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2023 Key Lab Macro Trends
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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

PAMA Cuts Have Simply Been Kicked Down the Road

PAYMENT RATE CUTS FOR CLINICAL LABORATORY TESTS, called for under the Protecting Access to Medicare Act of 2014 (PAMA), have been avoided temporarily—again.

A down-to-the-wire bill in Congress to keep the federal government funded into the new year included a provision to delay PAMA cuts to the Clinical Laboratory Fee Schedule (CLFS) for 2023. This is welcome news for clinical labs and pathology groups, who otherwise faced 15% cuts in payments for 800 diagnostic tests.

But the congressional vote is not a long-term solution to the problems that surround PAMA cuts for lab test reimbursement. Lawmakers have simply kicked the can down the road for the third time since 2020. That means short of solid action on Capitol Hill in 2023, PAMA cuts will again loom on Jan. 1, 2024.

Laboratories have argued for years that PAMA's cuts unfairly hurt hospital labs and small lab companies. The core of the problem rests with how the federal **Centers for Medicare and Medicaid Services** (CMS) collected test payment data and then used it to determine prices for the Medicare Part B CLFS. That data tends to overly rely on payment reporting from larger national labs. Such organizations generally receive lower payment rates from private health insurers in exchange for higher test volumes.

This past fall, members of Congress—acting on behalf of concerned labs and industry groups—presented a bill that sought to change the situation. The Saving Access to Laboratory Services Act (SALSA) proposed to cap future payment decreases to the CLFS and adjust how CMS calculates lab test payments.

As 2022 closed without SALSA being put to a vote, attempts were made to add it to a larger spending bill. Political competition was no doubt fierce as many, if not all, lawmakers wanted their pet causes in the spending package, so SALSA was left out. The potential costs of implementing SALSA probably played a factor.

SALSA or a similar proposal should be revived in 2023. Clinical laboratories and pathology practices need long-term comfort that their test payment rates will not be subjected to stiff reductions. That's a New Year's resolution all laboratory leaders should collectively strive to achieve. TDR

Eight Macro Trends for Clinical Labs in 2023

Explore important themes for medical laboratories, anatomic pathology, and genetic testing services

CEO SUMMARY: Laboratory administrators and pathologists will want to carefully study eight important trends that will guide their business strategies in 2023. Many of these macro trends center on financial and operational difficulties and ways to steer around these obstacles. Another broad theme is how established technology is poised in the new year to tackle chronic problems with staffing shortages while also improving the time and efficiency to reach patient diagnoses.

It was 13 years ago when **The Dark Report** last detailed a list of upcoming important macro trends for clinical laboratories and anatomic pathology groups.

While some themes have continued to percolate from 2010 into 2023 (e.g., the need to capitalize on automation, albeit today there is more urgency to do so), newer trends have also emerged (e.g., finding innovative ways to recruit pathologists when current demand exceeds those seeking positions.)

The Dark Report's 2023 review of major trends and developments in the marketplace is useful as a strategic planning tool for laboratory executives and pathologists. It provides context for interpreting current developments and describes how the clinical lab testing marketplace may evolve in the immediate future.

Meanwhile, *in vitro* diagnostics (IVD) manufacturers and laboratory informatics vendors can also study these trends to better position their products and services to meet the needs of lab and pathology customers.

Our 2023 macro trends for clinical laboratories broadly split into two main categories: operations and technology. We offer a synopsis below, while full details appear on pages 5-12 of this issue.

Several of the eight lab macro trends for 2023 are directly or indirectly associated with the eroding finances at many hospitals and health systems. As we reported throughout 2022, some health systems lost hundreds of millions of dollars every quarter during the year.

The anticipated expiration of the federal government's public health emergency for the COVID-19 pandemic will

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likely further increase financial tensions, forcing health system executives to explore other ways to make up budget gaps.

The industry-wide lack of pathologists and lab bench staff will add to both financial concerns and workload volumes heading into the new year. Forward-thinking lab leaders will need to identify and deploy new solutions that favor process changes over simply searching for hard-to-find talent. Further, reimbursement difficulties for genetic testing, including an uptick in prior authorization requests from payers, will strain timely payments to labs.

Market forces will make technology choices—some of which have been around for more than a decade—more attractive and viable in 2023. For example, automation has long been recognized as a way to improve operational efficiency in clinical labs and pathology groups. Thus, the need to address chronic staffing shortages in the new year will be bring added motivation to adopt automation.

Similarly, digital pathology systems will garner greater attention as their benefits become more evident in the post-pandemic working environment. The fact that new Class III Current Procedural Terminology (CPT) codes for digital pathology activities took effect on Jan. 1 will encourage adoption of digital pathology solutions. Pathologists using these CPT codes have an opportunity in 2023 to demonstrate with this data how digital pathology aids in improving diagnoses.

Watch for upcoming federal action on updated provisions for next-generation sequencing technology as well.

Now that 2023 has arrived, your team at THE DARK REPORT hopes that these eight macro trends for clinical laboratories will be useful in helping you shape your clinical, business, and financial strategies in a sustainable manner. **TDR**

Looking Back at 2010's Trends in Clinical Lab Market Reveals How Priorities Have Changed in Past Decade

IT WAS **2010** WHEN WE LAST PRESENTED OUR LIST OF clinical laboratory macro trends. Here are highlights from back then.

