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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

In Tough Times, All Labs Need Success Strategies

BY ANY MEASURE, IT IS TOUGHER TODAY for clinical laboratories and anatomic pathology groups to generate the revenue needed to deliver state-of-the-art diagnostic testing services while remaining financially viable. Four recent trends prove the point.

First, every year, the Medicare program and private health insurers are cutting the prices they pay for medical laboratory tests.

Second, most labs find it difficult to retain access to patients or gain access to new pools of patients. That is because private payers are narrowing their networks, typically to exclude regional labs, independent labs, and hospital outreach laboratories. Meanwhile, enrollment in Medicare Advantage plans is growing at double-digit rates. These plans consistently exclude local labs from their provider networks in favor of the national lab companies. As a consequence, access to the proportion of Medicare Part B patients that can be served by any lab shrinks year-after-year.

Third, government health programs and private health insurers continue to institute more restrictive coverage guidelines (or require pre-authorization and/or more documentation) for larger numbers of medical laboratory tests.

Fourth, audits of labs by the Medicare program and private payers are recognized to be more rigorous and more detailed. Labs then find themselves hit with a large number of denied claims and recoupment demands that can often total in the millions or tens of millions of dollars.

THE DARK REPORT can track labs that have gone out of business as a result of each of these negative trends in the clinical laboratory marketplace. Much is known about how these developments are disrupting clinical labs and pathology groups across the nation. But not much is known about how some innovative medical labs are succeeding—both clinically and financially—because of the strategies they use to respond effectively to healthcare's new dynamics.

To help you and your lab team learn about what's working to fuel the success of these top-performing labs, the 24th annual *Executive War College on Lab and Pathology Management* has invited leaders from these exemplary labs to share their lessons learned. It takes place in New Orleans on April 30-May 1. Plan now to attend and learn how to keep your laboratory on the path to success. **TDR**

Senator Asks: Are Lab Test Payments Too High?

GAO report on PAMA implementation shows confusion among federal agencies about fee cuts

CEO SUMMARY: It is ironic that, after the federal Centers for Medicare and Medicaid Services (CMS) enacted the deepest price cuts to the Part B Clinical Laboratory Fee Schedule in more than 50 years, a U.S. Senator now asks CMS why it will pay billions more for lab testing. The question from Iowa Senator Chuck Grassley is based on a recent report to Congress from the Government Accountability Office about how CMS has implemented the Protecting Access to Medicare Act.

Clinical lab industry experts sharply criticized the **Government Accountability Office** (GAO) after it issued a report to Congress stating that payment rates from the federal **Centers for Medicare and Medicaid Services** (CMS) may lead Medicare to pay billions of dollars more than is necessary for clinical laboratory testing.

The report could be an example of how one government agency (in this case the GAO) can trip over the actions of another (CMS). A quick read of the report led journalists and at least one U.S. Senator to conclude that the GAO may be correct, which could cause the industry to face still deeper price cuts than it has experienced since Jan. 1, 2018.

In the report sent to Congress on Nov. 30, "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments," the GAO concluded that the way CMS instituted new payment rates under the Protecting Access to Medicare Act of 2014 (PAMA) was incorrect and may result in CMS paying $733 million more than it should pay for clinical lab tests starting last year and continuing through 2020.

The report led Senate Finance Committee Chairman Chuck Grassley (R-Iowa) to send a letter on Jan. 23 to **Health and Human Services** Secretary Alex M. Azar II and CMS Administrator Seema Verma asking them to explain what his press office said is "the potential for a striking increase in costs to Medicare for laboratory services." He demanded answers from HHS and CMS by Feb. 6.

While the GAO report and Grassley's questions are a concern for the clinical lab industry, there may be a silver lining in

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

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that Grassley is asking questions of Azar and Verma that lab industry leaders want answered as well. *(See sidebar, "Grassley Is Asking Questions the Lab Industry Wants Answered," page 5.)*

"The administration ought to be doing all it can to ensure fiscal responsibility prevails when it comes to Medicare payments," Grassley said in a prepared statement. "It's the right thing to do for patients, taxpayers, and for the preservation of Medicare for future generations."

