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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Is Your Lab Prepared for More Tough Challenges?

THERE IS A NEW FAVORITE WORD WALL STREET ANALYST USE when they want to describe an industry that is going to experience tough times that will make it difficult for companies to grow and remain profitable. That word is "headwinds" and it can aptly be applied to the multiple tough challenges that are about to confront the nation's clinical laboratories and anatomic pathology groups.

The good news is that the upcoming 24th annual *Executive War College on Lab and Pathology Management* has scheduled sessions and expert speakers specifically to help you develop ways to overcome the different headwinds about to buffet your laboratory. When you and your team join us in New Orleans on April 30-May 1, here are the most important negative market forces that will be addressed, along with useful strategies and solutions:

- **Declines in lab reimbursement and budgets:** effective strategies to generate new revenue streams; marketing and sales programs to win new clients and expand market share.
- **Ongoing pressure to cut lab costs:** ways to use process improvement and quality management tools to slash expenses, boost productivity, and sustain quality.
- **Demand by payers and physicians for more data:** useful middleware products that help labs pull together valuable data in forms that physicians in ACOs and health insurers find valuable—and for which they will pay your lab!
- **New federal law prohibiting paying sales commissions:** expert attorneys to guide you through the new Eliminating Kickbacks in Recovery Act of 2018 (EKRA) section of the Support Act and how it conflicts with the long-established safe harbors for paying commissions in the federal Anti-Kickback Statute.

This is just a partial list. The big news for this *Executive War College* is that we've added 25 more sessions, which means you'll have 80 powerful learning sessions, featuring more than 115 experts, speakers, and strategists.

Today, the message for you is simple. Your laboratory is part of an industry that faces multiple headwinds during the next year or two. Some headwinds may be of hurricane force. By joining us in New Orleans this spring, you'll acquire the knowledge you need to keep your lab at the forefront of clinical care and financial solvency. TDR

LabCorp to Acquire Iowa's Metropolitan Medical Lab

105-year-old laboratory company decides to sell; becomes latest example of an independent lab closure

CEO SUMMARY: Without making an announcement, LabCorp said it would acquire the Metropolitan Medical Laboratory, a privately-held laboratory founded in 1914 in Davenport, Iowa. The local newspaper reported that some 136 employees from Metro Medical's laboratory operations in Moline, Ill., may lose their jobs. Last month, LabCorp said Medicare and other cuts in payment to the nation's smaller and regional labs could cause some of those labs to seek joint ventures or sell out to larger labs.

ONE OF THE NATION'S OLDEST CLINICAL LABORATORIES will change hands on April 1, ending a run of 105 years in Davenport, Iowa.

Without an announcement, **Laboratory Corporation of America** confirmed this week that it will acquire the **Metropolitan Medical Laboratory**, a privately-held laboratory founded in 1914. Some 136 employees from its laboratory operations in Moline may lose their jobs, according to reporting by Alma Gaul of the *Quad City Times*, a newspaper in Davenport.

Last month, LabCorp's executives told Wall Street stock analysts that more of the nation's smaller and regional laboratories were becoming aware of the effects that reductions in Medicare payments under the Protecting Access to Medicare Act (PAMA) were having on operations and finances. As a result, many of those labs may be willing either to be acquired or to work more closely with larger labs.

LabCorp's Chairman and CEO David King said, "This presents us with a number of attractive tuck-in lab acquisition opportunities, which typically deliver significant synergies and high return on invested capital."

However, no official from either LabCorp or Metro Medical Labs was willing to discuss the reasons why the pathologists who own Metro Medical Labs chose to sell their business at this time. Executives and staff from Metro Medical did not return multiple messages left last week.

About the deal, LabCorp's Donald R. von Hagen, Vice President, Corporate Communications, said, "With respect to Metropolitan Medical Laboratory, I can confirm that we still anticipate the transaction to close on April 1, and that

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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we do not anticipate making a formal announcement about it. Other than that, we are not providing information beyond what was reported this week in the *Quad City Times*." The newspaper serves the Quad Cities of Moline and Rock Island, in Western Illinois and Bettendorf and Davenport in Eastern Iowa.

It's safe to assume the deep cuts to Medicare Part B clinical lab test prices that resulted from the PAMA private payer market price study were a factor in the decision by the owners of Metro Med Labs to sell. What's unknown is whether those Medicare price cuts were the deciding factor in the timing of the sale.

Interviews with clinical laboratory executives familiar with the recent history of Metro Medical explained that the lab has lost lab testing volume over the past six years while continuing to retain a large and far-flung operation.

Sale of Lab Assets in 2013

In 2013, THE DARK REPORT reported that Metro Medical sold the laboratory assets it owned at two hospitals in Davenport to **Genesis Health System**, also of Davenport.

At the time, THE DARK REPORT reported that Genesis Health was a five-hospital system that served patients in 12 counties in Eastern Iowa and Western Illinois. *(See "Hospital System Acquires Labs in ACO Strategy," TDR, July 8, 2013.)*

Before the sale, Metro Medical Labs ran the laboratory operations in two different hospitals known as the **Genesis Medical Center** in Davenport. One hospital had 252 beds and the other had 174 beds, TDR reported. At that time, Genesis hired all 90 lab employees employed in the two Metro Medical Lab facilities.

However, Metro Med Labs remained a large clinical laboratory company. *Quad City Times* said that, in 2015, Metro Med Labs employed more than 400 people, according to its human resources officer. The *Times* also noted that, in 2015, the lab company "had 3,500 ordering clients with more than 5.4 million test results for 230,000 patients seen per year."

Metro Med Labs lost more business in April, 2017, when **UnityPoint Health**, a health system in the Quad Cities, acquired the lab testing services from about 30 physician clinics that had been sending their clinical lab and pathology tests to Metro Medical Labs, said a lab executive familiar with the history of lab testing in the area.

