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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...

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Goodbye Clinical Labs! Hello Genetic Testing Labs!

Is the classic model of the independent pathologist-owned clinical laboratory that is the sole source provider of all routine, reference, and esoteric testing to physicians in its community on its way to extinction? There is strong evidence to support a "yes" answer to that question.

The heyday of the local, pathologist-owned independent lab company was the 1980s and 1990s. That's when every city and town had a least one or two of these labs. They provided a full soup-to-nuts test menu and their clinical pathologists personally knew the referring physicians and were familiar with many patients, particularly those with chronic diseases.

In the early 1990s, it was estimated that 5,000 independent clinical lab companies operated in the United States. Those days are over. Beginning about 1985, publicly-traded lab companies began buying those pathologist-owned lab companies. In 2021, it can be challenging to find a pathologist-owned independent lab company that performs all the routine, reference, and estoric testing for its clients.

Instead, the clinical lab industry has a new engine of growth—companies that specialize in genetic testing. Starting about six to eight years ago, the number of new genetic test company start-ups began to increase. Many of these new enterprises have proprietary or patent-protected genetic tests.

Meanwhile, the need for local routine and reference testing has been filled by two primary types of labs. One type are the hospital and health system labs that provide routine and reference testing to the outpatient and outreach providers in their communities. The other type are the handful of billion-dollar public lab companies, including **Labcorp**, **Quest Diagnostics**, **BioReference Laboratories**, and **Sonic Healthcare**.

Of course, it is facetious to say "goodbye clinical laboratories." The need for routine and reference testing will continue. The point here is that the profession of laboratory medicine has lost the benefit of a local clinical pathologist running his or her independent lab company in ways that benefit physicians and patients in that community.

In its place, either a local hospital lab or a national public lab company now provides those routine and reference testing services. Meanwhile, genetic testing is the sector of laboratory medicine experiencing explosive growth. TDR

Artificial Intelligence Is Ready to Deliver for Labs

In the past 24 to 36 months, some labs have quietly begun using AI-powered apps

CEO SUMMARY: Artificial intelligence (AI) may be one of the most over-used terms to describe a host of different applications, software tools, and products. However, during the past year, some truly revolutionary digital tools are now in use by a small number of innovative clinical laboratories. These applications are being used to improve operational work processes, to streamline coding/billing/collections, and for analyzing digital pathology images.

by Robert L. Michel

COMING TO A CLINICAL LABORATORY NEAR YOU—AND SOONER THAN YOU THINK—will be powerful informatics tools driven by true artificial intelligence (AI) engines. These tools will cover all aspects of lab operations, including managing daily workflow, simplifying lab coding/billing/collections, and advancing diagnostic precision in clinical laboratories and anatomic pathology laboratories.

For nearly a decade, artificial intelligence (AI) has been touted by developers and experts alike as a technology and a tool that will change every aspect of daily life, including healthcare and clinical laboratory medicine.

During this period, adjectives that were frequently used to describe the probable impact artificial intelligence would have on business, social, and cultural activities ranged from disruptive and sweeping to revolutionary and transformative.

Collectively, bold futurists using these terms were declaring that—once AI takes root in a multitude of uses and settings—our society will have knowledge and capabilities unimagined even by the science fiction writers of the 1950s, 1960s, and 1970s.

Wall Street investors jumped on the artificial intelligence bandwagon in a big way. In recent years, a steady stream of start-up companies developing informatics products have been funded with tens of millions of dollars. This is true of firms targeting healthcare and particularly true of emerging companies that want to introduce products that can analyze digital pathology images specifically to make a primary diagnosis without the review of a pathologist.

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Invariably, these new firms will describe their technologies and products as artificial intelligence. But the reality is that they are using such informatics technologies as machine learning, neural networks, image analysis, and more in their attempts to replicate the capabilities of the human mind.

The point is that investor-owned companies are quick to describe their products as artificial intelligence. Clinical laboratory professionals should be skeptical of this hype and understand that these enabling technologies may be remarkable at handling vast amounts of data, but will certainly fall far short of meeting the definition of artificial intelligence that functions at the same level as a human brain.

AI Products Arrive in Market

With this background as a starting point, the good news for clinical laboratories and anatomic pathology groups is that a surprising number of products and tools that use AI are arriving in the market. What is common with the most successful of these products is that they can suck up large amounts of data from multiple sources, and then use that data intelligently to accomplish three goals.

First, they automate the work processes they target. Second, they improve the accuracy and quality of those processes. Third, they reduce or even eliminate the labor formerly required to accomplish this work.

These three areas of laboratory medicine now have viable AI-powered solutions reaching the market. Probably best-known, are the early entrants into digital pathology image analysis and diagnosis.

The second area features multiple companies with surprisingly effective tools utilizing AI that are designed to improve all aspects of coding, billing, and collection of lab test claims. The third area involves AI-powered approaches to the lab's workflow spanning pre-analytical, analytical, and post-analytical functions.

In assembling session topics and speakers for the upcoming *Executive War College on Lab and Pathology Management* that takes place in San Antonio on Nov. 2-3, 2021, we have had fascinating conversations with entrepreneurs working in the AI field. Their companies now have lab customers using their products and achieving impressive results.

Some Labs Using AI Tools

THE DARK REPORT has issued intelligence briefings about how these AI-powered tools are being used by innovative labs. For example, in the last issue, Lance Berberian, Executive Vice President and Chief Information and Technology Officer at Burlington, N.C.-based **Labcorp,** told our clients and readers about how the company had deployed AI for use in a wide range of lab functions and activities.

One example is a vision-based AI used in an internally-designed specimen-handling robot system that recognizes loaded test tubes and their appropriate positioning. The AI also identifies and tracks tubes with insufficient specimen quality. In turn, that has helped the lab proactively deal with TNP (test not performed) issues.

