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FDA Moves on LDT Regulation!

Publishes proposed rule to require review of laboratory developed tests

(See pages 3-7)

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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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

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Two Forces Push for More FDA Oversight of LDTs

Clinical and genetic testing labs may suddenly feel themselves stuck in the middle of a yin-yang situation when it comes to laboratory developed tests (LDTs).

One force, the **U.S. Food and Drug Administration** (FDA), is pulling on laboratories by proposing more stringent requirements for LDTs.

Another force, this one by means of Congress, is attempting to legislate LDTs through a bill commonly known as the VALID Act. The formally titled Verifying Accurate, Leading-Edge IVCT Development Act also aims to move LDT regulation under the FDA. The bill has been parked on Capitol Hill for several years, unable to muster a vote into law, and is back before lawmakers in 2023.

Now, for the first time, both the VALID Act and the FDA proposal are on parallel tracks. It seems one way or the other, the clock is ticking down on labs that develop LDTs under the existing provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

By most accounts, LDT work under CLIA is simpler and less costly than going before the FDA for review. For that reason, opponents of increased LDT regulation argue that FDA involvement will increase costs and muzzle future innovation.

The FDA and lawmakers behind the VALID Act counter that lab tests need to be safer and more reliable for patients. Current LDT provisions have resulted in tens of thousands of genetic tests on the market with little oversight given to them.

For labs that have a stake in LDTs, it may never be more important than now to get involved. The FDA proposed rule has a 60-day public comment period, which is slated to end on Dec. 2. This is a prime opportunity for labs to outline their views about LDT oversight to regulators.

Meanwhile, labs can also contact their representatives in Congress to explain their support or opposition to the VALID Act.

Lab leaders should expect proponents of increased LDT regulations—including *in vitro* diagnostics companies—to also lend their sizable voice to the debate. Sitting on the sidelines does not seem like a viable option for LDT developers. TDR

FDA Issues Proposed Rule to Further Regulate LDTs

If the agency has its way, existing LDT oversight under CLIA rules may come to an end before 2028

CEO SUMMARY: Publication of the FDA's draft rule on LDT regulation starts the clock on public comment. The proposal seeks to clearly identify laboratory developed tests (LDTs) as in vitro diagnostic devices, which then places many of these tests under increased regulatory review. Clinical laboratory managers and pathologists have until Dec. 2 to submit comments to the FDA.

THIS WEEK, the **U.S. Food and Drug Administration** (FDA) took the necessary first step to regulate laboratory developed tests (LDTs). Many in the clinical laboratory oppose the FDA on this point.

Last week, the agency made the draft rule public, prior to its official publication this week. This move by the FDA—which picked up significant momentum over the past year—will not be received warmly by the clinical laboratories, genetic testing companies, and pathology groups that develop and perform LDTs.

However, *in vitro* diagnostic (IVD) manufacturers are on record as welcoming this proposal, as these companies have argued that LDTs do not operate on an equal playing field compared to similar IVD products.

The FDA's 83-page rule, which is scheduled to publish in the *Federal Register* on Oct. 3, proposes the following, according to a prepublication version available online:

- Amend FDA regulations to make explicit that IVDs are devices, including when the manufacturer of such devices is a clinical laboratory.
- Phase out the FDA's general enforcement discretion approach for LDTs (i.e., the current approach of allowing LDT developers to not undergo FDA review). If the proposal is finalized, IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

"The FDA believes all patients deserve to have access to safe and effective tests regardless of where those tests are made. This rule is an important step to help ensure that healthcare decisions are made based on test results patients can trust," the FDA said in a news release on Sept. 29.

The public comment period will last for 60 days following publication of the

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proposed rule. This established Dec. 2 as the deadline for comments. It is possible for the FDA to extend the comment period, particularly if a lot of remarks pour in. Once the comment period closes, there is no established timeline for the agency to release a final rule.

LDT Complexity Has Evolved

In a Sept. 29 news release, the FDA argued that LDTs have changed significantly since the introduction of the Medical Devices Amendments of 1976.

"The risks associated with most modern LDTs are much greater than the risks that were associated with LDTs used decades ago," the FDA stated. "The agency has become increasingly concerned that some LDTs may not provide accurate test results or perform as well as FDA-authorized tests and others complying with FDA requirements."

On the surface, the FDA's proposal seems to take aim at the tens of thousands of genetic tests available to patients today. Many of these molecular assays were brought to market by single labs via current LDT procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

In its proposed rule, the FDA expressed concern about the use of modern LDTs—which can involve complex instruments and software to screen for serious health conditions—when agency review does not occur.

LDTs Are a 'Loophole'

Additionally, IVD manufacturers have long cried foul about current LDT requirements, arguing that they have created a loophole that allows labs to sidestep FDA reviews of their novel lab assays that traditional IVDs must undergo.

Critics of increased LDT oversight counter that review of these tests by the FDA will stifle innovation, particularly at academic medical research centers. And that FDA review of an LDT will take more time and money to accomplish, which may lead to some labs no longer being able to develop their tests.

In comments about the proposed rule, the FDA estimated in its proposal that approximately 50% of IVDs offered as LDTs would not require premarket review.

The **American Clinical Laboratory Association** (ACLA) was quick to criticize the FDA's announcement. "ACLA strongly believes FDA regulation of LDTs could only be done through legislation that establishes a diagnostic-specific, risk-based framework that recognizes the essential role of clinical laboratories in advancing public health, preserving and fostering innovation, and maintaining access to critical testing services that physicians and patients rely on every day," the association stated.

Valid Act Still Pending

The legislation that the ACLA referred to would be the Verifying Accurate Leading-Edge IVCT Development Act (VALID Act), which is again before Congress this year. *(See the sidebar on page 5 for more details.)*

"Unilateral FDA action is the wrong policy prescription," said Susan Van Meter, President of the ACLA, in an interview with THE DARK REPORT before the FDA posted the proposed rule.