Loss of Physician Referrals

"When Metro Medical lost the lab testing work of those 30 or so physician clinics, that's about the time when I believe Metro really started to struggle," the lab executive said. He asked not to be named. "At the time, Metro Medical probably was left collecting lab testing work from only about two sizeable independent groups.

"And Metro Medical still had a big freestanding patient service center (PSC) presence because people had used those draw stations for years, and Metro Medical's patients remained loyal to Medical Metro and Metro Medical remained loyal to those patients," he said. "Looking back on it, though, it might have been better if Metro Medical closed some of those PSCs after selling parts of its hospital testing business and then losing a part of its physician outreach testing.

Did Not Cut Large Overhead

"It could be that the reason Metro Medical struggled financially was because it just didn't have the volume to support large lab operations anymore," he commented. "For example, the lab maintained its big reference testing menu and microbiology lab because it had done the reference lab work for two large hospital systems and all the providers in the area. Metro Med Labs didn't downsize those operations."

Given these facts, it's reasonable to assume the Medicare lab fee cuts of 2017 and 2018 were the financial setbacks that led the lab's owners to decide to sell. TDR

—Joseph Burns

COLA: GAO Should Address PAMA's Effect on Patients

GAO's report last fall did not discuss how PAMA changes Medicare and other patients' access to tests

CEO SUMMARY: In a recent statement, COLA, an organization that accredits clinical labs, expressed strong concern about how a report from the Government Accountability Office did not address how the Protecting Access to Medicare Act of 2014 (PAMA) affects patients' access to testing, especially in rural areas. COLA said its surveys of providers across the nation provides evidence that Medicare patients already have less access to lab tests compared with access before Medicare cut lab fees.

In its report issued in November about how the Protecting Access to Medicare Act of 2014 (PAMA) would affect clinical labs, the **Government Accountability Office** (GAO) left out significant information about how the law would affect patients, said John Daly, MD, **COLA's** Chief Medical Officer.

Instead of focusing on patient care, the GAO report, "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments," addressed how the federal **Centers for Medicare and Medicaid Services** (CMS) could end up overpaying for clinical lab tests. Those overpayments would result in billions more in Medicare spending, the GAO estimated.

"What really concerns COLA about the GAO report is that it does not include any discussion about how PAMA affects patient's access to testing, especially in rural areas," stated Daly. "And, these [Medicare fee] cuts reduce access to laboratory testing to more than Medicare patients because the closure of community laboratories will affect all patients—including pediatric patients."

In addition to failing to address how PAMA affects patients, Daly also was concerned that the GAO report focused attention on a hypothetical problem. *(See sidebar, page 6.)*

Under PAMA, CMS has cut payments to clinical laboratories by 10% last year, 10% this year, and will cut payments by 10% next year. Then, CMS can cut payments by a maximum of 15% a year from 2021 through 2023. The cuts are already taking a toll on patient care, Daly said. But the GAO report did not include an analysis of how these new payments have affected Medicare beneficiaries' access to clinical laboratory services, he added.

COLA's National Lab Survey

A nonprofit organization that accredits some 7,000 medical laboratories, COLA collected data over the past two years on the availability of clinical laboratory testing in rural and urban areas nationwide. More than a third of the laboratories that responded to a survey COLA did said that they were referring more patients to other labs, making changes in their test menus to control costs, and were not updating their

equipment, stated Daly. "That shows that many of these medical laboratories may be getting ready to close the doors," he added.

"A lesser number of labs have laid off staff and didn't renew service contracts," Daly added. "And, again, this means that they may close. Other surveys have shown that some labs have already closed because of the financial erosion from PAMA [and cuts to Medicare Part B clinical lab fees]. Labs serving nursing homes and nursing home administrators themselves are very concerned."

Is Patient Access Reduced?

Despite the effects of lower payments on clinical labs, there has been little reporting on PAMA's effects on patient care, noted Daly.

"We are all in agreement that there needs to be a more constructive dialog with GAO and others in government about how PAMA is affecting Medicare, particularly in rural America and how it's affecting infirm adults in urban areas," Daly commented. "In nursing homes and long-term care facilities, there are very vulnerable patients."

Those patients need what COLA calls near-patient testing. "We've taken a critical look at the value of near-patient testing," Daly explained. A survey COLA did in 2017 and 2018 showed that 90% of physicians in all regions of the country—particularly those in areas with fewer than 20,000 people—believed that elderly patients would be exposed to more serious healthcare risks if they lose access to near-patient testing.

"For most patients, near-patient testing gives recipients better outcomes," emphasized Daly. "And, the cuts in payment under PAMA could have adverse effects on healthcare quality and patient outcomes. But GAO did not evaluate this aspect of how PAMA affects testing." For more information, see COLA's site on near-patient testing at *www.NearPatientTestingMatters.org.* TDR

—Joseph Burns

Contact Matthew Spenny at 800-981-9883 or mspenny@cola.org.

GAO: Findings Do Not Reflect Industry Practice

IN ITS REPORT TO CONGRESS IN NOVEMBER, the Government Accountability Office (GAO) said that spending for Medicare could rise by $10.3 billion from 2018 through 2020 if the federal **Centers for Medicare and Medicaid Services** (CMS) stopped paying bundled payment rates for certain panel tests.

The problem with this part of the report is that the estimates of how CMS pays for panel tests are hypothetical, said **John Daly, MD**, COLA's Chief Medical Officer. These hypothetical effects in the report led U.S. Senator Chuck Grassley (R-Iowa), Chairman of the Senate Finance Committee, to ask officials from the federal **Department of Health and Human Services** and from CMS to explain "the potential for a striking increase in costs to Medicare for laboratory services."

In response to the GAO report, clinical lab associations criticized the agency. In recent communications between the **American Clinical Laboratory Association** (ACLA) and GAO officials, the congressional watchdog agency admitted that the report does not reflect actual industry payment practices.

