Volume XXXI, Number 3 Monday, February 26, 2024

Prepare for a Perfect Storm

Developments in regulatory, managed care, and compliance may wreak havoc on unprepared labs.

See pages 3-5

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

More Labs Recognize Big Changes Are Coming

ONE WAY TO DISCERN THE NEAR FUTURE FOR THE CLINICAL LABORATORY INDUSTRY is to recognize what is different today, compared to the recent past. One source of these insights here at THE DARK REPORT is the many conversations we have as we finalize selecting 140 speakers and panelists to take the podium at 88 sessions at the upcoming *Executive War College* on April 30-May 1, 2024, in New Orleans.

These conversations represent much anecdotal evidence, along with first-hand experiences and trade gossip about what is working and what is not within the clinical laboratory marketplace. All of this information informs the processed intelligence that we present in each issue. Its accuracy and relevance in helping savvy lab leaders is what has made us the premier source of news, analysis, and commentary for this industry's senior leaders, pathologists, and managers.

The first signal that things are changing across the clinical lab market is the fact that, as of today, registrations to this spring's *Executive War College* are 100% greater than last year, which had record attendance in its own right. We take that as a sign that it is not "business as usual" for labs. These registrants need to hear from the industry's innovators and network with the industry's lab management movers-and-shakers.

Another signal of marketplace change is that our peers in the publishing game—along with officers from lab associations—tell us that the big *in vitro* diagnostics (IVD) manufacturers are spending much less on marketing. This is true whether it is advertisements in trade journals and magazines, or exhibits and sponsorships at lab association meetings and conventions. That mirrors our experience with our spring meeting. As of this date, only two of the major manufacturers of core lab automation and instruments are sponsoring. For most of the 2000s and 2010s, almost all of the top 10 IVD manufacturers were major sponsors of the *Executive War College*.

A third signal of major marketplace change is trade gossip about the surprising amount of unpaid claims now plaguing genetic testing companies. For example, we are told one major health insurer has between $500 million and $1 billion in unpaid lab test claims dating back 24 months! Should this be representative of the situation with other major health insurers, it affirms why so many of the genetic testing companies are in financial trouble. TDR

Labs Should Prepare for Arrival of 'Perfect Storm'

Three significant dynamics are poised to reshape how labs comply with FDA, CLIA, and get claims paid

CEO SUMMARY: In the near future, clinical labs and pathology groups will need to address three major developments. One involves the FDA proposed LDT rule. A second is the adoption by payers of guidelines that require genetic test claims to have Z-Codes. The third centers around coming reforms and updates to the 1992 CLIA rules. Here is a look at what labs can expect.

THERE IS A PERFECT STORM HEADING TOWARD THE CLINICAL LABORATORY INDUSTRY. It can be described as a trifecta of regulatory, managed care, and compliance developments.

This perfect storm has the potential to wreak financial havoc on those labs that fail to anticipate and prepare for the changes to come in the next 12 to 36 months.

Importantly, this perfect storm—as a result of three disruptive forces in how labs will conduct business—is not yet on the radar screen of most lab administrators, executives, and pathologists.

In this Trifecta, the first horse out of the gate will be the federal **Food and Drug Administration's** (FDA) proposed laboratory-developed tests (LDT) rule. Observers believe the agency will issue a final rule as early as April.

The second horse in this Trifecta is private payer adoption of requirements for genetic testing companies to use Z-Codes with genetic test claims. **UnitedHealthcare** (UHC) was first to issue such a policy last year, although it has delayed implementation several times. Other major payers are watching to see if UHC succeeds with this requirement.

Rounding out the Trifecta—and the compliance initiative that is probably least known by lab managers—is an initiative underway to reform and update the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This work is being done by the Clinical Laboratory Improvement Advisory Committee (CLIAC). It is overseen by the Division of Laboratory Services at the federal **Centers for Disease Control and Prevention** (CDC).

What makes this a perfect storm is that each of these three developments will impact a substantial number of clinical laboratories and anatomic pathology

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).

groups in the United States. For that reason, key influencers in each of these regulatory, compliance, and managed care coverage areas will be keynote speakers at the 29th annual *Executive War College on Diagnostic, Laboratory, and Pathology Management*, when it convenes on April 30-May 1, 2024, at the Hyatt Regency Hotel in New Orleans.

Perfect Storm Element 1

FDA's DRAFT LDT Rule

FDA's LDT rule is currently the headline story in the lab industry. Speaking about this development and two other FDA initiatives involving diagnostics will be pathologist Tim Stenzel, MD, PhD, former Director of the FDA's Office of In Vitro Diagnostics and Radiological Health. He will also discuss harmonization of ISO 13485–Medical Devices and the FDA's recent memo on reclassifying most high-risk *in vitro* diagnostics to moderate-risk as a way to ease the regulatory burden on companies seeking agency review of their diagnostic assays.

Perfect Storm Element 2

CLIA Reforms and Updates

On the second development—increased use by private payers of Z-Codes for genetic test claims—the speaker will be pathologist Gabriel Bien-Willner, MD, PhD. He is the Medical Director of the MolDX program at **Palmetto GBA**, a Medicare Administrative Contractor (MAC). It is the MolDX program that oversees the issuance of Z-Codes for molecular and diagnostic tests.

Perfect Storm Element 3

Use of Z-Codes for Test Claims

The third element of the Trifecta is coming reforms and updates to the CLIA regulations. Speaking to this will be Reynolds Salerno, PhD, Acting Director, Center for Laboratory Systems and Response at the CDC. He will also cover the CDC's efforts to foster closer connections with clinical labs and their local public health laboratories, as well as the expanding menu of services for labs that his department now offers.

One significant change to the CLIA rules that will greatly affect clinical labs doing genetic sequencing is proposed language that would define data as a sample and therefore subject to CLIA requirements. If this proposal makes it into the final updated CLIA rule, it would directly affect the "wet labs" that produce raw DNA sequences and the "dry labs/virtual CLIA labs" that receive the raw DNA sequences and do the analysis, interpretation, and diagnosis of the data—which is returned to the original lab for reporting to the ordering physician.

