be watching the ongoing increase in the use of telehealth and virtual consultations by consumers. This has also been driven by advancements in technologies. Hand in hand with these dynamics is the trend of direct-to-consumer laboratory testing. These forces have the potential to cut—by half—the workload of our primary care physicians.

EDITOR: It is widely recognized that the Millennial and Zoomer Generations want immediate access to healthcare. They will not spend hours to get to a doctor's office, wait until they get a 20-minute consultation, and then drive back to home or work.

SIMPSON: This is one reason we saw **Labcorp**, **Quest Diagnostics**, and others start to offer direct-to-consumer laboratory tests. For those of us who need to call a doctor from time to time, trying to get an appointment is almost impossible. I needed a consult a couple of months ago, and my specialist was booked out for months. And I know that he will order some laboratory tests when my appointment occurs. Can't you just give me those lab tests today? This is the piece where direct-to-consumer testing and telemedicine can really take the workload off general practitioners, specialists, and hospitals. In the future, we're going to get to some dramatic value in this area.

EDITOR: Did the SARS-CoV-2 pandemic open the door for direct-to-consumer tests?

SIMPSON: COVID-19 taught us that point-of-care testing is not as bad as we thought. Five years ago, the healthcare industry used to think there was no way consumers could ever do their own laboratory tests and have any kind of quality with it. But depending on who you talk to today, those COVID-19 tests that people took were 90% valid. At the end of the day, there are going to be more of those types of diagnostic tests that consumers can run from home and then, via telemedicine, get a follow-up clinical test.

EDITOR: Another important development in the digital age is the move to the cloud. Is this a priority for Clinisys?

SIMPSON: Your question opens the door to discuss a high priority for us at Clinisys—and the move to cloud-based informatics services that will be a requirement for successful labs; indeed, all providers. The reason we are investing all our efforts and time into our new platform is that it is cloud native, it is SaaS [software as a service].

EDITOR: What are the benefits of moving to the cloud?

SIMPSON: We can now use the ChatGPTs, the same type of advanced solutions that **Microsoft**, **Amazon**, and **Google**—along with other players—are offering their customers. These firms no longer install on-premises hardware and software systems. Moreover, there is no ChatGPT that I can install in my computer room. It is essential for us to move to the cloud. Those lab systems that do not move to the cloud will be unable to take advantage of ChatGPT and similar solutions.

EDITOR: Do hospital administrators, physicians, and lab managers recognize the need to be in the cloud?

SIMPSON: Five years ago, the answer would have been no. Now, every single customer we talk to knows they have to get there. The question is: How do they get there cost effectively? This is why Clinisys has invested so much in the

laboratory platform to help labs be cloud native. Along with building the necessary structure here in America, we must have data centers in half of the countries in which we operate. For example, Germany doesn't want its data outside of Germany. France wants to keep it inside of France. Accordingly, we need the right cloud partners and the right technology partners to enable us to do this.

EDITOR: How important is cloud-based technology to the future of clinical laboratories?

SIMPSON: Microsoft, Amazon, Google and all the other big players out there are not putting advanced solutions in on-premises systems. They're using cloud-based systems. There is no ChatGPT to install in my closet. I've got to go to the cloud for that. Laboratories that do not move to the cloud will not be able to take advantage of any of that upcoming technology because their data will be stuck in a 20-year-old LIMS in a closet, and that type of legacy system will always just be a little factory.

EDITOR: That's an expensive transition.

SIMPSON: The question will be: How do labs get there cost effectively with the right speed and the right controls in place? This is why Clinisys is investing so much in a cloud-native laboratory platform. We need to make sure that we have the infrastructure—not just here in the United States—but in other countries we operate in. That's because every country's health system wants its data kept within their own nation. Having the right cloud partners and the right technology partners to enable us to do that is pivotal.

EDITOR: What's your message to labs that need to get to the cloud but are worried that either they've fallen behind or don't know how to take that next step?

SIMPSON: The number one worry that I always see is on the financial side. Moving to the cloud isn't cheap. But look at the alternative. What people forget is that lots of organizations spent lots of money to put LIMS on a server that is placed under somebody's desk. Someone has to maintain those on-premises systems. Someone has to change the hard drives every once in a while. There's a cost behind that, but laboratories don't always think about these issues.

EDITOR: Do labs that stay away from the cloud risk being left on their own?

