Volume XXVI, Number 17 Monday December 16, 2019

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TOP 10 Lab Stories 2019
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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Is Health Price Transparency at Its Tipping Point?

Is it a coincidence that a number of uninsured consumers filed separate lawsuits in federal courts against **Laboratory Corporation of America** and **Quest Diagnostics**—alleging, in both cases, that they were overcharged for clinical laboratory tests—just months before the federal government published final rules requiring hospitals and other providers to publish their prices?

Last month, the federal **Centers for Medicare and Medicaid Services** (CMS) issued a final rule that is proving unpopular with the hospital industry. It is titled, "Calendar Year (CY) 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC)" and is scheduled to become effective on Jan. 1, 2021.

Both developments have the potential to change the way patients and consumers expect clinical laboratories and anatomic pathology groups to make their lab test prices easy to find and easy to understand.

Today, tens of millions of Americans have high-deductible health plans (HDHPs). These individuals are responsible for annual individual and family deductibles of as much as $5,000 and $10,000, respectively, or more. For them, knowing the price of a medical service or clinical laboratory test in advance of service is essential because they know they have to come up with the cash to pay their share of what may be a large percentage, even 100%, of the lab test or medical treatment.

The current leadership at CMS is determined to advance price transparency. In the press release announcing the final hospital price transparency rule, CMS Administrator Seema Verma said, "Under the status quo, healthcare prices are about as clear as mud to patients ... we are throwing open the shutters and bringing to light the price of care for American consumers ... Today's rules usher in a new era that upends the status quo to empower patients and put them first."

It probably did not escape the notice of many pathologists and clinical lab administrators that the hospital industry voiced strident opposition to this rule. Experts predict that hospitals will file lawsuits to overturn or temper this final rule on price transparency. However, it's likely these actions will only slow down the current trend toward full price transparency. TDR

2019's Top 10 Lab Stories Reveal Major Lab Trends

This year brought more bad news to laboratories than positive developments, but opportunities exist

CEO SUMMARY: There are both surprises and several valuable insights to be harvested from THE DARK REPORT's "Top 10 Lab Industry Stories for 2019." Financially, 2019 proved to be a tough year for both clinical labs and anatomic pathology groups in the United States. One reason is because Medicare and private payers continue to use several methods to cut what they pay for lab testing services. The big question is when the collective year-after-year cuts to clinical lab and pathology fees reaches the point where many labs lack the revenue needed to stay open.

No single event shook the clinical laboratory industry in 2019. Rather, 2019 might be aptly described as the year that laboratory finances endured the proverbial "death by a thousand cuts."

Stated differently, a review of the clinical laboratory industry's top 10 biggest stories during 2019 shows that the repeating theme is how both government and private payers are actively cutting what they pay for clinical laboratory testing and anatomic pathology services. Payers do this by refusing to cover an ever-increasing number of lab tests while, at the same time, slashing the prices they pay for those lab tests they do cover.

Consistent with this multi-year trend is THE DARK REPORT's pick for the number one story of its list of 2019's Top 10 Lab Industry Stories. It is how the price cuts to the 2019 Medicare Clinical Laboratory Fee Schedule—enacted per the Protecting Access to Medicare Act (PAMA)—have opened the door for state Medicare programs and private health insurers to enact their own deep cuts to the prices they pay labs for testing.

This is how the Medicare cuts triggered 2019's flood of price cuts for lab tests. The overall reduction in what labs are paid directly eats away at the financial stability of most of the nation's independent laboratories and hospital/health system-based labs. *(See story #1, page 5.)*

Reinforcing this year's number one story—the overall impact of the PAMA lab test price cuts—are other stories that make the 2019 top-10 story list. Stories number three and number four highlight the wider impact of Medicare lab fee

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

cuts and how flawed updates to National Correct Coding Initiative (NCCI) guidelines caused certain labs to go unpaid for many types of molecular and genetic tests. *(See stories #3 and #4, page 6.)*

Four Stories Have Bad News

More bad news for clinical labs and pathology groups is reflected in four of the 2019 top 10 stories. For example, the **Centers for Medicare and Medicaid Services** (CMS) issued a final rule that gives it new power to fight Medicare fraud and abuse. It requires providers to disclose affiliations—both current and going back five years—when providers apply to enroll or re-enroll. Attorneys tell The Dark Report that the language of this new federal rule has the potential to ensnare even compliant labs. *(See story #2, page 5.)*

Similarly, federal prosecution of an Arkansas pathologist for manslaughter and other criminal charges, along with the national news of patient deaths at three different Houston hospitals (each incident involving that hospital's lab), shows that the public has much less tolerance for medical errors. *(See story #5, page 7.)*

17.5% Fewer Pathologists?

One story that may have been unexpected within the lab industry during 2019 is the peer-reviewed study published in May by *JAMA Network Open*.

Titled, "Trends in the US and Canadian Pathologist Workforces from 2007 to 2017," the study describes how researchers determined that the number of active pathologists in the United States had declined by 17.5% between 2007 and 2017. That's 2,728 fewer pathologists at the end of 2017. *(See story #7, page 8.)*

The implications of this study need to be fully understood. One easy conclusion may be that, as Medicare and private health insurers pay pathologists less for professional services, it motivates working pathologists to retire early and encourages medical students to select other specialties. Pathologists may be debating the findings of this study for years to come, because it strikes to the financial health of their medical specialty.

Despite the important stories in 2019 that represent bad news for the clinical laboratory and anatomic pathology professions, there were several bright spots.

New Clinical Laboratories

For example, the annual growth in the volume of lab tests performed in the United States continues to be strong enough that a number of larger laboratory organizations are building huge, new, state-of-the-art laboratory facilities. The Dark Report published information about these major lab construction projects. The facilities range in size from 36,000 square feet to 250,000 square feet. *(See story #8, page 8.)*

Coming Soon: Drones!

Maybe the most unique story to make the 2019 list of the lab industry's top 10 stories is the first pilot project in the United States that uses a drone to move specimens every day between a physician's office and a health system lab facility. This happened this spring at **WakeMed Health** and the prime vendor is **UPS**, the international delivery company. Experts watching this and other drone pilot programs predict that drones will be moving lab specimens, prescription drugs, and other medical supplies on a surprisingly fast timeline. *(See story #9, page 9.)*

As we do each year, The Dark Report editors suggest lab administrators and pathologists use this top 10 stories list as the basis for strategic planning. The goal should be to alert the lab's management team to the wide scope of influences actively shaping how lab testing services are reimbursed and how the delivery of lab testing is changing. TDR

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2019 1 Second Year of PAMA Cuts Brings More Financial Disruption to Labs

IT'S NO SURPRISE that deep, ongoing price cuts to the Medicare Part B Clinical Laboratory Fee Schedule are ranked number one on our 2019 list of biggest lab industry stories. These price cuts are pervasive and every lab in the United States is experiencing revenue loss.

Significantly, 2019 is only the second year of the six-year period of price cuts authorized under one section of the Protecting Access to Medicare Act (PAMA). The federal **Centers for Medicare and Medicaid Services** is able to cut prices for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) by no more than 10% in each of the years 2018, 2019, and 2021. CMS will be able to cut lab test prices by up to 15% in each of the years 2022, 2023, and 2024.