"ACLA has long held the position that the FDA does not have the authority under current law to regulate LDTs as medical devices," Van Meter added. "We're going to continue to encourage the FDA to not take that unilateral action."

As part of its proposal, the FDA spells out estimated costs for the agency and for labs. Best-guess estimates peg the health benefits of increased LDT regulation from $22 to $31 billion. "We quantify benefits to patients from averted health losses due to problematic IVDs offered as LDTs," the FDA said in the proposed rule.

Meanwhile, costs related to LDT compliance and oversight would run an esti-

mated $5.6 to $5.9 billion (with $501 million to $530 million being added costs to the FDA). From that point of view, labs could be looking at a collective $5 billion in new costs related to increased LDT regulations.

Phaseout over Four Years

As proposed, the phaseout of LDT enforcement discretion by the FDA would occur over four years. That timeframe would account for public health needs for IVDs offered as LDTs while allowing clinical labs time to comply with adjusted requirements.

The FDA intends to apply the phaseout to IVDs that are manufactured as LDTs by laboratories that meet the regulatory requirements under CLIA to perform high-complexity testing. The proposed phaseout comprises five stages:

- **Stage 1**: End the general enforcement discretion with respect to medical device reporting requirements one year after the FDA publishes a final phaseout policy.
- **Stage 2**: End the general enforcement discretion with respect to requirements—other than medical device reporting, quality system, and premarket review requirements—two years after a final phaseout policy.
- **Stage 3**: End the general enforcement discretion with respect to quality system requirements three years after a final phaseout policy. In some cases, IVDs for which all manufacturing occurs within a single CLIA-certified lab may be able to satisfy parts of this stage if CLIA requirements are met, the FDA noted.
- **Stage 4**: End the general enforcement discretion with respect to premarket review requirements for high-risk IVDs three-and-a-half years after a final phaseout policy, but not before Oct. 1, 2027.
- **Stage 5**: End the general enforcement discretion with respect to premarket review requirements for moderate- and low-risk IVDs that require premarket submissions four years after a final phaseout policy, but not before April 1, 2028.

"The FDA anticipates the benefits of phasing out the FDA's general enforcement discretion approach for LDTs would include a reduction in healthcare costs associated with unsafe or ineffective tests, including tests promoted with false or misleading claims and from therapeutic decisions based on the results of those tests," according to the proposed rule.

For clinical labs that currently perform laboratory developed tests, the FDA proposal represents a major change in how they develop and offer LDTs. Laboratory leaders interested in reading the full rule and commenting to the FDA should go to *www.federalregister.gov*, select Browse and then Dates from the drop-down options at the top of the page, and find the Oct. 3 entries under the FDA heading. TDR

Congress Continues to Consider the VALID Act

With the news that the U.S. Food and Drug Administration (FDA) will publish a proposed rule for regulating laboratory developed tests (LDTs), it is worth noting that potential federal legislation about LDTs also remains active.

The Verifying Accurate Leading-Edge IVCT Development Act (VALID Act), a well-known bill that is again before Congress, seeks to move oversight for LDTs from the Clinical Laboratory Improvement Amendments of 1988 to the FDA. The bill remained before the House of Representatives Subcommittee on Health at press time.

The VALID Act's bill number is H.R.2369. It is not yet clear what will happen to the VALID Act if the FDA's proposed rule becomes finalized, or vice versa.

FDA's Road to Regulation of Lab Developed Tests

➤It's been a lengthy, nine-year journey by the FDA to establish authority to oversee lab developed tests

➤➤CEO SUMMARY: Today's generation of clinical lab managers and pathologists should understand that the FDA's efforts to publish a draft rule defining its authority to review laboratory developed tests (LDTs) goes back at least to 2014. That's the year when the FDA first issued a notice to Congress that it intended to regulate LDTs. Even the VALID Act, which would authorize the FDA to oversee LDTs, was first introduced in Congress in 2018 and every Congress since, without passage.

When it comes to federal oversight of clinical laboratories, 2014 can be considered a seminal year. During that year, two milestone events occured.

First was the enactment of the federal Protecting Access to Medicare Act (PAMA) on April 1, 2014. Within the clinical lab industry, PAMA is best known for requiring **Medicare** officials to collect data on the lab test prices paid by private payers, and then use that data to determine Medicare Clinical Laboratory Fee Schedule (CLFS) prices. But there are other sections of the law that changed how Medicare officials establish coverage guidelines and prices for new lab tests.

The second significant event was the **Food and Drug Administration's** (FDA) notice to Congress in July 2014 that the federal agency intented to issue draft guidance to regulate laboratory developed tests (LDTs). The FDA did this to follow the statutory requirement in the Food and Drug Administration Safety and Innovation Act of 2012.

The FDA's notice to Congress that it intended to regulate LDTs caused an immediate uproar among clinical laboratory executives and pathologists. *(See sidebar for more information.)*

That was nine years ago. Despite the many criticisms of the FDA's intent to regulate LDTs, the agency continued to push ahead. In 2018, the first version of the Verifying Accurate, Leading-edge IVCT Development (VALID) Act was introduced into Congress.

➤VALID Act and the FDA

This bill would give the FDA the authorization to regulate LDTs. Different versions of the VALID Act were introduced into each successive Congress, but the bills never came up for a vote.

From 1970 to 2000, LDTs were not a legislative or regulatory issue. That's because, for the most part, it was academic center labs using LDTs as the concept was originally designed. The LDT exception was intended to allow researchers to develop new assays, then work with clinicians in clinical settings to gather data on their tests' performance and value in improving diagnostic accuracy and guiding selection of appropriate therapies.