SIMPSON: One of the first questions I ask the laboratory is, "Do you want to continue to be a factory, or do you want to be a change agent in healthcare?" Few customers ever just want to be a factory. They want to be part of this evolution of using real-time data to improve care. But they don't know how to get there today. Clinisys' job is to get them there, whatever LIMS they may be currently using.

EDITOR: Is the cost of moving to the cloud going to be a barrier for labs?

SIMPSON: What those labs have to do for us is allocate enough funds and time to get [to the cloud]. It's an education because many people—and I put myself in the same bracket—look at this as a huge amount of money to spend. I understand that. If I spent $100,000 on a LIMS 10 years ago, I sure don't want to go spend a half a million in the future. But costs have changed. And if your lab really wants to be part of this AI world and not be left behind, you need a partner who can get you there.

EDITOR: How do you convince labs that there is a valid return on investment going to the cloud?

SIMPSON: Labs will increase productivity and get the payback of the cost of the cloud. They will save costs in IT, maintenance, and support. But it's not a simple answer. Many lab managers believe they need their arms around their data and their servers. But if they persist in that thinking, how are they going to integrate better with the EMR? How are they going to get all the diagnostics data that they want? The only way they're going to be able to do that is to get on the cloud.

EDITOR: Here is a question that describes many hospital and health systems in the United States, along with their clinical labs. These organizations have a huge investment in on-site computer hardware and various software systems. What happens to this investment?

SIMPSON: Focusing specifically on the United States, we all know that the vast majority of major healthcare organizations went to **Epic**, **Cerner**, etcetera. In some hospital systems, there is an investment of millions, even half a billion dollars, on this information technology. This won't change anytime soon. But at some point, they must figure out how they get to the cloud.

EDITOR: Does Clinisys see a path forward as medical laboratories in these health systems recognize the imperative to move to the cloud?

SIMPSON: Such a path has not been determined.

EDITOR: Have you identified any segment of the clinical laboratory industry that is likely to lead the move to the cloud?

SIMPSON: Yes. Here in the United States our focus is more on the life sciences side, especially independent labs. Companies like **Myriad Genetics**, **ARUP Laboratories**, and similar reference testing laboratories are already doing very impressive next-generation gene sequencing. We believe we can effectuate change in life sciences and add value in their cloud-based service mix.

EDITOR: What about academic medical centers and their laboratories?

SIMPSON: There will be university medical centers doing lots of this advanced diagnostic testing. However, as noted earlier, because of the tens of millions of dollars invested in on-site computers and software, they will tend to take longer to transition fully into the cloud.

EDITOR: Do you have an example of how diagnostic and lab testing services are now based in the cloud?

SIMPSON: Yes. Take reflexive testing, particularly for genetics and cancer. If you think about it, lab organizations offering these services are already in the cloud. We have an innovative customer with our product in Spain where—with the permission of our customers—this cloud vendor has the algorithm and gets the data from the labs. It then spins that data in the cloud and returns the result. This is how things will work going forward.

EDITOR: Let's stay with the topic of reflexive testing—meaning where an initial test result indicates that follow-on testing is appropriate for an accurate diagnosis. Do you think that cloud-based tools that incorporate machine learning and AI will be developed that will pass federal **Food and Drug Administration** review and give labs a new way to expand reflexive testing in a medically appropriate manner that gives the referring physician a more precise diagnosis?

SIMPSON: Yes. I firmly believe that these types of algorithms will arrive in the next five years. This is absolutely where laboratory medicine is headed. Moreover, this will be a solution to the problem of which tests to order, given a patient's symptoms and history.

EDITOR: Can you dig into that more?

SIMPSON: Today, we have clinical labs out there with 30,000 fixed rules that are doing the same thing you mentioned. These rules developed from the collective intelligence of the pathologists who created them in response to actual medical cases. Machine learning will eventually replace all of those rule systems. In their place will be even more precise tools for reflexive testing and interpretation of results. Pathologists will need to work themselves into these new capabilities rooted in augmented intelligence. TDR

Contact Michael Simpson via Paul Jackson at Paul.Jackson@clinisys.com.

Clinisys CEO Discusses Adoption of AI and Why Healthcare Needs Safeguards with AI, ChatGPT

CHATGPT STANDS FOR CHAT GENERATIVE PRE-TRAINED TRANSFORMER. It uses artificial intelligence (AI) to generate text that is based on past conversations and additional context.