ACLA said the GAO's role is to examine how taxpayers' dollars are spent and provide Congress with objective, reliable information to save money and work efficiently. "And yet, following growing pushback to a recent report on laboratory billing practices in the Medicare program, James Cosgrove, GAO health care director and author of the report, shared that the GAO's findings are not actually reflective of current industry practice—but rather are based on a hypothetical scenario," the ACLA said.

"We weren't analyzing what labs are or aren't doing," Cosgrove told ACLA. "We were analyzing what the exposure to Medicare would be."

LIS-EHR Fees Increasing, Say Hospital Lab Execs

Just when clinical labs most need to control costs, some EHR vendors are charging more for interfaces

CEO SUMMARY: Hospital and health system lab managers say some vendors of electronic health record systems for independent physicians are aggressively raising the fees they charge labs. Labs serving outreach physicians now pay more in two ways, they say. First, they pay the price the vendor charges to implement an LIS-to-EHR interface. Second, they pay per-order fees each time a physician orders a lab test using the lab interface. These price increases are an unwelcome development.

AT ONE TIME, it typically cost only about $2,000 to create an electronic interface between a clinical laboratory's information system (LIS) and the electronic medical record (EMR) or electronic health record (EHR) system of a client's medical group or physician office.

That was in the early days after Congress passed the **Health Information Technology for Economic and Clinical Health Act** (the HITECH act) as part of the American Recovery and Reinvestment Act of 2009. The HITECH act was written to encourage what federal lawmakers call "the adoption and meaningful use" of health information technology.

One goal of meaningful use was to replace the paper documents and fax transmissions doctors were then using to share patients' records with hospitals and other providers. Another goal was to enable electronic ordering and reporting among physicians, clinical labs, pharmacies, and other ancillary providers.

The days of the $2,000 LIS-to-physician-EHR interface are gone now, however, according to some clinical lab directors. The cost of connecting physicians using hospital lab outreach programs is rising to exorbitant levels, they say. One lab director characterized the fees some EHR vendors charge as "price gouging."

To be clear, the issue of high fees relates to connecting physicians who are not part of the hospital or health system and are sending outreach testing to the hospital or health system lab. On the other hand, physicians who are affiliated or employed within the hospital or health system typically do not need an interface because they're already on the system.

Labs Pay Higher EHR Fees

The steady increase in the fees EHR vendors charge labs for these interfaces is a problem for two reasons. First, it increases the operational costs of a clinical lab when Medicare has been cutting what it pays for 1,300 tests on the Clinical Laboratory Fee Schedule, thus reducing lab revenue.

Second, as clinical labs grow their businesses and add new client physicians, the increased interface fees some EHR vendors charge substantially raises what it costs labs to serve these new client physicians.

This trend is not a new development. Year after year, some labs have seen some EHR vendors raise their interface fees significantly. What makes this trend particularly troubling today is that labs need to cut costs to offset declining revenue from the Medicare lab price cuts under the **Protecting Access to Medicare Act of 2014** (PAMA).

In covering these developments, THE DARK REPORT encountered lab managers who named three EHR vendors the managers considered to be aggressive at increasing the cost of their LIS-to-EHR interfaces. These lab managers asked not to be identified because they don't want the EHR vendors to take punitive actions against their laboratories. THE DARK REPORT is honoring those requests in order to help readers understand how certain EHR vendors are raising prices.

"Most hospitals or health systems like mine already have electronic bidirectional orders and results for the physicians they employ," stated one laboratory administrator. "Therefore, each time the hospital lab wants to boost revenue by adding outreach volume, it needs to pay these high fees to some EHR firms, which adds to the cost of serving these new client physicians."

EHR Vendors Raising Prices

In interviews with three hospital or health system lab managers, the managers identified three EHR vendors charging what they said were high prices.

"For example, **athenahealth** wants $1 per order for lab orders flowing through their system," another lab director said in an email. "Our lab currently has one provider group with 230 providers. Even one lab test order for each of these physicians for 21 work days is $4,830 in fees for the month and many of them have 10 to 20 lab test orders each day!"

"**Practice Fusion** charges $10,000 for a hub, plus a transaction fee for every lab test order," stated another lab director. "**Greenway** charges $18,500 for a bidirectional interface." Athenahealth, Greenway, and Practice Fusion did not respond to multiple requests for comment.

This lab director has had no luck in his efforts to negotiate lower rates with each of these vendors, he said in an interview with THE DARK REPORT.

Similiar Problems

Many hospitals and health systems face similar problems, said Michelle Del Guercio, Vice President, Marketing, at **Sunquest Information Systems**, in Tucson, Ariz. Over the past 10 years, Sunquest has seen this trend develop nationwide.

"For the past decade, hospitals and health systems have acquired physician group practices," explained Del Guercio. "This often makes it costly for hospital outreach labs to set up and serve new physician groups.

"Each individual EHR vendor needs to establish a bidirectional interface to the hospital's LIS for each doctor," she noted. "Each connection requires an investment of time and money to make it function effectively."

Some hospitals find the cost so high that they don't require EHR vendors to make the connections in both directions, Del Guercio said. Instead, they connect electronically so that the lab can send test results back to physicians' EHRs but not so the physicians can order tests electronically, she said.

"What these labs often don't realize is that with the right technology in place, there is huge benefit in capturing orders electronically, such as to help reduce duplicate testing, ensure medical necessity validation, and even help routing test orders to other labs," Del Guercio commented. "Labs need to weigh the benefit over the long-term versus the initial cost of the interface."

To Del Guercio's point, not receiving orders electronically is the opposite of what Congress intended when it passed the HITECH act.