In this second year of PAMA lab test price cuts, the full consequences are easily visible. The majority of state Medicaid plans have been swift to enact similar cuts to their lab test prices in both 2018 and 2019. *(See TDRs, Feb. 25, Apr. 8, and Apr. 29, 2019.)*

Likewise, a substantial number of national and regional health insurance companies were quick to make similar price cuts to what they paid to clinical laboratories.

Thus, by the end of 2019, many of the predictions about the financial devastation of clinical lab finances are now coming true. If there is an unexpected outcome, it is that the prediction that there would widespread closures or sales of local labs has not occurred—yet!

2019 2 Medicare's New Anti-Fraud Rule Creates New Risks for Labs, Pathologists

IT'S A MAJOR STORY WITH GOOD NEWS AND BAD NEWS for the clinical lab industry. The federal **Centers for Medicare and Medicaid** (CMS) issued a new rule, effective Nov. 1, 2019, that gives the agency new power to fight healthcare fraud.

The final rule is titled, "Program Integrity Enhancements to the Provider Enrollment Process." It gives CMS new measures to allow it to revoke and deny enrollment in an attempt to stop fraud in the Medicare, Medicaid, and Children's Health Insurance (CHIP) programs.

CMS' power to fight fraud has expanded and labs may be a priority target. Now, when a provider wants to enroll or re-enroll in the Medicare program, it must disclose current affiliations and affiliations going back five years.

CMS can revoke or deny enrollment if a provider or supplier bills for services from a non-compliant practice location, exhibits a pattern of abusive ordering or certifying of Medicare Part A or Part B services or drugs, or has an outstanding debt to CMS that CMS has referred to the Treasury Department. *(See TDRs, Oct. 14 and Nov. 4, 2019.)*

THE DARK REPORT interviewed four attorneys and all agreed this new anti-fraud rule can help rein in fraud and abuse in the Medicare program. Each attorney, however, also pointed out different ways even compliant clinical labs and pathology groups could find themselves at risk of having their Medicare provider status denied. Time will tell if this new rule curbs fraudulent behavior.

2019 3 Managed Care Companies Continue to Cut Lab Prices, Restrict Networks

DURING 2019, MULTIPLE LARGE HEALTH INSURANCE COMPANIES initiated major changes to their laboratory networks and deep cuts to the fees they pay clinical labs and anatomic pathologists.

The common motivation behind these actions is to reduce what health plans spend for clinical laboratory tests and anatomic pathology services. This multi-year trend continued robustly into 2019.

Probably the first significant action in 2019 was **UnitedHealthcare's** (UHC) announcement on April 22 that it was creating a preferred laboratory network on July 1 that included just seven lab organizations. UHC indicated that its goals for the preferred laboratory network were the triple aim of delivering a better patient experience of care, improving the health of populations, and reducing the per capita cost of care. *(See TDR, Apr. 29, 2019.)*

During the course of 2019, on a state-by-state basis, **Anthem, Inc.**, notified pathology groups that it was lowering the prices it paid for many pathology CPT codes by 50% to 70%. It was also moving pathology contracts from its physician professional services division to its ancillary services division. Also during 2019, **Aetna, Inc.** continued its efforts to reduce or eliminate what it pays for clinical pathology professional services. *(See TDR, July 1, 2019.)*

UnitedHealthcare and Anthem each insure more than 40 million Americans. Thus, their actions will have a major influence on the revenues and financial stability of labs in every community in the United States.

2019 4 Many Labs Struggle to Get Paid Because of Flaws in NCCI Guidelines

REVISED RULES CONTAINED IN the National Correct Coding Initiatives (NCCI) that became effective on Jan. 1 were poorly-written and caused major disruption in how many labs bill for the tests covered by the revised guidelines.

The revised guidelines affect the policy manuals for both Medicare and Medicaid. Payment made to labs for Medicare and Medicaid beneficiaries also are affected. *(See TDRs, Apr. 8 and Apr. 29, 2019.)*

After implementation of the new guidelines, the resulting widespread uncertainty in how to correctly code and bill for many genetic and molecular tests caused nine major lab asssociations to sign a letter to the federal **Centers for Medicare and Medicaid Services** (CMS). The letter requested that CMS withdraw the newly-revised guidelines and work with clinical laboratory directors and pathologists on alternatives.

Throughout 2019, a significant number of labs and coding/billing consultants continued to report that payers were denying a significant proportion of claims due to confusion on how labs are required to comply with the new NCCI guidelines.

Problems with the 2019 NCCI guidelines can be viewed as an example of how disruptive new molecular and genetic testing technologies are for government and private payers.

2019 5 Federal Prosecutors Indict Arkansas Pathologist for Patients' Deaths

MEDICAL ERRORS THAT CAUSE PATIENT HARM are getting more scrutiny—not only by healthcare regulators, by also by patients and the media. This is true of laboratory errors, particularly when a lab error causes the death of a patient.

One big story in 2019 was the arrest and indictment of pathologist Robert Morris Levy, charged with three counts of involuntary manslaughter, 12 counts of wire fraud, 12 counts of mail fraud, and four counts of making false statements. Federal prosecutors allege that he diagnosed cases while under the influence of alcohol and other substances. *(See TDR, Sept. 3, 2019.)*

In Houston, over a period of several months, three major hospitals each reported the death of a patient due to medical errors that, in some part, involved the clinical laboratory. At **Baylor St. Luke's Medical Center**, a patient died after a labeling error caused her to be transfused with the wrong type of blood.

At the **University of Texas MD Anderson**, a patient died as a result of being transfused with blood tainted with a bacterial infection after a labeling error. A patient death at **Ben Taub Hospital** was attributed to staff failure to follow federal patient care and safety requirements, during which the reporting of critical lab test results was involved. *(See TDR, July 22, 2019.)*

Each event was covered by national news sources and triggered enforcement action from the **Centers for Medicare and Medicaid Services**. Each incident is a reminder to pathologists and lab managers of the consequences when a medical error causes major harm to a patient.

2019 6 Huge Data Breach of a Lab Vendor Involves 25 Million Lab Patients

BECAUSE OF ONE LAB BILLING CONTRACTOR, at least 13 clinical lab companies had to disclose major breaches of their patients' protected health information (PHI). Collectively, the data of more than 24 million lab patients was breached.

It was national news in June when four major lab companies announced that the data of their patients had been compromised by one of their billing vendors. That vendor was the **American Medical Collection Agency**, a medical bill and debt collector in Elmsford, N.Y.

The companies were: **BioReference Laboratories** (a subsidiary of **Opko Health**); **Laboratory Corporation of America**; **Quest Diagnostics**; and **Sunrise Laboratories** (a division of **Sonic Healthcare USA**). Together, these labs disclosed that the data breaches involved about 20 million patients.