CMS Issued Guidance in 2017

David Gee, a partner in the Seattle office of the law firm **Davis Wright Tremaine**, pointed out that on Nov. 17, 2017, CMS issued guidance specifying that for calendar year 2018, payment for tests bundled into panels, which CMS calls automated test profiles or ATPs, would instead be paid at the individual HCPCS code level. This guidance relates to GAO's concerns about test panels.

The CMS guidance continued, "In other words, we will pay for each appropriately billed HCPCS code based on the CLFS amount for the specific code billed by the laboratory. Moving forward we will continue to consider the efficiencies of ATPs and the appropriate payment methods for these tests under the new [PAMA] private-payer rate-based CLFS. Medicare administrative contractors will continue to apply editing to ensure that if a laboratory panel HCPCS code is submitted and is payable, an individual laboratory HCPCS code that is part of the same panel is not also paid separately."

GAO's Assessment

One year later, Gee added, the GAO concluded that CMS' implementation of this change could allow clinical labs to drive up sharply the amount they charge for panels of tests by unbundling and charging for each test individually. "The problem with the GAO's assessment is that the Medicare National Correct Coding Initiative (NCCI) requires labs to report the CPT code for the panel (not the individual tests) if the laboratory performs all tests included in one of these AMA-defined panels," Gee explained.

In fact, labs generally do not unbundle tests included in the organ and disease testing panels established by the **American Medical Association** (AMA-defined panels), Gee and other lab experts told The Dark Report.

"Moreover, HHS responded to the GAO on Nov. 7, to specifically clarify its position on panels, Gee said. "In its response, CMS said the following, 'With regard to panel tests that have their own CPT code, whether the laboratory bills for the CPT panel code or component tests, per HHS policy the laboratory should be paid the CPT panel code amount when applicable.'

"In addition," Gee continued, "HHS informed GAO that 'HHS is working to update the claims processing system to detect these claims in an automated fashion. This edit will be similar to one implemented in earlier versions of the Clinical Laboratory Fee Schedule payment system until a change related to an instruction [was] issued in 2016. This update is targeted to be operational no later than summer 2019. In addition, HHS plans to release sub-regulatory guidance by the end of 2018.'"

'Unsubstantiated' Claim

Mark S. Birenbaum, PhD, Administrator of the **National Independent Laboratory Association**, in a report to NILA members, said HHS issued guidance on this issue in amendments to the NCCI manual. "GAO's claim that CMS could be paying billions in excess payments between 2018 and 2020 is unsubstantiated based on amendments CMS made on Dec. 12 to require laboratories to bundle test panels as outlined in the National Correct Coding Initiative Policy Manual for Medicare Services for 2019," Birenbaum wrote.

Grassley Sends Questions to HHS and CMS That the Laboratory Industry Wants Answered

IN HIS LETTER TO FEDERAL HEALTH OFFICIALS, Sen. Chuck Grassley (R-Iowa) asks questions that many in the clinical laboratory community have been asking for more that two years.

In fact, clinical lab associations have even filed a lawsuit against Health and Human Services Secretary Alex M. Azar II over some issues Grassley raised in the letter he sent to HHS and to CMS Administrator Seema Verna on Jan. 23. *(See, "In PAMA Appeal, ACLA Says Federal District Court Erred," TDR, Jan. 14, 2019.)*

Most of the questions Grassley asked Azar and Verma relate to panel tests. In his first question, he asked what steps the agencies have taken to ensure that all laboratories that are expected to report PAMA data to HHS actually do so.

Here are the four questions on panel tests that Grassley asked in the letter:

1. Does HHS believe that it has the authority to create CPT codes for panel tests where they do not currently exist, or take other steps to ensure the completion of a bundled payment, while remaining compliant with the provisions of PAMA and other relevant federal laws? Please explain why or why not? If yes, why has HHS paid individual rather than bundled rates for these panel tests unnecessarily?
2. Did CMS make a systems edit to its claims processing system that prevented CMS from detecting whether individually billed tests should have been bundled? If so, why did CMS make that edit?
3. What is the status of efforts to detect panel tests where CPT codes do exist but have not been billed correctly by laboratories? When do you expect that CMS will be able to effectively detect and correct the billing problems?
4. During the time the claims processing system was unable to detect when a panel CPT code was appropriate, does CMS know how many laboratories billed individual tests and received a higher reimbursement rate when they should have billed as a panel code? Is CMS able to perform an audit to determine that number and the cost in excess reimbursement? If so, will CMS perform the audit?