"It's not unusual that the cost of these LIS-EHR interfaces are higher than they were 10 years ago," observed one lab director. "But these interfaces and per-order fees are happening when our lab is experiencing decreased reimbursement for two straight years. It's like a perfect storm for health system labs running outreach programs.

"As cost keeps going up, our lab has less to work with, which means we can justify making these connections for fewer customers," he added. This lab director is responsible for deciding which physician practices get bidirectional interfaces.

"When I was getting quotes for this work, I came across athenahealth's fees and found they want a dollar for each requisition. That's just outrageous," he stated.

"The economics are obvious," he added. "We serve a group of 150 physicians. If we have to pay a dollar to the EHR vendor for every requisition, that group alone will cost us many thousands of dollars a month. Our outreach lab cannot justify spending that amount.

Falling Reimbursement

"Such a big bill seems ridiculous in a time when reimbursement is going down but when EHR vendors want more," he added.

Knowing that CMS planned to make the second round of steep cuts in payment under PAMA to start on Jan. 1, this lab director began working with EHR vendors last year. He asked each one to consider reducing its connection fees, and was rebuffed each time, he said.

"They're very cavalier about these fees," he explained. "These are the fees they've set, and they expect our clinical lab to pay them. The problem is that these interfaces for ordering and reporting lab tests are the crux of outreach. If you can't do the interfaces, then you can't do outreach, and that means you can't compete." TDR

—Joseph Burns

Contact Michelle Del Guercio at 520-570-2000 or michelle.delguercio@sunquestinfo.com.

Middleware Vendors Offer EHR Solutions

ONE WAY TO SOLVE THE PROBLEM of connecting multiple physicians in outreach programs is to use a middleware product, said Michelle Del Guercio, Vice President, Marketing, at Sunquest Information Systems, in Tucson, Ariz. Sunquest offers such products to clinical labs as a result of its acquisition in 2015 of **Atlas Medical**, a provider of clinical process and connectivity solutions.

As an example, she referred to a case study that Sunquest published last year about how when the clinical laboratory at the **Henry Ford Health System** (HFHS) needed to make such connections to its own physicians and to physicians outside of the health system, it contracted with Sunquest to do so.

At the time, test results of patients seeing physicians outside of the health system were not getting into the health system's electronic health record (EHR) system, said J. Mark Tuthill, MD, Division Head of Pathology Informatics at HFHS. When patients who had previously seen physicians outside of the health system became inpatients, treating physicians had no access to their past lab test results.

"So, when patients came over to the inpatient side, we had a blank picture of what the patient looked like," Tuthill said. "None of their lab work was going to the EHR." The solution HFHS adopted helped to prevent missing lab orders and also helped improve revenue and turnaround time as a result of producing cleaner orders and claims, according to the case study.

"Labs looking at middleware to support LIS-EHR connectivity should look at the long-term benefit, such as more efficient order capture and specimen intake, and improved service to physicians," commented Del Guercio.

Many Hospital Labs Don't Know They Must Report!

Best Ways to Gather, Assess, Report PAMA Price Data to CMS

CEO SUMMARY: All clinical labs required to report their private payer lab test price data are now in the midst of collecting that data. One big change in PAMA reporting is that the federal Centers for Medicare and Medicaid Services now defines most hospital and health system labs as "applicable labs" and requires them to report private payer price data. However, few hospital CEOs are aware of this federal requirement. In 2017, Healthline Laboratory Network reported its data to CMS and now shares its lessons in how to collect complete and accurate price data.

For the second time in three years, clinical laboratories defined as "applicable laboratories" under the **Protecting Access to Medicare Act of 2014** (PAMA) are collecting data on what private health insurers pay them for lab tests. Once the data are compiled, labs will submit the data next year to the federal **Centers for Medicare and Medicaid Services** (CMS) on what they're paid and on the volume of tests they run.

During this data-gathering and reporting cycle, it is essential that hospital laboratory administrators and pathologists—as well as hospital CEOs and CFOs—understand two important features that make this reporting cycle different from what happened during the first PAMA reporting cycle in 2016 and 2017.

First, CMS expanded the definition of applicable laboratories in such a way that most of the nation's hospitals and health networks are now required to report their private payer lab test price and volume data to CMS. While PAMA has been in place since 2014 and this is the second reporting cycle under the law, it is significant that many hospital CEOs, CFOs, and clinical laboratory administrators remain unaware that the current PAMA final rule requires their organizations to report their labs' private payer test price and volume data to CMS.

Second, lab industry experts tracking these developments say that the odds are higher this time that CMS will assess penalties against some applicable labs that fail to comply with the requirements to report price and value data accurately. In that first data-collection and reporting period in 2016 and 2017, CMS did not assess penalties against any applicable labs.

Penalties of $10,000 Per Day

The penalties are substantial. Under PAMA, Congress set penalties of as much as $10,000 per day for any applicable laboratory that fails to report or that reports inaccurate or incomplete data.

Thus, hospital and health system laboratories that now meet the definition of applicable labs—but remain unaware of their legal requirement to report their private payer lab test price data to CMS—are at risk for such penalties.

Labs Now Collecting Data

Meanwhile, across the nation, applicable laboratories are collecting those data. The key requirements of this data-collection period are:

- Between Jan. 1 and June 30 of this year, applicable labs must collect the data on the payments and test-volume amounts they get from private (non-public) health insurers.
- Then, the applicable laboratories must submit their price and volume data from this six-month data collection period to CMS in the first quarter of next year (2020).

Clinical laboratories will see a difference in this PAMA private payer price reporting cycle versus what happened in the first cycle, in which applicable labs collected price and volume data from Jan. 1 to June 30, 2016, and reported that data between Jan. 1, 2017 and May 30, 2017.

That difference is how CMS expanded the definition of "applicable laboratories" to include all hospitals that bill for clinical laboratory tests using the Form CMS-1450 14x Type of Bill (TOB) and which bill Medicare more than $12,500 in one year for non-patient laboratory services.