- **Quality Management Systems**. In the late 2000s, the first clinical labs began using ISO 15189: Medical Laboratories to guide their quality management approach. ISO 15189 has gained popularity with innovative labs since then.
- **Workflow as a Management Driver**. Redesigning diagnostic work processes has become a hallmark of more efficient labs in recent years. Automation and artificial intelligence helped reveal the value of streamlined workflows.
- **Automated Instruments Improve Turnaround Time**. As evidenced in our 2023 list, automation continues to be key to efficient clinical lab management. Improved worker productivity amid staffing shortages joined established benefits, such as increased quality.
- **Lab Outreach Earns New Respect**. In 2010, hospital CEOs began to note that laboratory outreach was a service-rich offering. Ironically, today national commercial labs are paying to acquire lab outreach programs from cash-strapped hospitals and health systems.
- **Cloud Computing Gains Wider Acceptance**. This trend has enveloped society, not just healthcare. Any lab manager or patient using an app to deliver or access services is intertwined with modern cloud computing.
- **Molecular Tests Show More Value**. Back in 2010, the promise of molecular and genetic testing was evident, but cost was a concern. Prices have dropped to an extent, but the public demand for genetic tests has only been matched by the sheer volume of options available. Payers are now more forcefully pushing providers to justify these tests.

2023 Key Lab Macro Trend 1

Labs Will Need to Re-evaluate Solutions to Staffing Shortages

PROBABLY THE SINGLE MOST OBVIOUS TREND FOR 2023 is the acute shortage of medical technologists/clinical laboratory scientists (MTs/CLSs), as well as with all the other skilled positions needed by labs. The new year opened with most labs reporting great difficulty in maintaining staffing at anything close to 100% of authorized levels.

Clinical laboratory staffing levels were already tight before the COVID-19 pandemic. However, stress and burnout during the height of the SARS-CoV-2 coronavirus led to an abnormal amount of healthcare workers—including medical technologists, medical laboratory scientists, and medical laboratory technicians—leaving the field as part of the Great Resignation.

Meanwhile, a general lack of interest among younger workers in laboratory science is exacerbating the staffing gap clinical labs face going into this new year.

There is no brigade of replacement workers coming—at least the kind that have traditionally filled laboratory bench jobs. So, new ways to do the work and improve productivity will become a priority for innovative lab managers.

What to Know

That means technology will get more attention. This will be particularly true in those areas of the lab which still have many manual processes, such as microbiology and histology.

Use of automated instruments enables remaining human staff to work up to their training and license levels rather than focus on routine tasks. In such cases, greater efficiency will be a new advantage coming out of the staffing crisis.

In the area of specimen collection and phlebotomy, several companies are developing technologies and new devices at blood draw sites that make it easier for less-skilled workers to collect specimens. *(See TDR, "Babson Diagnostics' Hybrid Model Combines Quality, Convenience," Nov. 21, 2022.)*

In fact, the notion of non-traditional workers stepping up to handle laboratory testing activities has caught the attention of the federal **Centers for Medicare and Medicaid Services** (CMS). In July 2022, as part of a proposed rule to amend the Clinical Laboratory Improvement Amendments of 1988, CMS sought to allow those with doctoral, master's, and bachelor's degrees in nursing to qualify as testing personnel for high and moderate complexity testing.

"We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency," CMS wrote at the time.

The **American Hospital Association** objected to the nursing language, and the **College of American Pathologists** stated that nurses should have supervision if performing these tests. A final rule from CMS has yet to be released.

Actions to Take

Lab managers should also explore Lean Six Sigma models, which seek to weed out processes that are wasteful or inefficient and potentially help existing staff better handle their volume of duties. *(See TDR, "Henry Ford Health System Laboratory Division Combines Lean with ISO 15189," Feb. 29, 2016.)*

2023 ➤ Key Lab Macro Trend 2

Multiple Factors Threaten Stability of Hospitals, Labs

HOSPITALS AND HEALTH SYSTEMS FACE ANOTHER ROUGH YEAR FINANCIALLY IN 2023. The hospital industry is besieged on multiple fronts, and this directly squeezes the budgets of hospital-based clinical laboratories.

Multi-hospital health systems bled red ink at unprecedented rates during 2022, and experts predict more financial stress for hospitals in the new year. Multiple factors are to blame. These include the inability to maintain enough nurses, ongoing staffing woes, dramatic upward swings in the cost of nurses (both salaries and payment for temporary nurses), supply chain concerns, and inflation.

In December 2022, Moody's Investor Services released a report that concluded the not-for-profit healthcare (hospital) sector outlook remains negative for 2023.

"Labor shortages will remain a primary driver of elevated expenses, which will restrain growth in margins," Moody's reported. "Higher inflation, persistent COVID-19 surges, supply chain disruptions, and continued cybersecurity investments will also increase expenses."

This predicts continuing financial pressure on hospitals and hospital labs in the coming year. The magnitude of 2022 losses experienced by hospitals may be duplicated during 2023. For example, **Brigham and Women's Hospital** in Boston reported a record operating loss for fiscal year 2022 of $432 million, according to a Dec. 21 story in *The Boston Globe*.

Experts further note that the public health emergency (PHE) associated with the SARS-CoV-2 pandemic is scheduled to end on Jan. 11, 2023. When the PHE expires, many patients covered by **Medicare**, **Medicaid**, or private insurance will face higher costs associated with COVID-19 treatment, including some diagnostic laboratory tests. If patients are unable to pay these costs, hospitals will absorb the resulting loss of revenue.

More significantly, as part of the PHE, hospitals have received a 20% payment increase for discharges of Medicare patients diagnosed with COVID-19, according to the **Kaiser Family Foundation**. That increase will end when the PHE expires.