In the following months, another nine laboratory companies announced breaches of their patients' data. These labs had also used American Medical Collection Agency and these breaches involved about four million patients. *(See TDR, Jul. 1 and Aug. 12, 2019.)*

This episode showed how clinical labs and anatomic pathology groups could be vulnerable to breaches of their patients' protected health information if their vendors do not have appropriate safeguards in place.

2019 7 Study Reveals Number of Pathologists In U.S. Declined 17.5% from 2007-2017

At least one research team published evidence indicating that the number of pathologists practicing in the United States declined by 17.5% during the years of 2007 to 2017. These findings have stirred up controversy within the pathology profession.

This story started on May 31, when *JAMA Network Open* published online the research study, "Trends in the US and Canadian Pathologist Workforces from 2007 to 2017." The study was conducted by pathologists from the United States and Canada. *(See TDRs, Jun. 10 and Aug. 12, 2019.)*

Not only did this research team determine that the number of active pathologists in the U.S. had decreased from 15,568 to 12,839 (-17.5%), but during that same period the number of Canadian pathologists increased from 1,467 to 1,767 (+20.5%).

The researchers did not offer reasons why the number of active pathologists in the U.S. decreased during that decade. Immediately, others in the pathology profession challenged those findings.

What makes this an important story for the lab profession is that such a reduction in the number of active pathologists during that decade could be interpreted as one consequence of payers reimbursing pathologists much less money today than, say, in 2005. In fact, some pathologists point out that today's job market for pathologists is quite robust.

2019 8 Demand for Testing Encourages Labs to Build Much Bigger Lab Facilities

There is irony in the fact that, even as the number of clinical laboratory organizations in the United States shrinks steadily year after year, the ongoing growth in the volume of medical laboratory tests performed motivates some lab organizations to build bigger—even huge—lab testing facilities.

Early in the year, **DaVita Labs** of Deland, Fla., opened a 150,000 square-foot lab in Deland. Similarly, **ARUP Laboratories** of Salt Lake City is now constructing a building that will have 200,000 square feet of new laboratory space. **Quest Diagnostics** is also building what it describes as a flagship laboratory in Clifton, N.J., that it said will be 250,000 square feet, will serve 40 million patients in seven eastern states, and will be operational in 2021. *(See TDR, Feb. 4, 2019.)*

In the hospital laboratory sector, two new, large lab facilities opened early in 2019. Both are in the New York City metropolitan area. In February, **Northwell Health** and the **NYC Health and Hospitals** corporation opened a new 36,000-square foot facility in the Little Neck section of Queens.

Then, later in the month, Northwell Health opened a second, larger new lab facility in its hometown, Lake Success, N.Y., that it said had 84,000 square feet devoted to clinical lab testing, along with the capacity to do 55 million tests per year. *(See TDR, Feb. 25, 2019.)*

This is a top 10 lab industry story because it shows that the volume of lab tests performed in the United States continues to increase, regardless of how poorly labs are reimbursed for test claims.

2019 9 Drones Arrive in Lab Industry as WakeMed, UPS Move Specimens

USE OF DRONES to pick up and deliver clinical laboratory specimens is now happening in multiple pilot projects in the United States, Canada, Switzerland, and several African nations.

In this country, THE DARK REPORT was first to provide business intelligence about how **WakeMed Health** in Raleigh, N.C., began moving clinical lab specimens from an on-campus clinic to the core laboratory in April. **UPS** is collaborating with WakeMed. *(See TDR, April 8, 2019.)*

It is significant that there are independent projects on three continents to use drones to move medical laboratory specimens from where they are collected to central laboratories where they will be tested. This shows how ongoing advances in drone technology are giving both government regulators and lab leaders confidence that patient samples can be transported safely—with the benefits of faster transport time and less cost.

In parallel with these early pilot projects to move medical laboratory specimens by drone, there are numerous other projects underway that use drones to convey medical supplies to providers and to deliver therapeutic drugs to patients living in remote areas.

For clinical labs, the benefits of moving clinical laboratory specimens by drones can be to shorten delivery times and reduce transport costs when couriers in cars, vans, and trucks are used.

2019 10 One Big Story That *Didn't* Happen! Few Owners Sold Their Labs in 2019

THERE WAS WIDESPREAD RECOGNITION that the PAMA lab test price cuts would do major financial damage to clinical labs. The common expectation was that deteriorating finances would cause many lab owners to sell their labs, file bankruptcy, or simply shut the doors and go out of business during 2019, the second year of PAMA price cuts.

However, the big surprise during this year was how few clinical lab companies either closed or sold after the Medicare and Medicaid fee cuts reduced their revenue. This outcome ran contrary to the popular wisdom of many lab experts.

Along with others, THE DARK REPORT predicted a wave of lab sales or closings this year after lab owners saw the PAMA price cuts shrink their labs' revenue below operating costs. Community labs serving primarily nursing homes and community hospital labs that saw their outreach revenues shrink substantially were the two lab sectors expected to suffer the most.

In 2017 and 2018, a number of labs did sell or close their doors, after calculating how the PAMA price cuts would take their labs from a small profit to a big loss. However, that is not the case this year.

Since the start of 2019, the number of lab sales or lab closures (caused, at least in part, by the PAMA fee cuts) has been surprisingly low.

That could mean, though, that the reckoning for the ongoing financial erosion of many lab organizations will show up in 2020 and 2021. TDR

Lab Market Update

Veritas Genetics to Close Its Testing Operations in U.S.

Testing company offered consumers a $599 whole genome sequence, but now is laying off staff

MAYBE CHARGING CONSUMERS THE LOW PRICE of $599 for a whole human genome sequence is not a winning financial strategy. That's one possible reason why closely-watched **Veritas Genetics** of Cambridge, Mass., will stop operations in the United States.

It was in July that Veritas announced it was cutting its already-low price to sequence a genome from under $1,000 to just $599. But last week, the genetic testing company told its customers via email it was ceasing operations in the United States. *CNBC* said it saw an email from the company and reported that the email stated, "Due to an unexpected adverse financing situation, we are being forced to suspend our operations in the United States for the time being.

"We are currently assessing all paths forward, including strategic options," the email said. At the same time, the company announced that it would lay off most of its employees in the United States. The number of employees being laid off was estimated to be about 50, *CNBC* said, quoting an unnamed source who is familiar with the company.

Only U.S. Operations to Close

A Veritas spokesperson told *CNBC*, "I can clarify this temporarily affects U.S. operations only. All of the customers outside of the U.S. will continue to be served by Veritas Europe and Latin America."

On its website, Veritas said the company got its start in the 1970s when George Church was a student at the *Massachusetts Institute for Technology*. "George Church, PhD's, work set countless genetic discoveries into motion, including the Human Genome Project, the first initiative to map all genes in the human genome," the website says.

Veritas had planned to expand to serve millions of consumers in the coming years by dropping the price of whole-genome sequencing (WGS) to just a few hundred dollars, and it raised more than $50 million in financing since it was founded in 2015, *CNBC* reported.

Genome for Under $1,000

It was in 2016 when the Boston-based company became the first in the world to map out a person's DNA for less than $1,000.