However, major changes came to the clinical lab industry during the 1990s. Investors discovered there was money to be made in developing a proprietary test as an LDT. They would create a lab company and send out sales reps to sell their LDT to physicians all across the United States.

Because it was an LDT, these investor-owned lab companies only needed to comply with the federal Clinical Laboratory Improvement Amendments Act (CLIA). Since 2000, the number of these lab testing companies has increased annually and the number of LDTs they offered grew exponentially.

175,000 LDTs Now in Market

Clients and regular readers of THE DARK REPORT are familiar with our tracking of this explosion in the number of LDTs offered within the United States. Data provided by **Concert Genomics** of Nashville, Tennessee, showed about 5,000 genetic tests being offered in the U.S. in 2017. Today, Concert Genetics identifies more than 175,000 genetic tests offered by 300 to 400 genetic testing companies. Almost all of these genetic tests are LDTs.

This presents a dilemma for both the FDA and the clinical lab industry. Regularly, news reporters publish stories and research scientists publish studies in peer-reviewed medical journals about inaccuracies and patient harm caused by inaccurate genetic tests—nearly all are LDTs offered as proprietary tests by investor-owned commercial lab firms.

This is public evidence that regulatory oversight of diagnostic tests is failing on some level. Patient advocacy groups are among those loudest in calling for federal oversight of LDTs and they have compelling evidence of patient harm to support their advocacy.

This ignores the plight of academic center labs that have legitimate reasons for using LDTs. Their fate may be tied to the actions regulators take, should they require investor-owned lab companies to submit their LDTs for review. TDR

Biggest Labs Opposed FDA Oversight of LDTs

IN 2014, WHEN THE FEDERAL FOOD AND DRUG ADMINISTRATION informed Congress of its intent to regulate laboratory developed tests (LDTs), and issued a draft rule to acomplish that in the fall, reaction from the CEOs of the nation's two multi-billion-dollar lab companies was clear in their opposition to the development.

Reporting on the two lab companies' third quarter 2014 earnings calls in our November 3, 2014, issue, THE DARK REPORT quoted each CEO, writing, "**Labcorp** CEO Dave King responded to an analyst's question by saying, 'My perspective on FDA regulation of LDTs is quite clear and I've been pretty vocal about it. Diagnostic testing is not a device, it's a medical service. The FDA, in our view, does not have the authority to regulate LDTs as medical devices. ... The [FDA's] attempt to make this kind of regulatory change through a guidance document ... on its face says that it's not binding on the FDA and only reflects their current views—and yet ... this document lays out a 10-year regulatory plan with registration requirements and penalties for those who don't register.

'To me, this is just incomprehensible. My perspective is this is one of the biggest land grab attempts in the history of regulation. And from my perspective, we intend to vigorously oppose it,' King explained."

On the same topic, we wrote "**Quest Diagnostics** CEO, Steve Rusckowski, was equally emphatic about opposition to the FDA's plans to regulate LDTs. On this point, Rusckowski stated, 'We continue to work closely with our trade association [ACLA] on another important issue. And that is to oppose the FDA's proposal to regulate laboratory developed tests, referred to as LDTs. We strongly believe that unnecessary and duplicative regulation could delay patient access to life saving treatments and compromise America's leadership in diagnostic discovery.'"

Regulatory Update

SALSA Bill Resurfaces, Poised to Reduce Upcoming PAMA Cuts

Without congressional action, clinical labs face price cuts of 15% for hundreds of tests on Jan. 1

Another round of stiff price cuts to the **Medicare** Part B Clinical Laboratory Fee Schedule (CLFS) is just months away, with the provisions of the Protecting Access to Medicare Act (PAMA) set to resume on Jan. 1.

In response to that looming threat, laboratory trade groups, including the **American Clinical Laboratory Association** (ACLA), are again working to get the Saving Access to Laboratory Services Act (SALSA) passed. If approved by Congress, SALSA would reform several key PAMA requirements, including a provision for reduced price cuts.

"This is coming on the heels of what has been three prior years of Congress approving delays in the PAMA reductions and reporting," Susan Van Meter, President of the ACLA, told The Dark Report. "The year-over-year patches have been helpful in preventing reductions, but SALSA is a moderate and appropriate pathway forward, and it's time to have comprehensive, long-term reform."

Congress instituted stop-gap measures from 2021-23 to temporarily halt PAMA cuts, largely due to the pandemic and to the realization that labs contributed greatly to the associated public health response. *(See TDR, "Congress Averts PAMA Cuts to Lab Test Rates for 2023," Jan. 3, 2023.)*

This year's SALSA bill is identical to one proposed in 2022 that did not get voted on by lawmakers. Its major provisions include:

- For 2024, planned CLFS price cuts will be reduced to 0%.
- For 2025, cuts will be capped at 2.5%.
- For 2026 and subsequent years, cuts will be capped at 5%.
- Caps on increases of 5% will be phased in by 2028.
- Adjustments will be made to how and when data is reported to federal agencies to determine price rates.

The Senate version of the bill is numbered S.1000, while the House of Representatives version of the bill is H.R.2377. The two versions are identical, Van Meter noted.

PAMA Hits Hundreds of Tests

SALSA's price reductions are a vast improvement from what PAMA calls for currently. If nothing is done before the end of the year, on Jan. 1, PAMA will institute CLFS price cuts of up to 15% for hundreds of lab tests on the Medicare CLFS.

"In 2024, there will be 15% cuts on about 800 tests, and then up to 15% for each of the following two years," Van Meter noted. "SALSA would immediately remove those steep reductions that we'd otherwise face in the near future."