➤ Unprecedented Market Impact

In its 29 years of publication, THE DARK REPORT has never seen three different market disrupters emerge almost simultaneously—each with the potential to dramatically change or disrupt a large proportion of clinical laboratories and pathology groups.

The proposed FDA LDT rule meets that description, as does the adoption by payers of a requirement that certain genetic test claims include appropriate Z-Codes. Of course, significant changes to current CLIA requirements would require compliance by 100% of the nation's CLIA-certified laboratories.

What will be equally unprecedented for the clinical laboratory profession is the appearance of three major lab regulatory bodies on a lab industry stage at one time. Not only will these three speakers address their primary topics, but attendees will hear how these three agencies interact with one another. That includes where each defines their authority over laboratories and the boundaries they recognize between their statutory authorizations.

"Every laboratory in the United States should recognize these three powerful developments are all in play at the same time and each will have direct impact on

the clinical and financial performance of our nation's labs," observed Robert L. Michel, Founder and Director of the *Executive War College*. "For that reason, every lab should have one or more of their leadership present to understand the implications of these developments.

Meet the Experts in Person

"Of equal importance, attendees will have the opportunity to personally meet and interact with these expert speakers," he continued. "Knowledge gained during these two days will give those lab leaders a head start in preparing strategies, particularly the strategies needed to prepare for the negative consequences from these developments."

Further, this perfect storm of regulatory, managed care, and compliance developments comes on the heels of the major disruptions caused by the SARS-CoV-2 pandemic. Both clinical labs and *in vitro* diagnostics (IVD) companies continue to deal with the lingering consequences of rising costs, burned-out lab staffs, and the challenges in getting reimbursed for genetic tests.

Woes for Genetic Test Firms

"It should also be recognized that the collective clinical laboratory and diagnostics industry is in dire financial shape," Michel noted. "For example, **Invitae**, a major genetic testing company, recently filed for bankruptcy." *(See story on page 9.)*

"Five or six other large genetic testing companies have posted substantial multi-year losses because of the difficulty in getting their test claims paid," he added. "Financial analysts expect some of these genetic testing firms will either file bankruptcy or be acquired. These analysts also believe that the FDA's proposed LDT rule is likely to compound the financial woes of these same firms."

Similar to genetic testing companies, lab suppliers are dealing with their own challenges. A number of consultants and lab association officers tell THE DARK REPORT that most of the major IVD manufacturers have reduced their marketing and sales budgets. In some cases for certain lab industry meetings, they are either not exhibiting or are substantially reducing their financial support.

Artificial Intelligence: Another Lab Disrupter

SAVVY LAB LEADERS ALREADY RECOGNIZE that the next big thing in healthcare and medicine will be artificial intelligence (AI). From that perspective, AI can be considered a fourth element in the coming "perfect storm" of potential disruption.

The topic of artificial intelligence is so important that the upcoming *Executive War College* on April 30-May 1 will devote both an entire general session and an optional full-day workshop to artificial intelligence and how it is poised to transform diagnostics and lab testing.

During the Wednesday, May 1 general session with artificial intelligence as the theme, speakers will include:

- **Michael Simpson**, CEO of **Clinisys**;
- **Ajit Singh, PhD**, Partner, **Artiman Ventures**;
- **Leo Grady, PhD**, CEO, **Jona**; and,
- **Joseph Mossel**, CEO, **Ibex Medical Analytics**.

Reality of Three Disruptors

The reality of three disruptors as described above means that all labs need to prepare for the consequences from these developments. Just as COVID-19 was a once-in-century global event, the perfect storm now brewing is a once-in-a-lifetime combination of challenges for clinical labs. TDR

Regulatory Update

HHS Publishes Final Rule for Health IT Interoperability

New rule is designed to make interfaces faster and cheaper, while penalizing information-blocking

There is a new federal rule intended to improve interoperability and portability of patient information. This rule could be a significant benefit for clinical laboratories and anatomic pathology groups.

In December, the US **Department of Health and Human Services** (HHS) Office of the National Coordinator for Health Information Technology (ONC) released its finalized rules for a regulation involving health information technology.

Initially proposed in April 2023, the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) rule was finalized at the end of 2023. It implements fundamental provisions of the 21st Century Cures Act and establishes:

- algorithm transparency requirements,
- adopts interoperability standards, and,
- bolsters information blocking requirements.

Rule May Benefit Labs

If there is any single class of providers who may benefit most from last December's publication of the final federal rule on healthcare IT interoperability, it will be clinical laboratories and pathology groups.

Labs must receive and transmit data daily with their medical office clients, hospitals, reference labs, and payers. They do this with bi-directional interfaces that are time-consuming and costly to establish.

This is why one objective of the 21st Century Cures Act was to ensure patient information and clinical records could be easily moved from one provider to another. However, some EHR companies viewed the patient data inside their systems as a source of value that could be monetized and were reluctant to share their data.

Excessive Charges

Some vendors also saw it as an opportunity to charge excessive amounts of money to write an interface that would allow different EHRs to talk to each other, or for a lab's laboratory information system to interface with a doctor's EHR.

These actions prohibited interoperability and portability of patient information, which ultimately led to the Cures Act and the HTI-1 regulations.

"The Cures Act was written to promote patient access to clinical information about themselves; to break down data silos between health systems and providers, payers, and IT vendors; and to utilize all this data to improve quality of care," said Greg Stein, founder and Chief Executive Officer of **Shadowbox, Inc.**, a Calif.-based company that specializes in healthcare automation, in an exclusive interview with The Dark Report.