➤ Actions to Take

As financial pressures mount on hospitals and health systems, laboratory leaders will want to be alert to any signs that their hospital leadership is entertaining proposals by commercial lab companies to buy their hospital's lab outreach services. THE DARK REPORT noted several such major lab outreach acquisitions in 2022. *(See TDR, "Public Laboratory Companies Eye More Lab Outreach Acquisitions," Aug. 29, 2022.)*

Efforts by lab administrators and pathologists to present lab outreach as a healthy revenue stream may keep those services in-house. There are steps labs can take to make outreach more consumer focused. *(See "Consumers Shape Modern Lab Outreach" on pages 13-15 for further information.)*

Innovative labs within health systems may want to work with other departments, such as care quality or business analytics, to tackle areas that have drained budgets. A collaborative effort may uncover savings that will present the lab as a driving force behind high-value changes. *(See TDR, "Lab's Anemia Program Brings in New Revenue," June 27, 2022.)*

2023 Key Lab Macro Trend 3

Digital Pathology Expected to Experience Wider Adoption

Entering 2023, advocates of digital pathology are optimistic that this is the year adoption of whole-slide images and digital pathology systems accelerates.

One factor generating excitement is the issuance of new Class III Current Procedural Terminology (CPT) codes covering the process of converting glass slides into whole-slide images. These CPT codes became effective on Jan. 1, 2023.

Another factor that is seen as encouraging adoption of digital pathology is the soaring demand for pathologists that outstrips supply. This will motivate anatomic pathology groups to look for ways to improve the productivity of their staff pathologists. Adoption of a digital pathology system is associated with improving the productivity of a group's pathologists.

By transitioning glass slides of specimens to whole-slide images, laboratories and pathology practices gain efficiencies in the following areas:

- Speed of diagnoses.
- Capability to assign cases to pathologists with available time for more work.
- Reduced physical storage space for slides.
- Potential for artificial intelligence to aid in evaluation of cases.
- Ability to review slides from any computer in the world.

The onset of the pandemic in March 2020 is also a major factor in the growing interest by pathology groups in "going digital." During the lockdown, many pathologists—working remotely from home—got comfortable with using digital pathology images. However, much like EHRs initially, digital pathology has been dogged by its hefty price tag and an uncertain return on investment (ROI).

It is hoped that the new CPT codes for digitizing pathology images from glass slides will help improve the ROI for digital pathology systems. Note that these CPT codes are not yet reimbursable—as Category III codes are a set of temporary codes assigned to emerging technologies, services, and procedures. These codes are intended to be used for data collection to substantiate more widespread usage or to provide documentation for the **Food and Drug Administration** (FDA) approval process.

Actions to Take

Pathology groups already using a digital pathology system should judiciously use the Category III codes to document the benefit of digital images in the diagnosis of cancer and other diseases for Medicare and private payers.

For those practices that are unsure about digital pathology technology, the new CPT codes may provide an incentive to at least begin an evaluation, because it is expected that payers will issue favorable coverage and reimbursement guidelines in coming years. As that happens, pathology groups would be able to file claims for the step of converting a glass slide into a whole-slide image. That would be a new stream of revenue that pathology groups could use to amortize the costs of their conversion to a fully-digital workflow.

All pathologists and their practice administrators should factor these developments into their group's strategic planning. Digital pathology is the future of the profession.

2023 ➤ Key Lab Macro Trend 4

Demand for Pathologists Exceeds Available Supply

DEMAND FOR ANATOMIC PATHOLOGISTS WILL CONTINUE TO OUTSTRIP SUPPLY, challenging pathology practices that have a growing number of case referrals, but not enough physicians to perform diagnostics work.

Consider these figures for full- and part-time pathologists as posted on the job board at *PathologyOutlines.com*:

- 2022 for Q1 though Q3 had 1,200 job postings, which looks for the full year to be pulling ahead of 2021 significantly.
- 2021 had 1,359 job postings, a 78.1% increase from 2020.
- 2020 had 763 job postings, a 9.7% decrease from 2018. Note the website did not compile totals for 2019.
- 2018 had 845 job postings, a 28% increase from 2017.

In reviewing the above statistics, it is conceivable that when *PathologyOutlines.com* releases its final 2022 figures, the amount of open pathologist jobs in the U.S. will have doubled within five years. The anatomic pathology industry is falling short of training enough pathologist to meet current demand and there are no signs that this will improve in 2023.

➤What to Know

It is widely acknowledged that the ongoing retirement of Baby Boomer pathologists is a factor in the marketplace supply/demand equation. Not only does the retirement of these pathologists reduce the supply of pathologists available to fill open positions, but these retirements are causing a shrinkage in the number of independent private practices.

In pathology groups of three to six physicians, the retirement of one or two of these pathologists—and the inability of the remaining partners to recruit replacements—often means that this independent private practice agrees to merge or sell itself to a larger regional pathology group.

This pattern of mergers and acquisitions involving pathology groups has been happening for years. A quick **Google** search shows an active year in 2022 for pathology practice consolidation.

➤Actions to Take

During 2023, acquisition-minded pathology practices should have a favorable market in which to seek out new opportunities. Big pathology groups are likely to become bigger over the course of the year.

Meanwhile, any pathology group being squeezed by the lack of available talent will need to assess their recruitment options to offer a combination of salary and benefits that attract all candidates, with the addition of work/life balance and perhaps even social causes that can attract younger pathologists who are Millennials or older Generation Z members.

Additionally, technologies such as digital pathology and artificial intelligence may gain a greater foothold in 2023 if they can ease logjams with case reviews.

For example, if digital pathology adoption increases in the new year, it may enable pathologists to remotely view cases from regions with limited access to these professionals. *(See Trend #3 on page 7 for more details.)*

It should be expected that the current imbalance in supply-versus-demand for pathologists will be a powerful force in reshaping what has been a quiet profession.