PAMA-related reductions could lead to a variety of hardships at clinical labs and pathology practices. "How a lab might respond to that is going to vary," she explained. "Price cuts could result in longer turnaround times or perhaps a curtailed test menu, which would be hard

because labs constantly strive to deliver for their patients as test orders come in."

Meanwhile, large national lab firms also stand to lose significantly if the PAMA cuts go through. During an investors call in July, **Labcorp** CEO Adam Schechter said that the company will set aside tens of millions to offset any PAMA-related losses.

"We've got to be prepared in case PAMA does get implemented again next year," Schechter noted. "We've built into a plan about $75 million of downside due to PAMA. I'm hoping that we won't realize that, but we have to create our business model assuming that [cuts will] occur."

Skewed Lab Data Collection

PAMA requires federal regulators to analyze private payer data to set prices for the CLFS. However, when the **U.S. Department of Health and Human Services** (HHS) implemented PAMA, many in the clinical laboratory industry believed that data collection for private payer rates skewed towards larger, independent labs. The result was that hospital outpatient laboratories and physician office labs were underrepresented in the data, resulting in Medicare payment rates being artificially lowered. *(See TDR, "CMS Shows Its Hand in New PAMA Draft Rules for 2019, July 30, 2018.)*

To adjust for this discrepancy, the language in SALSA focuses on gathering "statistically representative samples" for affected clinical labs to determine price rates. HHS would need to use a method known as the Maximal Brewer Selection, which in prior independent research tended to produce less biased estimated payment rates.

"The good thing about the statistical sampling is that it will pull in data that's representative of all segments of the lab industry: big and small, hospital, physician office, and commercial laboratories," Van Meter said.

"That was the initial idea of PAMA," she added. "Unfortunately, implementation has really thwarted that and led to cuts that are much, much deeper than what was originally anticipated."

SALSA would also extend the data reporting window for labs from every three years to every four, starting in 2027.

Court Ruling on PAMA

The nature of PAMA's data collection led to ACLA filing a lawsuit against HHS. In July 2022, the **U.S. Court of Appeals for the District of Columbia Circuit** ruled that the implementation of PAMA was flawed and negatively affected many labs' reimbursement rates from Medicare.

The appeals judges remanded the case back to U.S. District Court but did not force changes upon HHS or the **Centers for Medicare and Medicaid Services** (CMS) regarding PAMA. *(See TDR, "On Appeal, ACLA Gains PAMA Victory in Court," Aug. 29, 2022.)*

"The courts unfortunately could not provide a remedy forcing CMS to reset the rates," Van Meter said, adding that the case has concluded. "We encouraged CMS to take a broader view of their authority and to ensure they would pull in more data and not impose the reductions. CMS did not share our view. That's why we're back at it on Capitol Hill."

December Timeframe

Any vote on SALSA—or a larger bill that SALSA gets attached to—isn't likely until December, when Congress debates year-end funding requests, Van Meter noted.

"But we anticipate that in December, towards the end of congressional session, we'll see a Medicare healthcare extender package being pulled together," she added. Extenders are policies that require frequent reauthorization from lawmakers.

"SALSA is very viable for that package," she said. "There's broad recognition in Congress that PAMA implementation needs to be addressed." TDR

Contact Susan Van Meter at svanmeter@acla.com.

Outreach Nets Hospital Lab $2.5M in One Year

Tucson Medical Center saw an opportunity to take back its former outreach business from commercial labs

Sanjay Timbadia

CEO SUMMARY: Tucson Medical Center had sold its outreach business to a commercial laboratory two decades earlier, but wanted to bring those services back to its in-house lab. Early work with the finance department proved crucial to determining the cost of the effort, which in the end has brought in millions in new revenue.

Sandy Richman

DURING THIS ACTIVE PERIOD OF LABORATORY OUTREACH ACQUISITIONS BY LARGE NATIONAL LABORATORIES, **Tucson Medical Center** (TMC) made a strategic case for the opposite: bringing outreach testing back to the hospital laboratory.

TMC in Tucson, Arizona, took the initiative to win back its long-lost laboratory outreach business with affiliated physician clinics by focusing on financial prudence and a belief that the move would improve patient care.

1st Year Revenue of $2.5 Million

"The transition has been successful. In our first full year of outreach in 2021, the lab realized $2.5 million in net contribution to TMC," said Sanjay Timbadia, MBA, MT(ASCP), Director of Laboratory Services. "That exceeded what we anticipated."

The path TMC took will be of interest to other clinical laboratory and anatomic pathology leaders who would also like to debut or return outreach services into their hospital labs.

Timbadia spoke at the *2023 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*. His session was titled, "Community Hospital Success and Revenue Generation with Laboratory Outreach."

TMC Health is a three-hospital system, the flagship of which is TMC, a 641-bed nonprofit hospital. TMC's hospital lab employs 131 full-time workers and performs approximately three million diagnostic tests each year.

TMCOne is TMC Health's affiliated physician group, with 65 practitioners who work at 11 primary care and specialty locations. Community members can get diagnostic testing through nine of these 11 clinics.

"About 20 years ago, Tucson Medical Center sold its outreach business," Timbadia said. "TMC had the largest lab outreach business in Tucson, but executives back then decided that the system needed the money and would sell this business. One of the large commercial labs bought it from us."

That setup eventually morphed into multiple lab providers, as the physician offices worked with a primary and a secondary commercial lab.

"However, about five years ago, TMC's lab leaders began asking, 'Hey, why don't we take some of that business back and at least do outreach lab testing for our physicians that work in our system?'" he added. "Finally, a CFO gave approval to move forward with the idea."

Initial talks about taking back outreach began in 2019, and TMC went live with the transition in 2020. "But we had to start from scratch," Timbadia said. "Twenty years ago, I had a big crew that ran outreach. But 20 years later, I was left with only two people from back then who were familiar with our past outreach business."