In addition to these differences, there is another issue under PAMA that labs need to know: There is a widespread lack of practical knowledge about how to comply with the PAMA price reporting requirement.

In December, **Quest Diagnostics** and *Modern Healthcare Custom Media* reported the results of a survey of hospital executives. It showed that almost 80% of respondents were not at all familiar, or only somewhat familiar, with PAMA and its effect on hospitals. In addition, 45% of hospital executives responded that they were not at all familiar

with PAMA and 33% said they were only somewhat familiar with the law.

To help clinical laboratories understand their requirements under the law, officials at CMS have issued documents, guidance, and information to explain PAMA price reporting and how labs must comply.

But government guidance and commentary are carefully crafted to be neutral about how clinical laboratories are to respond to the various requirements in the PAMA final rule. Also, government guidance generally avoids going into detail on those key issues that might be subject to regulatory challenge or litigation in federal courts.

Guidance from CMS

Consequently, applicable labs have many questions about what steps to take to gather private payer lab test price data, then properly analyze and verify the data, package the numbers correctly, and submit these data to CMS. Applicable labs need to know how to comply confidently with the PAMA statute and the final rule of private payer lab price reporting and thus avoid federal penalties.

To understand how one clinical lab faced the challenges of collecting and reporting private payer data under PAMA, THE DARK REPORT interviewed **Dean Hoppes, MBA**, Chief Financial and Administrative Officer for **Health Network Laboratories**, in Allentown, Pa. His lab reported its data to CMS during the first PAMA reporting cycle in 2017 and is collecting data now in this second data-collection cycle.

Independent, Regional Lab

Founded in 1983, Health Network Laboratories (HNL) is an independent regional laboratory that does more than eight million billable tests each year, 99% of which it performs in-house. The seven-hospital Lehigh Valley Health Network is one of its chief sources of volume.

HNL has some 1,000 employees throughout the lab system, including 35 board-certified pathologists and scientific directors and more than 400 certified lab scientists and phlebotomists. It operates multiple labs. One is a 100,000 square foot facility in Allentown.

Also, HNL has 60 patient service centers and draw sites in Pennsylvania and in New Jersey. The lab's clients include physician offices, hospitals, long-term care facilities, employers, and industrial accounts.

"The **Lehigh Valley Health Network** (LVHN) represents about 50% of our work and the other 50% comes from our outreach program," Hoppes said. "We're the exclusive laboratory for LVHN.

"In addition to serving the Lehigh Valley area, we also go out to Central Pennsylvania as far west as Chambersburg," he noted. "We have one patient service center in New Jersey, along with quite a few clients, including physicians' offices, hospitals, nursing homes, and long-term care facilities."

Lessons from 2017 Reports

When HNL submitted its data under PAMA in 2017 during the first reporting cycle, its management team learned important lessons—some painfully. "Just the sheer volume of the data we needed to report made this a major challenge," admitted Hoppes.

"At the same time, we did have the proper systems in place and a highly-skilled billing staff," he noted. "These resources helped us work through all the serious issues of collecting the data and reporting those numbers accurately.

"Also, throughout this entire reporting cycle, our clinical laboratory team was aware of the steep federal fines that could result," he added. "We understood the need to submit complete, accurate data that was documented in the event that officials from CMS might do a detailed review or audit of our data."

HNL did the job so well in 2017 that Hoppes and the billing staff were fully confident the numbers were accurate and thorough for three reasons:

1. HNL worked with **XIFIN**, a company in San Diego that helps clinical labs improve their billing and collection processes and has assisted its lab clients in complying with PAMA.
2. HNL uses electronic billing and payment systems that speed the payment process and improve the accuracy of both claims submitted and payments received from payers.
3. HNL has dedicated billing specialists who find and correct errors in payments and ensure that the data are accurate. This team pays close attention to how allowed amounts are reported.

In 2017, HNL's lab team recognized that a key to collecting and reporting PAMA data smoothly and accurately was its relationship with and use of a third-party billing system, Hoppes said.

"We use the XIFIN billing system, and XIFIN was proactive in recommending ways for us to develop an effective, systematic method to collect the data we needed to report to CMS," he added.

Two Years of Experience

"Therefore, during the reporting year of 2017, HNL had the experience of working with XIFIN for almost two years," stated Hoppes. "This meant that our lab had a history with the XIFIN team, and they had a good understanding of our operation."

Most of HNL's private-payer data were collected electronically, but not all. "There were many exclusions that we had to go through, and most of these needed a manual review," explained Hoppes. "For example, we had to exclude accounts that the payer did not fully adjudicate with a denial or in an appeal. Also, of course, we had to exclude all payments from government sources, such as those from Medicare and Medicaid.

HNL's Bank Lends a Hand with Payments

ONE EFFECTIVE METHOD THAT HEALTH NETWORK LABORATORIES uses to speed up the management of payments is by working closely with its bank to handle patients' payments.

When a patient sends a check to cover a deductible, HNL's bank will create an electronic remittance for the lab, explained Dean Hoppes, MBA, the lab's Chief Financial and Administrative Officer.

"Prior to establishing the process, it was a nightmare when the team had to manually post every single patient payment that arrived," he said. "But now, when a patient sends a check to our lockbox, the bank converts each patient's remittance statement into an electronic file so that it posts automatically and generates an electronic summary report for our lab."

This one bank service eliminates almost all of the manual processing of patients' payments that HLN's billing staff previously did manually.

"In addition, our billing team had to exclude all of the payments HNL gets through capitation," he added. "That's because those contracts reimburse our lab on a per-member-per-month basis and not with a fee-for-service payment for each individual test.

"All of this work took time in our billing department, where we have about 37 full-time employees," commented Hoppes. "HNL has a skilled billing team that fully understands all of our insurance contracts down to the individual plan level. That helps when identifying which numbers need to be reported and which do not.