Grassley also asked if HHS agreed with the GAO recommendation that CMS phase in payment-rate reductions based on actual rather than maximum rates, and if yes, what steps did the agencies take to implement that recommendation.

But then the GAO apparently disregarded these HHS responses, Gee commented. "In its report, the GAO claims CMS rules will result in unbundled payments for panels of tests, and in Medicare potentially paying $10.3 billion more than it would if it continued to automatically bundle payments for test panels, as it has done since the late 1990s," he said.

Based on the erroneous GAO report, Grassley was sharply critical of what *Modern Healthcare* magazine called "newly unbundled payments for panel tests," as if, as the magazine reported, labs have in fact stopped billing for AMA-defined panels on a bundled basis.

Cost to Taxpayers

In his letter to HHS and CMS, Grassley wrote, "The estimated cost to taxpayers as a result of that decision is staggering."

But, in fact, lab industry experts said, the GAO's findings about unbundled billing for test panels are factually incorrect because clinical labs must follow the Medicare NCCI billing rules for AMA-defined panels. Those rules do not allow unbundling, the experts said.

For clinical laboratories, the erroneous GAO analysis may mean CMS will consider still deeper cuts than those already implemented under PAMA, warned Birenbaum. Under PAMA, CMS cut the spending it pays for clinical lab tests by 10% last year, 10% this year, and 10% in 2020. CMS spends about $7 billion annually on clinical lab tests.

On the issue of how labs bill for AMA-defined test panels, Lâle White, Executive Chairman and CEO of **Xifin**, a lab revenue cycle management company, was unequivocal, telling newsletter *360Dx* that labs do not bill Medicare for AMA-defined panels on an unbundled basis.

"Labs continue to bundle automated chemistries consistent with the AMA panels in accordance with the CPT billing guidelines," White told the publication. The GAO's assertion that labs have been unbundling basic metabolic, comprehensive metabolic, lipid, renal, and electrolyte panels is based on an erroneous assumption from the GAO, she added.

Medicare NCCI Rules

Gee agreed, saying, "The Medicare NCCI rules require labs to report—and bill—the CPT code for the AMA panels and not the individual tests. Nor does CMS' change in methodology eliminate the requirement that the lab must have a valid test order for any test; and for a test panel, the lab would need a valid test order for each of the component tests in the panel. That means the ordering physician must order each individual test, and Medicare coverage rules require that each test must be medically necessary.

"The fact that CMS changed its reimbursement methodology for panels that previously were automatically bundled by the Medicare contractors doesn't negate the Medicare NCCI rules or eliminate Medicare's medical necessity requirements," Gee added. "I'd be surprised if any reputable lab made any significant changes to its protocols for billing panels.

"Also, CMS has indicated its intent to update its claims processing system to detect any 'unbundled' AMA panels in an automated fashion," Gee explained. "What's most disappointing is that the GAO report gave absolutely no evidence that panel billing patterns actually changed after CMS implemented PAMA last year, thus falsely alarming labs and others by raising the hypothetical yet erroneous possibility that labs could and would suddenly begin to unbundle their billing to Medicare for AMA panels."

'Hypothetical Scenario'

Julie Khani, President of the **American Clinical Laboratory Association** (ACLA), also criticized the GAO's report, saying it concocted "a hypothetical scenario that suggests labs are unbundling these tests and receiving higher reimbursement. This is grossly inaccurate. According to a recent survey of more than 20 million lab claims, labs consistently billed panel tests as required."

In a prepared statement, she added, "The underlying assumptions for GAO's analysis and recommendations reflect a serious misunderstanding [by the federal agency] of standard industry practice for laboratory reimbursement and ignore unprecedented [price] cuts to clinical laboratory tests that pose serious harm to beneficiaries."