Factors Propelling the Effort

Several important business reasons influenced the decision to bring lab outreach for affiliated physicians back in-house:

- **Using excess capacity in the laboratory to reduce cost per test**. "The lab is a high fixed-cost business," Timbadia observed. "The instruments and the clinical laboratory scientists are already there to do the work. These costs typically don't increase when adding volume through outreach."
- **Contributing to the health system's bottom line**. "Lab outreach testing is still profitable," he noted.
- **Supporting TMC Health's ambulatory strategy**. "TMC Health wanted to provide laboratory testing across the care continuum using one lab," Timbadia said. "By switching back, the affiliated physicians could be within the same electronic medical record system as the hospital, with patients having the same medical record number throughout the system."
- **Providing better patient care**. "Decreased turnaround time was appealing, as was access to a local lab team," he noted.
- **Offering better customer service to affiliated physicians**. "The physicians can call anyone in the TMC lab and speak directly to the med tech that ran a test or get hold of me," Timbadia commented.

Based on these aspects, TMC began exploring whether laboratory outreach was a feasible goal to pursue.

Planning Begins in 2019

Initial planning took place from May through August 2019. "I knew the lab was going to need help with this," Timbadia said. "TMC already had a relationship with **ARUP Laboratories** because it is our reference lab, and ARUP agreed to project manage this for us."

Together, TMC and Salt Lake City-based ARUP Laboratories put together a business plan for the outreach business and created a *pro forma*, which is a method for calculating future business results using certain projections. *(See the sidebar on page 13 for details on prelaunch and year-one costs.)*

Also, interviews took place with key stakeholders, including affiliated physicians, the information systems (IS) team, the patient accounting office, and reimbursement specialists.

"The project team met with IS to go through workflows and what needed to be replaced at draw sites—such as PCs, monitors, label printers, and network printers," he added. "And then, of course, we had to test the new interfaces."

In September and October, the laboratory hammered out issues with billing and test menu consolidation.

"We had several different things to vet out, like which billing company to use," Timbadia recalled.

"Our internal billing company at the hospital was not robust enough to take over this, so we had to pick a third-party biller," he added.

Billing implementation began in January 2020, and around the same time, TMC purchased courier vehicles and office furniture. TMC also notified the lab companies of its intent to terminate its

outreach contracts—those contracts had 30-day notices worked into them.

Over the next few months, the clinical laboratory began hiring and training phlebotomists, phlebotomy supervisors, couriers, and additional testing personnel. In March 2020, the SARS-CoV-2 pandemic began, although the project kept moving forward.

"One thing that made the project successful was all the organizational work that went into that business plan," said Sandy Richman, MBA, C(ASCP), Director of Healthcare Advisory Services at ARUP Laboratories.

"The laboratory had a counterpart in the finance department at Tucson Medical Center who was very helpful in vetting the *pro forma*," said Richman, who helped coordinate the outreach project and also spoke at the *Executive War College*.

"We did many risk analyses. We didn't plan for a pandemic, but we did best-case and worst-case scenarios that centered on reimbursement variables," he added.

Phased Approach

Despite the onset of the pandemic, the lab outreach project went live in May 2020 and was staggered over four weeks among nine physician office locations. Rather than switching all nine clinics at once, the hospital chose a phased approach.

"We decided we wanted to do it in phases because these clinics were supposed to be serviced by a commercial lab until a given Friday, when they would shut down before the weekend," Timbadia explained.

"That gave the project, facilities, and IT teams Saturday and Sunday to get ready to open up Monday with TMC phlebotomists and our system.

"We didn't want to do the big bang option for this project because that would be nine locations to do at one time," he continued. "It was too much work for our facilities and IT people. So, we took the approach of doing two clinics at a time."

Managed Care Concerns

An important aspect to tackle for any hospital lab launching outreach services is how payers will view the project.

"It's important to have a strong relationship with the health system's managed care group to review contracting and pricing," Richman noted. "That can help a lab uncover any clauses that would exclude it from providing outreach lab services. Working with finance and affiliated physicians, the project team was able to look at the existing agreements that were in place.

"When the project team did its analysis, the fee schedules that were in place with the payers were already competitive," he added. "It didn't look like the transition would result in huge out-of-pocket expenses for patients except for those that were self-paying.

"The lab didn't want to affect those patients who were the least able to pay," Richman said. "So, the team came up with a separate charge list rather than using the hospital chargemaster. The lab reduced some charges but didn't negotiate any new contracts."

However, a letter sent by **UnitedHealthcare** complicated matters. The correspondence indicated that as of May 2020, hospital laboratories would no longer be allowed to bill the payer for reference testing for members who are not hospital patients. The move was meant to clamp down on hospital labs that submitted test claims for outreach patients using their hospitals' inpatient fee schedule, which generally priced services higher. *(See TDR, "New UnitedHealthcare Policy for Hospital Reference Tests," March 9, 2020.)*

"Luckily the managed care vice president that the project team was working with had a strong relationship with UnitedHealth," Richman recalled. "He was able to call them and figure out

exactly what our lab needed to do, because this announcement was right before the transition went live.

"Our lab needed to get credentialed as an independent reference lab and had to accept a lower fee schedule, but it could have been much worse," he added. "The lab resolved this issue within a month."

Benefits Noticed Quickly

Once the nine physician offices started using the TMC hospital lab for outreach, positive changes were immediate.

"The turnaround time impact was tremendous for the physicians after the switch," Timbadia said. "If the lab got test orders in the morning at 10 or 11 o'clock, the physicians had the results typically within two or three hours. When working with the commercial labs, they had to wait a day or two for results. Physicians noticed that improvement right away."