CNBC also reported that investors from China may have become reluctant to invest in an American company after the Trump administration started cracking down on Chinese firms making investments in U.S. companies. For Veritas, uneasiness about having investors from China meant that new investors who were interested in the business became worried about the potential for U.S. oversight from the federal agencies, *CNBC* reported, again citing a source familiar with the company.

Another problem for Veritas may have been a lack of health insurance coverage for its test, as *Dark Daily* reported in October. Kathryn Phillips, PhD, Professor of Health

Economics at **University of California, San Francisco**, said health insurers are uncertain that genetic sequencing will lead to improvements in clinical diagnoses.

"Insurers are looking for things where, if you get the information, there's something you can do with it and that both the provider and the patient are willing and able to use that information to do things that improve their health," Phillips told *CNBC*. "Insurers are very interested in using genetic testing for prevention, but we need to ... demonstrate that the information will be used and that it's a good trade-off between the benefits and the costs."

Gene Sequencing Challenges

Another expert echoed Phillips' comments, suggesting that tying WGS into personalized medicine that leads to actionable diagnoses continues to be a challenge. Robin Bennett, PhD, a board-certified senior genetics counselor and Professor of Medicine and Medical Genetics at **UW School of Medicine**, told *CNBC*, "[Healthcare] may be moving in that direction, but the payment for testing and for services, it hasn't moved in the preventive direction. So, unless the healthcare system changes, these tests may not be as useful because … the healthcare system hasn't caught up to say, 'Yes, we support payment for this.'"

The result of these problems is that Veritas has been in talks with potential acquirers in recent months, *CNBC* reported.

While Veritas has problems now, it was not long ago that the firm said it hoped to be competitive with **Ancestry.com** and **23andMe** by offering more genetic-test result information for about the same price, *CNBC* added.

As, *Dark Daily* reported, Veritas was planning to attract more consumers by dropping the price for its whole-genome sequencing test. At the time, Church had said he hoped to sequence 150,000 genomes by 2021.

"By announcing an annotated whole-genome sequencing (WGS) service to consumers for just $599, Veritas Genetics is establishing a new price benchmark for medical laboratories and gene testing companies," *Dark Daily* said. Before making this announcement, Veritas had priced its standard myGenome service at $999.

"There is no more comprehensive genetic test than your whole genome," Rodrigo Martinez, Veritas' Chief Marketing and Design Officer, told *CNBC*. "So, this is a clear signal that the whole genome is basically going to replace all other genetic tests. And this [price drop] gets it closer and closer and closer."

Once Veritas dropped the price to $599, pathologists, clinical laboratory managers, and lab industry experts watched to see if this target became a standard throughout the genetic testing industry. At the time, that price included not only the sequencing, but also an expert analysis of test results that included information on more than 200 conditions, Veritas said.

Interpretation Capabilities

"The focus in our industry is shifting from the cost of sequencing genomes to interpretation capabilities and that's where our secret sauce is," said Veritas CEO Mirza Cifric in a news release. "We've built and deployed a world class platform to deliver clinically-actionable insights at scale." The company also says it "achieved this milestone primarily by deploying internally-developed machine learning and AI [artificial intelligence] tools as well as external tools—including **Google's** DeepVariant—and by improving its in-house lab operations."

Veritas probably had fewer customers for its $599 than it projected. Unable to raise more capital, it decided the best option was to close down U.S. operations, stay open overseas, and wait to see how the gene sequencing market develops. TDR

—Joseph Burns

CEO SUMMARY: Two lawsuits filed in federal courts against Laboratory Corporation of America and Quest Diagnostics may have consequences for the entire lab industry. The plaintiffs are patients who allege that the two defendant lab companies charged them as much as 10 times more than what Medicare, Medicaid, or commercial health plans charged. Allegations include overcharging, that labs should disclose prices to patients in advance of service, and other related issues. This article reviews the details of the lawsuit against LabCorp.

LabCorp, Quest face similar complaints from patients who say they were overcharged

Lawsuits Alleging Overcharges to Proceed in Two Courts in 2020

Second in a Series

Are there consequences when a clinical laboratory company charges patients anywhere from two to 10 times more for lab tests than what Medicare would pay for that same test? Consumers are pursuing this question in two separate lawsuits filed in federal courts against **Laboratory Corporation of America** and **Quest Diagnostics**.

Next year, lawyers for LabCorp and Quest will defend their clients in federal courts in New Jersey and North Carolina against charges that they overcharged consumers for clinical lab testing. Robert C. Finkel, an attorney with **Wolf Popper** in New York, filed the lawsuits on behalf of 33 plaintiffs. The case against LabCorp is pending in the U.S. District Court for the Middle District of North Carolina, Greensboro Division, on behalf of 14 plaintiffs in eight states. Nineteen plaintiffs from 11 states filed a similar case against Quest in U.S. District Court in New Jersey. Both sides will begin discovery in the coming weeks, and the cases are scheduled to proceed throughout 2020.

As covered in part one of this multi-part series, both lab companies deny the allegations in the lawsuits and asked the courts to dismiss the cases. *(See "Lawsuits Allege LabCorp, Quest Overcharged Some Patients," TDR, Nov. 25, 2019.)*

One significant factor that distinguishes the LabCorp case from the case against Quest is that an unnamed former executive of the lab company charged that overbilling self-pay patients was 'embedded in the culture of the company' and was so common it was difficult to retain some physician-clients, the lawsuit alleges. *(See sidebar, "Unnamed Witness in Court Case Says Overbilling Certain Patients Was Routine," page 16.)*

Other issues in the LabCorp case center on plaintiffs' allegations that LabCorp had a tenuous relationship with patients that left them vulnerable to overcharges, that LabCorp does not reveal charges before the bill goes out but recognizes that doing so is important to patients, and that LabCorp knows how much Medicare will pay for lab tests and informs Medicare beneficiaries of these charges under the advance beneficiary notice provisions. The lawsuit also includes complaints from the 14 named plaintiffs.

In October, LabCorp filed a 285-page answer to the plaintiffs' amended complaint, saying that the company denied "each and every allegation" in the complaint. *(See sidebar, "In Court Filings in Separate Cases, LabCorp Denies Charges, Quest Responds to Plaintiff's Allegations," page 15.)*

In each lawsuit, the plaintiffs allege that the lab companies overcharged them for laboratory testing services by two to three—and sometimes as much as 10—times higher than what the companies charged consumers whose health insurers fully covered their testing. The plaintiffs were either uninsured or underinsured, meaning their insurance plans did not cover the full cost of their clinical laboratory tests.

Note that in part one, The Dark Report outlined the most serious charges against Quest and Quest's response. In this part two, we focus on the charges LabCorp faces and the company's response.

A Tenuous Relationship

At the heart of both cases is whether the defendants should have informed patients of the charges they would face for clinical laboratory tests physicians order.

The plaintiffs argue that they have an implied right to know what they would be charged before the testing is done. Knowing the price beforehand is important so that these defendants could decide to proceed with the testing, seek another lab, or forego testing.