"[HTI-1 is] significant because, quite frankly, there are some actors whose behaviors run counter to the goals of the Cures Act," Stein noted. "And when the federal government invests tens of billions of dollars in encouraging and

incentivizing the use of electronic health records, they want it to be used for the purpose of achieving public health. It is a problem when any actor stands between that investment of public dollars and the utility for public health."

HTI-1 Advancements

The HTI-1 final rule advances patient access, interoperability, and standards and includes the following:

- **Algorithm Transparency**: First-of-its-kind transparency requirements for artificial intelligence (AI) and other predictive algorithms are expected to make it possible for clinicians to access a consistent set of information about the algorithms they use to support their decision making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.
- **USCDI Version 3**: Establishes the United States Core Data for Interoperability (USCDI) Version 3 as standard baseline within the ONC Health IT Certification Program effective January 1, 2026. This new version focuses on the advancement of more accurate and complete patient data that could help promote equity, reduce disparities, and support public health data interoperability.
- **Enhanced Information Blocking Requirements**: Revises certain information blocking definitions and exceptions to encourage secure, efficient, standards-based exchange of electronic health information.
- **Interoperability Focused Reporting Metrics for Certified Health IT**: Implements the 21st Century Cures Act's requirement to adopt a Condition of Certification for developers of certified health IT. This part of the new rule will require developers to report certain metrics as part of their participation in the Health IT Certification Program and provide more insight into how certified health IT is used in support of care delivery.

"HHS intends this rule to guide innovation that eases data access and data exchange between technologies, along with ensuring patients are able to obtain copies of their data and share their health information with providers in a way they feel most comfortable," stated Sara Shanti, Partner in the AI and Healthcare Industry Teams at law firm **Sheppard Mullin** in an interview with THE DARK REPORT.

"Technology needs to be both interoperable and accessible to prevent an uneven playing field that restricts the industry as a whole," she added. "The new rule is written to encourage innovation while moving the whole industry forward."

Stein believes the new rules will give labs opportunities to access patient data using advanced technologies at a fraction of the cost. It will enable the movement of data in a timely and efficient manner in ways that will ultimately save lives.

Charging for Data Access

"The truth is that the lab industry has been at the mercy of the health IT vendors who often charge monopoly rates to access patient data. The cost of accessing data prior to the Cures Act was so prohibitive," Stein noted. "It's terrible for public health and patient health and it's terrible for labs that are trying to provide quality services and good clinical data and get appropriately compensated for those services."

Both Shanti and Stein are optimistic regarding how HTI-1 will benefit healthcare providers and lab professionals as well as patients. Having access to complete patient data in a timely manner can only help in diagnoses and treatment plans.

"We've seen some exciting things from our clients and our network," Shanti explained. "There is now going to be an even playing field where our clients can bring their own innovations onto a hospital platform and establish certified technology. I think the rule will allow labs to

use their own innovations while helping to meet some of their business demands. This will make their lives much easier."

"This is also an opportunity for hospital labs to actually implement cost-effective outreach programs," Stein added. "Prior to the Cures Act and prior to all of this wealth of new technologies that have come to market, it was cost-prohibitive for labs to run an outreach program and gain community referrals. Now, they can make better use of their on-site assets and access data from all sorts of different EHRs that are not connected through traditional methods."

Some Challenges for Labs

Labs will face some challenges when implementing the new HTI-1 rules. In addition to initial compliance costs, most lab information management systems (LIMS) were not designed to provide test results to patients directly upon request. There will be a need to enable these systems to deliver test results to patients. Stein believes those issues can be addressed with clinician and patient education to make documentation clear and transparent.

"I think the HTI-1 rule will dramatically reduce friction between labs and patients," Stein said. "Patients will be able to trust that they are getting information about themselves rapidly, effectively, and successfully."

Stein believes the implementation of HTI-1 will have a positive effect on patient care. Labs will have access to complete patient data so they can perform services without having to seek out more information from patients and doctors.

"There is hope that improved interoperability between healthcare systems will benefit labs in several ways," Stein added. "When labs can access data across multiple sources, that should improve their delivery of lab testing services and improve payment for their test claims.

Physicians Support Interoperability Rule

AMONG THE GROUPS THAT WELCOMED the December publication of the final federal HTI-1 rule on interoperability is the **American College of Physicians** (ACP).

"Physicians are now expected to take steps to ensure that their patients' electronic health information is accessible and usable per new regulations," said Deepti Pandita, MD, Chair of the ACP Medical Informatics Committee, in the news release.

"Information blocking is defined as practices that interfere with, prevent, or otherwise restrict the exchange or use of electronic health information," stated Pandita. "The key is for physicians to be aware of what constitutes information blocking and make sure their electronic medical records allow for information sharing."

"Equally important, better interoperatiblity has the potential to produce clean data," he noted. "In turn that will cut resources clinicial laboratories spend to track down missing information. They can now focus more of their resources on bringing new technologies and tests to market in ways that support patients and save lives."

Enforcing Blocking Laws

Stein also observed that, "as of September 1, 2023, the Office of the Inspector General and the ONC are now enforcing information blocking laws. This is notice to IT vendors, clinicians, payers, and labs to start playing by the rules."

Lab administrators and pathologists will find it timely to review the HTI-1 final rule with their attorneys and chief information officers. Labs should assess their responsibilities under the rule, and understand what is now required of IT vendors. TDR

Contact Greg Stein at greg@shadowbox.com.

Lab Market Update

Genetic Testing Firm Invitae Files Chapter 11 Bankruptcy, Pursues Sale

Invitae may be the first of several struggling genetic testing firms to file for bankrupcty protection

INVITAE CORP., A MEDICAL GENETICS COMPANY, got the go ahead in mid-February from the **U.S. Bankruptcy Court for the District of New Jersey** "to find a buyer and exit from Chapter 11 by late July," *Reuters* reported.

Invitae said in a news release that it was filing for voluntary chapter 11 protection "to safeguard its business, customers, patients, and employees while working to execute an efficient and value-maximizing sale process with support of its senior noteholders."