Labcorp is also using AI across all 2,000 of its patient service centers. The AI automates many functions when patients arrive to provide specimens. That includes scanning driver's licenses, with the AI system accurately recognizing thousands of different formats of licenses and other forms of identification. *(See TDR, "Labcorp Now Using AI for Operations, Patient Care," July 6, 2021.)*

Revenue Cycle Management

In the area of lab revenue cycle management, we spoke last week with a CEO who has an AI tool in the market that fully automates the intake of a patient's information for lab billing purposes. He described how his system instantly looks at documents such as driver's licenses and corrects all inaccurate information in real

time. He pointed out that even a driver's license can have inaccurate information if the individual has a new address, or has a new name because of a recent marriage or divorce.

Anatomic pathology may be the most active area of lab medicine for applications that use artificial intelligence. Last month, I was in Philadelphia and chaired a discussion involving **Proscia** CEO David West and Scott Gottlieb, MD, former Commissioner of the **Food and Drug Administration** (FDA).

Proscia has a contract with the federal **Joint Pathology Center** to digitize the Center's 55 million glass slides and enable access to those images. Both Gottlieb and West spoke to the speed with which AI and computational algorithms will come to market and be used to analyze whole-slide images, and to generate primary diagnoses with accuracy comparable to a pathologist.

AI in Digital Pathology

Another example of an AI-powered system that is almost ready for use by pathology labs is last month's FDA announcement that it had accepted the pre-market application of **Ibex Medical Analytics** of Tel Aviv, Israel, for expedited review. This system is designed to make a primary diagnosis of a whole-slide image. In May, Ibex obtained EU clearance for its Galen Breast Cancer product, which uses AI to analyze the digital images.

There are already companies delivering AI-based solutions to labs for use in digital pathology diagnosis. The FDA recognizes this development, which may be one factor in its decision to do an expedited review of the Ibex system.

AI-type applications are delivering value in a number of innovative clinical laboratories and anatomic pathology labs. The *Executive War College* is planning to invite some of these lab organizations to present on their experience applying AI apps in ways intended to streamline processes and add value. TDR

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Science Fiction Writers Never Envisioned Internet

SCIENCE FICTION WRITERS OF THE POST-WORLD WAR II SOCIETY were professional futurists. Many predictions from the books of Robert Heinlein, Kurt Vonnegut, Arthur C. Clarke, Isaac Asimov, and others became reality in the last half of the 20th Century.

But one major development this group of famed science fiction writers apparently never envisioned in their books was how the Internet would appear in the 1990s and evolve into its present form.

Meanwhile, in 1950, British scientist Alan Turing, PhD, published a paper, titled, "Computing Machinery and Intelligence." Based on his previous 15 years of working with computing machines, Turing articulated the idea that computers would become so powerful, they would think.

He was one of the first to foresee that artificial intelligence (AI) could become reality. In 2012, *Scientific American* published a story by New Zealand-based computer scientist Ian Watson which described Turing's test for artificial intelligence.

Watson wrote, "How would Turing know if a machine was intelligent? He devised the Turing Test: A judge sitting at a computer terminal types questions to two entities, one a person and the other a computer. The judge decides which entity is human and which the computer. If the judge is wrong the computer has passed the Turing Test and is intelligent."

Seventy years have passed since publication of Turing's paper. We may now be at point where the end game of artificial intelligence—the ability of machines to duplicate human thinking, reasoning, and creativity—may be closer than at any time in history.

Genetic Tests Grow in Number, Complexity

➤Payers, providers, laboratories are all frustrated in the need to cope with Tsunami of new genetic tests

➤➤CEO SUMMARY: Getting paid for genetic tests continues to be a challenge. This is true for both payers and the labs that perform the tests. Even physicians are dissatisfied with the status quo because they must deal with patients unhappy about the high cost of genetic tests. The problem is likely to get worse before it gets better, because, as Concert Genetics points out, not only are there 166,450 genetic tests offered by more than 300 lab companies, but 39 new genetic tests come to market every day.

GENETIC TESTING LAB COMPANIES ARE OVERWHELMING government and private health plans with an ongoing, multi-year flood of new and different genetic tests. Compounding the problem of obtaining payment for genetic test claims is the fact that the CPT coding system is unable to respond in a timely fashion to this flood of new genetic tests.

Few pathologists and clinical laboratory managers realize that at least 166,450 genetic tests are offered by U.S.-based, CLIA-certified labs, according to data tracked by **Concert Genetics** in Nashville, a software and managed services company focusing on management of genetic testing and precision medicine.

➤Just 2,000 Unique Lab Tests

Long-serving pathologists can remember back just 15 years ago when the typical clinical laboratory's catalog of routine, reference, and esoteric tests numbered about 1,500 to 2,000 unique assays. Managing utilization of molecular and genetic tests during that era was much simpler than it is today.

Moreover, Concert Genetics says that 39 new genetic tests enter the market every day. But this ongoing surge in new genetic tests coming to market is just one aspect of a challenging problem for health insurers. This is equally true of health systems and hospitals that want to manage how their providers utilize expensive genetic tests.

➤Complexity of Genetic Tests

"It's really about the complexity of those tests. We track about 30 different kinds of domains (or specialties) of genetic testing," said Rob Metcalf, Chief Executive Officer of Concert Genetics, during a recent webinar sponsored by THE DARK REPORT, titled, "State of the Genetic Testing Marketplace—Getting Paid for All Your Lab's Genetic Test Claims: What's Changing, What's Not, and What's Working Best."

"These 30 different genetic test domains are what makes it difficult for any stakeholder to stay current," he commented. "For example, an increasing number of health systems now come to us and ask, 'Can you help us understand this complexity as we try to manage the ordering and resulting of genetic tests across

the multiple physician specialties in our health system?'"