Unbundling Not Likely

It is unfortunate that the GAO's report was not accurate in how it concluded that the unbundling issue would make it feasible for labs to bill the Medicare program for billions of dollars. The lab industry experts quoted above provide a clear explanation of this issue and why clinical labs would not be unbundling for the tests in question. TDR

—Joseph Burns

Contact Mark Birenbaum at 314-241-1445 and nila@nila-usa.org, or David Gee at 206-757-8059 or davidgee@dwt.com.

Useful Lessons for Labs That Report PAMA Data

In second reporting period, most hospital labs are required to report private payer lab test prices

***CEO SUMMARY:** Will clinical labs heed the lessons learned from the first PAMA private payer market price reporting cycle that CMS conducted in 2017? One major difference is that the definition of applicable laboratories now includes most hospital labs. This creates the opportunity for a larger number of clinical labs to submit their price data to CMS. Private health insurers pay higher lab test rates to hospitals labs, making their data significant for any calculations CMS would make.*

For the second time in two years, clinical laboratories will gather data on the prices private insurers pay them for clinical lab tests, then report that data to the federal **Centers for Medicare and Medicaid Services** (CMS), as required under the Protecting Access to Medicare (PAMA) statute of 2014.

The new twist in this second reporting period is the fact that CMS expanded its original definition of applicable laboratories for reporting. In this reporting cycle, all hospital labs that bill with CMS-1450 14x claims are applicable laboratories and required to report. *(See TDR, Dec. 4, 2018.)*

Many lab executives and pathologists consider CMS' first market price data collection and Part B price-setting effort to be an abject failure. The primary criticism was that CMS designed a flawed rule that did not fulfill the language of the PAMA statute nor the intent of Congress.

Under PAMA, CMS was instructed to conduct a market study of the prices that private health insurers paid for clinical laboratory tests. In its first data-collection effort, CMS excluded nearly all hospital and physician office labs from reporting by limiting the definition of "applicable laboratories" required to report. A report issued by the **Health and Human Services Department's Office of Inspector General** stated that from January to March 2017, only 1,942 labs submitted PAMA data to CMS. To put this number in perspective, the OIG had earlier reported that 61,040 labs received Medicare payments in 2015.

Another primary criticism involved the serious inaccuracies in the data that the relatively small number of clinical labs submitted to CMS.

Evidence of Bias

Experts who studied how CMS used that data identified a number of ways that CMS biased its use of the data to justify setting prices lower than the conclusions that might result from using more reliable analytical methods.

Following its analysis of the market price data it received, CMS aggressively cut many lab test prices on the revised Medicare Part B Clinical Laboratory Fee Schedule (CLFS) it announced for the

years 2018, 2019, and 2020. The PAMA law limits price cuts to a maximum of 10% in each of those years. Thus, for some tests, the cumulative price cuts can total as much as 30% over 36 months.

That cap changes in the next market price reporting and price-setting cycle. The PAMA statute limits CMS to a maximum cut of 15% per year to the price of any test in 2021, 2022, and 2023. The prospect of still lower payments should motivate lab managers of applicable labs to be more diligent in how they compile and report the lab test prices they get from private health insurers.

One expert in clinical laboratory revenue cycle management recommended exactly that. "The mistakes the industry made last time mean that all applicable labs need to be much more careful when reporting their next data sets," advised Lâle White, CEO of **Xifin Inc.**, a company that helps labs enhance revenue.

"Probably the best way to validate the data in your billing system is for labs to go straight to the source documents—the electronic remittance advice (ERA) and the paper explanation of benefits (EOB)—which are integral parts of the data captured in the billing system," she said. White made these comments at the annual conference of the **California Clinical Laboratory Association** last fall.

"Using the ERAs and EOBs, labs can document what they were paid and for which lab testing services," she explained. "Also, labs can use the ERAs/EOBs to compare what the lab billed to the actual amount insurers paid.