ChatGPT functions as a chatbot. Users asks it either vocally or in writing to create content, such as, "Give me an update on the top 10 movies at the box office this weekend."

On one hand, the technology has been heralded as a game-changer in terms of how humans and companies might be able to use artificial intelligence in a real-world manner. On the flip side, ChatGPT has been criticized by some observers for at times providing incorrect information in the content it creates.

In his interview with THE DARK REPORT, Clinisys CEO Michael Simpson discusses the early influence that ChatGPT has had on businesses and cautioned about the lure of the tool.

EDITOR: Artificial intelligence in the form of ChatGPT is getting lots of news. How might this play out within the clinical laboratory sector?

SIMPSON: That's a question that has yet to be answered in the marketplace. One of our core values is to take care of our customers and get their problems solved quickly. Things like ChatGPT will help there. As a company, we are studying how we establish our own service so that we can protect our customers' data with a high degree of confidence.

EDITOR: But every new technology comes with unexpected flaws or setbacks. What concerns do you have about AI and ChatGPT?

SIMPSON: One early lesson that Amazon learned very quickly—as did several other companies—is that if you use the ChatGPT website, quite rapidly, proprietary information will end up within their model somewhere.

EDITOR: How has that experience influenced your assessment of ChatGPT?

SIMPSON: Let me speak to that from the perspective of our parent company, **Roper Technologies**. Roper is one of largest diversified software health software companies in the world. It employs 18,000 people and generates $6 billion in revenue in different verticals, from construction to education, to customer relationship management to healthcare. And all these business units are considering how ChatGPT, and similar technologies, can augment all of our solutions.

EDITOR: Have you identified hurdles or challenges to be solved with this AI tool?

SIMPSON: Number one, we must ensure the efficacy, security, and reliability of the AI models. This is a technology where we will be working with natural language, and we will get there with ChatGPT and related technologies. But this must be done within a safe model, where the data is protected, and we can guarantee a patient's privacy.

EDITOR: Is that stance even more important given that clinical laboratory patient data is involved?

SIMPSON: Safeguards must be in place before we use this technology. You've seen Microsoft introduce ChatGPT with its Bing search engine, along with other applications. Our case is different. Our company and our lab customers work daily with the data from real patients. If we make a mistake in handling that data, protected health information could be compromised, or a patient could be harmed or even die. We must have total confidence that we can guarantee the privacy and security of the models before we offer them to laboratories.

Virchow

Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Gaining Network Access with Payers Is Often about Geography

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

SMALLER CLINICAL LABORATORIES WANTING TO ATTAIN IN-NETWORK STATUS with payers often assume they need to offer an expanded test menu or a unique assay. While those types of tests will certainly garner interest, a payer's decision on inviting a lab into a network may depend just as much on the communities and regions where a lab offers its services.

Recently, THE DARK REPORT noted succinctly that **Labcorp** and **Quest Diagnostics** dominate the market. *(See TDR, "IVD and Lab Consolidation Reduces Choices for Labs," Sept. 11, 2023.)*

➤ Can Small Labs Stand Out?

Most health insurers are at capacity and aren't seeking more medical laboratories to be in-network. Payers also see that smaller labs are having a hard time staying afloat. That is a concern for insurers.

It is also hard for a smaller lab to stand out amid the big national lab companies. If a small chemistry lab wants to get in-network and that lab does only basic complete blood counts, it's not going to sway the payer. That health plan probably has enough basic chemistry labs in-network.

When a lab asks to be added to a payer's network, there are two big questions that the payer will ask. They are:

- What can a new lab offer that is proprietary or unique?
- What does a lab bring that a payer doesn't already have in its network?

It's critical for laboratories to think about those answers from not only a clinical point of view, but also the strategic business standpoint of the health insurer.

➤ Location Can Be Pivotal

An important point here is that a "unique service" doesn't always have to mean a clinical test. Instead, it could be the geographic region that a lab serves.

For example, maybe a lab is in the boondocks where the big national labs are not going to build a brick-and-mortar patient center. That might get a payer's attention because health plans field a lot of complaints about the lack of services in rural areas.

Here's another location angle for labs to think about: mobile phlebotomy services, which are a hot topic right now. Insurance rates are high for this type of work currently. Is a lab willing to go to patients' homes?

There are many people who work remotely and don't want to leave their

home to get their blood drawn. Or perhaps they have young children or an illness that makes travel to a traditional collection site difficult.