2023 Key Lab Macro Trend 5

Expect Greater Payer Scrutiny of Genetic Test Reimbursement

With an estimated 175,000 genetic tests on the market—and that number will rise by the thousands this year—the scrutiny of genetic test reimbursement from **Medicare** and private payers will increase for genetic testing companies and labs.

Payers are not equipped to deal with a deluge of claims for 175,000 different types of genetic tests—many of which lack comprehensive documentation of their accuracy and how the test results guide physicians to improve patient care.

Medicare reimburses genetic test claims for diagnostic purposes only in limited situations, such as when a physician orders the test to treat a patient's specific condition. Medicare does not cover genetic testing done for predictive purposes. Likewise, private payers have set up limits on when they will reimburse for genetic tests.

Meanwhile, it is widely acknowledged that precision medicine and value-based care is the future of healthcare. Molecular and genetic tests are the backbone of precision/personalized clinical services. Such tests can provide early clues about potential hereditary illnesses and what treatments work best based on a patient's genetic makeup.

Genetic testing companies will need to tread carefully with reimbursement claims throughout 2023 given the heightened interest from federal auditors.

What to Know

The groundwork for this scrutiny was laid by the government in a December 2021 report from the **Office of Inspector General** (OIG) at the federal **Department of Health and Human Services**. That document chronicled the rise in referrals and payments for genetic tests from 2016 through 2019. During that four-year period, Medicare payments for genetic tests quadrupled, to $1.4 billion in 2019.

What followed in 2022 were payer audits and at least 13 indictments on genetic test and related telemedicine fraud in the amount of half a billion dollars. Some of the cases alleged that defendants ordered medically-unnecessary genetic cardiovascular lab tests for patients via suspicious telemedicine consults. *(See TDR, "Feds Target Genetic Test and Telemedicine Fraud," Sept. 19, 2022.)*

Some of these cases will go to trial in 2023 pending any attempts to negotiate settlements. The sheer amount of money allegedly involved will make headlines and further embolden prosecutors.

Meanwhile, a 2019 case concluded recently with a jury conviction against Minal Patel, 44, owner of **LabSolutions** in Atlanta, for submitting $463 million in fraudulent lab test claims. Patel conspired with patient marketing firms, telemedicine companies, and call centers to target Medicare beneficiaries with telemarketing calls falsely stating that Medicare covered genetic tests for cancer. Patel is scheduled to be sentenced on March 7 and faces up to 20 years in prison.

Actions to Take

Genetic testing lab companies may want to review seven characteristics of potential telemedicine pitfalls as outlined in OIG Special Fraud Alert, "OIG Alerts Practitioners to Exercise Caution when Entering into Arrangements with Purported Telemedicine Companies."

2023 ➤ Key Lab Macro Trend 6

More Prior Authorization for Molecular and Genetic Tests

Prior authorization of genetic tests is, in many ways, an attempt by health plans to lasso the fast-growing genetic test market, which offers an estimated 175,000 tests. Insurance carriers, unsure of which genetic tests are legitimate and actually solve patient care problems, want to know where their reimbursement money will go ahead of time.

Prior authorization requirements are a burden for both referring physicians and the genetic testing labs providing these services. Much paperwork and effort is required, particularly when a genetic test request is denied during prior authorization. Often the genetic test company will run the test anyway, specifically to keep the referring physician happy while the denial of that claim is appealed.

➤What to Know

Tufts Health Plan, based in Canton, Massachusetts, perhaps offered a preview of what the genetic testing industry will face this year. As of Oct. 1, 2022, the company now requires members of Tufts Public Health Plans to receive prior authorization for genetic tests in 11 broad areas, including whole genome sequencing, prenatal testing, and tumor markers.

AIM Specialty Health, a third-party health benefits management company in Chicago, administers the prior authorization program on behalf of Tufts.

Meanwhile, earlier in 2022, **Optum**, owned by **UnitedHealth Group**, launched a widely available laboratory benefit management solution designed to help health insurers improve utilization of genetic tests. *(See TDR, "UnitedHealth's Optum to Offer Lab Test Management," June 27, 2022.)*

Prior authorization requirements appeal to health plans because there are administrative costs of $125 for every genetic test claim, as reported previously by **Concert Genetics** in Nashville, Tennessee. Multiply that dollar figure by tens of thousands of genetic test claims, and it is easy to see the financial benefit for payers to manage those claims more tightly.

➤Actions to Take

Genetic test laboratories should look at prior authorization requests as a chance to bolster their argument in favor of the test order, said Kelly Athman, Senior Director of Medical Affairs at **InformedDNA**, a genomics services company in St. Petersburg, Florida.

"In general, I would say prior authorization offers providers an opportunity to submit information about the test that's being requested, such as the test name, the performing laboratory, the billing codes, their procedure codes for the test, and also some medical information about how that test will help someone change their care plan or impact their care plan," Athman told *AIS Health* on Sept 15.

"So, that could be in the form of medical records for some laboratories that have [performed the test] to show the need for this genetic testing, or even a letter of medical necessity," she added. "Some providers choose to write that very specifically to a health plan."

Prior authorization is an uphill climb. When labs submit pre-authorization requests for genetic testing, 40% to 50% of those requests are denied. *(See TDR, "How to Achieve Success with Genetic Test Prior Authorization," July 26, 2021.)*

2023 Key Lab Macro Trend 7

Wider Adoption of Automation in Labs, Microbiology, Histology

Interest in further automation across the span of lab workflows and processes is on the increase, not the least because many clinical laboratories are unable to hire enough medical technologists and skilled laboratory scientists to handle their current volume of testing.

This will be particularly true for automating workflows in microbiology and histology. These are two areas where manual work processes are still common in most labs. By contrast, the majority of high volume core laboratory tests involving chemistry, immunoassay, and hematology are extensively automated.