As the case against LabCorp moves forward in court next year, the 14 plaintiffs from eight states will allege that the lab company has a tenuous relationship with patients for several reasons. These reasons leave patients vulnerable to overcharges, the lawsuit charges.

The relationship is tenuous because physicians order clinical lab tests and often collect blood or other specimens in the doctors' offices, the plaintiffs charges.

Then, the physician sends those samples to a lab the physician or health insurer chooses and the lab tests are run before the lab determines the patient's financial responsibility.

LabCorp does not reveal price information to patients before bills go out, but the lab company recognizes that revealing prices before performing lab tests is important to patients, the plaintiffs charge. Also, LabCorp says it supports "greater transparency about costs, providing estimates of anticipated out-of-pocket cost prior to specimen collection," they allege. As a result, the lawsuit says, "Patients are being forced to pay exorbitant sums for clinical lab testing services when they are the party responsible for payment."

➤'Arbitrary List Price' for Tests

In addition, LabCorp does not have written agreements with patients before testing, the lawsuit states. "As such, the amount such a patient is charged is not a negotiated or contractual rate, but LabCorp's arbitrary list price," plaintiffs allege.

In pursuing this argument, the plaintiffs explain that commercial insurance companies, Medicare, and Medicaid all have agreements with LabCorp and other lab companies about what they will pay for their members' lab tests.

"Accordingly, the market rate for clinical lab testing services can be determined by analyzing the amounts paid by third-party payers who reimburse service providers on a fee-for-service basis (which represent approximately 83% of LabCorp's United States clinical lab testing revenue), in contrast to the amounts charged for similar services, which are rarely paid and based on arbitrary, unilaterally imposed list prices," the plaintiffs assert.

For clinical lab tests, Medicare rates are based on third-party payer rates, Medicaid rates are based on state-specific determinations of reasonable rates, the plaintiffs argue. But, they add, commercial insurers consider their rates to be proprietary and maintain them as closely-guarded secrets.

When serving Medicare patients, LabCorp knows how much Medicare will pay for patients and informs patients under Medicare's advance beneficiary notice requirements. LabCorp could do the same for uninsured and underinsured patients, the plaintiffs charge.

On that point, the plaintiffs go a step further, alleging that in the absence of an agreement on price, the price may be supplied by law, meaning the court can determine a reasonable price for LabCorp's services for the uninsured and underinsured, the lawsuit explains.

Without such an agreement, LabCorp charges high rates for uninsured and underinsured patients. To describe these rates, LabCorp and other healthcare providers use various terms such as the "fee schedule rate," "list price," and "charge-master rate." In this article, we use the term "list rate."

Note that at this point in the 142-page amended complaint, the lawsuit compares the list rate to the clinical laboratory fee schedule (CLFS) rates that Medicare published in 2016. "The CLFS provides a reliable reference point for analyzing the reasonableness of list prices associated with clinical lab testing services, as well as determining the market rates thereof, because the CLFS rates are based upon the actual paid amounts of third-party payers," the plaintiffs allege.

➤Plaintiffs' Complaints

After explaining the difference between the list price and CLFS rates, the lawsuit spends 50 pages to explain the details of each of the 14 plaintiffs' complaints. In the first one, the lawsuit names Sheryl Anderson, a resident of Alabama who was insured through **Blue Cross Blue Shield of Alabama**.

In Court Filings in Separate Cases, LabCorp Denies Charges, Quest Responds to Plaintiff's Allegations

IN ITS COURT DOCUMENTS, LABCORP DENIED THE PLAINTIFFS' ALLEGATIONS in the amended complaint. It also asked that the case be dismissed.

In its filing, LabCorp said the amended complaint violates federal civil procedures because it seeks to present an argument and conclusion to which no response is required. Also, LabCorp did not answer some of the allegations because they relate to claims that have been dismissed.

"To the extent LabCorp must provide an answer to these allegations, LabCorp denies those allegations," the company said. It also said that if there are any headings or footnotes in the amended complaint that constitute an allegation, LabCorp denied those charges.

"LabCorp further denies any remaining allegations of the complaint, if not expressly admitted herein," the documents added. In response to a request from THE DARK REPORT, LabCorp said it does not comment on pending litigation.

In a separate federal case with similar allegations of overcharging uninsured patients, Quest Diagnostics has argued that the plaintiffs failed to state a claim for breach of implied contract because Quest never agreed to charge the consumers a negotiated third-party rate, nor did it omit the price.

Quest also said the plaintiffs failed to demonstrate that the chargemaster rates were unreasonable. Therefore, the court should dismiss the plaintiffs' claims of an implied contract, the company said.

In filings next year, Robert C. Finkel, an attorney with the law firm **Wolf Popper** who represents the plaintiffs in both lawsuits, will seek to certify that each case is a class action lawsuit brought on behalf of all of LabCorp and Quest's patients who have been overcharged.

In November 2016, Anderson had blood drawn at **Sunrise Dermatology** in Mobile. Under Anderson's insurance plan, Quest was the exclusive provider for her clinical lab tests and the plan provided no coverage for lab tests that LabCorp performed.

The lawsuit makes an important point here, noting that LabCorp is an authorized provider for other health insurance plans that BCBS of Alabama offered.

Sunrise Dermatology sent Anderson's blood sample to LabCorp for testing without her knowledge, the lawsuit alleges. "LabCorp was provided by Sunrise Dermatology with Anderson's insurance information and either knew or was reckless in failing to know that Anderson's insurance did not cover clinical lab tests performed at LabCorp," the plaintiffs charge.

At this point, LabCorp should have informed Anderson about the lack of coverage because LabCorp was a provider with a contract with BCBS of Alabama and had a relationship with Sunrise Dermatology, the plaintiffs allege.

"LabCorp was in the best position to advise Anderson that her LabCorp tests were not covered by her BlueCross insurance, and what rates LabCorp would charge for those tests," the lawsuit says.

Asked to Reduce Charge

On its invoice to Anderson, LabCorp charged $170 for three tests identified with CPT codes 85025 ($31), 90076 ($41), and 80061 ($98), but did not provide a diagnosis, the lawsuit alleges. When Anderson asked LabCorp to reduce the charge, the lab company refused, the lawsuit alleges.

If LabCorp had used the Medicare CLFS rates, Anderson would have been

Unnamed Witness in Federal Court Case Says Overbilling Certain Patients Was Routine

ONE OF THE MOST SIGNIFICANT DIFFERENCES BETWEEN THE TWO LAWSUITS alleging that **Laboratory Corporation of America** and **Quest Diagnostics** overbilled uninsured or underinsured patients is that the LabCorp lawsuit includes allegations from an unnamed former LabCorp executive.

The former executive charges that overbilling self-pay patients was common at LabCorp. Physician-clients often would complain about the high rates LabCorp charged to self-pay patients, the lawsuit alleges. After making such complaints, some physicians would refuse to send patients' specimens to LabCorp, court documents show.

Amended Complaint

In the amended complaint that the plaintiffs filed in the case, the unnamed former executive is identified as Confidential Witness 1 or CW1.