Genetic testing complexity affects reimbursement to labs, particularly by commercial payers, according to Metcalf. "There is ambiguity around the medical policies of the different health insurers as to what's covered and what's not," Metcalf said.

However, even as health insurers struggle to develop coverage guidelines, establish reimbursement for individual genetic tests, and process these claims in a timely manner, genetic testing labs themselves are a major part of the problem.

Use of Multiple CPT Codes

Metcalf observed that, for their part, labs often file test claims that lack genetic testing identification or use multiple CPT (current procedural terminology) codes.

Misuse of coding, coverage ambiguity, and denials lead to administrative costs for both payers and labs. Concert Genetics data show:

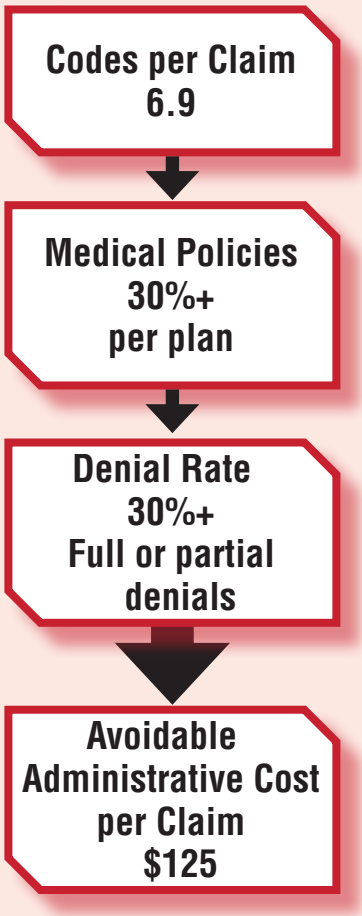
- 6.9 codes per claim.
- 10 to 90 medical policies per plan.
- Denial rate (full or partial denials) of 30% or more.
- $125 per test in avoidable administrative cost.

"These administrative costs impact the laboratory business, and they also impact us as healthcare consumers," Metcalf declared. "That's because ultimately those costs get passed on in one form or another. Administrative costs are a big issue across the healthcare system and genetic testing is certainly part of it."

Coverage for genomic testing varies and is unclear throughout the United States. And utilization of genetic tests is inconsistent—even in states with favorable coverage polices—according to a report, titled, "Understanding Genomic Testing Utilization and Coverage in the U.S.," which was released last year by the **Personalized Medicine Coalition,** along with Concert Genetics, **Blue Cross Blue Shield Association**, and **Illumina, Inc**.

Concert Genetics IDs Cost of Genetic Claims

COMPLEXITY OF GENETIC TEST CLAIMS is why both laboratories and payers are frustrated with the process of adjudicating and reimbursing for these tests. During a recent webinar, Concert Genetics CEO, Rob Metcalf, showed the three distinct factors within a genetic test claim that add to its complexity. The end result is that the potential exists to avoid administrative costs of as much as $125 per claim if payers and labs were more successful at automating processes and developing more effective prior-authorization steps. For example:



"We don't have an explanation for all of those factors," Metcalf said. "But the data suggest that provider behavior is different in different places. And payer behavior is different in different places."

Health Plans, Providers, Labs

Concert Genetics takes an ecosystem view of precision medicine, looking at relationships between health plans, providers, and genetic testing lab companies. It found a disconnected infrastructure that prohibits effective and efficient use of genetic tests.

"The relationships involving providers who order the tests, labs that perform the tests, and payers who reimburse for the tests—at least digitally—are not well connected. And that has implications," Metcalf noted.

According to Concert Genetics, disconnects between the stakeholders are evidenced in:

- Unclear coverage criteria for genetic tests and inability to measure impact of precision medicine.
- Excessive prior authorization and high denial rates.
- No learning from genetic results.
- Test errors and lost results.
- Inability to inform physicians.
- Surprise bills and angry patients.

Clarity in Test Orders, Results

"What we want to see is improved infrastructure between health plans and providers around understanding coverage," he stated. "Similarly, lab companies performing genetic tests need clarity in the way their tests are ordered and resulted.

"Medical policy, quality, and coding can all be more transparent, simpler, and ultimately computable," recommended Metcalf. "Our company watches this genetic testing space with all of its ambiguity and dynamism and our services are designed to help streamline many processes involved in how genetic tests are ordered, reported, and reimbursed."

During the webinar, Metcalf explained how both health plans and labs work with Concert Genetics. The goals include modernizing clinical policies, establishing quality reporting, standardizing test coding, and streamlining the process of editing test claims.

"We have tools to make medical policy clear and machine-readable," he explained. "Similarly, we can take quality metrics and make those comparable across genetic testing labs.

"Another major activity is our work with providers, health plans, and laboratories to standardize coding of genetic tests," Metcalf commented. "The ultimate objective is to automate those improvements in systems used by genetic testing lab companies and health plans."

Precision Medicine

To enable precision medicine and genetic testing value in the future, labs need to commit to standards for quality and service that include billing integrity, according to Concert Genetics. And health plans need to adopt machine-readable policies with real-time enforcement without prior authorization.

Even personal relationships need to improve between labs and health plans, Metcalf says. "We need to move from an antagonistic approach to transparency and clarity and where innovation is rewarded and transaction costs are reduced," he noted.

This intelligence briefing demonstrates why the number of new genetic tests coming to market each day overwhelms the existing payer systems for determining coverage, establishing prices, and adjudicating claims. It also makes clear the need for genetic testing companies to better document the clinical value the results of their genetic tests deliver to clinicians. Also, labs that implement improved automation and integration within their lab billing systems, and with payers, will benefit by helping payers process their claims. TDR

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Systems for CPT Coding and Claims Payment Overwhelmed by How Genetic Tests Are Billed

THERE SEVERAL REASONS WHY GOVERNMENT AND PRIVATE HEALTH PLANS are struggling to handle claims for genetic tests. The first reason is the intimidating number of genetic tests offered in today's clinical market. Nashville-based Concert Genetics has a database that includes 166,450 genetic tests offered by 300+ labs in the United States. The second and third reasons are listed below.