Visiting patients in their homes can be unpredictable work for a clinical laboratory because phlebotomists don't know what they might encounter. There might be an aggressive pet at the patient's house. Currently, few clinical labs offer this type of service.

Serving Difficult Patients

A lab can also stand out if it's willing to work with a difficult population of patients, such as nursing homes, for example. Phlebotomists have to go into a nursing home at four in the morning and collect samples from patients who may not understand what's happening.

Also, the lab needs to provide transportation to these sites, and the reimbursement rate is not great. But if a lab is willing to do work in long-term care facilities, that might interest a payer.

Let's say a small lab offering something unique piques the interest of a payer. Right off the bat, that lab is going to have to accept a laboratory fee schedule from the payer that is probably 50% of what Medicare will reimburse.

Most small labs can't survive on that type of money. And the lab will also have to contractually accept the payer's policies and procedures, including prior authorization requirements.

That's when the lab needs someone experienced at managed care contracting to step in as the contract is negotiated. That could be a person in-house, like the lab's CEO, or an external consultant.

Meeting with Payers

When a lab is initially faced with rates from the payer that will be 50% of what Medicare reimburses, the negotiator could go back to the plan and say, "We'll accept that payment in year one of the contract, but we want a 5% bump in year two if we increase lab business in an underserved region. And if you give us two or three other underserved areas where we could offer services and we accomplish that, then we want another bump up in year three."

With that approach, the lab can essentially lay out its parameters and see how the payer responds. If the plan is agreeable, maybe within a three-year period, the lab goes from 50% up to 60% if it performs well for the payer. But to accomplish this goal, the lab must have somebody skilled in how to barter with health insurers.

Once a lab has established a new relationship with one payer, it can build off that effort with other health plans. "We provided this mobile phlebotomy service for ACME Insurance," the lab might tell a competing plan. "We could do this for you, too."

Once a clinical laboratory is in-network, it needs to designate someone to

Labs Can Directly Pitch Self-Insured Employers

FOR LABORATORIES HOPING TO GET INTO PAYER'S NETWORK, an effective strategy may be to approach self-insured employers, who wield a lot of weight with health plans.

A laboratory will need to convince a self-insured employer that the lab is going to save the company money. This discussion will likely center on genetic test spending. For example, a company may offer employees fertility testing benefits that cost the employer $500,000 a year. If a lab can provide that testing for $300,000 through a pilot program, an employer may be interested in that cost savings.

It's key for a lab to staff a commercial team that monitors the self-insured employer market, at least locally, so that the laboratory is well versed in what these employers need. The commercial team has got to be ready with its sales pitch and data to back up that pitch.

oversee managed care matters and stay in touch with payers.

Most big labs have this type of designate on staff, but at a small- or medium-size lab, managed care duties may fall to the lab director.

Managed Care Oversight

Also, for some lab directors, managed care is not their priority. Their attention is on running the lab. So, some of this dilemma boils down to relationship building 101. Who in the lab is going to build the relationship with the payers? Labs should be reaching out to payers often just to find out what's new. *(See the sidebar for more about this aspect.)*

It's crucial for labs to find out who the decision-makers are on the payer side. I think many labs, particularly smaller ones, focus on staying afloat, getting specimens in the door, working with the docs, and taking care of the patients.

But those same labs don't think enough about sales and getting paid. "Well, reimbursement is not my department," a lab director might say. "That's for the businesspeople to handle." That's the wrong approach.

Closing Suggestions

Clearly it is a difficult task for a smaller clinical laboratory to not only compete in the market with the large national lab companies, but to also get in-network with payers. In conclusion, my suggestions for lab managers at these smaller organizations include the following:

- Do not focus on promoting services that an insurance plan likely has plenty of from other in-network labs, such as basic chemistry services.
- Figure out how to position the laboratory as unique or innovative, which may not always hinge on diagnostic offerings (although a unique test is appealing to payers).
- Labs may also have luck with plans if they can provide services in underserved communities or in sites (such as homes) where other labs aren't going.

Making a laboratory stand out from other labs in a network is a good approach to gaining a payer's attention and winning network status. TDR

Hold Regular Meetings with Health Insurers

IF A LABORATORY IS IN NETWORK FOR A PAYER, it's important to meet with that plan regularly or risk not staying informed about important changes.

