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Major Developments in CLIA Accreditation and Efforts to Update CLIA Regulations!

(See pages 2-8, 16-18.)

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Alert! Changes to CLIA Accreditation, CLIA Revisions

MEDICAL LABORATORIES HAVE LIVED WITH THE REGULATIONS FOR THE CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS (CLIA) since they were first implemented in 1992. Over the past 30 years there has been no major revision or updating of CLIA regulations. Nor has there been much change in the long-standing status quo associated with how labs choose which deeming authority they use to earn accreditation to CLIA.

That appears to be no longer the case, at least in the world of CLIA regulation and inspections. This issue of THE DARK REPORT presents intelligence briefings on both topics.

As to CLIA lab inspections, the past year has seen major developments without precedent. Early in 2021, it became public knowledge that two large national health systems—**Ascension Health** and the **Veterans Administration**—had signed agreements to switch their preferred CLIA accrediting organization. *(See TDR, "Why Are Health Systems Changing CLIA Accreditors?" January 19, 2021.)* Similarly, in the past 60 days, one CLIA deeming organization has decided to not recognize the accreditations of another deeming organization. On pages 3-8, you'll read about the decision of **The Joint Commission** (TJC) to no longer recognize the CLIA accreditations issued by COLA for labs located within TJC-accredited facilities, effective January 1.

The second aspect of CLIA compliance is an effort underway in recent years to review the current state of diagnostic technologies and how they are utilized by clinical labs and pathology groups. The goal is to do a major revamp of the current CLIA regulations. These regulations have not had a significant overhaul or revision since their implementation in 1992—30 years ago!

THE DARK REPORT presents its exclusive interview with one of the principles involved in coordinating the different committees tasked with identifying specific aspects of daily lab testing operations that did not exist in 1992. *(See pages 16-18.)* Genetic tests, whole genome sequencing, and use of machine learning algorithms to analyze large volumes of lab test data are examples of diagnostic technologies in wide use today that did not common in 1992.

There is a significant message here for every lab manager and pathologist tasked with keeping their labs compliant with CLIA: changes are happening and the consequences of these changes are unknown. However, you can depend on THE DARK REPORT to keep you informed as things develop. TDR

Joint Commission Will Not Accept COLA Accreditation

COLA says it is 'surprised and disappointed' by the decision, which has a two-year phaseout

CEO SUMMARY: This may be a first in the 40-year history of CLIA accreditation of clinical laboratories. The Joint Commission (TJC) announced it will no longer recognize COLA's laboratory accreditation program within "TJC-accredited facilities," effective Jan 1, 2023. COLA-accredited labs within TJC-inspected facilities have two years to switch their CLIA accreditation provider. The reasons behind The Joint Commission's decision remain unclear.

INTERESTING THINGS ARE UNFOLDING IN THE COMPETITIVE MARKET FOR CLIA ACCREDITATION. As of Jan. 1, **The Joint Commission** (TJC) ceased recognizing **COLA** accreditation of clinical laboratories at TJC-accredited facilities.

This action may have no precedent in the 30 years since the regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) took effect in 1992. Until now, a CLIA lab accreditation issued by any of the organizations granted deeming authority by the **Centers for Medicare and Medicaid Services** (CMS) has been generally recognized by the other deeming bodies.

This new development is the latest sign that a long-standing status quo in the competitive market for the CLIA accreditation business of complex laboratories is coming to an end. Emerging signs indicate that the major organizations with deeming status—dominated by the **College of American Pathologists** (CAP) and The Joint Commission—are interested in capturing a larger share of the CLIA accreditation business of larger labs.

This is particularly true of the accreditation business of hospital and health system laboratories. In the past 24 months, several very large health systems changed their choice of CLIA accreditor. Consistent with those developments, TJC's policy change covers "TJC-accredited facilities."

Many in healthcare would interpret this as describing primarily acute care hospitals, where core laboratories and satellite laboratories perform a substantial number of tests daily. On its website, TJC

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states, "Today, The Joint Commission accredits approximately 3,800 general, pediatric, long term acute, psychiatric, rehabilitation, and specialty hospitals."

A spokesperson for TJC told The Dark Report last week that approximately 300 facilities would be affected that have a lab accredited by COLA.

An Interesting Question

TJC's decision to no longer accept a COLA-accredited lab in a TJC-accredited facility raises a key question. Under the CLIA statute and associated federal regulations, can one deeming organization cease recognizing the CLIA accreditation status of a lab inspected by another deeming organization that is in good standing with CMS?

The Dark Report asked this question to several attorneys experienced in aspects of the CLIA statues and associated regulations. None of them had heard of this situation before and said they could not answer the question. At the same time, each attorney declaimed that TJC's policy may not be in violation of the CLIA requirements.

COLA seems to be caught equally flat-footed by TJC's new policy. "We were surprised and disappointed by this decision," COLA CEO Nancy Stratton wrote in a letter to member laboratories on Dec. 5. "COLA did not elect to terminate the relationship or seek to change the terms of the agreement. TJC made this decision unilaterally and without prior discussion or consultation with COLA." *(See COLA's full letter on p. 7.)*

TJC sent a statement to The Dark Report that said, in part, "After thorough review and careful consideration of COLA's laboratory accreditation program, in keeping with the terms of our cooperative agreement, The Joint Commission determined that continuing our recognition of COLA did not best support our mission for quality and safety within Joint Commission accredited facilities."

Recognition of COLA accreditation by TJC stretches back to 1997. In an interview with The Dark Report, Stratton said she did not know—and would not speculate about—what precipitated TJC's decision.

"The Joint Commission made a business decision, and it's not a devastating thing to us in any way," Stratton said. "We at COLA need to dig our heels in and just continue going as we've been going the last few years."

She touted the organization's successes, including re-entering the pathology accreditation market last year. *(See TDR, "COLA Re-enters CLIA Accreditation for Pathology," April 4, 2022.)*

When asked, Stratton said that COLA and TJC had not discussed TJC's authority under the Clinical Laboratory Improvement Amendments of 1988 to not recognize another deemed clinical laboratory accreditor.