"Once you know what your lab billed and what it was paid, you can establish some audit criteria to validate the accuracy of the payment data," White commented. "We know health insurers regularly make mistakes in what they pay and in the units paid when multiple units are submitted. Thus, it's essential that labs not report incorrect payment rates to CMS, especially if those rates are lower than they should be.

"Another important lesson we learned from the last data-reporting cycle is that labs should be getting paid correctly," she warned. "If a lab doesn't review the payments it receives and then asks insurers to correct under-payments or over-payments, there is a high probability the lab will report incorrect prices."

Reporting incorrect data increases the risk labs face from CMS. "If the prices a lab reports are wrong, then that lab could face fines of as much as $10,000 a day from CMS," noted White. "Moreover, if the prices labs report are lower than what insurers actually paid or should have paid, then CMS could end up setting what it pays all labs less than it should pay for these tests.

Clerical Errors in Payments

"In the first reporting cycle, audit data demonstrated that there was a 10% to 15% clerical payment error rate for payments posted manually from an EOB into lab billing systems," she said. "Also, we saw labs improperly reporting allowables too low when payments were reduced by the 2% cuts that Congress imposed under sequestration across the board. If any lab didn't take sequestration into account, then those labs reported lower payment rates than they should have reported.

"Facing cuts of as much as 15% in each of three consecutive years (2021, 2022, and 2023), I advise labs to be much more diligent about submitting accurate data on what they were paid by private payers," she cautioned. "To be confident that your lab is reporting accurate prices, it is absolutely critical that your lab team understand the allowable payments."

Applicable labs also need to review their managed care contracts carefully to ensure pricing equity, White added. To do so, labs should not couple their contracts to Medicare prices because many of those contracts do not reasonably reflect equitable market pricing, she explained.

"When gathering your lab's price data, it's important to ensure that your lab's contracts with payers have been negotiated

When Reporting Esoteric and Outreach Data to CMS, Laboratories Should Take Extra Care

FOR ALL CLINICAL LABS, Xifin's Lâle White, recommended taking extra care when gathering and reporting data to Medicare on esoteric and outreach testing.

"In this PAMA reporting cycle, how esoteric and reference laboratories compile and submit their data on the molecular and genetic test prices private health insurers pay will be hugely important," observed White, Xifin's Chairman and CEO. "These data are important for two reasons.

"First, by definition, these tests are not the routine, automated, high-volume tests that labs run," she said. "Second, private payers typically pay more for these assays than they pay for routine testing. For this reason, it is essential that labs submit accurate and complete data on what they're paid for these tests. Then CMS will have the data to set new Medicare lab test fees that truly are based on the private pay marketplace."

Hospital labs that fit CMS' definition of an applicable laboratory also have an important role in ensuring that CMS gets accurate lab-payment data, White explained.

"Hospitals and health systems should recognize the importance of their data in this second PAMA market price study," she noted. "Health insurers recognize that hospitals have higher costs and often pay higher rates to hospital labs for all lab tests. Hospital labs also perform esoteric molecular and genetic tests because the patients they serve often have complex diseases."

One other factor hospital labs need to consider is the effect hospital consolidations have had. "Any time hospitals become part of larger health systems, such a change in ownership could affect the hospital's outreach labs, meaning referral relationships may change," White said. "After any merger, the labs of the hospitals involved need to review all the managed care contracts for their laboratory outreach programs.

"This issue is critical because hospital outreach labs get higher reimbursement rates from private health insurance companies than independent labs, and they get incrementally higher rates than hospital outreach labs that have to bill under a separate national provider identification number."

Outreach operations are useful for hospitals seeking to defray some of the costly infrastructure required to run an inpatient lab because outreach volume helps to lower the overall cost of all testing. "The higher commercial reimbursement rates allow hospitals to develop and grow their outreach lab businesses to a profitable level," White concluded. "Essentially, the outreach business helps hospital and health systems labs be profitable, and those labs might not be profitable without that outreach business."

properly," suggested White. "This means all labs need to review their contracts extremely well to make sure that they understand the direct and incremental cost of each test, meaning where reimbursement has been set too low or below cost.