"For example: HNL has a contract with one particular insurance plan in which our lab gets a capitated payment," he said. "For those payments, we have a

specific payer identification number in our billing system. That allows us to isolate any capitated payments based on that ID number."

Another challenge that all labs face when reporting private-payer data under PAMA is understanding the allowed amounts. "The allowed amount is what health insurers will pay for a test under the contracted arrangement," said Hoppes. "The payment amount is not used since many patients are responsible for the allowed amounts."

Most labs know well that many patients today have high-deductible health plans (HDHPs) and thus are responsible for most or all of their medical costs until the annual deductible is met. While these patients are responsible for such payments, many labs have found that patients with HDHPs often pay nothing or a small percentage of their patient portion of the allowed amount.

Payer's Allowed Amount

Determining the allowed amount can be difficult for any provider, but Health Network Laboratories collects most of its payments electronically—a factor that simplifies the process.

"When a health insurer pays HNL, we get paid with an electronic remittance advice called an EDI 835," he noted. "This explains what our lab was paid and why.

"One advantage we had in collecting our private payer price data is that we have electronic data interfaces with about 99% of our payers," commented Hoppes. "Thus, all claims go out electronically. We only send paper claims for a small proportion of our test volume.

"Plus, when the remittance comes back, about 90% of our claims are posted electronically," he noted. "Those amounts automatically post into our system, based on the explanation of benefits (EOBs). We get the allowed amount from these EOBs.

"If part of the allowed amount is related to a deductible, that amount gets flipped over to be the patient's responsibility," he explained.

"Of course, often that patient-responsibility amount becomes bad debt because patients simply default on what they owe our laboratory. In about 10% to 15% of our cases, patients default and so we know we won't be paid for the full allowed amount the payer showed on the EOB.

Included in PAMA Report

In the PAMA data we submit to CMS, we report the allowed amount," stated Hoppes. "But we don't report any amounts if a claim is denied."

Another key lesson HNL learned during the first data-collection and reporting period is that getting paid electronically improves accuracy significantly.

"Because 90% or more of our payers use electronic remittances, we don't have to post payments manually from a paper EOB," Hoppes explained. "That's a significant advantage because when your lab must do manual interventions, it reduces quality and accuracy.

"If one of our team members posts payments manually, there's a chance that we could make errors in terms of the allowed amount," he added. "If the allowed amounts are wrong, that would obviously affect the amounts we report to CMS as being paid.

"As we did in 2017, in this reporting cycle we are using a team approach to gather and validate the data," he said. "For example, we have a billing analyst in our billing department who helps extract all the data and make sure those numbers are accurate. Our billing analyst works with the cash posters because they see any anomalies that need to be included or excluded.

"Another lesson we learned during the 2017 PAMA reporting period is that not all payers are alike," emphasized Hoppes. "Each one adjudicates claims differently.

"Some payers will actually allow an amount based on a quantity of tests. But

other payers don't seem to care about quantity," he noted. "Payers in this second group will assign a quantity of, say, one to a number of tests. When they do that, it drastically changes the allowed amount.

"In these cases, we must be extremely careful because one payment in this manner for a large number of tests could skew the data," Hoppes advised. "During the 2016-2017 data collection period, our billing analyst was validating payments.

"However, in this current PAMA reporting cycle, we'll have him work more closely with our cash posters because they're familiar with the idiosyncrasies of our individual payers and how each one adjudicates claims," he continued. "The cash posters in our billing department recognize which health plans are tricky in that way and which ones are usually fine."

Validating the Data

In 2017, before HNL reported the data it collected, the billing analyst and other staff validated the data. "Once we had all the payment data together, we reviewed the allowed amounts based on the quantities the payers used and found discrepancies," Hoppes explained. "That meant we had to reconcile the payment against the allowed amounts. We know what we billed for each test, and we had to match the billed amount to the quantity and the allowed amount as remitted by each payer."

During its analysis of the collected data, the billing staff did what any auditor would do—it reviewed a sample of data. "Because we process more than one million claims a year, it would be impossible to validate all those claims," observed Hoppes. "Instead, we take a sample and then look for anomalies.

"That's where the cash posters play a valuable role because they know how to spot errors in the EOBs," he added. "Plus, they know which payers typically code the quantities wrong every time."

Workshop Teaches How To Report PAMA Data

DURING THIS PAMA PRIVATE PAYER PRICE REPORTING CYCLE, thousands of hospital and health system laboratories are required to report their price data to the federal Centers for Medicare and Medicaid Services. Failure to report can result in penalties of $10,000 per day.

To help hospital CFOs and lab administrators meet this federal reporting requirement, on May 2 there will be a special one-day workshop on PAMA lab price reporting at the ***Executive War College*** in New Orleans.

This comprehensive workshop features presentations by CFOs who reported their data in 2017, attorneys knowledgeable about the requirements of PAMA, three billing companies and consultants, and a web session with CMS officials.

Visit ***www.executivewarcollege.com*** to register.

Once the validation was complete during the first PAMA reporting cycle, Hoppes met with the billing staff to assess their comfort level with the accuracy and completeness of the numbers before sending the data to CMS.

"Before we submitted the data, we circled back with the team to ask everybody how comfortable they were with the data," commented Hoppes. "All the team members said they were confident that the data was as accurate as we could possibly get it.

"Moreover, CMS did not get back to us to ask any questions," he recalled. "This is why I didn't have any concerns about the first data reporting and I don't have concerns for this current PAMA price reporting period either." TDR

—Joseph Burns

Contact Dean Hoppes at 484-425-8151 or dean.hoppes@healthnetworklabs.com.