Two-Year Phaseout

In a letter to healthcare organizations, Heather Hurley, Executive Director of Laboratory Accreditation and Health Systems Strategic Accounts at TJC, wrote that there is a two-year phaseout of COLA accreditation for affected labs. *(See TJC's full letter on p. 6.)*

Hurley noted that if a COLA lab is part of a TJC-accredited organization, the laboratory has until Dec. 31, 2024, to gain accreditation from The Joint Commission or another partner. Though not specified, presumably the lab accredited by COLA would switch to any of the six remaining organizations that currently have deeming status, including TJC and the College of American Pathologists.

"If your healthcare organization currently utilizes COLA as its laboratory accreditor (for one or more CLIA certificates within your organization), and your organization is accredited under any Joint Commission accreditation program, transition of your laboratory accreditor will be

required," Hurley wrote. "We understand that this is an impactful change and are extending a two-year transition period to allow organizations ample time to make this change."

TJC's policy change will not involve any clinical laboratories accredited by COLA that are not part of a TJC-accredited healthcare facility. However, for labs that are part of a TJC-accredited healthcare facility, replacing the COLA lab accreditation by switching to The Joint Commission or another TJC-acceptable deeming organization will be a burdensome change to undertake within the two year timeline.

While TJC cannot force a lab in a TJC-accredited healthcare facility to drop COLA, by contract, it can go to that accredited organization, inspect the lab, and make the organization pay for that inspection, according to a source familiar with the situation.

Stratton said she did not know by number how many clinical laboratories would be affected by The Joint Commission's decision, but she added that laboratories within TJC-accredited facilities are "not a large component" of COLA's accreditation mix.

CMS Reviewing the Situation

The federal **Centers for Medicare and Medicaid Services** (CMS) grants certain organizations deemed authority to accredit labs and pathology practices on behalf of the Medicare program and CLIA. As noted earlier, both TJC and COLA have deemed authority from CMS.

THE DARK REPORT believes this is the first time since CLIA's inception that one deemed authority has elected to cease recognizing another deemed authority within the lab accreditation field.

Asked about TJC's move, a CMS spokesperson told THE DARK REPORT that the agency is looking into how such situations might comply or conflict with regulatory provisions of CLIA.

CMS Lists Seven CLIA Organizations

ON THE CENTERS FOR MEDICARE AND MEDICAID SERVICES WEBSITE, these seven organizations are approved accreditation organizations under the Clinical Laboratory Improvement Amendments (CLIA):

- **AABB**, Bethesda, Maryland
- **American Association for Laboratory Accreditation**, Frederick, Maryland
- **Accreditation Commission for Health Care, Inc (ACHC)**, Cary, North Carolina
- **American Society for Histocompatibility and Immunogenetics**, Mt. Laurel, New Jersey
- **COLA**, Columbia, Maryland
- **College of American Pathologists**, Northfield, Illinois
- **Joint Commission**, Oakbrook Terrace, Illinois

"While most aspects of the business agreements and arrangements involving healthcare entities and accrediting organizations (AOs) are internal to those organizations, we are reviewing all applicable statutory requirements, as well as CMS' AO oversight regulations, to determine what authority, if any, CMS may have in these situations," the CMS wrote.

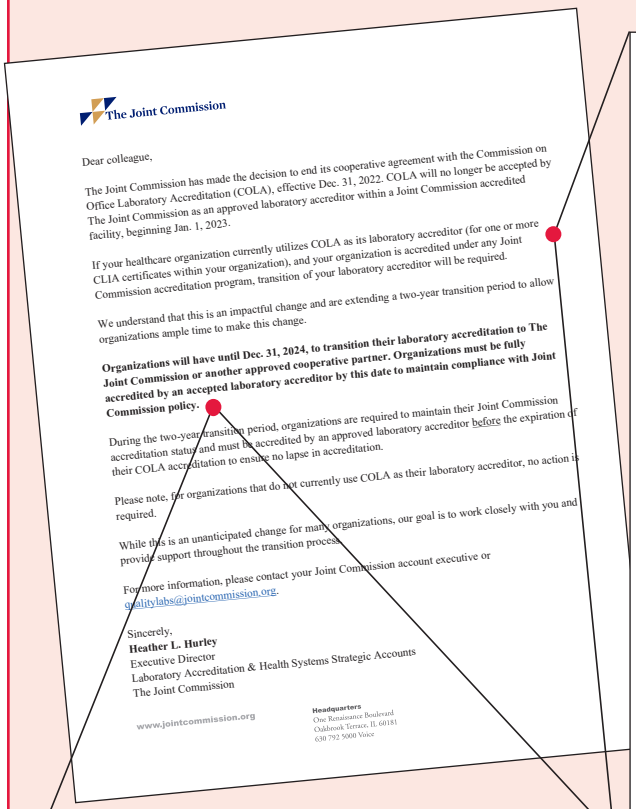
COLA's letter states clinical laboratories accredited by COLA that operate within organizations also accredited by TJC have three choices:

- Labs can remain with COLA if the hospital or system chooses to change its accreditation from TJC to another accrediting organization.
- Labs can remain with COLA and also enroll in TJC accreditation.
- Labs can withdraw from COLA.

"While this is an unanticipated change for many organizations, our goal is to work closely with [clinical laboratories] and provide support throughout the transition process," Hurley wrote. TDR

Under The Joint Commission's New Policy, Accredited Facilities Have Two Years to Labs Accredited to CLIA by COLA in TJC-Engage a Different CLIA Accreditation Body

In December, hundreds of healthcare facilities accredited by The Joint Commission (TJC) received a copy of the undated letter reproduced below, sent by TJC. The letter announced that TJC had terminated its cooperative agreement with COLA concerning CLIA accreditations of clinical labs issued by COLA in TJC-accredited facilities. As of Jan. 1, the affected facilities have two years to switch the CLIA accreditation of their clinical laboratories to another deeming organization acceptable to The Joint Commission.



The Joint Commission

Dear colleague,

The Joint Commission has made the decision to end its cooperative agreement with the Commission on Office Laboratory Accreditation (COLA), effective Dec. 31, 2022. COLA will no longer be accepted by The Joint Commission as an approved laboratory accreditor within a Joint Commission accredited facility, beginning Jan. 1, 2023.

If your healthcare organization currently utilizes COLA as its laboratory accreditor (for one or more CLIA certificates within your organization), and your organization is accredited under any Joint Commission accreditation program, transition of your laboratory accreditor will be required.

We understand that this is an impactful change and are extending a two-year transition period to allow organizations ample time to make this change.