Fig 1. Average Number of Codes per Claim by Domain of Genetic Testing

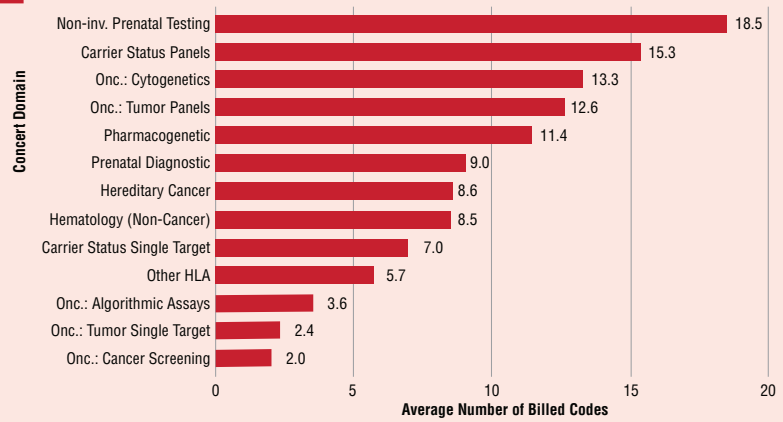

Figure one above shows the second reason why payers are overwhelmed by genetic test claims. Concert Genetics determined the average number of CPT codes per domain of genetic testing. For example, the non-invasive pre-natal testing domain averages 18.5 codes per test.

Fig 2. Number of Distinct Code Signatures Observed within Each Domain

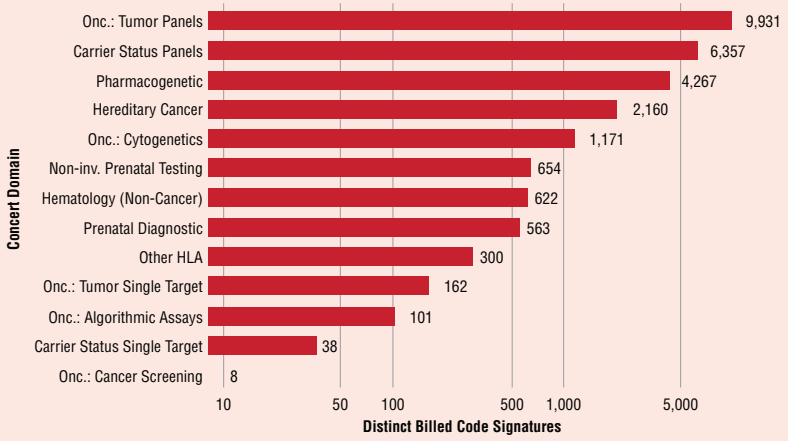

Figure two above shows the third reason why payers are overwhelmed by genetic test claims. Concert Genetics determined that, for the same code, there may be thousands of "distinct code signatures" in the claims submitted. One example is the oncology tumor panel domain, where Concert Genetics identified 9,931 distinct code signatures. By contrast, the oncology cancer screening domain only had eight distinct code signatures.

CLIA Accreditation Market: More Competitive Now?

➤Facing competition, deeming organizations may be ready to add more value to accreditation services

➤➤CEO SUMMARY: It's been three decades since compliance with the Clinical Laboratory Improvement Amendments (CLIA) became mandatory. During that time, there has been little competition among the major organizations with deeming status by the Medicare Program to accredit labs to CLIA. However, decisions by several major health systems to change the CLIA-accreditation provider they had used for years may be the catalyst for a new period marked by intense competition among the deeming organizations. If true, this will benefit labs that use these services.

Change seems to be happening in the once-quiet market for CLIA accreditation services. This change may bring welcome benefits to all clinical laboratories that must comply with the requirements of the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 and thus use the accreditation services of one of several organizations granted deeming status by the Medicare program.

➤Three System Labs Switched

It was The Dark Report that broke the news earlier this year that three of the nation's large health systems had independently made a similar decision. Over the proceeding eighteen months, each health system independently decided to move its CLIA accreditation business away from the **College of American Pathologists** (CAP) and give that business to **The Joint Commission** (TJC). *(See TDR, "CAP Loses Accreditation Clients to Joint Commission," and "Why Are Health Systems Changing CLIA Accreditors?" Jan. 19, 2021.)*

The only public announcement of a health system switch was on Sept. 14, 2020, when The Joint Commission issued a press release stating it had been "selected to provide Laboratory Accreditation Program services for the **U.S. Department of Veterans Affairs** (VA), effective September 15, 2020. Services include education on the accreditation process, on-site and post-survey reviews, ongoing monitoring activities, and data and measurement activities."

In the following months, The Dark Report learned that **Ascension Health** and **Providence Health** had independently made similar decisions to move their respective CLIA accreditation business to The Joint Commission.

These were important and significant developments in a critical area of lab management and operations. Since implementation of CLIA in 1992, the CAP has generally been considered to hold the largest market share of CLIA accreditation services in the United States.

Yet here, in the space of less than 12 months, three major health systems

had made independent decisions to begin using a new deeming organization for the CLIA accreditation of their clinical laboratories. The three health systems operate 372 hospitals, which shows the magnitude of the market change represented by these decisions. The number of hospitals operated by each health system is:

- Veterans Admin., 170 hospitals,
- Ascension Health, 151 hospitals,
- Providence Health, 51 hospitals.