Many labs have joint operating committee meetings with payers to discuss policy and reimbursement updates. However, if a lab doesn't request to hold joint operating committee meetings, the payers aren't going to bother.

Additionally, all payers send out monthly bulletins with updates on policies and coverage. When I worked for a payer, I used to ask some of the smaller labs who had the job of reviewing those monthly bulletins. Many smaller labs simply don't have someone designated to do that.

Yes, it's good for labs to focus on testing and patients. But they also must focus on the business end of their work: how they're going to get paid, maintaining that payment, or asking for more money.

The two big national laboratory companies have these activities down cold. They constantly ask for better payment arrangements and meet with payers.

At the same time, payers may only have so much capacity to meet with smaller labs. Ideally, labs want to meet with their payer contacts on a regular basis. If labs don't ask to meet regularly, they get pushed to the back burner. Then, a year down the road, a lab realizes it needs to catch up with the payer, and subsequently that lab is overwhelmed by the policy and personnel changes that have occurred.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Earlier this summer, a 16-year-old completed his bachelor of science degree, along with his certification as a Medical Laboratory Scientist (MLS). The faculty at **LSU Health-Shreveport** reported that Isak Schmidley, MLS (ASCP)BC is the youngest graduate of its Medical Laboratory Science Program to earn both the BS and the MLS certification. Schmidley earned his associate's degree at the age of 14. He told a reporter from *KSLA,* "I thought it would really be a struggle and a challenge to get acclimated to such an environment, but all of my classmates, all of the faculty, and the staff here have just been so welcoming. And I really just appreciate that. I don't think I could make it without all their help and support."

MORE ON: *16-year-old Medical Lab Scientist*

KSLA reported that Schmidley already has a job. His LinkedIn account shows him with an internship at **Ochsner Health**.

LABCORP ACQUIRES BAYSTATE HEALTH'S LAB OUTREACH

On Oct. 3, **Labcorp** announed that it had acquired the outreach laboratory business and select operating assets from Springfield, Mass.-based **Baystate Health, Inc.** This transaction includes Labcorp taking over Baystate's laboratory service centers, as well as the establishment of a Labcorp regional laboratory facility in Baystate Health's facility in Holyoke, Massachusetts.

EU ORDERS ILLUMINA TO DIVEST GRAIL

It is rare for a government to challenge a completed merger and issue an order for the acquiring company to divest its acquisition. But that is exactly what is happening in the European Union (EU). Earlier this month, the European Commission (EC) issued an order to San Diego-based **Illumina** that it must divest **Grail**, a company it bought in August 2021 for $8 billion. This is a major development in the next-generation gene sequencing market. In 2022, The EC levied a US$476 million fine against Illumina. Illumina has said it will appeal this decision while taking steps to effect its divestiture of Grail.

TRANSITIONS

- Phil Febbo, MD, joined **Veracyte** as its Chief Scientific Officer and Chief Medical Officer (CMO). He held prior positions at **Illumina**, **Varian Medical Systems**, **Genomic Health**, and **UCSF**.

- Cindy Jacke has joined Labcorp as its newest Senior Executive Director, Health Systems. Jacke previously held positions with **BioReference Laboratories**, **Pathline Emerge Pathology Services**, **Halfpenny Technologies**, and **Quest Diagnostics**.

- **GeneDx** announced the selection of Melanie Duquette as Chief Growth Officer. Duquette previously held executive positions at **Invitae** and **DNA Genotek**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 13, 2023.

Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*

Executive Publisher: Bob Croce *bcroce@darkreport.com*

Managing Editor: Michael McBride *michaelmcbride58@gmail.com*

IVD Reporter: Donna Marie Pocius *donna11019@att.net*

Copyright 2023 by The Dark Intelligence Group, Inc. All Rights reserved. None of the contents of this publication may be reproduced stored in a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission of the publisher.

THE DARK REPORT

UPCOMING...

- Part two of TDR's exclusive interview with Clinisys CEO Michael Simpson on LIS and more.
- California lab owner convicted in federal case involving $379 million in fraudulent lab test claims.
- State of the profession for academic pathology: opportunities, obstacles, and new ways to add value.

For more information, visit:

www.darkreport.com

DARK Daily

Serving Clinical Labs & Pathology Groups

Sign Up for Our FREE News Service!

Delivered directly to your desktop,
***DARK Daily* is news, analysis, and more.**

Visit www.darkdaily.com