Organizations will have until Dec. 31, 2024, to transition their laboratory accreditation to The Joint Commission or another approved cooperative partner. Organizations must be fully accredited by an accepted laboratory accreditor by this date to maintain compliance with Joint Commission policy.

During the two-year transition period, organizations are required to maintain their Joint Commission accreditation status and must be accredited by an approved laboratory accreditor before the expiration of their COLA accreditation to ensure no lapse in accreditation.

Please note, for organizations that do not currently use COLA as their laboratory accreditor, no action is required.

While this is an unanticipated change for many organizations, our goal is to work closely with you and provide support throughout the transition process.

For more information, please contact your Joint Commission account executive or qualitylabs@jointcommission.org.

Sincerely,
Heather L. Hurley
Executive Director
Laboratory Accreditation & Health Systems Strategic Accounts
The Joint Commission

www.jointcommission.org

Headquarters
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
630 792 5000 Voice

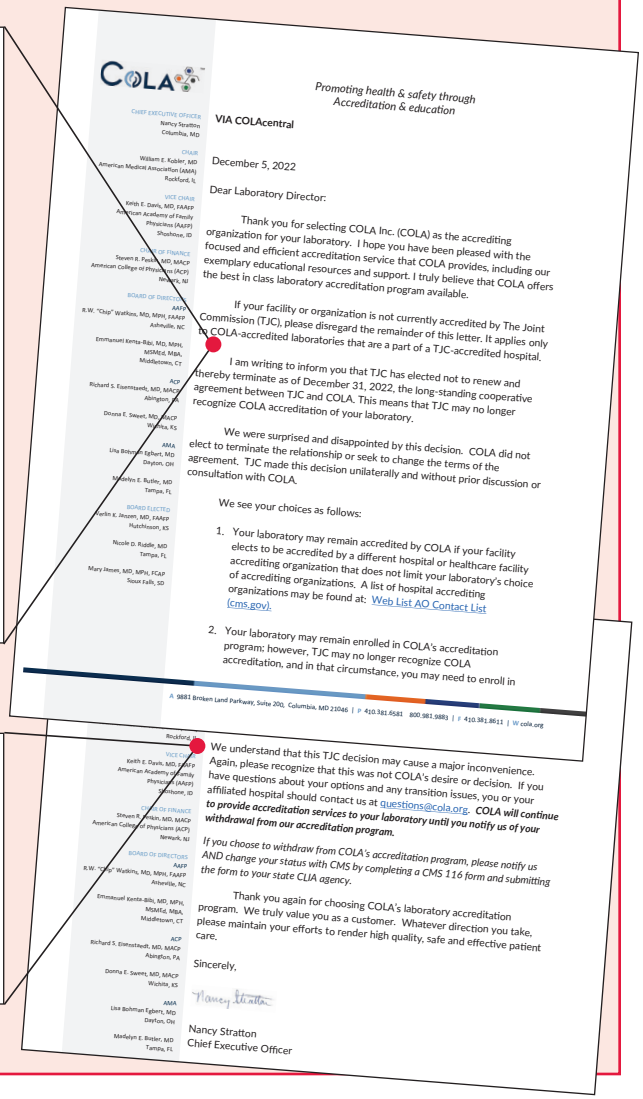
The Joint Commission has made the decision to end its cooperative agreement with the Commission on Office Laboratory Accreditation (COLA), effective Dec. 31, 2022. COLA will no longer be accepted by The Joint Commission as an approved laboratory accreditor within a Joint Commission accredited facility, beginning Jan. 1, 2023.

If your healthcare organization currently utilizes COLA as its laboratory accreditor (for one or more CLIA certificates within your organization), and your organization is accredited under any Joint Commission accreditation program, transition of your laboratory accreditor will be required.

We understand that this is an impactful change and are extending a two-year transition period to allow organizations ample time to make this change.

Organizations will have until Dec. 31, 2024, to transition their laboratory accreditation to The Joint Commission or another approved cooperative partner. Organizations must be fully accredited by an accepted laboratory accreditor by this date to maintain compliance with Joint Commission policy.

Following the decision by The Joint Commission (TJC) that it would no longer accept a CLIA accreditation issued by COLA in TJC-accredited facilities as of Jan. 1, 2023, COLA sent the letter below to certain TJC-accredited facilities. COLA acknowledged that it was a unilateral decision by TJC to terminate "the long-standing cooperative agreement between TJC and COLA." The letter also identified the appropriate steps these facilities should take to select a new CLIA accrediting organization and notify the Centers for Medicare and Medicaid Services (CMS) of this change.



COLA

Promoting health & safety through Accreditation & education

VIA COLAcentral

December 5, 2022

Dear Laboratory Director:

Thank you for selecting COLA Inc. (COLA) as the accrediting organization for your laboratory. I hope you have been pleased with the focused and efficient accreditation service that COLA provides, including our exemplary educational resources and support. I truly believe that COLA offers the best in class laboratory accreditation program available.

If your facility or organization is not currently accredited by The Joint Commission (TJC), please disregard the remainder of this letter. It applies only to COLA-accredited laboratories that are a part of a TJC-accredited hospital.

I am writing to inform you that TJC has elected not to renew and thereby terminate as of December 31, 2022, the long-standing cooperative agreement between TJC and COLA. This means that TJC may no longer recognize COLA accreditation of your laboratory.

We were surprised and disappointed by this decision. COLA did not elect to terminate the relationship or seek to change the terms of the agreement. TJC made this decision unilaterally and without prior discussion or consultation with COLA.

We see your choices as follows:

1. Your laboratory may remain accredited by COLA if your facility elects to be accredited by a different hospital or healthcare facility accrediting organization that does not limit your laboratory's choice of accrediting organizations. A list of hospital accrediting organizations may be found at: Web List AO Contact List (cms.gov).

2. Your laboratory may remain enrolled in COLA's accreditation program; however, TJC may no longer recognize COLA accreditation, and in that circumstance, you may need to enroll in

9881 Broken Land Parkway, Suite 200, Columbia, MD 21046 | P 410.381.6581 800.981.9883 | F 410.381.8611 | W cola.org

I am writing to inform you that TJC has elected not to renew and thereby terminate as of December 31, 2022, the long-standing cooperative agreement between TJC and COLA. This means that TJC may no longer recognize COLA accreditation of your laboratory.