In microbiology, automation is making steady progress, often centered around solutions provided by **bioMérieux**, **Becton Dickinson**, and **Copan Diagnostics**, for example. Histology has been slower to automate, primarily because of the wide range of specimen types and the number of stains that are handled by a busy histology laboratory.

Two urgent factors stand behind the motivation to increase adoption of automation: keeping up with more technology-savvy pathology practices and finding new ways to close the workflow gap created by the difficulty in hiring experienced histology technologists. *(See Trend #1 on page 5 for more details.)*

The obvious targets for automation in histology labs are these manual work processes:

- Slide preparation for embedment in paraffin and cutting.
- Slide staining.
- Slide labeling.

In addition to improving the productivity of labor, automation can also reduce the variation in how each specimen is processed. That can improve turnaround time and may increase the accuracy of diagnoses. Automation can also integrate with laboratory information system workflows, improving process efficiency.

What to Know

As with many examples of healthcare automation, use of automated solutions in core lab, microbiology, and histology has wider implications in terms of artificial intelligence and deep learning algorithms, particularly for anatomic pathology. Deep learning is a form of AI that simulates human learning.

Through automated processes, tissue specimens can be prepped quicker thanks to the elimination of manual steps, which then allows AI to analyze more diagnostic data. Digital pathology can also serve efforts to automate recognition of infected tissue.

Actions to Take

Clinical laboratories and pathology practices facing competitive pressures, or which lack success in recruitment efforts, should step back and consider whether it is time to instead deploy technology such as automation.

A multidisciplinary team, including bench staff, pathologists, billing, quality of care, and IT, should evaluate available automation tools and analyze whether implementation costs would outweigh recruitment and competition risks.

For pathology groups that are part of a hospital or health system, presenting a cost analysis of an automation system installation to administration and procurement teams will also be necessary.

2023 ➤ Key Lab Macro Trend 8

Next-Generation Sequencing May Be Part of CLIA Updates

Long-overdue revisions to the Clinical Laboratory Improvements Amendments of 1988 (CLIA) will be evaluated and possibly implemented during 2023. Some of the potential significant changes involve next-generation sequencing (NGS).

The federal **Clinical Laboratory Improvement Advisory Committee** (CLIAC)—which includes representatives from clinical laboratories, healthcare, and consumers—has an important role going into the new year. The CLIAC Regulatory Assessment Work Group is examining three reports that were presented to the full committee in 2019, one of which focused on NGS. Those reports generally suggest that CLIA should be modified to better reflect modern biomarkers, new informative capabilities, and genomic technologies, including next-generation gene sequencing (NGS).

➤What to Know

Reynolds Salerno, PhD, Director of the Division of Laboratory Systems (DLS) at the federal **Centers for Disease Control and Prevention** (CDC), outlined some of the changes in an exclusive interview with The Dark Report.

"In my opinion, this is the most assertive CLIAC has been in convening work groups and assigning them mandates regarding the need for revision of the CLIA regulations," including for NGS, Salerno noted. "I anticipate that CLIAC will begin to pressure the federal government to make more substantive changes to the CLIA regulations." *(See TDR, "Newsmaker Interview: Director of CDC's Division of Laboratory Systems Talks COVID-19, CLIA, and More," Oct. 31, 2022.)*

Among the eight NGS-themed recommendations presented in 2019 were the following:

- The federal **Department of Health and Human Services** should update CLIA responsibilities of bioinformaticists; establish more appropriate quality control measures for NGS; and determine delivery of NGS data to patients.
- Federal health agencies should encourage professional societies to develop or update NGS guidelines for areas such as revalidation of analytical targets, data retention, and data sharing.
- The CDC should survey clinical laboratories and other organizations that perform NGS to collect data on bioinformaticists, including training requirements, salaries, and job turnover.

➤Actions to Take

The focus on bioinformaticists is an interesting aspect for lab leaders to pay attention to in upcoming NGS discussions. If that job role is added to CLIA language, it raises the profile of that position considerably.

"Bioinformatics expertise has minimal overlap with the expertise of a pathologist, laboratorian, or geneticist related to NGS technology," the **College of American Pathologists** stated in prior comments to CLIAC. "Therefore, a category of bioinformatics should be added to CLIA for the personnel performing bioinformatics or pathology/laboratory informatics activities."

The CLIAC meeting to discuss NGS will take place on April 12-13, according to Salerno. Interested clinical laboratory leaders can join the meeting via phone or Zoom. *(Go to www.cdc.gov/cliac/upcoming-meeting.html for further details.)*

How Consumers Shape Modern Lab Outreach

Hospital labs must consider generational preferences when offering outreach services

Jane Hermansen

CEO SUMMARY: Each of the different generations engaging with clinical laboratory outreach programs bring their own set of expectations to a blood draw. Innovative hospital lab outreach programs should serve these differences by offering multiple options to provide appointment convenience, testing price transparency, and encouraging customer feedback.

Catering to the current demands of healthcare consumers, especially those in younger generations, may spell the difference between a hospital or health system's successful clinical laboratory outreach program and a faltering one.

This theme repeats itself throughout the medical industry. By paying attention to how and where different patients want to access their laboratory services—whether it be at a traditional draw station, local retail pharmacy, or at home with the assistance of telehealth—forward-looking lab outreach managers can stay ahead of competitors in the community.

"Community outreach is a tremendously strong activity for any hospital laboratory," stated Jane Hermansen, MBA, Manager of Outreach and Network Development at **Mayo Clinic Laboratories** in Rochester, Minnesota. "Lab managers should think about their patient populations and direct their laboratory services accordingly."