He observed that communication between the lab and physician clinics improved as well. "The lab created an email group that went to all lab leaders," he said. "So, someone from the lab could respond to any kind of email questions from physicians right away. The physician offices didn't really have that type of arrangement with the commercial labs."

Being able to keep laboratory specimens within the Tucson region also had its advantages. "In terms of sample quality, with locally operated outreach, there is less chance for lost or compromised specimens because they all stay within Tucson," Richman said.

Measures of Success

Timbadia deemed the project a success, particularly in the years following go-live in 2020. As noted earlier, the lab's 2021 net contribution from outreach was $2.5 million, with an added volume of more than 800,000 tests. Today, outreach makes up about 15% of the three million annual tests performed by the TMC laboratory.

Costs to Bring Outreach Back into Hospital Lab

TUCSON MEDICAL CENTER'S DECISION to bring laboratory outreach services back in-house had cost implications:

Pre-Project Costs (2019)

- New billing interface
- Two courier vehicles
- Facilities work at the outreach clinics
- Information system installations
- New laboratory information system interface

Total: $314,000

Year-One Costs (May-December 2020)

FTE Expenses

- Phlebotomy supervisor
- Two couriers
- 13.65 in-office phlebotomists
- Two clinical service reps
- Two clinical lab scientists
- Two specimen processors
- **FTE total: $1,016,714**

Additional Operating Costs

- Incremental supply costs
- Reference testing
- Billing
- Courier vehicle maintenance
- Other supplies and expenses

Operating total: $1,344,427

"The yearly growth rate from our lab outreach program has been greater than 10%," Timbadia said. "We added four additional clinics to our outreach program in 2021 and 2022. We plan to add more clinics as TMCOne gets more physicians to join the team.

"The biggest gauge of our success was the financial picture," he concluded. "Getting the finance team to evaluate test volumes, revenue generated, and expenses was a crucial step." TDR

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➤➤Virchow

➤Medicine ➤Money ➤Managed Care

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

How Private Payers Audit Labs for Possible Claims Fraud

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

IN RECENT YEARS, I've seen the **Department of Justice** (DOJ) expand its areas of prosecution for labs. This includes greater scrutiny of fraudulent genetic testing claims and dubious relationships labs have with telemedicine firms.

Curious clinical laboratory managers may wonder if private payers have investigative units currently looking into similar alleged problems. Generally, the answer is yes. In many cases, a search online will reveal a payer's fraud and compliance unit. How robust are these units? That depends on the payer.

After all, the DOJ's healthcare fraud unit has a lot of resources at its disposal, including 80 prosecutors on staff. It also has ties to the **FBI**, **Department of Health and Human Services' Office of Inspector General** (OIG), **Centers for Medicare and Medicaid Services**, **Drug Enforcement Administration**, and even the **Federal Deposit Insurance Corporation**.

A private payer's audit unit doesn't have as much muscle as the government, but it can still be formidable. I am familiar with one payer that has an investigative group with claims and audit representatives. They look for abnormalities—for example, a doctor's name that suddenly keeps coming up over and over again with associated large dollar claims.

➤'Why Did Lab Spend Go Up?'

Here's a real-world example: Back in 2018, a small rural hospital with a tiny clinical lab all of a sudden had its lab claims go up 1,000% in a year. The payer's investigative group noticed that and asked, "Why did the lab spend go up so quickly?"

The group had an auditor look into it, and it turned out that an external toxicology lab was funneling claims through that hospital's chargemaster. The motivation for this scheme is obvious. An inpatient hospital laboratory's claims are reimbursed by Medicare at a much higher rate than outpatient lab claims.

The payer determined that this arrangement with the toxicology lab was not on the up and up. Accordingly, the hospital was notified that its contract with the payer did not allow it to subcontract and behave like a reference lab. And the payer recouped the overcharged reimbursement money.

Here's an intriguing aspect: In the situation I described above, the payer also turned information about this scheme over to the OIG.

Sometimes, if one private payer's investigative group finds potential fraud involving a lab that not only affects that payer, but affects other health plans and possibly the Medicare program, that payer's investigative unit is going to contact the federal government. If the OIG gets information of this type from multiple payers, then it may suspect that something fishy is going on with the lab in question.

Is It Fraud, or Not?

Payer audits don't always turn up fraud. I was once asked by an investigative group at a payer to get on the phone with a lab to discuss some higher-than-expected claims. On the call, the lab's representatives thought they could file the claims a certain way, but the payer's payment integrity folks told the lab it couldn't do it that way. And the lab team said, "Holy cow, what did we do wrong and how can we fix it?"

In my experience, if a lab is reputable with how it operates, the first thing it's going to do during a problem is fix it with the payer and make things right on its own initiative.

Prepayment Flags

Keep in mind that one big difference in investigative power between the DOJ and private payers is that payers can't formally interview people at labs that are suspected of wrongdoing. However, private plans can issue prepayment flags.

A prepayment flag postpones claim reimbursement for a specific lab while the payer requests medical records associated with claims under investigation. Using this approach, a payer basically can make the lab's life miserable, asking for documentation and not paying until it sees those documents.

Ultimately, payers can remove a problem lab from participating in a health plan if the lab resists and doesn't comply with a payer's requests. This is when the payer says, "Your contract is up. We're going to give you the 90-day notice for not complying with our payment integrity unit. After that date, we're going to terminate the contract."

This is the payer's ultimate weapon. I know of two large labs that were terminated by a payer over non-compliance, so it does happen occasionally.

Lab leaders might wonder whether payers can recoup money if they determine overpayments have occurred. Yes, they can. Some of that is spelled out in contracts with labs and other healthcare organizations. Under these contracts, payers have the right to go back and recoup if they find overpayments. *(See TDR, "Insurers Get Aggressive with Years-old Audits," Aug. 16, 2021.)*

Recouping Overpayments

Also under the contracts, payers often can go back five years to audit claims. Labs fight with payers about this all the time. I've been involved in these fights.