This is a significant shift in the market share of CLIA accreditation services. One way to estimate market share of CLIA accreditors is to compare the number of hospital labs switching their CLIA provider as a percentage of all community, acute care hospitals. Recent information from the **American Hospital Association** (AHA) shows that, in 2020, there were 5,198 community hospitals. Thus, the 372 hospitals involved in the switch represent 7.2% of all community hospitals in the U.S.

Magnitude of Market Shift

A second, possibly more relevant, way to understand the true magnitude of the market shift in favor of TJC is to subtract out the 1,821 rural hospitals reported by the AHA. The 372 hospitals switching their CLIA accrediting bodies thus represent 11% of 3,377 non-rural community hospitals.

Over the past seven months, THE DARK REPORT has had conversations with a substantial number of clinical lab professionals and individuals within the major CLIA deeming organizations. The public disclosure that 372 hospital labs' worth of CLIA accreditation business had decided to switch to another deeming organization caught the full attention of many lab leaders.

What was common to all these conversations was a request for confidentiality. As long as it would be "off the record," sources were willing to share some of the good, the bad, and the ugly of their experiences with the common process of a CLIA accreditation assessment of their clinical laboratories, regardless of which deeming organization they happen to use. This has enabled our editorial team to better understand the dynamics at play in CLIA lab accreditation. Some of these findings will be positive for those pathologists and lab administrators who spend substantial amounts of money with their choice of a CLIA accrediting organization.

This intelligence briefing is to follow up the original reporting from January. To have as much as 11% of the CLIA accreditation market for non-rural community hospitals switch to the same deeming organization over an 18-month period was big news for the lab industry.

CAP May Be Ready to Enhance CLIA Services

WITHIN THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP), last January's news report about the switch of three of its bigger and long-standing health system clients to another deeming organization appears to have triggered a significant assessment of the College's CLIA accreditation program. Beyond one public statement provided to THE DARK REPORT by CAP in January, the College has not commented further.

Individuals with knowledge of some internal conversations say that the CLIA accreditation program now has the full attention of the CAP board and senior administrators. There is recognition of the need to be more responsive to the expectations of lab clients. The price of accrediting services is being reviewed. Another element is how the peer-assessment team is used for the on-site inspection of laboratories.

If true, this may mean that labs using the CAP's CLIA accreditation services might eventually see a more customer-responsive CLIA accreditation process, one that may even be less expensive than current services.

One important positive development from the change in CLIA accreditation market share is how it signals that competition for lab accreditation business is intensifying.

Improving CLIA Services

Clinical laboratory administrators and pathologists now have reason to hope that this intensified competition among deeming organizations will improve the CLIA accreditation services upon which they rely. Every deeming organization should want to devote consistent effort to learn whether or not it is meeting the minimum expectations of its lab customers if it wants to win new clients and expand its share of the CLIA accreditation market.

A second positive development from these market-disrupting events is that labs may see lower prices from the deeming organizations. It is a long-standing complaint by labs that CLIA accreditation services are expensive for the benefits they provide. It is reasonable to expect that more competition among the major CLIA accrediting organizations may mean lower prices for labs. Or—if not lower prices—more value for the money.

There may be a third benefit that follows from the independent decisions of three large health systems to move their CLIA lab accreditation business away from one organization and to another. In tandem with the disruption in CLIA accreditation lab inspections caused by the pandemic during 2020, the entire process of how labs are assessed for CLIA compliance may be reassessed and reconfigured to reflect the reality of today's lab operations.

This may happen because the deeming organizations now have an incentive to go to officials at the federal **Centers for Medicare and Medicaid Services** and argue that it is time to complete a comprehensive revision and update to the CLIA framework in place since 1992.

Both Medicare officials and the CLIA accreditors have experience with remote lab assessments conducted during the pandemic. Lessons were learned about what parts of the 1992 CLIA requirements can be dropped as irrelevant or inappropriate to how labs operated in 2021.

Meanwhile, it is important for pathologists and lab executives to have a better understanding of the types of issues that motivated three major health systems to independently decide to move their CLIA-accreditation business away from a deeming organization they might have used for decades and instead endure the disruptions needed to bring in a new CLIA accrediting organization.

The lack of public announcements means that unnamed sources are needed to fill in some of the missing details. Those details include several complicating factors that led to the VA's decision to use The Joint Commission, along with some of the political issues involved.

There is also an unusual tale about a meeting in St. Louis that appeared to doom CAP's chances of retaining Ascension's accrediting business because of a failure to send enough members of CAP's senior staff, according to an anonymous source. That source spoke to THE DARK REPORT on the condition that the source's name would not be revealed.

Complicating Factors

One complicating factor behind the VA's decision to use The Joint Commission instead of continuing to use CAP for its lab-accreditation services is that pathologists from VA labs have often been used to do CLIA assessments of the clinical lab facilities operated by publicly-traded companies. Those companies include **Quest Diagnostics**, **Labcorp**, **BioReference Laboratories**, and others.

As a large federal agency, the Veterans Health Administration wants to avoid any hint of favoritism toward one vendor or another, the source explained.

"For many reasons, the VA considers itself to be politically neutral," the source commented. "For example, that is why, when a pathologist from a VA hospital

lab visits a Quest or Labcorp site for an assessment, the VA pathologist would need to take a vacation day to fulfill the VA's obligation to remain politically neutral in every possible way.

"That taking of a vacation day creates an awkward situation for the VA and perhaps for the publicly-traded lab company involved as well," the source added.

Another relevant factor about how the CAP would assess clinical laboratories that publicly-traded companies run is that if the CAP personnel doing the assessment did not have the technical expertise to assess complex aspects of a particular lab—such as molecular genetics—then the CAP would send a team to that lab from an academic medical center to do the more complex assessments, sources said.

Is Saving Money a Factor?

As with every issue in healthcare, saving money on services from outside vendors is critically important. A source told THE DARK REPORT that one question that remains unanswered is why the VA would switch from the CAP to The Joint Commission. Could it be that the most likely reason is to save money?