We were surprised and disappointed by this decision. COLA did not elect to terminate the relationship or seek to change the terms of the agreement. TJC made this decision unilaterally and without prior discussion or consultation with COLA.

We understand that this TJC decision may cause a major inconvenience. Again, please recognize that this was not COLA's desire or decision. If you have questions about your options and any transition issues ... contact us at questions@cola.org.

We understand that this TJC decision may cause a major inconvenience. Again, please recognize that this was not COLA's desire or decision. If you have questions about your options and any transition issues, you or your affiliated hospital should contact us at questions@cola.org. ***COLA will continue to provide accreditation services to your laboratory until you notify us of your withdrawal from our accreditation program.***

If you choose to withdraw from COLA's accreditation program, please notify us AND change your status with CMS by completing a CMS 116 form and submitting the form to your state CLIA agency.

Thank you again for choosing COLA's laboratory accreditation program. We truly value you as a customer. Whatever direction you take, please maintain your efforts to render high quality, safe and effective patient care.

Sincerely,

Nancy Stratton
Chief Executive Officer

Lab Accreditation Update

What's Behind Joint Commission Move to Not Accept COLA Labs?

DURING THE NEXT TWO YEARS, a substantial number of hospitals and healthcare facilities will need to respond to **The Joint Commission's** (TJC) decision to no longer recognize CLIA accreditations issued by **COLA** in "TJC-accredited facilities."

In the 30-year history of the current Clinical Laboratory Improvement Amendments (CLIA) regulation, it is believed that there is no precedent for one of the organizations granted deeming status by the **Centers for Medicare and Medicaid Services** (CMS) to cease to recognize the laboratory accreditations of another deeming organizations.

New Policy Effective on Jan. 1

Hundreds of TJC-accredited organizations have at least one laboratory site currently accredited to CLIA by COLA. TJC's new policy took effect on Jan. 1, and to keep their TJC accredition, those facilities will need to select another deeming organization for CLIA accreditation.

THE DARK REPORT contacted The Joint Commission to ask the reasons why TJC officials decided to take this action. The public communications office of TJC provided the following statement last week, which is reproduced in full:

The Joint Commission decided to end its cooperative agreement with the Commission on Office Laboratory Accreditation (COLA). Beginning Jan. 1, 2023, COLA is no longer accepted by The Joint Commission as an approved laboratory accreditor within a Joint Commission accredited facility.

After thorough review and careful consideration of COLA's laboratory accreditation program, in keeping with the terms of our cooperative agreement, The Joint Commission determined that continuing our recognition of COLA did not best support our mission for quality and safety within Joint Commission accredited facilities.

If an organization currently utilizes COLA as its laboratory accreditor (for one or more CLIA certificates), and the organization is accredited under any Joint Commission accreditation program, transition of its laboratory accreditor will be required.

We understand that this is an impactful change and are extending a two-year transition period to allow organizations ample time to make this change.

It is known that the deeming organizations have agreements with each other. TJC references such an agreement with COLA in its communications with healthcare facilities about the decision to no longer recognize CLIA accreditations issued by COLA.

Areas of Concern?

It is not known why TJC is taking this action at this time. Lab leaders familiar with the system of CLIA lab accreditation surmise that it could be because TJC may have concerns about COLA's accreditation reviews. That notion is supported by a Joint Commission statement that COLA's program "did not best support our mission for quality and safety."

Another theory is that competition for additional lab accreditation clients is increasing between all the deeming organizations and this move is related to that market dynamic. TDR

Lab Informatics Update

Labcorp Selects Oracle Cerner to Streamline Lab Workflows

New arrangement may give Cerner access to significant lab data at dozens of hospitals

There is a unique corporate collaboration unfolding that involves **Labcorp** and **Oracle Cerner**. Announced in November, Labcorp will leverage Oracle Cerner's lab information systems to update clinical laboratory workflow processes and support the sharing of patient data across healthcare organizations.

The Labcorp/Oracle Cerner arrangement also intends to demonstrate that the collected health data from hospital laboratory information systems (LIS) can serve as valuable currency.

Highlights of the Deal

In a blog post on its website, Oracle Cerner in North Kansas City, Missouri, detailed its agreement with Labcorp in Burlington, North Carolina. Among the highlights:

- Oracle Cerner's LIS will help Labcorp streamline clinical laboratory workflows and processes at a hospital system's labs across 10 states.
- The collaboration will allow Labcorp to expand and standardize the labs' existing technologies, which will support diagnostic data sharing across the providers in these systems.

Unsaid in Oracle Cerner's announcement—though likely a prime motivation—is at least some level of access to Labcorp's laboratory data through the LIS setup.

Patient data, even if anonymized, is a highly sought-after resource for technology companies because of the information's value in personalized medicine and artificial intelligence. *(See TDR, "AI Fuels New Efforts in Computational Pathology," Oct. 10, 2022.)*

Cerner's blog noted that the deal involved "one of the nation's leading nonprofit Catholic health systems," a description that fits that of **Ascension Health**.

Ascension is a Catholic health system based in St. Louis that operates 142 hospitals in 19 states and the District of Columbia. Labcorp signed a deal in 2022 to manage at least 75 inpatient labs at Ascension hospitals, and to acquire the laboratory outreach business at a number of Ascension locations. *(See TDR, "Labcorp to Buy Outreach, Manage Ascension Labs," Feb. 22, 2022.)*

The outreach agreement alone was worth $400 million. It was one of several lab outreach deals Labcorp signed over the past six years. Commercial lab companies hope to encourage more such transactions as hospitals facing steep financial losses look for a sizeable inflow of cash.

Most recently in August, Labcorp acquired the lab outreach business of **RWJBarnabas Health** in New Jersey.

Few Public Comments

Oracle Cerner did not return a request for comment. Labcorp declined to make anyone available to The Dark Report to interview. However, Labcorp CEO Adam Schechter dropped some details about the Ascension deal during a fireside chat at

the **J.P. Morgan** Healthcare Conference, a private event for the investment firm's clients that took place Jan. 9-12 in San Francisco. A recording of his appearance was posted to Labcorp's investor relations website.

"We are now running the labs for almost 100 hospitals across the Ascension hospital system," Schechter said. He also noted that his company transitioned approximately 5,000 former Ascension employees, many of them likely lab workers, onto Labcorp's payroll.