Hermansen spoke during the 2022 *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*. Her session was titled, "Achieving the Patient/Consumer Centric Laboratory Outreach Service: Trends and Access Points, Ensuring Easy Access and Scoring Patient Satisfaction."

Anyone who went to school after the internet became available likely has different healthcare habits than their parents or grandparents. *(See TDR, "New Players May Alter Who Buys and Who Orders Lab Tests," June 14, 2021.)*

Preferences Across Ages

Hermansen, however, noted that generations do consistently agree on the following broad factors when seeking services from clinical laboratories, as follows:

- Brand reputation and loyalty.
- Insurance coverage.
- Costs.
- Lab wait times.

"Brand loyalty is a commitment between a customer and a brand that causes the customer to make repeat purchases," she said. "Clinical laboratories should consider their own brand and how they are perceived in the community."

An organization's website can be a beneficial tool in attracting new customers, as well as maintaining the loyalty of existing customers.

"It's important for labs to have a strong online presence and this isn't only for the young kids who always have computers in their hands," Hermansen stated. "It's also for older generations who are looking for a good service provider. They search online for information as well. Having good, accurate information is key to helping people understand what services are available from that healthcare organization.

"Clinical laboratories can use websites to provide content that helps customers know how the lab can be accessed, whether the customer is a physician or a patient," she added.

"An accurate search function on a laboratory webpage or a side-column directory of services are helpful tools for directing patients to content they need," she said. "Clearly noting lab locations and hours is also effective."

Scrutinize Lab Wait Times

Wait times are critical components of customer satisfaction. Hermansen acknowledged that some in the clinical laboratory industry believe it is acceptable for patients to wait 15 to 20 minutes to have their blood drawn. She instead champions a shorter window of five minutes.

"I want to park my car, get poked, and get out. It's a five-minute park and poke. Make that your slogan," Hermansen joked. "It comes down to helping patients manage their expectations and giving them more control over their experience."

Consumers are also increasingly price-sensitive when it comes to utilizing lab testing services. They consider cost and insurance coverage when selecting a lab.

In her presentation at the *Executive War College*, Hermansen referred to **Kaiser Family Foundation** survey results from 2015 that indicated 75% of patients cited out-of-pocket expenses as either "extremely important" or "very important" in weighing health plan options.

Reporting on survey data from **TransUnion Healthcare** (now owned by **FinThrive**), *PatientEngagementHIT* further noted in 2019 that 75% of patients were researching the cost of healthcare services online. The survey showed smart patients will balance out-of-pocket expenses with quality-of-care metrics to determine whom they seek out for services.

"It is important for laboratories to ensure that fees are accessible for customers so they know what they are going to pay," Hermansen said. "Prices don't need to be rock bottom, but they need to be viewed as competitive."

An online patient cost-estimator tool is a good feature to help consumers track their potential laboratory-related costs. And some lab service preferences skew by generation, she observed.

"For example, laboratory locations and hours of operation are Generations X, Y, and Z," Hermansen noted. "Gen X consumers may be trying to care not only for themselves, but also for young children and aging parents."

Appointment Scheduling

She suggested that labs provide various ways for patients to schedule appointments, such as online, via phone calls, or with a QR code they can scan with their phones to make an appointment. She advised laboratories to also offer walk-in appointments for patient convenience.

Additionally, some patients want blood-draw options available at their homes or workplaces. *(See TDR, "Telemedicine Firms Offer Home Phlebotomy Service," Sept. 19, 2022.)* "Lab managers should consider ways to change policies and procedures that make them more patient focused," Hermansen said.

Telehealth options are also becoming increasingly important to certain customers, particularly younger individuals. "Laboratories must connect their capabilities to telemedicine and telehealth initiatives because those options are not going away," Hermansen stated. "Younger gen-

erations are going to continue to want on-demand services. They want healthcare access on their terms."

Conversely, patient satisfaction scores and overall quality of care rank higher to older generations. For example, Baby Boomers will seek out opinions of other customers of a facility when selecting where to obtain medical testing and treatments, according to revenue cycle management firm **Etactics**.

Patient Acquisition Costs

Laboratory outreach managers should remain alert to how quickly a poor experience can sour a patient's view of a clinical laboratory. Looking at unsatisfied customers in terms of patient acquisition costs can be useful.

Say, for example, an organization spends $100 per patient in acquisition costs, which includes advertising, marketing, and sales expenses. If things go poorly for a newly-acquired patient during a lab visit, the money spent to bring in that person could be wasted, and his or her lifetime value as a customer drops.

"It takes about 10 seconds to annoy and lose a customer, and 10 years for bad word of mouth to go away," Hermanson explained. "We have to understand that it's not only formal patient satisfaction surveys that are important, but informal patient feedback as well."

With social media apps such as **Facebook** or **Snapchat**, users can spread a good or bad message about a lab's service within hours or even minutes. To offset this possibility, Hermansen suggests laboratories use simple, quick surveys to obtain meaningful feedback from customers. The surveys should be available in a variety of formats—such as hardcopy, online, text, or at a kiosk in the lab or hospital—to encourage participation from all age groups.

"Parents who experience good outcomes with their children at hospitals can become patients for life," Hermansen said. "Strong loyalty to a healthcare organization—resulting from good patient experiences—can make or break the process, especially in markets where consumers have multiple choices among providers. It makes a big difference."

Multiple Generations Engaging in Healthcare

CONSUMER PREFERENCES INFLUENCE HEALTHCARE and clinical laboratories must consider generational differences when interacting with various patient populations.