"According to CW1, overbilling self-pay patients was 'embedded in the culture of the company,'" the amended complaint alleges. The amended complaint was filed in August 2018 in the case of *Anderson, Carter and others against Laboratory Corporation of America Holdings* in the U.S. District Court for the Middle District of North Carolina, Greensboro Division. Discovery in the case is scheduled to commence next month.

The unnamed witness worked in Ohio for LabCorp in several positions over 15 years, ending in August 2016. CW1's job titles included District Manager, Specialty Sales Representative, and Business Development Executive, the complaint explains.

"While employed by LabCorp, CW1's primary responsibility was encouraging oncologists and pathologists to use LabCorp's diagnostic services for their patients," the lawsuit shows. "CW1 was the primary point of contact between LabCorp and those physicians.

"According to CW1, LabCorp has multiple sets of fee structures. LabCorp has fee structures for third-party payers, such as insurance companies (e.g., **Blue Cross**, **Aetna**, **UnitedHealthcare**), that were substantially below the fee structures for 'self-pay patients,' (i.e., persons who either did not have insurance, or whose insurance failed to cover the LabCorp lab testing). CW1 explained that the negotiated rates for third-party payers are highly guarded," the complaint alleges.

At least once a month, CW1 fielded complaints from ordering physicians about the fees LabCorp charged to self-pay patients, court documents show.

"For example, CW1 recalls that LabCorp would charge a self-pay patient $5,500 for a flow cytometry test, whereas it would accept payment of $800 from a third-party payer for the same test, and as little as $400 from hospital clients who wished to be billed directly, while cost was below $200," the complaint alleges.

'CBC Test Billed at $300'

"Another example, according to CW1, is a CBC (complete blood count) plus routine chemistry profile that would cost LabCorp about $1 to run, and would be billed at $18 to an insurer such as UnitedHealth, but would be billed at approximately $300 to a self-pay patient," the lawsuit shows.

"LabCorp's practices with respect to overbilling self-pay patients sometimes made it difficult for CW1 to maintain good relationships with his clients. As such, CW1 would speak frequently within LabCorp about these matters. One such conversation concerning rates LabCorp charged to self-pay patients occurred in August 2016 with a company vice president, the lawsuit says. The vice president and others at LabCorp told CW1, that it was LabCorp's "policy to charge the list price fee (the highest fee schedule) to self-pay patients," court filings allege.

The lawsuit continues, "According to CW1, when an insured person is referred for testing, price is never questioned by either the physician or the patient. The uninsured are vulnerable to price gouging as they are grouped in with the insured while being processed for testing. Thus, they are, by default, charged the list price."

It was difficult for self-pay patients to know what they would be charged, the lawsuit charges. "CW1 also emphasized that it would be unreasonable for a patient to ask about pricing when blood is being taken in the physician's office or one of LabCorp's draw stations because the phlebotomist (individual who draws blood) would have no idea or access to pricing information," the lawsuit alleges.

"CW1 had first person knowledge of these allegations. S/he was provided the opportunity to review these allegations and consented to their use in this complaint," the lawsuit section concludes.

charged a total of $43.22 for the three tests, or $10.59 for 85025, $14.39 for 80053, and $18.24 for 80061, the lawsuit alleges. Note that the lawsuit refers to two different CPT codes (90076 and 80053) for the second test in question. At press time, Finkel was checking on the discrepancy.

In the lawsuit, the plaintiffs allege that the reimbursement rates under the CLFS are consistent with the rates that BCBS of Alabama paid LabCorp when it covered other clinical lab tests for Anderson in 2016. For CPT codes 87086, 87186, 87088, and 87077, the insurer paid $29.10 (or 18.65%) of a $156 claim that LabCorp submitted, the lawsuit charges. Also, BCBS of Alabama paid **Springhill Hospitals** $38.62 for three CPT codes for Anderson (80050, 80061, and 81003), or 10.55% on a claim for $365.84, the lawsuit alleges.

Invoice Referred for Collection

LabCorp sent Anderson a collections letter from **LCA Collections**, which the letter identified as an in-house division of LabCorp, the lawsuit charges. Later, LabCorp referred Andersons' invoice to **American Medical Collection Agency** (AMCA).

In a second example, the lawsuit explains the details of charges LabCorp sent to Mary Carter, a patient in Maryland, who was insured with **Cigna**. In May 2015, a physician prescribed blood tests for Carter, saying the tests were medically necessary, the lawsuit alleges. The blood was drawn at a LabCorp facility and LabCorp performed eight tests. Cigna denied coverage for the tests saying Carter's plan provided benefits only for covered expenses for treatment or diagnosis of an injury or illness.

LabCorp's bill for the eight tests was $711 and would have been $189.90 under the 2016 CLFS, the lawsuit alleges. Carter paid $484 by credit card but then was billed $227. After LabCorp sent her a collection letter demanding payment, Carter paid the full amount and now seeks a refund of the $227, the lawsuit alleges.

These two federal lawsuits could result in rulings and court decisions that set a legal precedent in how all labs are to quote prices to patients before service. For that reason, lab managers may want to track the progress of these cases through the federal court system. **TDR**

—Joseph Burns

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Pathology Update

Details Emerge in KU Hospital Misdiagnosis by Pathology Chair

After a patient filed a lawsuit against a pathologist at the **University of Kansas Hospital** for fraud and negligence in a case stemming from a misdiagnosis of cancer in 2015, details about a settlement in the case were sealed. Now, some details have come out.

Last month, *NPR* station *KCUR* in Kansas City reported that the **Kansas Health Care Stabilization Fund** paid the patient, Wendy Ann Noon Berner, $1 million on behalf of the pathologist, Meenakshi Singh, MD, and paid Berner $800,000 on behalf of KU Hospital.

The state stabilization fund provides professional liability coverage for Kansas healthcare providers and is a secondary insurer. In this role, it pays claims after a primary insurer has paid its share.

In this KU Hospital case, the court records were sealed when the case was settled last year. Therefore, it's unknown how much any primary insurer paid on behalf of the hospital and Singh, *KCUR* wrote. "But the excess insurance payments suggest the overall settlement totaled at least several million dollars," the station added. The details were revealed in response to a request *KCUR* made under the Kansas Open Records Act.

In addition to claims of a misdiagnosis, the case involved an unnecessary surgery and a cover-up involving Singh, the former Chair of Pathology. After the misdiagnosis, a pathologist-turned whistleblower filed a lawsuit that led the federal **Centers for Medicare and Medicaid Services** (CMS) to investigate. CMS found deficiencies in care delivery that left hospital patients at risk.

In August 2017, Berner sued for fraud, negligence, and civil conspiracy, alleging that she was misdiagnosed with pancreatic cancer in 2015 and that the hospital covered up the case. At the time of the misdiagnosis, Singh was Chair of KU Hospital's pathology department. Since then, she has left the hospital and could not be reached for comment, the station reported. A spokeswoman said KU Hospital would not comment.

Wrong Cancer Diagnosis

The Dark Report first reported this case of the alleged pathology chair's diagnostic error and patient harm described in the court documents. The matter first came to light when Singh's predecessor as pathology Chair, Lowell Tilzer, MD, filed a whistleblower complaint in mid-2016 alleging that Singh had misdiagnosed a patient with cancer and then covered up the mistake after parts of an unspecified organ were removed.