"No one in the lab business will ever tell you that the primary reason that a large health system changed from one CLIA accrediting authority to another is money," the source told THE DARK REPORT. "There is not a health system in the United States that will ever state publicly that it is considering making such a change to save money. No one in a health system would ever admit that they want to save money, because doing so implies that they are sacrificing quality to do so.

"Patients don't want to be associated with health systems that do anything but promote quality healthcare," the source noted. "Health system administrators will always say that they provide the best quality and that the best quality is worth every penny.

"That said, we all know that, in truth, if healthcare administrators can save money they will do so," the source noted. "But if they make a change to save money, they will never say so."

Collectively, feedback from numerous sources indicates that this newly-intensified competition among deeming organizations may result in more value for CLIA accreditation services. This competition could even produce lower prices for CLIA accreditation services. Clinical labs would welcome these developments. TDR

Compass Group Labs Sent Letter to CAP

IN THE WEEKS FOLLOWING THE THE DARK REPORT'S STORY about how The Joint Commission had won the CLIA lab accreditation business of three major health systems that collectively operate 372 hospitals, at least one association of hospital lab leaders expressed their concerns in writing to CAP.

The Compass Group is an organization of 30 not-for-profit IDN System Laboratory leaders "who have established collaborative relationships to identify and share best practices and strategies to help ensure the survival of the not-for-profit laboratory industry." Their leaders sent a letter to CAP expressing concerns about the College's CLIA accreditation process and service.

Given the timing of that letter following publication of the news that three other major health system laboratories had decided to move their CLIA accreditation business to another deeming organization, it can be assumed that Compass Group member labs probably had similar concerns about how the College priced and delivered its CLIA accreditation services.

When THE DARK REPORT asked for a copy of that letter and for a commment, the representative of The Compass Group confirmed that a letter had been sent, but declined to provide the letter or offer a comment.

Genetic Test Update

How to Achieve Success with Genetic Test Prior Authorization

Expert provides insights and advice on how labs should respond to payers' often-onerous requirements

As managed care payers increasingly require prior authorization for genetic tests, clinical laboratories should understand the ins and outs of what it takes to get reimbursed for testing they provide.

Almost all payers now require prior authorization (PA) for genetic testing, said Heather Agostinelli, Vice President, strategic revenue operations, with **XIFIN Inc.**, a revenue cycle management firm based in San Diego. Tests that most commonly require PA are:

- Cystic fibrosis,
- Fragile X syndrome,
- SMA (Spinal Muscular Dystrophy),
- ClariTest,
- Exome testing, and,
- STD testing.

While prior authorization should be initiated by the ordering physician, all too often that does not happen and the clinical laboratory is left to seek approval for testing, Agostinelli noted.

Seeking Prior Authorization

"Seeking PA can require submission of test requisitions, test results, notes of any genetic counseling that has occurred, along with medical records and notes from the ordering physician," she said. "There is no standardization among payers regarding the PA process, so labs must address each submission separately.

"Labs know if they want to get paid, they have to take control," Agostinelli explained. "Unfortunately, seeking PA through a manual process can be time consuming, often taking at least 30 minutes per authorization, if not more."

Among the biggest challenges in receiving PA from a payer are:

- Not meeting medical necessity,
- Unable to obtain necessary documentation from the ordering physician,
- Missing a deadline for requesting PA (some insurers give 48 hours from the time the specimen is received), and,
- Payer requirements that genetic counseling be performed prior to the test being run and PA being granted.

Critical Info from Doctors

Automation of the process can greatly reduce time spent on seeking PA, but it does not necessarily make it easier to obtain critical information from ordering physicians. There are vendors (e.g., **Infinx**, **Glidian**, **Cover My Test**) who will assist laboratories or physicians with prior authorization. But labs that do not have an automated PA system, or that do not use a billing company or outside vendor, will need to call the provider to get the information.

"Often, physicians are slow to share their notes and records and require multiple follow-ups to spur them into action," Agostinelli stated. "That makes getting prior authorization even more difficult."

When clinical laboratories submit pre-authorization requests for genetic testing, 40% to 50% of those requests are denied. "Some labs are now changing

their processes so that they no longer automatically run the test before they get prior authorization," she observed.

"In these cases, if the PA is denied, the lab will contact the patient and ask if they want to be moved to a self-pay rate or if they want to cancel the test," she added.

If a lab chooses to put this policy in place it should involve both its finance and sales department, Agostinelli advised. "This is a sensitive area," she said. "A lab does not want to anger its referral sources, but at the end of the day, labs need to make a profit." *(See sidebar at right.)*

Medical Necessity Criteria

Receiving prior authorization approval from a payer for a molecular test does not necessarily mean that the claim will be paid, she added. Prior authorization simply means the test meets the medical necessity criteria, but it does not address the payer coverage policies. If the payer policies prohibit out-of-network labs from being paid for testing, then the PA may not override the noncoverage policy.

A clinical lab that performs an unusually high number of genetic or clinical tests might be targeted by payers for prepayment review audits. These payers will then require that a lab—when it submits a claim—to also submit extensive documentation, such as the requisition, test results and medical notes from the ordering physician.

Prepayment Review Audits

"**Anthem** and **UnitedHealthcare** (UHC) are known for conducting prepayment review audits," Agostinelli noted. "During the time of this audit, and while the claims are being reviewed, the lab won't be paid by that payer.

"This process can easily take three to six months or more," she continued. "It is a financial cash-flow hit to that lab if the audit is by one of the large payers in their payer mix. Once the audit is over, in most cases those claims are released and billed to the payer. The lab should not have to deal with timely filing policy, as that should be waived by the payer.

"Prepayment review audits are very painful because they are manual and the lab's response takes considerable time to prepare," Agostinelli said. "These payers should go directly to the ordering physician—not to the lab—for any documen-

Are Referring Sources Profitable or Not?