Invitae's bankruptcy filing may be the first domino to fall, as multiple other genetic testing companies are reporting substantial losses over multiple years. Analysts expect some of these firms will either file bankrupcty or be acquired.

Sales, Divestitures, Layoffs

The San Francisco-based company reported a $1.4 billion loss in nine months ending Sept. 30. It had recently sold reproductive health assets to **Natera**, Austin, for $52.5 million; divested assets of **Ciitizen**, a health technology platform; and cut 235 employees, THE DARK REPORT noted. Ciitizen's divesture and the layoffs were expected to save Invitae $90 million to $100 million.

"We have worked diligently over the past 18 months to improve our cash position by realigning our portfolio and focusing on our most impactful business lines," said Ken Knight, Invitae's CEO. "These strategic initiatives accelerated our path to positive cash flow in order to realize our potential as an industry-leading genetics platform. However, we still need to address the company's debt position through these chapter 11 proceedings," he added.

In its court filing to the **U.S. Securities and Exchange Commission**, Invitae noted agreement to "support the sale transaction through a court-overseen sale and auction process."

Chief Judge Michael Kaplan set April 10 as the deadline for bids and scheduled an auction for April 17, *Reuters* noted.

Invitae's Acquistions

According to *Reuters*, Invitae has already received some bids after it reached out to potential buyers in December.

Nicole Greenblatt, attorney and Partner at **Kirkland & Ellis**, which is representing Invitae, provided the court with background on Invitae's "13 acquisitions during the period of 2019 to 2021," *Reuters* said.

Some of those acquisitions TDR previously reported on: **ArcherDX**, a genomics analysis company purchased in October 2020; and Ciitizen, a San Francisco-based company using artificial intelligence, acquired in 2021.

"While acquisitions helped Invitae expand into new markets and round out its product portfolio and improve customer experience, they also required large sums of capital for investment and significant operating expenses," Greenblatt said.

Invitae will operate during the bankruptcy proceedings using its cash on hand. It has assets of $500 million to $1 billion and liabilities of $1 billion to $10 billion, *Seeking Alpha* pointed out. TDR

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.

Is There Evidence That Some Doctors Wish to Use Local Labs?

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.

CONVENTIONAL WISDOM HOLDS THAT ECONOMIES OF SCALE enable the two billion-dollar laboratory companies—**Quest Diagnostics** and **Labcorp**—to offer much lower prices to private payers than smaller regional labs. Managed care companies certainly see it that way.

Managers at health insurers find it easy—even safe—to contract with the billion-dollar lab corporations. After all, those labs serve most of the nation. They are able to move quickly to provide services when a health plan expands its membership into new areas. In fact, managed care companies often push those labs to offer service in regions that they don't currently offer lab testing services.

Another tactic of the managed care plans is to give those lab firms value-based contracts with bonuses for bringing in doctors who are using out-of-network clinical labs.

All of that has been true for many years. However, things seem to be changing. I see a different attitude among physicians, at least in some places. Our service teams hear doctors telling them, "We're not real crazy about the big labs anymore." Some managed care colleagues at other health insurers tell me that they are getting similar feedback from office-based physicians.

The fact that our internal teams are reporting this type of feedback is an early sign that at least some doctors in different areas of the country are interested in working with local providers, including their clinical laboratories.

More Interest in 'Buying Local'

This is similar to the farm-to-table trend in the food industry. More consumers want to buy their groceries from a local farmer because they want to personally know who produces the food they eat. This consumer trend is reinforced by the regular national media exposés of how agribusinesses grow animals in crowded conditions and use large volumes of fertilizers and pesticides in row crops of genetically-modified seeds.

It is a fact that health plans see a recognizable proportion of office-based physicians who want local lab testing services. This was not true as recently as the pre-pandemic period. In fact, this shift seemed to begin during the COVID-19 pandemic. The biggest lab companies had long delays to return COVID-19 test results. In some cases, smaller labs stepped up to the plate and delivered accurate results in shorter

turnaround times, according to media reports at the time.

It should be recognized that the two billion-dollar lab companies have done a consistent job of moving specimens from surrounding regions into the large regional labs throughout the United States. Both lab companies can pick up specimens from hundreds of miles away from each regional lab facility and deliver results to physicians early the next morning.

At the same time, there are many areas across the United States where it is a challenge for the major labs to sustain next day lab test results. This is why health plans include regional and community laboratories in their provider networks. They want their beneficiaries in these communities to have easy access to phlebotomy services and accurate and timely lab test results.

Outside the Big Cities

This might explain some of the shift in attitude by some physicians, especially in smaller metropolitan areas and rural areas. Providers in small communities generally feel neglected. When the big labs come in and try to service them, local patients lose the personal relationships they had with local phlebotomists. Physicians lose the local lab's courier who, after years of service, is often considered "one of the family" at the doctor's office.

Health plans are painfully aware of these situations because some patients will complain, both to their doctors and to their health plans.

Doctors are sensitive to these complaints. Our network managers will hear physicians say, "We don't want our lab samples being flown to Dallas or to Denver. We want them tested right here in our town. We want to know that we can get pathologists on the phone and talk to them or go to the lab and see them in person."

The two big labs typically respond that they have clinical pathologists available to speak with doctors. This is true, but that pathologist—located at a huge regional

Quest, Labcorp Shop for Hospital Outreach Labs

QUEST DIAGNOSTICS AND LABCORP have made no secret of their intent to acquire hospital laboratory outreach businesses. They're also looking for deals to manage inpatient hospital and health system labs. *(See TDR, "Labcorp and Quest Discuss Outreach Acquisition Potential," Oct. 2, 2023.)*

The biggest transaction by far came in February 2022, when Labcorp announced a deal with **Ascension Health**, one of the largest health systems in the United States. Under the agreement, Labcorp will manage Ascension's hospital-based laboratories in 10 states. The company also acquired certain assets of Ascension's outreach laboratory business. The deal closed in October 2022. *(See TDR, "Labcorp to Buy Outreach, Manage Ascension Labs," Feb. 22, 2022.)*

Since then, Labcorp has announced more deals to acquire all or part of the outreach laboratory businesses of the following health systems:

- **RWJBarnabas Health** in New Jersey.
- **Providence Oregon**.
- **Jefferson Health** in the Philadelphia area.
- **Tufts Medicine** in the Boston area.
- **Baystate Health** in Western Massachusetts.
- **Legacy Health** in Oregon.