Five primary groups of patients are recognized by generational categories:

- **Silent Generation or Traditionalists**—born before 1946.
- **Baby Boomers**—born from 1946 to 1964.
- **Generation X**—born from 1965 to 1980.
- **Generation Y or Millennials**—born from 1981 to 1996.
- **Generation Z**—born from 1997 to 2012.

The youngest patients, who are not yet buying healthcare services on their own, comprise **Generation Alpha**, whose members were born after 2012.

Three Takeaways

Hermansen suggests that clinical laboratory outreach managers develop a consumer-centric program centered on these major efforts:

- Maintaining multiple ways to communicate and engage with all the different generations.
- Establishing clear, accurate pricing for lab services across all age groups.
- Meeting customers when, where, and how they need laboratory services.

"Clinical quality differentiates a lab from the competition as well," Hermansen concluded. "Clinical quality leads the way to building patient loyalty." TDR

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Regulatory Update

Congress Averts PAMA Cuts to Lab Test Rates for 2023

Move offers only a temporary halt to PAMA cuts to Medicare fees without more solid legislative action

CONGRESS ENACTED LEGISLATION LAST MONTH that suspends implementation of the next round of price cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) that was scheduled to take effect on Jan. 1. This is a welcome development for the medical laboratory industry.

A two-paragraph inclusion in a 4,000-page, year-end government spending bill instructs federal health officials to suspend payment cuts called for under the Protecting Access to Medicare Act (PAMA). President Biden signed the spending bill into law on December 29 after the **House of Representatives** and the **Senate** passed it the week before.

However, much like a similar effort at the end of 2021, the reprieve is only temporary and falls short of PAMA-related reform that many in the clinical laboratory industry have called for. More action will be needed on Capitol Hill in 2023 to avert additional PAMA cuts in coming years.

Details of Reprieve

Under the spending bill provision, there will be no reductions in Medicare payments for diagnostic tests through 2023. Had this provision not gone into effect, laboratories faced a 15% cut in payments for approximately 800 clinical lab tests for 2023 as called for in PAMA. However, without additional legislative action the rate cuts will resume on Jan. 1, 2024.

Additionally, the bill also suspended PAMA-related reporting requirements for labs in 2023 for one year. Per the PAMA statute, in 2023, the **Centers for Medicare and Medicaid Services** (CMS) was to have labs report the prices for tests that were paid by private health plans. CMS would then use that private payer price data to set prices for the CLFS.

That data previously resulted in Medicare paying labs 10% less for tests in each of the years 2018, 2019, and 2020. Some aspects of the data collection resulted in a lawsuit by the **American Clinical Laboratory Association** (ACLA). *(See TDR, "On Appeal, ACLA Gains PAMA Victory in Court," Aug. 29, 2022.)*

Congress delayed scheduled PAMA cuts in 2021 and 2022 due to a combination of the pandemic and the resulting raised awareness about the role clinical laboratories played in combatting SARS-CoV-2.

SALSA Effort Sidelined

In 2022, a bipartisan group of lawmakers worked with the laboratory industry to craft a proposed bill called Saving Access to Laboratory Services Act (SALSA). The bill aimed to overhaul how PAMA dealt with lab test payments and data reporting. *(See TDR, "PAMA Cuts Might be Reduced to Zero for 2023," Aug. 8, 2022.)*

Efforts to include SALSA in the recent year-end spending bill were unsuccessful, possibly due to finances. The **Congressional Budget Office** estimated SALSA would have cost $6 billion over 10 years, while a one-year delay to PAMA cuts would instead save $730 million over 10 years in reduced test payments, according to a *360Dx* report on Dec. 21. TDR

IVD Update

Siemens Healthineers Plans to Streamline Product Offerings

Company will sunset legacy systems as part of effort to cut $314 million in costs by 2025

During a 15-month stretch from 2006-2007, **Siemens Healthineers** spent $14 billion to acquire three competing companies and their various technologies.

Today, Siemens is preparing to sunset as many as half of its legacy instruments and assays, which is likely the endgame of its purchasing spree long ago. As a result, clinical laboratory and pathologist customers of Siemens Healthineers' *in vitro* diagnostics (IVD) services can expect a more integrated product suite centering on the company's Atellica brand.

The move was announced during the company's Q4 earnings call in November. Information provided by Siemens indicated that while diagnostics sales revenue had increased in 2022 over 2021, COVID-19 test revenues overcompensated for higher logistics and supply chain costs.

These and other factors provided the impetus for pulling the trigger on the company's decision to sunset a number of lab analyzers and related products. It is part of a plan to cut €300 million (US $314 million) in costs by 2025.

However, it was also clear that Siemens' sunsetting activities had been in consideration for some time. "Growing Atellica will help us improve our competitiveness in the market," Kimberly Nissen, PR Manager at Siemens, told The Dark Report. "Given the considerable headwinds that are impacting our business and industry—including logistical constraints, component shortages, lockdowns, and global inflation—the timing is right to move forward with our transformation."

Siemens Healthineers is optimistic about the future sales potential of Atellica analyzers. A delay in the launch of the company's Atellica CI 1900 system during the pandemic put expected revenues from that product on hold. CI 1900, which will automate sample preparation and workflows in lower-to-mid-volume laboratories, is expected to be available in 2023.

"We will undertake significant measures to reduce [product] complexity by reducing the number of our platforms by more than 50% over time following the CI 1900 platform launch," CEO Bernd Montag noted during the earnings call. "Our portfolio complexity has been a particular burden in the current challenging … supply chain environment."

Shuttering Legacy Products

Nissen said that streamlining the company's product suite would make for a stronger offering by Siemens Healthineers. "Some of our legacy platforms are the result of several acquisitions and have been on the market since as early as 1989," she noted. "Unifying our portfolio under the Atellica family is a necessary step to strengthen our product offerings."