Implementing Automation

A big goal of the Ascension deal is to maintain and eventually improve test turnaround times for patients. "We have to make sure there's a smooth transition as we go from the hospitals' laboratory systems into our laboratory systems," Schechter said. He did not mention working with Oracle Cerner, but it is reasonable to assume Cerner is playing a role in this transition.

One of Oracle Cerner's goals in the partnership was to minimize manual interactions with technology in favor of auto-verification features and automatic reporting of test results. Doing so will lead to faster diagnostic decisions, the company stated.

Labcorp's efforts to streamline lab operations at Ascension hospitals will likely take several years to fully carry out, Schechter noted. "Over time, we'll find ways to combine procurement and to ensure we have consistent systems across the hospitals that will make them more efficient," he added.

Whether the Labcorp deal plays into Oracle Cerner's long-term plans remains to be seen.

In June, during a virtual presentation by Oracle, Chairman and Chief Technology Officer Larry Ellison outlined plans for Cerner's products. *(See TDR, "Oracle's Plans for Cerner Might Increase Value of Lab Test Data," June 27, 2022.)*

Oracle–Cerner Deal Was Worth $28 Billion

ORACLE CERNER IS THE NEW NAME of the former Cerner Corporation. Oracle acquired Cerner in late 2021 in a blockbuster deal worth $28 billion. *(See TDR, "Oracle's $28b Cerner Deal Shows Value of Health Data," Jan. 31, 2022.)*

At the time, the hype of the acquisition centered on Cerner's Millennium electronic health record (EHR) system. That system gained prominence over the prior decade as the federal government offered financial incentives to hospitals to install EHRs.

The move by Oracle to acquire Cerner—one of the nation's leading provider of EHRs and other types of clinical information systems—was widely seen by Wall Street analysts as a smart way for Oracle to enter the market for healthcare information systems. It immediately gave Oracle access to the pools of patient data maintained by Cerner clients throughout the nation. The novel new collaboration with Labcorp shows Oracle is ready to act.

At the time, Ellison mentioned that Oracle planned to develop a cloud-based, national health records repository on top of thousands of existing electronic health record (EHR) systems at hospitals.

Oracle's Long-Range Goals

With the amount of laboratory diagnostic results stored in EHRs and LISs, digital patient data has become valuable to Oracle and other technology companies in terms of patient treatment and anonymized testing information.

Entrepreneurial clinical laboratory managers and pathologists may want to explore the ramifications of the deal between Labcorp and Oracle Cerner. Inspired by this arrangement, it could be that other LIS vendors may get creative in striking new deals with clinical laboratories over diagnostic data, with the goal of creating a new revenue stream for both partners to the arrangement. TDR

Lab Market Update

National Lab Says It Will Help with Supply Chain Services

RECOGNIZING THAT SUPPLY CHAIN ISSUES are troublesome to some of its clinical laboratory customers, one national lab company has announced it would like to help solve those issues.

In September, **Quest Diagnostics** issued a press release describing a novel relationship in which it will act as a supply chain partner for one of its clinical laboratory customers.

The global market is riddled with supply chain difficulties. These stem from the COVID-19 pandemic (including continued lockdowns in China), staffing shortages across the industry, and the war in Ukraine. Within that environment, at least one commercial lab company sees an opportunity to add value for its customers.

Logistics Expertise Cited

In its press release, Quest announced it will partner with Fort Myers, Florida-based **Lee Health**. Quest will provide supply chain skills in laboratory equipment, supplies, and procurement processes for five hospitals owned by Lee and certain outpatient centers. Quest will continue to perform reference testing for Lee.

"The ability to leverage Quest's purchasing power for equipment and supplies, and their expertise in supply chain logistics, allows us to continue to provide high-quality care to our patients," Lawrence Antonucci, MD, President and CEO at Lee Health, said in the press release.

As this issue of THE DARK REPORT went to press, there was little independent comment about this type of arrangement and what it might mean to the clinical laboratory industry at large.

One way to look at the Lee Health/Quest Diagnostics laboratory supply chain arrangement is that it is a public lab company leveraging its buying power and passing those benefits along to one of its lab clients. The other motive behind this unusual arrangement may be less about price and more about simple access to essential lab tests, reagents, and consumables that the Lee Health laboratories are unable to acquire on their own.

Traditionally, *in vitro* diagnostics (IVD) companies have supplied clinical laboratory customers with analyzers, test kits, reagents, and consumables. Will IVD companies accept arrangements where they sell their products to a national laboratory company, only to see those same lab products "resold" by that national lab company to one or more of its client laboratories?

If the health system was after a lower price for the lab products involved in this arrangement—and if more of these types of reseller agreements surface—IVD companies would have a motive to protect their own profit margins by challenging these arrangements in court, or by writing language into their contracts with the nation's larger labs to restrict or prohibit such product resales to customer labs.

Meanwhile, during Quest's Q3 2022 earnings call, CEO James Davis noted that the company had purchased more than $2 billion in pre-analytical and analytical lab supplies. Of that amount, about 80% is price-protected by contract, so Quest has some protection against price increases from inflation. Quest may see opportunity to pass along those "supply price locks" to some of its lab clients. TDR

New CPT Codes Debut for Digital Path Services

Though not yet reimbursable, the new codes mark a major step forward for digital pathology adoption

Giovanni Lujan, MD

Diana Richard

***CEO SUMMARY:** New digital pathology CPT codes took effect Jan. 1. Because the new codes are designated as Category III, they are not subject to Medicare and private payer reimbursement yet. Instead, federal health officials will monitor the use of the new codes in 2023 to determine how often they are used in diagnosis and treatment.*

IT'S AN IMPORTANT FIRST FOR DIGITAL PATHOLOGY! As of Jan. 1, new Current Procedural Terminology (CPT) codes of the **American Medical Association** that recognize the process of converting a glass slide to a digital whole slide image went into effect.

These 13 new CPT entries for digital pathology are Category III codes, meaning they are temporary procedural terminology codes that do not receive reimbursement. Category III designates emerging services and technologies.

CMS Will Assess Codes

The **Centers for Medicare and Medicaid Services** (CMS) now enters a "tryout" period for at least a part of 2023 to gather data about the use of the new CPT codes in clinical lab and anatomic pathology groups.