Quest Diagnostics has also been acquiring outreach laboratory businesses, either all or in part:

- **Summa Health** in Northeastern Ohio.
- **Northern Light** Health in Maine.
- **NewYork-Presbyterian** in the New York City area.
- **Steward Health Care System** in Pennsylvania and Ohio.

lab facility hundreds of miles from the physician's practice—probably does not have the same knowledge of that doctor's patients and medical practice as the local pathologists in the hospital across the street from those physicians.

Of course, the big labs can always emphasize that "our fee schedules are better." But some of the smaller laboratories actually have very competitive pricing, sometimes lower for a wide range of routine and reference tests.

Bring Lab Outreach In-House

Here is an example of a multi-hospital health system, which I cannot identify, that previously used one of the big companies to manage its laboratory. They decided to take back the business and set up their own outreach laboratory.

This lab outreach program established a fee schedule that was lower than the national lab companies! That caught the attention of our network manager. We've been told that, in this local market, everybody knows everybody. Doctors can pick up the phone and get personal interaction with the lab staff.

If doctors have an issue, their office is in a building attached to the hospital. They can go over to the lab and talk to someone in person. The clinical pathologist knows these physicians and often knows the medical history of their patients who have chronic conditions and thus are tested frequently. These factors are consistent with the consumer trend to "buy local."

Remember also that managed care companies must keep their customers satisfied. Those customers include the self-insured company paying the premiums and the employees and their families who are covered by the company's health plan. If both patients and physicians make it clear that they prefer a local provider, like a clinical lab, payers will recognize that fact.

Might we be seeing the early stages of a general trend where both physicians and their patients are rethinking "big" and taking steps to work with local labs? Don't forget another element in this equation. The big lab companies tend to focus on the large metropolitan areas. That is where volume is greatest and costs are lowest, thus maximizing profits.

Meanwhile, in small communities and rural areas, the evidence is accumulating that there are physicians ready to support local labs with friendly staff, reasonable prices, and even same-day turnaround times for selected tests. TDR

Some Hospitals Relaunch Lab Outreach Business

NOT ALL HOSPITALS ARE READY TO SELL THEIR LAB OUTREACH BUSINESSES. Some hospitals have actually restarted lab outreach years after selling an earlier lab outreach business to one of the major lab companies.

One example is **Tucson Medical Center** (TMC) in Arizona. It brought outreach testing back in house, a move that netted $2.5 million in revenue in its first year. *(See TDR, "Outreach Nets Hospital Lab $2.5M in One Year," Oct. 2, 2023.)* This came 20 years after the hospital sold its outreach business to a large commercial lab.

Speaking at the *2023 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*, Sanjay Timbadia, MBA, MT(ASCP), TMC Director of Laboratory Services, said that other benefits of the lab outreach program included faster turnaround time and improved communication. In addition, the hospital reduced the possibility of losing or compromising laboratory specimens by keeping them within the region, he said.

Part of this success can be attributed to the fact that physicians in TMC's service area considered local testing to be more advantageous for their patients and their medical practices.

CMS Issues AI Guidance for Medicare Advantage

Experts say it is the role of Congress to decide on how artificial intelligence is to be regulated

CEO SUMMARY: With its guidance on how Medicare Advantage plans should use artificial intelligence (AI) when making treatment decisions involving individual patients, the federal Centers for Medicare and Medicaid Services has opened one door in the coming debate on how the federal government is to regulate AI's role in patient care. Labs have a major stake in this area because AI will be used to diagnose patients.

RECENT GUIDANCE FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) sheds light on the agency's thinking about acceptable uses of artificial intelligence (AI) in healthcare, though legal experts who spoke to THE DARK REPORT cautioned that it will ultimately be up to Congress to determine how far CMS and other federal agencies can go to regulate the technology.

The guidance came in the form of a Feb. 6 "Frequently Asked Questions" memo that clarified certain aspects of the agency's final rule (CMS-4201-F) regarding **Medicare Advantage** (MA) coverage in 2024. One section addressed whether Medicare Advantage plans can use software tools, including those that employ AI, to make coverage decisions.

The answer, in essence, was "yes," as long as the software "complies with all applicable rules for how coverage determinations by MA organizations are made," the memo stated. That's regardless of whether or not the plan uses conventional software algorithms or artificial intelligence. *(See sidebar, "Defining Artificial Intelligence" on page 14.)*

One scenario cited in the memo involved termination of coverage for post-acute care. Here, "an algorithm or software tool can be used to assist providers or MA plans in predicting a potential length of stay, but that prediction alone cannot be used as the basis to terminate post-acute care services," the memo stated.

Fair Use of AI

What does this mean? "CMS is saying that the plan still needs to assess a patient record before concluding a continued stay is not medically necessary," explained healthcare attorney Andrew Tsui, JD, of **Greenberg Traurig, LLP**. "I can't imagine that is contentious. If the AI makes determinations that comply with the regulation, CMS is leaving open the possibility that it could be a fair use of the technology."

But Tsui, who previously worked in the Office of the General Counsel for the CMS Division, added that the agency is "not actually addressing the elephant in the room, which is, "Where is CMS headed when it comes to regulating technology? It's not clear that CMS will have that authority. CMS only has the authority that's been conferred by Congress," Tsui noted.

The guidance is "not trying to create runways for new technology," he said.