IN SOME CASES, CLINICAL LABORATORIES DOING GENETIC TESTING will have referral sources who consistently order testing that is denied because it does not meet medical necessity criteria. When that happens, laboratories need to take a close look at what revenue those referral sources generate, advised Heather Agostinelli, Vice President, strategic revenue operations, with XIFIN Inc.

"To determine this requires looking at the referral source at a very granular level, using the monthly reports showing what the referral source yields in payment and denials," she said. "You should be able to identify those offenders and that allows your lab team to make business decisions about those offenders. Small labs may not want to 'fire' clients, but they should keep in mind that big labs regularly review the cost-benefit tradeoff and definitely will fire clients whose business is unprofitable."

Agostinelli said it is worthwile to attempt to educate the problematic referral sources about what constitutes medical necessity before cutting ties. Some physicians may not have a good understanding about what medical necessity requirements are for a particular genetic test.

Education can go a long way toward solving the problem. However, if the offending provider continues to order unnecessary tests, the lab must make a business decision about whether it is worthwhile to continue that relationship.

tation they require from the ordering physician. The lab can provide the claims, the requisition, and the results. But the payer should go to the provider for the clinical notes.

"Unfortunately, that rarely happens, and clinical laboratories often end up obtaining the provider records and notes themselves," she explained, noting, "This is a major pain point for most labs billing for genetic tests."

Genetic Test Coverage

One challenge clinical laboratories face is staying current with the various payer policies governing coverage of genetic testing, especially molecular testing that requires PA. Certain payers are good about putting out regular updates with changes to coverage policies, but others are not, Agostinelli noted.

"**UnitedHealthcare** (UHC) is the insurer with the most restrictive coverage policies," she said. "For example, UHC has a strict coverage policy for ClariTest, which identifies the risk for fetal chromosomal abnormalities. UHC will only cover the test for women 35 and older who have a family history. **Cigna**, **Humana,** and **Aetna** also have relatively strict policies. In addition, most Medicaid programs do not cover genetic testing.

"Labs that are most successful at navigating the PA process and subsequent appeal, have strong payer relations teams," she said. "The majority of labs do not. It's something in which your lab must invest. It's more than just hiring someone who can make phone calls; you want to hire people who have deep contacts within the industry. Your lab must spend what is necessary to have a strong payer relations team."

Antiquated Payer Policies

Some payer policies are simply antiquated, Agostinelli noted. "A clinical laboratory can challenge a policy by requesting an objective review. But that can be expensive for both the lab and the payer. What's more, the lab must weigh the pros and cons of challenging a payer, given that good relationships with payers are critical.

"In addition to having a strong payer relations team and keeping up with payer policies, it is essential for clinical labs doing genetic testing to have appeals strategies in place," Agostinelli advised. Labs may need to appeal a denial as many as two or three times before getting paid, she added.

For tests that may not meet medical-necessity requirements, Agostinelli suggests that clinical labs either not perform the test or establish a self-pay rate. "It's not sustainable for labs to keep performing genetic tests for which they are not paid. Labs need to have policies in place for what happens when a test does not meet medical-necessity requirements of a patient's health plan."

Use of More Specific Codes

Another issue involves coding. "Clinical laboratory personnel should also take the time to ensure they use the correct codes on their claim submissions," Agostinelli stated. "CPT code 84179, a genetic tier 2 molecular pathology code, is one of the most-denied CPT codes.

"Take the time to find out if there is a more specific code," she continued. "It pays to have someone on your team who really knows coding. It's worth it to have an outside coding expert come in periodically to review your coding against your test menu. The goal is to ensure your lab uses the most appropriate code and is using all codes for which your lab is entitled to bill."

While it may seem there are a lot of hoops to jump through in order to get paid for genetic testing, the payoff in the end will be worth it, Agostinelli notes.

"Many diagnostic providers take a portion of their profits to invest in new testing that benefits us all," she said. "So, getting these labs paid is crucial to advance genetic and molecular testing." TDR

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IVD Update

PacBio Beefs Up with Purchase of Omniome for $800 Million

Gene sequencing company will have both long-read and short-read DNA sequencing

Forward-looking pathologists and lab administrators understand that the next big game in medical laboratory testing will be assays built upon genome sequencing. They also know that several companies are racing to produce gene sequencing instruments that are faster, simpler, and less costly in order to serve the needs of clinical labs.

Currently, **Illumina, Inc.**, of San Diego is one of the biggest players in the genome sequencing market. It holds a major share of the market for genome sequencing systems. But there is one upstart company that would like to challenge Illumina for leadership in the genome sequencing marketplace. It is **Pacific Biosciences** (PacBio), of Menlo Park, Calif.

Two Sequencing Technologies

Last Thursday, PacBio announced it would acquire **Omniome** of San Diego, for about $800 million. When the transaction is completed later this year, the acquisition will give PacBio a unique mix of two gene-sequencing technologies. Financial analysts predict PacBio wants to adopt the two technologies for use in diagnostics, particularly for non-invasive prenatal testing (NIPT) and for cancer testing.

Each company starts with a different core strength. PacBio is one of the early leaders in long-read sequencing. Its proprietary system can produce long sequences with high levels of accuracy. Researchers using PacBio systems say they are identifying single nucleotide polymorphisms (SNPs) that have many more base pairs because of the long-read capabilities of the sequencer.

By contrast, Omniome is developing short-read sequencing systems. In describing the company's proprietary technology, one analyst said, "their scar-free, Sequencing by Binding (SBB) technology provides enhanced precision of nucleotide and DNA matching by leveraging the natural matching ability of the polymerase, decreasing runtimes, and increasing the number of samples per run."