"All pathologists should participate in this data collection now in order for the CPT codes to become reimbursable in the future," recommended Giovanni Lujan, MD, Director of Digital and Computational Pathology at the **Ohio State University Wexner Medical Center** in Columbus, Ohio.

"The new CPT codes are associated with the different activities that pathologists perform, like examination of a biopsy, a resection specimen, or immunohistochemical stains. So, in all those cases, if we digitize the image to make the diagnosis, we need to add this extra CPT code as a tag to the claim," explained Lujan, who is also Co-Chair of the Reimbursement/Market Access Task Force for the **Digital Pathology Association**.

This development is less about gaining immediate reimbursement for the digital pathology activities and more about accumulating workflow data on electronic specimen handling and diagnostics, Lujan noted.

CMS will monitor the activity of these new codes to see how they are involved with supporting patient care and shortening the time to diagnosis. From there, federal health officials and private payers will assess future reimbursement levels for the steps accounted for in the new CPT codes.

There is not a future guarantee that the new CPT codes will receive reimbursement. In many ways, that decision rests on the efforts of clinical laboratories and

pathology practices to use the temporary codes in 2023, said Diana Richard, Senior Director of Pathology and Strategic Development at revenue cycle management firm **XIFIN** in San Diego.

"If pathologists follow the protocol of adding the new codes to Medicare claims and CMS receives a substantive amount of data from these submissions, I imagine in 2023 we'll see that conversation evolve into new reimbursable codes for digital pathology, potentially as early as 2024," Richard explained.

"However, if CMS does not collect a substantive dataset, it could mean conversations around digital pathology reimbursements stall for the next couple of years—or at least until additional incentives or cost savings are put into place to help motivate adoption," she added.

That initial process of data gathering could take six to 12 months to complete, Lujan said. "CMS will review the results of the digital pathology CPT code usage, and they will determine whether the new codes will be permanent," he noted. "If they are permanent, CMS will determine the reimbursement value and move them to Category I CPT codes."

Richard is not aware of any private payers that have independently established rates for the Category III codes or initiated their own feedback process. "The commercial payers are watching and waiting, but I believe their adoption will closely mirror whatever CMS decides to do with digital pathology," she said.

Digital Pathology Decision

For pathology groups that remain undecided about when and how to implement digital pathology, the CPT codes represent a positive development. This may eventually lead to digital pathology workflows becoming fully reimbursable and allow labs to monetize the cost of acquiring and using digital image scanners and systems.

THE DARK REPORT's sister publication, DARK DAILY, noted in 2021 that a full-featured digital pathology scanner can cost $250,000 or more. Additionally, buying the systems needed to fully incorporate digital pathology into daily workflows can total $500,000 to $1 million.

Those expenses must figure into the bigger financial picture that any lab or pathology group tackles.

"Groups evaluating digital pathology need to consider if the cost structure make sense for the business," she said. "Establishing a return on investment where efficiencies can be gained, and costs can be mitigated, is an important step in establishing appropriate expectations."

With that in mind, Richard recommended pathology practices consider the following factors that tie into adoption of digital pathology tools and systems:

- Potential reductions in courier costs.
- Improved turnaround time and care for patients at rural hospitals and labs.
- Greater efficiency to offset higher workloads as retirements increase.

Digital Adoption May Help Pathologist Shortage

WITH HUNDREDS OF OPEN ANATOMIC PATHOLOGIST JOBS IN THE U.S., practices will need to lean on technology to create more efficiencies. *(See TDR, "Eight Macro Trends for Clinical Labs in 2023," Jan. 3, 2023.)*

Digital pathology can help in this regard because of its ability to let pathologists remotely review cases regardless of their location.

"We have a shortage of physicians in the marketplace," said Diana Richard, Senior Director of Pathology and Strategic Development at XIFIN. "If practices have a large number of pathologists on the retirement track and they're struggling to recruit, digital pathology allows for additional efficiencies into workflows, and it enables the scaling of test volume."

The 13 New CPT Codes for Digital Pathology

NOTE THAT EACH OF THESE CODES should be listed separately in claims in addition to the code for the primary procedure.

- **0751T**—Digitization of glass microscope slides for Level II, surgical pathology, gross and microscopic examination.
- **0752T**—Digitization of glass microscope slides for Level III, surgical pathology, gross and microscopic examination.
- **0753T**—Digitization of glass microscope slides for Level IV, surgical pathology, gross and microscopic examination.
- **0754T**—Digitization of glass microscope slides for Level V, surgical pathology, gross and microscopic examination.
- **0755T**—Digitization of glass microscope slides for Level VI, surgical pathology, gross and microscopic examination.
- **0756T**—Digitization of glass microscope slides for special stain, including interpretation and report, group I, for micro-organisms (e.g., acid fast, methenamine silver).
- **0757T**—Digitization of glass microscope slides for special stain, including interpretation and report, group II, all other (e.g., iron, trichrome), except stain for micro-organisms, stains for enzymes constituents, or immunocytochemistry and immunohistochemistry.
- **0758T**—Digitization of glass microscope slides for special stain, including interpretation and report, histochemical stain on frozen tissue block.
- **0759T**—Digitization of glass microscope slides for special stain, including interpretation and report, group III, for enzymes constituents.
- **0760T**—Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, initial single antibody stain procedure.
- **0761T**—Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each additional single antibody stain procedure.
- **0762T**—Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each multiplex antibody stain procedure.
- **0763T**—Digitization of glass microscope slides for morphometric analysis, tumor immunohistochemistry (e.g., Her-2/neu, ER, PR), quantitative or semiquantitative, per specimen, each additional single antibody stain procedure, manual.

- Ability to facilitate use of artificial intelligence and thus improve the accuracy of diagnoses.
- Ability to establish flexible models for distributing work with a group.

History would suggest that the rate CMS eventually assigns to the new CPT codes will drop if digital pathology becomes the standard of care and upfront costs have stabilized, Richard noted.