Nissen did not provide more details about what specific products would be discontinued.

Starting in 2006, Siemens Healthineers—then known as **Siemens AG**—spent billions to acquire three com-

panies' instruments and assays. Those acquisitions included:

- **Diagnostics Products Corporation** for $1.86 billion in 2006.
- **Bayer Diagnostics** for $5.21 billion in 2006.
- **Dade Behring** for $7 billion in 2007.

THE DARK REPORT noted in 2007 that the Dade Behring acquisition would likely increase the consolidation of the IVD market, which did happen and, in fact, has continued to occur through 2022. *(See TDR, "Siemens Acquires Dade, Builds IVD Powerhouse," Aug. 6, 2007.)*

The acquisitions also vaulted Siemens up the ranks of the top IVD companies in the world. Most recently, THE DARK REPORT ranked Siemens No. 6 on that list. *(See TDR, "2021 Rankings of the World's Top 12 IVD Companies," Aug. 29, 2022.)*

But the acquisitions of three different IVD companies also created a mishmash of different technologies under the Siemens Healthineers umbrella. It was challenging to market the different brands, and as Montag noted, supply chain problems since the pandemic have made it increasingly difficult to secure the various materials and components needed for each product suite.

➤ *Reuters*: Layoffs Possible

In addition to product sunsetting, Siemens said it will take other steps to reach $314 million in cost savings within three years.

"We will streamline our supply chain and service setup and run a leaner and more clinically focused R&D operation," Montag said during the earnings call. "Overall, we will create a much leaner organization and footprint with a significant reduction in its internal complexity in the coming years."

Reuters reported on Nov. 9 that in practical terms, those decisions will translate into less staff and buildings. "Sources from within the company said the plan involves cutting jobs and abandoning certain locations," *Reuters* wrote.

Siemens Healthineers Imaging Revenue

ASIDE FROM *IN VITRO* DIAGNOSTICS (IVD), a large part of Siemens Healthineers revenue comes from medical imaging and radiology equipment.

It is interesting to note that imaging brings in almost double the revenue of IVD, which has been consistent for at least the last five years. Siemens earned €21.7 billion (US $22.7 billion) for fiscal year 2022, which ended on Sept. 30. Figures provided by Siemens as part of year-end reporting show this breakdown of revenues from IVD and medical imaging:

- €11 billion for imaging (US $11.5 billion).
- €6.1 billion for IVD (US $6.4 billion).

Looking at those figures as percentages, imaging makes up approximately 51% of Siemens Healthineers revenue, while IVD encompasses 28%. Back in fiscal year 2017, imaging made up 59% of revenue and IVD comprised 31%.

Siemens Healthineers also markets advanced therapies via medical devices, which is a relatively small part of its revenue. However, a big difference maker in the percentages from 2017 to 2022 was the acquisition of **Varian**, a cancer treatment software company, in 2020. In fiscal year 2022, Varian made up 14% of Siemens' earnings.

Siemens competes with **GE Healthcare** and **Phillips** in the radiology space.

Clinical laboratories currently using those legacy products that Siemens Healthineers plans to sunset may want to inquire with their Siemens sales reps about future plans for those instruments. Sunsetting often involves complex transitions to new products, or a loss of software updates and component maintenance if an organization decides to keep the legacy instrument. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

At the moment, it appears that the controversial Verifying Accurate Leading-edge IVCT Development (VALID) Act will have a hard time passing in Congress. The bill, which is intended to shift regulation of laboratory-developed tests (LDTs) to the federal **Food and Drug Administration**, fell to the wayside during year-end spending negotiations in Congress. Despite a strong push by proponents in November and December, the VALID Act was not included in the omnibus spending bill that will keep the government funded until next September.

MORE ON: *VALID Act*

Some in the industry believe the VALID Act is dead for good because of public opposition by pathologists at academic medical centers. Furthermore, one of the bill's architects, Sen. Richard Burr (R-N.C.), recently retired from Congress. However, there is no legal obstruction that would prevent lawmakers from filing the VALID Act or a similar bill in the future. There was good news for pathologists in the omnibus year-end spending bill that Congress passed. Originally, a 3.6% reduction on **Medicare** spending for pathology professional fees was scheduled to go into effect on January 1. However, language in the spending bill instead reduced that amount to about 1.1% for 2023, according to the **College of American Pathologists**.

QUEST BUYS LAB OUTREACH BUSINESS

Hospital and health system laboratory outreach programs continue to be attractive acquisition targets for national labs. In December, **Quest Diagnostics** acquired certain assets of the lab outreach business of **Northern Lights Health** based in Brewer, Maine. Quest will also provide lab management services for nine of Northern Lights' hospital laboratories, along with a cancer center lab. The deal will potentially increase competition in market territory covered by **NorDx Labs**, part of **Maine Health**. Like many hospitals that sell their outreach programs, Northern Lights may be under financial pressure. The health system closed acute rehabilitation inpatient services at one of its hospitals in December and laid off rehab staff, *WABI TV-5* reported.

TRANSITIONS

- Stan Schofield retired as of Jan. 1, 2023, as Senior Vice President Laboratory Services at **MaineHealth** and President of **NorDx Laboratories**, a division of MaineHealth. He assumed this position in 1996. He will continue as Managing Principle of **The Compass Group**.

- Rita Romano has been named CEO at the **Laboratory Alliance of Central New York**. Romano returned to the group after a stint as President of **Quadrant Laboratories** in Syracuse, N.Y. She previously served as Director of the Operations Center at the Laboratory Alliance's main lab.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 23, 2023.

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- ***Understanding the clinical lab industry landscape for 2023: Why big labs are getting bigger and consolidation continues.***

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