The payer's claim investigation team will inform a lab that it found $500,000 that should be recouped, for example. The team will present the lab with all of the claims that are associated with that $500,000. Naturally, a lab's going to respond, "Whoa, we don't have $500,000 just to hand over."

So, the lab will go back line by line and say, "Wait a minute, $200,000 of this is beyond the five years under contractual obligation." Eventually, after negotiations, the lab and the payer usually arrive at an agreement—say for $300,000 of the original $500,000.

Once that happens, the lab can handle the repayments in a couple of ways. A lab can pay in installments, and both sides will work out a payment plan. Or a lab will ask to have the amount deducted from upcoming test claims.

In other words, until the lab makes up that $300,000, it won't get paid for any new claims.

If a payer and a lab can't reach an agreement about repayments, then a payer can take the lab to civil court. This is different than the DOJ, which can prosecute offenders in criminal court.

With a civil case, the lawyers get involved on both sides and it's messy. Lawyers will start arguing over specific charges. The lab might point out an individual charge of $500, for example, and claim that was because a patient used an expired insurance card when they went to a provider. Because the insurance was billed incorrectly, the lab was left holding the bag for the claim amount. Doctor's offices don't have the staff to verify every detail of a patient's information on every lab test order.

➤Civil Court as a Last Resort

As with any civil case, either the parties eventually settle the case, or it goes to trial.

I want to end by reiterating that reputable labs will want to talk to payers about discrepancies. When a payer's contract administrator and payment integrity representative call a lab manager—and if the lab is honest—the lab will admit if there was a mistake.

Maybe a disputed claim occurred because there was staff turnover. In that case, the lab's manager may have been shouldering too much work, missed a policy update, and didn't change it in the billing system. That's understandable.

Many clinical laboratories have been in those situations. In my experience, when faced with such problems, most labs don't want to end up with a prepayment flag because that's where real trouble starts. When a lab does not get paid and it has to send medical records to a payer to verify claims, that takes time and probably gets the attention of executives.

There are reasonable explanations for problems, and reasonable people can solve them. Reputable labs will take those steps with payers proactively. TDR

Private Payers Eye COVID-19 Test Fraud

NOW THAT WE'RE OUT OF THE PUBLIC HEALTH EMERGENCY FOR SARS-CoV-2, payers are starting to take a closer look at COVID-19 testing claims—much like the federal government is. *(See TDR, "Labs Can Expect COVID-19 Test Audits, Investigations," May 16, 2022.)*

Because of the public health emergency, it was hard for payers to truly audit COVID-19 test claims. They were mandated to pay those claims.

Some dishonest labs performed all kinds of other, medically unnecessary testing and attached them to COVID-19 claims. It was a natural setup for fraud.

During the pandemic, I worked for a payer, and we had a daily call about COVID-19 testing and vaccines. We talked about potential fraud all the time and how to follow the money.

We'd joke about the number of COVID-19 labs that popped up out of nowhere. Some of these pop-up labs were people simply setting up an analyzer in their garage. For a couple hundred bucks, someone could get a CLIA certificate for their garage lab.

The CLIA program doesn't have the staff to come out and verify that everyone is who they claim, especially during a public health emergency when resources are tight. And it's going to take CLIA two years to get out to inspect that suspicious lab.

Those lab owners figured by then they'd have their millions and be gone. It's just the reality of greedy people. Fortunately, whistleblowers, patients speaking up, and the media stopped some of those labs from operating.

Lab Market Update

Labcorp and Quest Discuss Outreach Acquisition Potential

The two national laboratory companies outlined their Q2 2023 earnings, including price per test

GIVEN THE POTENTIAL UPSIDE OF HUNDREDS OF MILLIONS OF DOLLARS IN ADDED REVENUES, both **Labcorp** and **Quest Diagnostics** remain on the prowl to acquire more hospital laboratory outreach businesses and seize opportunities to manage inpatient hospital and health system labs.

That topic figured prominently into both companies' Q2 2023 earnings calls with financial analysts. For lab administrators and pathologists, acquisition of lab outreach businesses is a sign of growing consolidation in the outreach market even as the sellers—typically financially strapped hospitals—welcome the infusion of cash generated from these transactions.

Burlington, North Carolina-based Labcorp, had a busy Q2 with acquisitions, including buying the outreach businesses of **Legacy Health** and **Providence Oregon**, both based in the Pacific Northwest. Labcorp will also manage inpatient hospital labs for Legacy. *(See TDR, "Hospital Lab Outreach Selloffs Continue with Labcorp as Buyer," July 31, 2023.)*

"I think the hospitals are looking for several things [from such deals]," Labcorp CEO Adam Schechter said during an earnings call on July 27. "First and foremost, you have to be able to give them patient continuity. They need to make sure that there's no impact to their patients if they do a laboratory agreement.

"Second thing is science innovation technology," Schechter added. "[Labs] want to find ways to actually do better science and get better information faster so they can get better patient care as they move forward."

Quest CEO James Davis reported base growth in its physician lab services during Q2, largely through partnerships with health plans. "A growing number of these involve value-based arrangements and are generating faster growth and share gains than the traditional relationships," Davis told analysts during a call on July 26.

The company's professional lab services business—which includes operating hospital labs or providing supply chain consulting—grew nearly 10% from Q2 2022 to Q2 2023.

Quest Q2 Revenue Down

For Q2, Quest Diagnostics reported the following:

- Overall revenue was down 4.7% year over year to $2.3 billion.
- Base business (i.e., non-COVID-19 testing revenues) increased 9.5% to $2.3 billion.
- COVID-19 testing sales dropped 88.3% to $41 million.