"CMS may ask whether practices gained efficiency and saved costs from digital pathology. If the answer is yes, CMS may therefore reduce reimbursements previously established for any digital pathology-specific codes," Richard hypothesized. "It's not to put a dark cloud over the progress we're making in this segment of our industry, but realistically we need to also consider how all of this could potentially evolve long term." TDR

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Lab Operations Update

Use Histology Laboratory Data to Illustrate Specimen 'Life Cycle'

One approach to improving staff productivity is to identify and eliminate bottlenecks in specimen flow

Because of the challenging labor market, pathology labs need ways to boost staff productivity. To help identify workflow bottlenecks, one approach is to examine lab data and encourage bench teams to think holistically about specimen movement in the lab.

Clinical laboratory managers and pathologists should not simply trust their eyes to catch these logjams, said Cory Roberts, MD, President of the Anatomic Pathology Division at **Sonic Healthcare USA** in Austin, Texas.

"When we dug into our lab data, we discovered bottleneck details we wouldn't have otherwise known," Roberts explained. "We know when staff accessioned the specimens, when specimens go to the grossing station, and when specimens move to the processing station. And we studied these peaks and valleys closely—which one would think could be identified simply by eyeballing the workflows—we learned that was not the case."

Roberts spoke at last year's *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* during a panel session titled, "Assessing the Potential of Developing Technologies in Histology and Digital Pathology."

Sonic Healthcare USA uses data as a building block to illustrate what Roberts described as the "life cycle" of a specimen. "The specimen has a complete life," he observed. "Labs can't view a specimen in phases, such as 'Well, grossing did their job, but there's a delay in histology.' The end product is the only thing that matters, which could be diagnosis delivery or a step before that, like slide delivery.

"Every part of the lab team must share that view and goal," Roberts added. "Bring those individual teams together and let them understand how the processes connect. Let them all own the same metric—such as slide delivery—as opposed to how many blocks are cut in an hour."

Connecting bench staff with lab data can let them see what steps are pain points. "We've found improvements simply by doing that, and it did not involve a technology investment," he said.

Seek Bench Staff Opinions

Another key point is to deliver data efficiently and let bench staff ruminate on it. "Simple things can help, such as sharing automated data reports generated by the laboratory information systems, so that people start thinking about the same processes," Roberts noted. "If labs do that, people will talk about the whole unit as opposed to just individual marks, thus creating an accurate life cycle of the specimen."

Managers must also let bench staff offer ideas to improve processes; data can't solely drive improvements, he said. "Bench workers know things that pathologists and managers may not—things that the numbers cannot reveal. We found many things that came directly from rank-and-file workers, but the only way that approach works is for everybody to see the whole process." TDR

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CLIA on Path to Recognize Lab Data As a Specimen

New recommendations also portend a new CLIA certification; plus approval of remote testing

Heather Stang

CEO SUMMARY: Discussions within the federal Clinical Laboratory Improvement Advisory Committee (CLIAC) are focusing on digital diagnostic data and clinical laboratory testing conducted remotely. CLIAC recommendations about these important topics may eventually be part of updates to CLIA, whose language has remained largely untouched since its inception in 1988.

Sweeping recommendations are before federal clinical laboratory officials about the need to permanently allow remote testing arrangements and recognize that digital data is a vital component of diagnostic specimens.

Those recommendations will eventually create a foundation for much needed updates to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). "The CLIA regulations have not been updated substantially since 1988, when they were published," said Heather Stang, MS, MT(AMT), Deputy Chief of the Quality and Safety Systems Branch at the federal **Centers for Disease Control and Prevention** (CDC) Division of Laboratory Services.

Stang also serves as Executive Secretary for the **Clinical Laboratory Improvement Advisory Committee** (CLIAC), a group managed by the CDC that provides scientific and technical advice about improvements in clinical laboratory quality and laboratory medicine. *(See TDR, "Director of CDC's Division of Laboratory Systems Talks COVID-19, CLIA, and More," Oct. 31, 2022.)*

A regulatory assessment workgroup under CLIAC has delved into data and lab personnel topics and it recently prepared a report with agreements that CLIAC discussed during a November 2022 meeting.

"The workgroup's charge is to look at the CLIA regulations and see how they may need to be updated to accommodate new and emerging technologies," Stang explained during an exclusive interview with The Dark Report.

Three Recommendations

The recommendations involve three areas of particular interest to clinical laboratory managers and pathologists:

- The need for CLIA to define data as specimen.
- A new CLIA certificate for entities that work with lab data.
- Changes to CLIA that will allow remote testing activities for clinical laboratory staff and pathologists.

Owing to technology developments, clinical laboratory data is a key part of lab operations, yet CLIA's wording does not recognize digital information.

"Data has never really been addressed in the CLIA regulations," Stang noted. "There have been very lively workgroup conversations on how to address data. One agreement that came from the workgroup is that there needs to be a definition for data in the CLIA regulations."

New Definitions for CLIA

The workgroup is aiming to include data as part of a bigger new definition for "materials" in the statute.

"The term 'materials' is used in the definition of a laboratory in the CLIA regulations," Stang said. "We all know that 'materials' references blood and body fluids derived from the human body that undergo diagnostic testing. But the term 'materials' itself is not defined in the CLIA regulations.

"So, CLIAC agreed that we need to put a definition for the term 'materials' into the regulations that notes it is the patient specimen, including the data derived from a human specimen," she added. "Such data could include images, genetic and protein sequences, -omics data, and other data that is used for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of the health of human beings."

Taking that approach creates a larger sphere of information to consider with specimens, as well as technology that relies on this data, such as next generation sequencing (NGS), whole genome analysis, and digital pathology.

Lab Data as 'Specimen'

"It opens the conversation up to the idea that data is considered a specimen," Stang said. "It's not only data as a specimen, but also the emergence of all of these new technologies."

Tied into the above discussion is the need to properly qualify people who analyze or interpret diagnostic data received from a clinical laboratory and then return that data to the lab for inclusion in a patient's record.

CLIAC has recommended that federal agencies create a new type of CLIA certificate for such work beyond the traditional Certificate of Compliance or Certificate of Accreditation.

"CLIAC agreed that entities that manipulate the data need some form of CLIA certificate," Stang said. "CLIAC recommended that this would be a new certificate type under CLIA."

Under this new designation, entities may be subject to some of the same regulatory requirements as the referring clinical laboratory.

Clinical laboratory data and associated technology has led to new job positions that deal with this work—roles that CLIA does not clearly cover yet. These jobs include:

- Bioinformaticists and variant scientists who analyze data.
- Image technicians, cytotechnologists, and histotechnologists who use digital pathology tools.
- Analysts who work with NGS.