Challenge to Defining Artificial Intelligence

CMS' MEMO MADE A DISTINCTION between conventional algorithms and artificial intelligence. Algorithms, it stated, "can imply a decisional flowchart of a series of if-then statements (i.e., if the patient has a certain diagnosis, [he or she] should be able to receive a test), as well as predictive algorithms."

On the other hand, "artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action."

"It's sub regulatory, which means it's lower than a regulation. Arguably, it's not even binding. It doesn't have the force and effect of law.

"That said, I always remind people that the **Medicare** program is a federal health insurance program, not a federal health insurance company. That's an important distinction. Companies make business decisions. Federal health insurance programs make legal decisions. They are bound by the four corners of the statute.

Limits on What CMS Can Say

"All CMS can do is remind people, 'Hey, there's a regulation. This is what it says. This application of AI does or does not comport with these medically reasonable and necessary coverage mechanisms. That's the legal determination, and we're not going any further than that.'"

Moreover, "one of the key features of Medicare Advantage plans is that they have autonomy to create and administer benefit packages in a way that saves taxpayer money. If AI is a component of that, assuming it's applied appropriately, I'm not sure that CMS has a ton of authority or interest in disrupting that," Tsui said.

In general, the new CMS guidance is "emblematic of big government struggling to respond to technically complex matters, and to keep up with the pace of development," Tsui mused.

In this case, "CMS articulated a concern about the ways in which AI could be misapplied in the Medicare Advantage context," he noted. "But CMS can't grapple with or create opportunities for AI until such time that Congress actually confers some new authority."

AI in Clinical Care

The issue becomes even more complicated in patient care, given thorny questions about the respective jurisdictions of the FDA and CMS, Tsui noted. That's especially true when it comes to clinical laboratories.

"The relationship between CMS and the FDA has always been awkward," Tsui said. "It's not always clear where to draw the line between the two agencies' regulatory authorities."

Tsui's colleague, healthcare attorney Charles Dunham, JD, also of Greenberg Traurig, agreed. "Whether it's genetic testing or another diagnostic technology that's telling you this person in Iowa has cancer, some government agency needs to confirm the clinical utility and analytic value," Dunham said. "There's a debate about whether that's the FDA, or if CMS already has that authority under CLIA, because CMS has to confirm the validation of the tests. That's why the FDA is seeking to put itself into the regulation of lab-developed tests (LDTs)."

The two agencies, Tsui noted, "are answerable to different statutes. The FDA operates under the authority of the Food, Drug, and Cosmetic Act. Its standard of review is whether or not something is safe and effective. CMS, under the Medicare Act, operates under the standard of whether something is medically reasonable and necessary for coverage and reimbursement purposes."

So, how does this relate to artificial intelligence? Again, "AI is disrupting faster than CMS can take account of," Tsui said. For example, "the industry is incorporating AI-enhanced Clinical Decision Support (CDS) software at a pace that is staggering. So, if the FDA approves AI-enhanced CDS software with a 510(k) clearance, how does CMS evaluate that?"

This points to what Dunham described as the "fragmented" nature of the healthcare regulatory system in the U.S., where one agency approves marketing of a product while another approves reimbursement. "In countries like Germany and France, they approve a device and then they fast-track the decision to reimburse for it in a public healthcare program," he said. "Here, the FDA says this product can be out on the market, and it still takes two or three years or more for it to actually get reimbursed."

Regulation is Coming

CMS itself is not exactly in the Dark Ages, Tsui said. "They have a relatively new Office of Information Technology that's tasked with trying to at least articulate a strategy for dealing with technology. And like a lot of the CMS contractors, they're already using AI-enhanced technologies to audit labs and other provider types. They're not just doing this stuff on a moleskin pad."

But when it comes to regulating clinical laboratories and other healthcare entities, "CMS is largely operating under a statute that was written in 1965, and only sporadically updated over the past half century," he pointed out, adding that the issues surrounding regulation of AI in healthcare will likely remain shrouded in uncertainty unless Congress steps in. "The short answer is that regulation is coming, but it's going to be clumsy," he concluded. TDR

Contact Andrew Tsui, JD, at Andrew.Tsui@gtlaw.com; Charles Dunham, JD, at dunhamc@gtlaw.com.

Medicare Advantage Plans Under Fire for AI

AUTOMATED CLAIM DENIALS BY HEALTH INSURERS have long been a sore point for clinical labs, and Medicare Advantage plans in particular are undergoing scrutiny for their claim denial processes. The issue now has the attention of Congress.

"Medicare Advantage insurers are required to provide beneficiaries with the same minimum level of coverage as traditional Medicare," said Sen. Richard Blumenthal (D-Connecticut) during a Senate subcommittee hearing last May. "Yet we have seen evidence indicating that in many instances, they are failing to do so."

He pointed to "growing evidence that insurance companies are relying on algorithms, rather than doctors or other clinicians, to make decisions to deny patient care."

Blumenthal called for greater transparency in how the Medicare Advantage plans use artificical intelligence (AI) to make coverage decisions. He noted that a bipartisan group of lawmakers had sent letters to **UnitedHealth**, **Humana**, and **Aetna** parent company **CVS** requesting internal documents about their decision-making processes.

"I want to put these companies on notice," he said. "If you deny lifesaving coverage to seniors, we are watching. We will expose you. We will demand better. We will pass legislation, if necessary, but action will be forthcoming."

In November, family members of two deceased patients in Minnesota filed a class action lawsuit against **UnitedHealthcare** over alleged use of an AI tool to wrongfully deny claims, *Becker's Payer Issues* reported. Humana is also facing a lawsuit over use of the same AI tool, known as nH Predict from **naviHealth**.

Lab News Briefs

New York Times Reviews DNA Testing Kits for Its Readers

It's a sign of the times when *The New York Times* considers it useful to conduct and publish a review of DNA ancestry testing kits to guide readers.