Tilzer alleged that the patient had not been informed of the misdiagnosis and that the hospital sought to retaliate against him after he informed **The Joint Commission** of the misdiagnosis. The Commission accredits and certifies hospitals. *(See "Pathologist's Error and Hospital's Cover-Up Lead to CMS Investigation," TDR, Sept. 18, 2017, and earlier coverage in TDR, July 25 and Sept. 26, 2016.)*

After the patient's surgery, other members of KU Hospital's pathology department examined tissue samples and determined that the organ was not cancerous, according to Tilzer's lawsuit. But Singh allegedly covered up the misdiagnosis by adding an addendum to her original report saying the original cancer diagnosis matched the removed organ. TDR

—Joseph Burns

Converting Paper Reqs to Digital Cut Lab's Costs

Eliminating manual data entry when entering paper requisitions improved TAT, staff productivity

CEO SUMMARY: Health Network Laboratories cut costs and shortened lab test turnaround time by converting paper requisitions to digital data. It did so by scanning paper requisitions and having a vendor do the required data entry. This helped the lab reduce errors in its patient data. Using this paper-to-digital system allowed the lab to adopt an enterprise master patient index (EMPI) that significantly reduced duplicate patient records and ensured demographic information was accurate. It also cut the number of incorrect addresses and returned mail, saving a projected $4 million annually.

Plenty of paper is still used today in most clinical laboratories and anatomic pathology groups, despite decades of advances in computer technologies. Slowly, though, the use of paper is declining as clinical laboratories adopt digital tools.

Paper is costly and traditionally requires staff to manually enter patient information and requisition data from the paper into an electronic health record (EHR) or laboratory information system (LIS). This error-prone, time-consuming process slows production from accessioning to results reporting.

Health Network Laboratories (HNL) in Allentown, Pa., found a solution to this problem. For the past eight months, the lab has been using a paper-to-digital (P2D) system from **4Medica** that allows it to directly convert paper requisitions to digital data, saving time and money.

One benefit of the lab's P2D system is that it helps the staff identify and correct errors in paper requisitions. This approach enabled the lab to significantly cut staff time and labor costs, improve customer service for client physicians and patients, and increase the number of clean claims, which triggered faster payments from health insurers.

The P2D system and the implementation of an enterprise master patient index (EMPI) helped to reduce errors in patient data so much that it produced savings—that when projected over a full year—would be almost $4 million in annual savings," said Joseph Cugini, HNL's Manager, Client Solutions.

More Accurate Patient Data

"This system helps us correct errors in patient data, such as addresses and other information," he said. "The P2D system and EMPI helped us to cut the volume of returned mail," he said. "Just that one improvement also allowed us to reduce the staff time previously needed to find patients' correct addresses.

"The annual cost of returned mail due to inaccurate patient addresses was $488,417," commented Cugini. "With

our new digital system, that amount has been cut to almost zero. What's more, the annual cost from missing address components in our patient data was $3.4 million. The total lost revenue was $3.9 million." *(See sidebar, "Lab's Paper to Digital Conversion Cuts Costs," page 21.)*

Cost-cutting is essential because Medicare, Medicaid, and commercial payers have all cut what they pay for clinical and anatomic pathology testing over the past several years. *(See, "Reacting to PAMA Cuts, Lab Works with Payers," TDR, April 9, 2019.)*

"The value of an EMPI grew over time as more of our lab's patients have become responsible for a greater share of their healthcare costs." Cugini said. "Over the past 20 years, employers and health plans have adopted high-deductible health plans (HDHPs), which shift a greater share of healthcare costs to patients.

Patients with HDHPs

"The number of patients with HDHPs increases each year, and they are now responsible for thousands of dollars in deductibles and coinsurance each year before their health insurers pay anything toward the cost of lab testing," he added. "That makes the laboratory responsible for collecting from patients what they owe. Yet, few clinical laboratories have the capabilities to collect these amounts from patients—at the time of service or later.

"Using an order entry portal capable of interacting with payer systems allows us to determine if patients are responsible for copays or deductibles and by how much," commented Cugini. "In addition, integrating the order entry portal with our financial system can display any outstanding balance owed by the patient from previous visits. The patient can then be offered an opportunity to pay all or a portion of that balance. An EMPI ensures that all the patient's data is consolidated into one record for the most accurate account information."

Before adopting the EMPI, HNL was like most labs in that the staff recognized that having paper requisitions was necessary but inefficient—particularly when processing hundreds of thousands of clinical lab tests and reviewing thousands of anatomic pathology specimens each year.

Daily Flow of Requisitions

HNL does not reveal the number of tests it runs, but Cugini estimated that HNL receives about 650 paper requisitions on an average workday. Among those 650 requisitions are 250 of HNL's standard requisitions, 200 for pathology or specialty lab work, 125 that are non-HNL orders from physicians' electronic health record systems, and other sources. The remaining 75 are handwritten.

The primary source of HNL's test volume is the **Lehigh Valley Health Network** (LVHN). **Health Network Laboratories** is the exclusive laboratory provider for LVHN, one of the largest health systems in Pennsylvania. About 60% of HNL's revenue comes from LVHN, and the balance is from the lab's outreach program. The lab contracts with all national companies, such as **Aetna** and **UnitedHealthcare**, and regional insurers such as **Highmark**, **Capital Blue Cross**, and **Independence Blue Cross**.

When patients who have insurance through any of these companies are referred for testing, the first step in HNLs' pre-analytical processes is to use the P2D to convert paper requisitions to digital data. Staff at 4Medica then verify that the data are accurate. Checking for eligibility for insurance coverage is a separate function that HNL does through its order-entry system.

Problem of Accurate Data

"Before introducing the P2D and EMPI systems, we had problems ensuring that we had accurate data on each patient," Cugini explained.

"When our EMPI became operational, we found that we had a duplication rate

close to 30% in our patient records," he said. "It meant we had duplicate records on almost a third of our patients." HNL might have one patient with two different addresses, for example, or it would have the correct address with two different but similar names.

"Using paper requisitions made it difficult to identify each patient accurately," Cugini said. "One way we cleaned up our data was through the use of the digital system to eliminate having our lab staff enter data by hand from the paper requisitions we received every day.

"By cleaning up our patient data, we drove the duplication rate down to less than 1%," he commented. "Our entire internal workflow—from accessioning to test results—now runs more efficiently."

Improving the data on patients had the added benefit of increasing the number of clean claims the lab submitted to insurers, boosting cash flow. Having accurate data also increased the lab's level of customer service, which patients and ordering physicians appreciate, he added.

Four Steps for Each Req

In the pre-analytical stage, HNL follows four steps for every requisition. First, it verifies insurance eligibility in real-time and then checks if preauthorization is needed. Next, it converts requisitions from paper to digital and then sends that data to the EMPI.

"At the start of this project, we wanted to improve data collection at the front end," Cugini commented. "Specifically, we wanted to verify health insurance eligibility for any patient in our patient service centers. Next, we wanted to identify any tests needing preauthorization."