Fla. Blue Cross Contract May Be Next Battleground

National lab firms expected to contest for one of the biggest remaining exclusive payer contracts

CEO SUMMARY: In Florida, the Blue Cross Blue Shield contract is coming up for renewal and the question is whether it will renew as exclusive to one national lab company. But Florida is not the only state where BCBS plans are planning to issue new contracts. Among the Blues plans that may ask for proposals for new clinical lab-testing contracts in the coming months are plans in California, New York, and Texas. These three state plans insure an estimated 110 million members.

WILL AN UPCOMING MANAGED CARE CONTRACT AWARD in Florida be the next battleground for the nation's two largest public lab companies?

In the coming months, **Blue Cross Blue Shield of Florida** will renew its exclusive lab-testing contract. The question now is which of the nation's largest labs will win this coveted prize? Will this new pact again be exclusive? Or might contracts be granted to both **Laboratory Corporation of America** and **Quest Diagnostics**?

Moreover, Florida may be just one of several Blues plans that could offer new lab-testing contracts in the coming months. Blue Cross Blue Shield plans in California, New York, and Texas also will be renewed. Those plans in California, New York, and Texas insure an estimated 110 million members, according to **Steven Rusckowski**, CEO of Quest Diagnostics.

In separate conference calls with Wall Street analysts last month, Rusckowski and **David King**, CEO of LabCorp, discussed the Florida contract and their respective companies' prospects for being named the in-network lab for Florida Blue's four million members. Florida Blue also serves some 15.5 million people in 16 states through its affiliated companies, according to **America's Health Insurance Plans** (AHIP), a trade association for health insurers.

Hopeful about Contract

Given that Florida Blue extended its contract with Quest in 2018, Rusckowksi was hopeful about signing when the contract renews. "We feel good about our presence in Florida," he said. "We have a strong working relationship with Florida Blue Cross Blue Shield and we feel we're in a nice position to deliver on picking up [marketshare] … because of that relationship and the great access we have in Florida."

He added that Quest may be able to add lives from Blues plans in California, New York, and Texas.

It's not known when the clinical laboratory test contract will renew. Quest did not want to provide any details about the contract other than to say that the company has a policy of not commenting on client contracts. Florida Blue declined to

comment, saying it considers its vendor relationships and contracts to be proprietary and confidential.

Compared with Quest, LabCorp was less hopeful about the contract, but not totally out of the picture. "Well, I think it's pretty well known that the major remaining exclusive is the Florida Blue contract and we do not participate in that agreement," King commented. "We have been engaged in conversations with Florida Blue on a number of fronts. We have **Walgreens**-located patient service centers in the Florida market.

Willing to Engage

"So, we're hopeful that we're going to see some progress there, but I can't give you a firm prediction about how it's going to turn out," King added. "We've been pleased with the fact that they've been willing to engage with us because we've been out of that contract for a good number of years."

One lab executive who asked not to be named said the big lab executives' comments are telling. "We can probably read between the lines of what both Rusckowski and King said in their comments," the lab executive said. "Those comments lead me to believe that an RFP is potentially forthcoming. That may mean the term of the Quest contract is up for renewal, possibly sometime next year.

"While King suggests there's been dialogue in some capacity, we should make no mistake about Quest's intentions," the executive added. "Quest definitely does not want to lose its exclusive grip on Florida.

Controlling Leakage

"Quest Diagnostics knows that it's much easier to manage an estimated four million members operationally on a peninsula—and to control leakage and redirection—than it is to do that nationally for Aetna, even with an estimated 20 million members," the executive explained.

Quest, LabCorp, BRLI In Horizon Network

IN NOVEMBER, HORIZON BLUE CROSS BLUE SHIELD OF NEW JERSEY announced that it would add Quest Diagnostics as an in-network lab while also retaining **Laboratory Corporation of America** and **BioReference Laboratories**.

The addition of Quest while retaining LabCorp and BRLI is significant because it may be another sign that health plans are moving away from exclusive contracts involving clinical laboratory testing services.

In its announcement, Horizon characterized the deal as "a new preferred national lab expansion strategy" for its members. As of Jan. 1, all 3.8 million Horizon members could use LabCorp for in-network lab services, Horizon said. Quest is in-network for Horizon BCBSNJ members (excuding BCBSNJ Medicaid members), the health plan added. BioReference Laboratories remains as an in-network option for Horizon BCBSNJ members with PPO and traditional plans.

Allen Karp, Horizon's Executive Vice President for Healthcare and Transformation Management, said the increased access for members will reduce the number of out-of-network claims, thus lowering the health plan's costs.

"For all these reasons, Quest has had the exclusive 'death grip' on the Florida Blue contract going back many years," he added. "And for much of that time, LabCorp was on the outside looking in."

Other sources added that they believed the contract changed hands over the years and that both Quest and LabCorp each had it for some time.

But now, Quest has a firm grip on it, the lab executive added. "The relationship between Quest and the Florida Blue has

been air tight," he commented. "A contact at Florida Blue once said that if they allowed any other labs in-network that offered testing comparable to what Quest was providing, then the plan had to pay financial penalties to Quest. In addition, Quest had the right to refuse to allow any new lab providers into the Florida Blue network."

Exclusive Network Contracts

While Quest's contract with Florida Blue is exclusive, and LabCorp also has an exclusive contract with **Independence Blue Cross in Pennsylvania**, other health insurers are moving away from exclusive deals, the executive noted. "The fact that **UnitedHealthcare** and Aetna both have unlocked their former exclusive relationships and let both LabCorp and Quest into their national networks, that's good news for all labs going forward. This shows that the pendulum is moving toward less exclusivity and more open contracts among most major health insurers."

One example of less exclusivity comes from **Horizon Blue Cross Blue Shield of New Jersey**, which in November added Quest as an in-network provider for 2.8 million members of Horizon BCBSNJ while retaining LabCorp and **BioReference Laboratories**. *(See sidebar, page 17.)*

"That said, these big contracts also mean that both LabCorp and Quest have incentives to cannibalize the smaller regional, independent, and outreach labs that offer comparable test menus," the lab executive concluded.