It may not take long for pathologists and clinical laboratory managers to see long-read and short-read technologies used in assays for clinical use, once clinical studies are completed. In a story about the merger, *Genetic Engineering and Biotechology News (GEN)* wrote, "Omniome's data accuracy should help the combined company, as PacBio eyes new markets for growth. They range, Christian Henry [PacBio CEO] said, from non-invasive prenatal testing (NIPT) to oncology applications, such as cell-free DNA for cancer screening and monitoring, liquid biopsy testing, and looking for residual disease."

Higher Sensitivity

GEN further described the reason why Henry was interested in Omniome's DNA sequencing platform, noting that Henry had said the platform applies Sequencing by Binding that, according to Omniome, delivers higher sensitivity, costs less, can run more specimens simultaneously, and

has faster throughput, along with better matching capabilities of nucleotides and DNA.

"We believe that the technology could be as much as—or more than—an order of magnitude more accurate than existing approaches out there," Henry said.

Keith Robison, PhD, who analyzes developments in genomics through his blog *Omics! Omics!*, believes that PacBio would like to use the short-read system to perform sequencing from cancer pathology samples that are preserved with FFPE (Formalin-Fixed Paraffin-Embedded). However, he also observed that "Omniome has not made public data on its platform, such as cost, turnaround time, etc. Omniome is a black box."

High-throughput System

Further evidence of PacBio's interest in clinical diagnostics is a separate announcement it made last week, in which PacBio stated that it was expanding an existing, multi-year collaboration with **Invitae**, the genetic testing company based in San Francisco.

This collaboration is working to take PacBio's HiFi, its long-read sequencing platform, and develop it into a "production-scale, high-throughput system" that could be used by clinical laboratories.

Along with Illumina and Omniome, other competitors in the short-read gene sequencing market are **Singular Genetics** of La Jolla, Calif., and **Element Biosciences** of San Diego.

Most clinical lab managers involved in molecular and genetic testing know that advances in gene sequencing moved faster than predicted, reaching the long-sought benchmark of $1,000 to sequence a whole human genome in 2018. Since then, companies have worked to shorten the time to sequence a genome, improve the accuracy of the sequence, and simplify the operation of the sequencing platforms, all to help clinical labs incorporate gene sequencing at some future date. TDR

Illumina Tried to Buy PacBio in 2019

THERE SEEMS TO BE A GOAL WITHIN THE GENOME SEQUENCING INDUSTRY for a company to have both short-read and long-read technologies. It was Illumina—a company with short-read technology—that first tried to accomplish this when it announced an agreement in 2018 to buy Pacific Biosciences (PacBio)—which is developing long-read technology.

In its acquisition agreement with PacBio, Illumina was prepared to pay about $1.2 billion for the company, working to bring PacBio's long-read genome sequencing technology to market. The deal was announced in November 2018.

Financial analysts pointed out that long-read sequencing technology is expected to be the method of choice for most precision medicine services. Thus, back in 2018, PacBio was considered to be better-positioned than Illumina to serve this sector of clinical care. By acquiring PacBio, Illumina would set itself up to be a global leader in both short-read and long-read genome sequencing systems.

Competing firms in the gene sequencing industry immediately complained to regulators in the United Kingdom. In the United States, on Dec. 17, 2019, the **Federal Trade Commission** (FTC) announced it had filed an administrative complaint in opposition to the merger. The FTC asserted that Illumina was acting to unlawfully maintain a monopoly in the next-generation sequencing marketing with the United States. It scheduled an administrative trial for August 2020.

In response to the FTC's actions, Illumina and PacBio canceled the transaction in January 2020. With its acquisition of Omniome, PacBio now has both short-read and long-read technologies. The odds are good that Illumina still wants to acquire a company with long-read genome sequencing technology.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Intermountain Healthcare of Salt Lake City announced that it plans to close 25 of its 26 retail pharmacies as early as next month. It cited declining business and a new business arrangement with **CVS Health**, the national pharmacy chain. Daron Crowley, Intermountain's media relations director, told the *Salt Lake City Tribune* that "they aren't being used enough by the community to remain open." If most of these pharmacies are located in medical office buildings operated by Intermountain Healthcare, then the fall-off in patients coming to see their doctors during the pandemic is probably a primary reason for the financial losses.

MORE ON: *Pharmacy Closures at Intermountain*

Crowley also stated that the retail pharmacies lost $11 million in 2020 and $6 million in the first five months of 2021. Another factor in the decision to permanently close these pharmacies—particularly if they are in medical office buildings—may also be due to more patients using telehealth and virtual primary care visits. After their telehealth session with their physician, patients likely go to the nearest retail pharmacy in their neighborhood to pick up the prescription. This development is an early warning to labs that patient service centers located in medical office buildings may see the number of daily collections decline as patients substitute a telehealth session for an in-person appointment with their physicians.

QUEST-MERCY OUTREACH LAB DEAL CLOSES

Last month, **Quest Diagnostics** announced that it had completed its purchase of the lab outreach business of **Mercy Health**. The deal involves outreach testing associated with 29 Mercy hospital laboratories and two independent clinic laboratories serving providers and patients in Arkansas, Kansas, Missouri, and Oklahoma.

TRANSITIONS

• **NeoGenomics, Inc.**, of Fort Myers, Florida, promoted George Cardoza to the position of President and Chief Operating Officer, Lab Operations. Prior to coming to NeoGenomics, Cardoza held positions at **Protocol Integrated Direct Marketing**, **Quest Diagnostics**, and **Sony Music Entertainment**.

• Gina Wallar is the new President of the Pharma Services Division at NeoGenomics. Formerly she served at **Labcorp** and **The Parkinson's Institute**.

• **Thermo Fisher Scientific** of Waltham, Mass., announced the selection of Karen E. Nelson, PhD, as its new Chief Medical Officer. She was previously President at the **J. Craig Venter Institute**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 16, 2021.

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