Failure to get prior authorization approved can result in running a test when no payment is ensured. In such cases, either the lab will be stuck with the bill, or the lab will need to bill the patient.

To do its eligibility checks, HNL uses third-party software from 4Medica. The software uses data from payers and other sources, such as credit bureaus. Taken together, these data allow Health Network Laboratories to verify how much each patient owes toward his/her deductibles, copayments, and co-insurance.

"These steps help us collect more of the revenue patients owe," Cugini added. "All that information gives us the opportunity to request payment from each patient at the time of service." Once these two steps are completed, HNL then scans the paper requisition to convert the information to digital data, again using a system from 4Medica.

Lab's Paper to Digital Conversion Cuts Costs

ONCE IT INTRODUCED A SYSTEM TO CONVERT PAPER REQUISITIONS TO DIGITAL ORDERS, Health Network Laboratories reviewed the resulting performance metrics and found that—not only did the lab save almost $4 million annually—but it also cut pre-analytical processing time sharply, said Joseph Cugini, HNL's Manager, Client Solutions.

Using the paper-to-digital (P2D) system, HNL can process 75% of its orders in less than 10 minutes each, according to a test it ran on 3,900 paper requisitions.

The test also showed that HNL had no orders that took more than 20 minutes to process, and almost 3,000 of those paper requisitions took less than 10 minutes to process.

"In addition, each batch of scanned requisitions takes approximately two minutes to be securely transmitted to 4Medica for processing," Cugini said. "That's a dramatic reduction from what we needed to process requisitions before introducing the P2D."

Health Network Laboratories also cut the number of lab test orders with errors from about 30% to about 1.2%, Cugini reported. And the cost to process each order was lowered to about $1, he said.

"This step in the workflow allows us to convert any manual paper requisition into an electronic order," he said. "Now staff in specimen management can process incoming orders more efficiently and prepare them for the analytic stage.

Less Manual Entry of Data

"In the past, we needed those same people in accessioning to do manual data entry on each line in each requisition," recalled Cugini. "That very tedious work was one reason our turnover in accessioning was so high.

"Also, when we brought in new employees, those new workers frequently made data-entry mistakes, requiring lots of retraining," he added. "Of course, mistakes made during manual data entry would show up in duplicate entries in our patient records and in other places.

"The paper-to-digital system now serves as an enhancement to staffing, not as a replacement for staff," Cugini said. "It also allowed us to shift the staff away from manual data-entry tasks, so that staff can take on other important pre-analytical work. In turn, that has improved the quality of our pre-analytical activities."

Overcoming Challenges

"Having a P2D system helps address the data capture challenges with these requisitions. After all, many paper requisitions have missing or incorrect information—such as patient demographic data, diagnosis codes, or insurance information," he stated.

"Some requisitions have ambiguous test orders or omit the ordering physician's name," Cugini added. "In other cases, physicians will add hand-written notes in different places, making it difficult to determine which tests were selected.

"Generally, requisitions from different EHR systems are easier to read but can vary in how they're formatted," he explained. "For instance, the demographic data may be in one place on one form and in another place on another form. That makes it hard for our staff to find that data easily. Hand-written requisitions are the most challenging because readability can be poor or physicians will use unfamiliar terms for certain tests. All of these challenges can slow processing in the pre-analytical stage.

"While we still work to overcome these challenges, the P2D and EMPI systems have significantly reduced the number of paper requisitions that require individual handling," he concluded. "Not only does our lab collect more revenue, but our physicians and patients get better service. You can say that our effort to reduce paper in our lab has been win-win for all." TDR

—Joseph Burns

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Cost Cutting and Error Reduction Initiatives

DURING A PRESENTATION AT THE DARK REPORT'S *LAB QUALITY CONFAB* in Atlanta in October, Joseph Cugini, Manager of Client Solutions at **Health Network Laboratories** (HNL), explained how the paper-to-digital (P2D) system of converting analog data on paper to digital is one of several cost-cutting initiatives.

Another is the Enterprise Master Patient Index (EMPI), which helps HNL to reduce errors from paper requisitions by having HNL's vendor, 4Medica, do quality assurance checking during the process of converting paper to digital data. Using digital data allows HNL to:

- Decrease the time required to submit claims to payers;
- Increase the number of clean claims at first submission, cutting settlement times;
- Boost revenue;
- Improve staff productivity; and,
- Decrease the errors cause by using paper requisitions.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

John M. Mattsen, III, MD, one of the founders of **ARUP Laboratories** of Salt Lake City, died on November 9, at the age of 86. As a pathologist and an executive leader, he was at the forefront of laboratory medicine for many decades. A graduate of **Brigham Young University** (BS) and **UCLA Medical School**, Mattsen was managing microbiology labs at the **University of Minnesota** when, in 1974, he was recruited to be a pathology professor at the **University of Utah**. Most lab professionals know Mattsen from his long service at ARUP Laboratories, where he served as founding President and CEO in 1984. In 1993, after stepping down from those roles, he served as Chair of the lab organization's Board of Directors until his retirement in 1999.

MORE ON: *Mattsen*

The late 1970s was a time when Albert Nichols, MD—and the lab he founded in 1971, **Nichols Institute**—was showing that there was a fast-growing national market for reference and esoteric testing services. Mattsen, in concert with his colleagues, was early to recognize this market opportunity, which led to the founding of ARUP Laboratories in 1984. That was the same year that Nichols Institute went public with big plans to grow rapidly. Over the next decade, under Mattsen's leadership, many lab executives would say that Mattsen outcompeted his peers. By 1994, Nichols Institute was gone, acquired by **Quest Diagnostics** (named **MetPath** at that time). Meanwhile, ARUP was in the midst of growing at double-digit rates, a rate that was unbroken and sustained during the entire time of Mattsen's tenure.

TRANSITIONS

- **DermTech** of San Diego announced three new executives. Its new Chief Operating Officer is Claudia Ibarra. Her prior positions were with **Exagen Diagnostics**, and **Genoptix**.

- DermTech's new Chief Financial Officer is Kevin Sun. He has held executive positions with **Dexcom**, **Inverness Medical Innovations**, **Biosite**, and **Raytheon**.

- DermTech appointed Dan Visage as its new Senior Vice President of Payer Access. Formerly, he served at **Progenity, CareCentrix**, **BioReference Laboratories**, **Inc.**, **Laboratory Corporation of America**, and **Florida Blue Cross**.

- **Neogenomics, Inc.**, of Ft. Myers, Fla., appointed Lawrence Weiss, MD, as its new Chief Science Officer. Previously, he was at **Clarient Diagnostic Services** and prior to that was the Chair of Pathology at the **City of Hope**.

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DARK DAILY UPDATE

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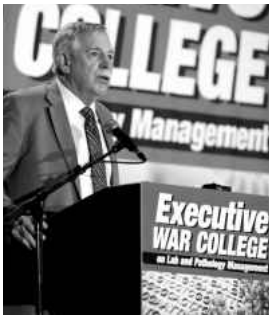

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