AncestryDNA of Lehi, Utah, was picked as "the most effective service" for an at-home DNA testing purchase. The "runner-up" was **23andMe**. **FamilyTreeDNA** of Houston was named the "upgrade pick," a *New York Times Wirecutter* review found.

"The aptly named AncestryDNA test stood out as the best DNA testing kit because it presents test results in a clearer manner than other services and places the ancestry information it provides in a useful historical context," according to the *Wirecutter* review.

AncestryDNA offers people the advantages of thorough reports and interface, the review added.

More than 22 million people are in the AncestryDNA database, as compared to 12 million people in 23andMe database, *The New York Times* reported.

The review acknowledged 23andMe's "polished site design, which makes navigating the myriad charts, reports, and explanatory documents easier than on competitors' sites."

Meanwhile, FamilyTreeDNA was recognized for its add-ons such as a "suite of testing options."

The review pointed out that DNA may raise questions as well as answer them. "There are two parts to the DNA tests offered by the major DNA testing companies that are relevant to genealogy: 1) The DNA match lists of relatives; and 2) The admixture or 'ethnicity' predictions. Testers should be extremely confident that the former is accurate. The latter should still be taken with a grain of salt, and vetted using the former," CeCe Moore, Genetic Genealogist and Consultant, told *The New York Times*.

The newspaper said it identified 15 U.S.-based ancestry DNA testing kits before narrowing the list to five companies and making its picks.

UK's NHS Offers "Blood Matching" Genetic Test

When it comes to blood transfusions, more than 18,000 people in England are expected to benefit from a new "blood matching" genetic test.

The United Kingdom's (UK) **National Health Service** (NHS) introduced the test to better prepare people who require transfusions due to inherited blood disorders, such as sickle cell disorder and thalassemia.

By enabling more precise matching, the test is expected to enhance accuracy of blood transfusions and minimize transfusion side effects, an NHS statement noted.

People with sickle cell, thalassemia, and transfusion-dependent rare inherited anemias are being encouraged by the **NHS Blood and Transplant, NHS England**, to have the test with routine blood tests.

"Being able to provide high quality and more personalized care to people with inherited blood disorders is an important step forward in helping to reduce health inequalities, and this innovative test will greatly improve the quality of life for people living with these disorders," said Bola Owolabi, MRCGP, MFPH Hon, FRSPH, NHS England National Healthcare Inequalities Improvement Program Director.

Rochester, Minn.-based **Mayo Clinic**, explains on its website that blood transfusions require preparation to ascertain if transfused blood will be compatible with a patient's blood type.

The NHS said it is the first national healthcare system worldwide to provide a blood genotyping test to curb transfusion side effects. Offered on such a large geographic scale, this test program represents a step forward in introducing a genetic testing component to UK clinical laboratories' test menu.

Labcorp Partners with Outcomes4Me on Cancer Care

In another sign of the importance of transparency of information to healthcare patients, **Outcomes4Me** is partnering with **Labcorp** and **Comcast NBCUniversal's Forecast Labs** to directly engage patients about availability of medical laboratory cancer testing information.

Outcomes4Me is an artificial intelligence (AI)-driven platform that helps patients with cancer care navigation.

After people provide their medical history to Outcomes4Me, the platform produces guidance "based upon their unique diagnosis and disease stage, including treatment options, clinical trials, and potential genetic testing options," Outcomes4Me explains on its website.

As part of the partnership, Labcorp, Burlington, N.C., will offer up "personalized insights" to aid Outcomes4Me, Boston, in identifying cancer patients who can benefit from more diagnostic testing, *Medical Marketing and Media* (*MM+M*) noted. NBCUniversal, New York, will use mass media to target messages to patients, thereby eliminating the "middleman."

"Often how patients find database information is either through healthcare organizations, doctors, or providers. In some sense, there's an intermediary there—whereas going through NBCUniversal and the world of mass media, it's about that direct bond," Outcomes4Me founder and CEO Maya told *MM+M*.

Quest, Fitbit Partner on Metabolic Health Study

Laboratory testing will be a key part of a collaboration between **Fitbit** of San Francisco, and **Quest Diagnostics**, Secaucus, N.J., to better understand metabolic health.

Along with lab testing, the Wearables for Metabolic Health (WEAR-ME) pilot study will explore behavioral and biometric data from Fitbit devices worn by about 1,500 participants.

Poor metabolic health can lead to conditions like heart disease, diabetes, and stroke, the companies noted in an announcement of the study. But diet, exercise, and sleep—all monitored by **Google**-owned Fitbit activity trackers—affect metabolic health. And it can be analyzed through lab tests of blood sugar, cholesterol, and triglycerides.

"The study aligns with our goal at Quest to empower people to take control of their health with convenient access to more than 75 lab tests with physician oversight, but without the doctor visit," said Richard Adams, Quest's Vice President and General Manager of Consumer-Initiated Testing.

Participants will be asked to share Fitbit data for three months and will have an opportunity to have lab tests.

"We think this study will help us uncover how biometrics measured by wearables can help [users] understand metabolic health," said Javier Prieto, PhD, Google Principal Investigator and Senior Staff Research Scientist.

It may be interesting if Quest determines—through WEAR-ME—consumers' general interest in the lab's collection of their wearable device data.

Since activity trackers continue to be used and valued by consumers, it may be time for clinical labs to find ways to store data generated from patients' Fitbits and other wearable devices alongside clinical lab test results.

DNA Testing Services Share Unexpected Results

One 23andMe customer thought there was some type of mistake when she learned through the Sunnyvale, Calif., DNA testing service that she shared a donor father with at least 200 siblings, *USA Today* reported.

The 24-year-old also found out her donor father's sperm is still sold by a sperm bank today.

The story suggests that direct-to-consumer genetic testing companies may be revealing secrets that formerly remained hidden throughout some people's lives.