Compared to Q2 2022, total test volume went up 0.2%. "Revenue per requisition declined 4.9% versus the prior year, driven by lower COVID-19 molecular volume," said Sam Samad, Chief Financial Officer (CFO) at Quest, during the earnings call.

"Base business revenue per req was up 2.5% due to more tests per req, changes in test mix, and benefits recognized with certain value-based arrangements.

"We are not expecting demand for respiratory panels to be as strong as we saw in last year's flu season," he noted.

Also in Q2, Quest launched Genetic Insights, a direct-to-consumer genetics health test ordered online. "This saliva-based test leverages our expertise in next-generation sequencing to analyze three dozen genes for inherited risk of conditions ranging from breast and colon cancer through carrier status for cystic fibrosis and Tay-Sachs [disease]," Davis said.

Davis also touted progress the company is making to roll out automated instruments in its own labs, particularly considering the continuing frontline staff turnover that Quest is experiencing. *(See the sidebar for more about staff turnover.)*

"When complete, four of our major medical laboratories will use automated microbiology lines with embedded artificial intelligence identifying positive and negative cases, leading to improved quality and productivity," he said. "In genomics, we're utilizing AI in bioinformatics to improve and speed variant classification and prioritization."

Labcorp Sales of $3B in Q2

Labcorp's Q2 numbers were as follows:

- Sales went up 3.8% to $3 billion year over year.
- Base business grew 13%.

"COVID-19 testing revenue was down 88% … as we performed an average of 3,000 PCR tests per day in the quarter," said CFO Glenn Eisenberg during the earnings call.

Overall test volume increased by 1.4% compared to Q2 2022, with acquisition volume largely contributing to this bump. Price per requisition increased 2.4% and was up more for base business (7.5%) thanks in part to a deal to run nearly 100 hospital labs for **Ascension Health** based in St. Louis, the company said. *(See TDR, "Labcorp: Ascension Deal Will Earn $550 Million in 2023," March 6, 2023.)*

Labcorp, Quest Chiefs Reflect on Staff Turnover

PERHAPS A REFLECTION OF THE INDUSTRY AT LARGE, Labcorp and Quest Diagnostics reported staff turnover as a lingering problem into Q2 of this year.

Quest CEO James Davis said before the pandemic, the frontline turnover rate at the company was 14%. As of December 2022, that rate was 23%. Frontline workers include those in phlebotomy, logistics, specimen processing, and call centers. It's not clear what percentage frontline workers make up of Quest's 50,000 employees.

"[The turnover rate has] come down modestly in the first part of the year, but still hasn't come down to the levels, obviously, of pre-COVID or to where we would like them," he said. "We've estimated that each turnover … can cost us upwards of $8,000 to $10,000 depending on the role … If you do the math, that could have upwards of a $20 million impact in the second half of this year."

Labcorp also continues to experience higher turnover compared to before the SARS-CoV-2 public health emergency.

"If we look at our turnover rates, although they're still higher than they were prior to COVID, they actually look better this year than they did last year, and we're seeing some improvement," said CEO Adam Schechter. "Wage inflation continues to be an issue, and we continue to use LaunchPad savings to offset that as best we can."

LaunchPad refers to Labcorp's business process improvement initiative, which seeks $350 million in savings over the three-year period ending in 2024.

Beginning with Q2, Labcorp reported financial results without the inclusion of **Fortrea**, its former clinical research business. Fortrea spun off into a separate public company on June 30. The new company will focus on clinical trial management, *WRAL News* reported. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Forming new relationships with non-traditional care providers is one way clinical laboratories can earn additional revenue. With that in mind, here's another sign of the changing landscape of primary care. Warehouse club **Costco** announced a new partnership with **Sesame** on Sept. 25. Sesame is a New York-based online marketplace of reduced-priced healthcare providers—including clinical laboratories—for patients who have no insurance or who have high deductible health plans. Under the deal, Costco members can receive low pricing through Sesame on a range of health services.

MORE ON: *Costco Deal*

Using Sesame, Costco customers can get a same-day, virtual primary care visit for $29 or a standard lab panel (plus a virtual, follow-up consultation with a provider) for $72. Details about which lab panels are available were not immediately clear on either Sesame or Costco's websites. Sesame does not take health insurance.

BIOMÉRIEUX INCREASES SALES 5.3% IN Q2

Continuing reporting in the last issue about *in vitro* diagnostics company earnings, at **bioMérieux** in Marcy l'Étoile, France, sales for Q2 2023 rose 5.3% over Q2 2022 to €864.3 million (US$925.4 million). Other Q2 2023 data the company reported included: Microbiology sales of €309.6 million (US$331.6 million) were up 13.3% quarter over quarter. Immunoassays sales of €91.6 million (US$98.1 million) were down 2.4%.

NO SURPRISES ACT DISPUTES HEARING IN CONGRESS

Purported flaws with the No Surprises Act's independent dispute resolution (IDR) process were on full display during a **U.S. House of Representatives** Ways and Means Committee meeting in September. Jim Budzinski, CFO at **Wellstar** in Marietta, Georgia, told the committee that out of 8,000 IDR requests filed by Wellstar, 588 have been resolved, of which 288 were in the system's favor. "Unbelievably, only one-third of those determinations in our favor had been paid by insurance companies, and the deficiency is with some of the largest insurance companies in this country," Budzinski said.

TRANSITIONS

- Lee Coppin is the new Director of Continuous Improvement at **FXI** in Radnor, Pennsylvania. He previously held similar positions at **Cook Medical** and **Becton Dickinson**.
- Kathryn Traughber, MS, MLS(ASCP) has been named Regional Director of Laboratory Services at **Saint Alphonsus Health System** in Boise, Idaho. She previously worked at **Saltzer Health** and **Interpath Laboratory**.

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

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