Evolving Job Roles in Labs

"We started looking a little bit closer into the bioinformatician and how those particular types of individuals may not qualify under CLIA right now as testing personnel," Stang noted. "We have a new work group that we'll be forming. It will be focused on the education, training, experience, and competencies that should be required by CLIA to qualify personnel performing NGS bioinformatic data analysis and interpretation.

"The workgroup will discuss whether CLIA should be updated to include these personnel or whether they are already defined in CLIA, and the CLIA interpretive guidelines just need to be updated," she added.

The SARS-CoV-2 pandemic brought remote work arrangements across many industries to the forefront, including at clinical laboratories and anatomic pathology practices.

Besides mitigating potential COVID-19 infections, remote testing also proved valuable in terms of serving rural or underserved communities that lacked easy access to pathologists.

The federal **Centers for Medicare and Medicaid Services** (CMS) issued a memorandum in 2020 that allowed remote pathology work as long as the COVID-19 public health emergency remains in effect.

Remote Testing Activities

"CMS did put out a notice that allowed remote pathology activities, but it was very specific to pathology," Stang noted. "During the CLIAC work group discussions, they wanted to open up the ability for remote testing to other diagnostic fields—for example, if a lab scientist looks at a Gram stain via their home."

Expect recommendations from CLIAC regarding permanently allowing remote testing arrangements for bench staff and pathologists. "The workgroup agreed that CLIA needs to be updated to modify and allow remote testing," Stang said. "CLIA needs more specificity to what is meant by remote testing."

Among the provisions that could be defined include that a remote workspace would be covered as an extension of a lab's CLIA certificate, and that the certificate would also cover staff using technology such as virtual private networks to view cases.

What's Next for CLIA?

Any changes to CLIA will require formal rulemaking through CMS, a process that can take months or years. Don't expect CLIA revisions on data as a specimen or remote testing in 2023, Stang said.

"We have to put any type of rulemaking activity on a unified agenda that is announced to the public," she explained. "The CLIA updates are not something that's on the 2023 CMS unified agenda.

"Behind the scenes, agencies could potentially discuss CLIA changes, but there's no CLIA rulemaking related to the recommendations made by CLIAC during the November meeting that will go out in 2023, or that would impact any clinical laboratory in 2023."

Note that the November discussions do not affect CLIA rulemaking that was released last summer. That proposed rule included potential increases in CLIA fees and possible changes to qualifications for personnel who handle high and moderate complexity testing. A final rule on those proposals could be published in 2023, Stang said. *(See TDR, "Clinical Laboratories Face 20% Increase in CLIA Fees," Aug. 29, 2022.)*

Pathologists and clinical laboratory managers with ideas and suggestions on ways to revise and update CLIA requirements to address new diagnostic practices that emerged since CLIA's 1992 implementation may want to send comments to the CLIAC workgroups. TDR

CLIAC Will Not Address Lab Staffing Shortages

AS IT EXAMINES POTENTIAL UPDATES OF PERSONNEL REQUIREMENTS, lab staffing shortages are not part of the discussion within the regulatory assessment workgroup under the Clinical Laboratory Improvement Advisory Committee (CLIAC).

"The workgroup itself did not focus on staffing shortages," Heather Stang, MS, MT(AMT), Deputy Chief of the Quality and Safety Systems Branch at the federal Centers for Disease Control and Prevention (CDC) Division of Laboratory Services.

"The workgroup was looking primarily at the CLIA regulations and what needs to be updated to reflect the current environment of clinical laboratory testing," Stang added.

She noted that the CDC's OneLab Rapid Education and Capacity-building Hub—or OneLab REACH—offers training resources for clinical laboratories facing staffing shortages. Go to reach.cdc.gov for more information.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

New data from the **Association of American Medical Colleges** (AAMC) offers further evidence of a decreasing talent pool of pathologists in the United States. Active physicians in anatomic and clinical pathology dropped from 13,201 in 2016 to 12,180 in 2021—a 7.7% decrease, according to the AAMC's Physician Specialty Data Report. Only pulmonary disease doctors had a greater decrease (10.8%) in that period. In fact, most physician subspecialities showed increased numbers during the reported years.

MORE ON: *Pathology Careers*

The AAMC also noted that since at least 2005, pathology has undergone rapid subspecialization. The association is conducting research with the **College of American Pathologists** into current subspecialties, with the goal of creating an expanded definition for the pathology profession. Currently, the AAMC definition for pathology does not include subspecialties such as microbiology or molecular genetics.

COMPUGROUP MEDICAL US ACQUIRES LIS FIRM

Healthcare technology company **CompuGroup Medical US** (CGM) in Phoenix has acquired **Medicus Laboratory Information Systems** from **Diagnostic Systems Consulting** in Weston, Florida. The move will allow CGM to expand its American presence in the small- and mid-sized clinical laboratory market. Medicus LIS is in more than 1,000 labs across the U.S., according to CGM. Financial terms of the deal were not disclosed.

LAB OWNER GETS TWO-YEAR SENTENCE FOR KICKBACKS

In January, a judge sentenced a former clinical laboratory owner to two years in prison for receiving kickbacks in return for test referrals, according to the **U.S. Department of Justice**. A jury found Richard Reid guilty in March for his role in helping **Northwest Physicians Laboratory** in Bellevue, Washington, obtain more than $3.7 million in kickback payments by steering urine drug test specimens to two labs that then billed **Medicare**.

TRANSITIONS

- **Sysmex America** in Lincolnshire, Illinois, announced that Chris Cappella is its new Chief Financial Officer. Previously, Cappella worked at **Roche** for 24 years, including as Vice President of Finances for core lab services.

- Jennifer Hunt, MD, has been appointed Chief of Staff for **University of Florida Health Shands Hospital** in Gainesville, Florida. Hunt will continue to serve as Chair of the Department of Pathology, Immunology, and Laboratory Medicine at the university's **College of Medicine**.

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

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UPCOMING...

- ***New Microsoft-Paige partnership illustrates Silicon Valley's growing interest in artificial intelligence for pathology.***
- ***Emerging 'data economy' sparks multiple viable ways for clinical labs to generate revenue from specimens.***
- ***Fujifilm stakes new territory in the digital pathology market in move to expand options it provides to customers.***

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