Low Price Still Important

As in many negotiations involving health plans making exclusive deals for clinical lab services, low price is an important factor, said another lab executive who asked not to be named. "The primary driver for the relationship is low prices and cost savings to the insurer," the executive added.

"Among all of the Blues plans, Quest has been the primary lab provider in some states, and LabCorp has been primary in other states," he continued. "Currently, Texas BCBS has both LabCorp and Quest in-network, but it seems to have a preference for Quest."

Looking back on the history of the Florida contract over the years, another lab executive recalled that Quest had the Florida Blues contract years ago and then it went to LabCorp before going back to Quest more recently. Again, this executive did not want to be named.

"I believe the reason it went back to Quest is that Quest learned a lot about that market while it was out of the contract," he added. "Then, it applied what it learned to win the contract back again.

"Keep in mind that in recent years, LabCorp had to roll out exclusive contracts with both Florida Blue and **Humana** and both of those roll-outs had to start up in a short window of time," commented the lab executive. "At that time, there were issues with both contracts, and both Florida Blue and Quest learned from those mistakes.

Pendulum Is Swinging

"These are reasons why I believe the pendulum is indeed swinging toward manager care contracts that are less exclusive, and allow more clinical laboratories to be network providers," he explained. "Health plans don't have the bandwidth to manage the lab network and so it makes sense for them to let LabCorp and Quest duke it out over volume. At the same time, the plans can provide incentives to both lab companies to get them to control costs and to redirect the out-of-network work that health plans don't want.

"And, there's another reason to move away from exclusive contracts," he added. "The employers have been complaining about accessibility to clinical lab test providers. Thus, those complaints give health plans another incentive to add both national lab companies to their provider networks to increase the number of access points for patients." TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Because of a $25 million grant from philanthropist Denny Sanford, the **Veterans Administration** and **Sanford Health** will provide free genetic testing to 250,000 veterans by 2022. These will be pharmacogenomic (PGx) tests designed to help VA physicians prescribe medication and dosages customized to the unique characteristics of individual patients. This innovative program was announced on Mar. 15 and plans are to make this testing available at 125 VA sites throughout the United States.

MORE ON: *PGx Tests*

Last summer, Sanford Health of Sioux Falls, S.D., began offering a genetic test panel to primary care patients which includes markers for 20 diseases and 20 medications. It is priced at $49 for the patient and the balance of the cost is subsized by Sanford Health. Reports are that this genetic test program is popular with patients.

$100 GENOME?

It may soon be possible to sequence a whole human genome for $100. *Bloomberg* reported last month that **Illumina** CEO Francis deSouza predicted that "two things need to happen for us to get to that price point. One is we need to do engineering work. The second one, which is equally important, is to make sure that our customers have been thinking about what they could do if they had a $100 genome."

CORRECTION: *For LabCorp's Q4-2018 Conference Call*

This is to correct errors in our reporting on the latest quarterly conference calls that executives from the nation's two largest publicly-traded clinical lab companies had with Wall Street analysts that was published in our issue of Feb. 25, 2019. We made three errors regarding the effects of the federal Protecting Access to Medicare Act (PAMA) of 2014.

First, we should have reported that both **Laboratory Corporation of America's** diagnostic testing business and **Quest Diagnostics** reported a decline in revenue in the fourth quarter of 2018 but an increase in revenue for the full year. For LabCorp in 2018, fourth quarter revenue for the diagnostic-testing segment was $1.69 billion, a decrease of 2.8% from $1.74 billion in the year-earlier quarter. For the full year, LabCorp reported revenue from its lab-testing business of $7.03 billion, an increase of 2.5% over the $6.86 billion it reported in 2017. For the fourth quarter, Quest reported revenue of $1.84 billion, down 1.4% from the $1.87 billion it reported in the year-earlier quarter and full-year revenue of $7.53 billion, an increase of 1.7% from the $7.40 billion it reported in 2017.

Second, LabCorp executives did not discuss Medicaid denials for certain tests or any increase in the application of prior-authorization rules. The comments about Medicaid denials for certain tests, and the increase in the use of prior authorization, should have been attributed to Quest's executives.

Third, PAMA will reduce LabCorp's lab-testing revenue by about 1.6% this year as a result of lower direct Medicare payments of some $85 million, and, LabCorp executives said, there will be an indirect effect that will lower other payments, primarily from Medicaid-related plans, by $30 million.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 8, 2019.

SPECIAL SESSION

Lab-Pharmacy Collaborations for Opioid and Sepsis Management

Monique Dodd, PharmD
Enterprise Clinical Solutions Specialist
TriCore Reference Laboratories, Albuquerque, N.M.

What We've Learned, What Comes Next, How Patient Outcomes and Cost of Care Improved

Opioid addiction is now a major substance abuse issue in America. Clinical laboratories can play a critical role in helping physicians and other caregivers diagnose and manage these patients. One way is for labs to include pharmacists when collaborating with doctors.

This session will take you inside one of the nation's earliest and most progressive clinical lab initiatives that is designed to deliver added value to office-based physicians, patients, and health insurers. You'll learn from TriCore's three years of experience leveraging lab test data with other clinical and demographic data to support primary care physicians as they diagnose, treat, and manage patients with opioid abuse problems.

Most importantly, this session provides you with an actionable road map—documented by outcomes and cost savings metrics—that you can take back to your lab and health system. It will put your lab on the path to delivering value in ways that create new sources of revenue. Register today!

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UPCOMING...

- *Strategies to Offset PAMA Cuts: Delivering Value to Payers, Signing New Contracts with SNFs.*
- *When Hospital CEOs Consider Lab Outreach Sale: How Savvy Lab Managers Demonstrate Potential Benefits from Keeping the Laboratory.*