"It's hard enough when you have an unknown medical history, but an inaccurate medical history adds layers of mental health struggles. Our health is a part of our identity. You have to unravel the shock of finding out your family history is different than you thought, all while dealing with anxiety over the unknown," commented Jana Rupnow, a Dallas-based psychotherapist and fertility counselor, in an interview with *USA Today*.

What may help is proposed legislation by the **U.S. Donor Conceived Council**. It aims to share with people who were conceived by donors the right to find their donor's identity and medical information and to "limit the number of families per donor," *USA Today* reported.

Colorado, in 2025, will reportedly be the first state to put the Donor-Conceived Persons and Families of Donor-Conceived Persons Protection Act into effect, *Above the Law* reported.

Intermountain Health Ends Precision Genomics Laboratory; Myriad Genetics Purchases Two Tests

Intermountain Health, a 33-hospital system based in Salt Lake City, Utah, announced it has ended and divested its **Precision Genomics Laboratory** effective Feb. 1.

"Over the past 10 years, the precision medicine market has rapidly evolved, new partners have entered, and this work has become financially unsustainable," according to a statement by Intermountain, which started the Precision Genomics Laboratory in 2014.

Myriad Genetics of Salt Lake City has purchased two tests that were offered by Intermountain. Two other tests have been discontinued: Precision Genomics, RxMatch; and TheraMap Myeloid Malignancies.

Also acquired was the Precise Liquid Test, which Myriad expects to launch later in 2024. "It will provide convenient comprehensive genomic profiling results from a blood draw," Myriad noted.

Financial terms of the deal were not disclosed. Myriad said the test additions complement its hereditary cancer and companion diagnostic testing offerings.

Becker's Hospital Review pointed out the cost of a genomic test, generally, can be $10,000 or more, and some treatments may exceed $100,000 a year. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Following an investment of $1.75 million, officials at **University of Maine at Augusta** (UMA) opened a new lab facility this month that allows it to double the number of medical laboratory technicians it can train, from eight to 10 to as many as 20. In its coverage of the new training lab's grand opening, the *Portland Press Herald* wrote: "Statewide there are currently 90 open positions for medical lab technicians, and those jobs generally pay between $25 and $28 per hour. UMA and **University of Maine at Presque Isle** both offer two-year medical lab technician programs and share professors, most of whom are from **MaineGeneral Health**."

ADD TO: *MLT Training*

It is widely acknowledged that the demand for medical laboratory technicians (MLTs) and clinical laboratory scientists (CLSs) substantially exceeds the number of training positions maintained in the United States. **COLA**, the CLIA accrediting organization, has organized the "Workforce Action Alliance" to address laboratory staffing shortages. The second summit for this group will meet on May 7, 2024, in Destin-Fort Walton Beach, Fla. Lab professionals who would like an invitation to participate should contact COLA.

SYSMEX, HITACHI TO DEVELOP GENE TEST SYSTEMS

Long known for its hematology testing systems, **Sysmex Corporation** is expanding a collaboration with **Hitachi High-Tech Corporation** specifically to create novel genetic testing systems based on capillary electrophoresis sequencers (CE sequencers). The two companies believe that their respective proprietary expertise can be combined to develop new genetic testing systems that would deliver two benefits: One would be faster running times. The other would be reduced cost for this type of genetic testing. The companies signed a feasibility study agreement in 2023 and this study's findings encouraged the two collaborators to move to the development phase.

TRANSITIONS

- **Myriad Genetics** of Salt Lake, City, Utah, named Paul Sheives as Vice President, Government Affairs. His prior positions were with **Delfi Diagnostics**, **Roche**, **Biotechnology Industry Organization**, and **Morgan, and Lewis & Bockius LLP**.

- Mark L. Spencer was named President of **L7 Informatics** of Austin, Tex. He was previously with **CliniSys**, **Abbott Informatics**, **Quality Star LLC**, **McKesson**, and **Sunquest Information Systems**.

- William Bonello joined **Craig-Hallum Capital Group** as Senior Research Analyst. He was formerly at **Neogenomics**, **Labcorp**, **Wachovia Securities**, and **Piper Jaffray**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 18, 2024.

Publisher: Robert L. Michel *rmichel@darkreport.com*
Executive Publisher: Bob Croce *bcroce@darkreport.com*
Managing Editor: Michael McBride *me@michaelmcbride.com*
IVD Reporter: Donna Pocius *donna11019@att.net*
Legal/Compliance Reporter: Stephen Beale *sbeale58@gmail.com*
Regulatory Reporter: Jillia Schlingman *jpschlingman@yahoo.com*

SPECIAL SESSION

EXECUTIVE WAR COLLEGE

April 30-May 1, 2024 • Hyatt Regency • New Orleans

Tim Stenzel, MD, PhD

Former Director
FDA's Office of In Vitro Diagnostics and Radiological Health

29 YEARS

FDA Proposed LDT Rule, Harmonization of ISO 13485, & Reclassifying High Risk Tests to Medium Risk Tests

HERE IS YOUR OPPORTUNITY to understand many aspects of the FDA's proposed rule on laboratory-developed tests (LDTs). The timing of this important session couldn't be better, as many predict the FDA will publish its final LDT rule in April, just weeks before *Executive War College!*

Along with providing insight into the proposed FDA LDT rule, Stenzel will also discuss how the FDA is working globally to harmonize ISO-13485 Medical Devices so that one country's review and clearance of a device or test will be accepted by other participating nations. The third subject to be discussed is the FDA's memo on reclassifying Class III devices (high risk) to Class II devices (medium risk).

All labs using LDTs will want to have their team present to hear and learn the implications of the FDA's proposed LDT rule. Register today to ensure your place!

It's Our 29th Anniversary!

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- ***Scott Gottlieb, MD, on navigating an evolving regulatory and policy landscape of diagnostic tests.***
- ***First guidance by CMS on artificial intelligence use by insurers with Medicare Advantage plans.***
- ***Too few pathologists? A look at the pathologist supply in the United States and globally.***