"If the pricing is too low, labs need to go back to their payers to negotiate equitable prices that more closely reflect the cost of performing each test," she advised. "Labs also need to review all payments received to make sure they get paid appropriately. If a lab finds it has been underpaid, the lab should appeal the payment rather than accept an unreasonable rate." TDR

—Joseph Burns

Contact Lâle White at 858-436-2908 or lwhite@Xifin.com.

Operations Update

Three Labs Make Big Bets to Build Major New Facilities

Even as some clinical laboratory companies are closing or selling following the deep cuts in what Medicare pays for lab tests, three major lab organizations are building new, supersized laboratory facilities.

Those three companies are **ARUP Laboratories**, **DaVita Labs**, and **Quest Diagnostics Inc.**

In September, DaVita Labs, a division of **DaVita Kidney Care**, opened a 150,000 square-foot lab in DeLand, Fla., adding 100 new jobs at the site. The new facility is an expansion of a lab on an existing site. *(See sidebar on page 12.)*

One month later, ARUP Laboratories broke ground for a new building to house 200,000 square feet of new lab space. The new lab will be the company's fifth building at its headquarters in Salt Lake City. As a nonprofit enterprise of the **University of Utah**, ARUP is the only one of the three companies that is not publicly traded.

Lab to Serve Seven States

At the end of November, Quest said it would build a flagship laboratory in Clifton, N.J., to enhance the service it provides to more than 40 million patients in seven states (Delaware, Maryland, New Jersey, New York, Pennsylvania, Virginia, and West Virginia) and in the District of Columbia.

Since that announcement, Quest began serving as an in-network lab for **UnitedHealthcare**, **Horizon Blue Cross Blue Shield of New Jersey**, and **Anthem Blue Cross and Blue Shield of Georgia**. As Quest's flagship lab, the Clifton facility will open in 2021, employ 1,100 employees, and will be the largest of the company's 20 labs nationwide, Quest said.

All three companies are experiencing increased growth, but for different reasons. ARUP is one of the nation's largest academic nonprofit reference labs and has had near double-digit growth in recent years, executives told The Dark Report.

DaVita's business has grown as many Americans develop kidney disease. The lab's parent company provides kidney care services to more than 200,000 patients each year. The lab runs 47 million tests annually. DaVita expects to add one million more tests to that number by 2023, the company said.

New Lab Automation

To manage the increased growth in lab test volume, each company will use new automated equipment to boost efficiency to handle as much specimen volume as possible. Automation is needed because workforce shortages make it difficult to find qualified applicants when the unemployment rate is low.

"Automation absolutely is a key reason why we decided to build this new lab," said Jonathan R. Genzen, MD, PhD, ARUP's Section Chief, Chemistry, and Medical Director of the Automated Core Laboratory. In a reference lab, automation is more challenging than it would be in most clinical labs, he said.

"As a lab company, we recognize that scalability, efficiency, and automation are important to keeping up with the overall lab marketplace," he added. "All clinical labs are dealing with a critical workforce shortage of lab professionals and we have to find solutions to that problem.

"One way to do so is to automate processes that don't require the advanced technical skills that lab professionals bring to the job," he noted. "That's why preanalytics are where labs tend to automate. Those are repetitive steps.

"In the new facility, we will dedicate significant automation to streamline pre-analytic processing and handling," he added. All labs have pre-analytics processing but a reference lab such as ARUP faces more complex challenges, not only because it manages a large volume of specimens, but also because it has many complex assays on its test menu and varied specimen-handling requirements.

Specimen Requirements

"We have unique specimen requirements and storage conditions because we get a large volume of frozen specimens," he said. "All of which is different from a hospital lab that receives most specimens at ambient temperature."

In the new building, ARUP will use automation to sort and distribute specimens to other sorters and to its 65 different subsections within its four interconnected buildings, he explained.

In the new four-story building, ARUP will devote the second floor to receipt and distribution of specimens coming from its client labs and other shipments. "For all those specimens, the staff handles accessioning, aliquoting, and preliminary sorting for the different labs on our campus," he said.

"Almost the entire second floor of 36,000 square feet in the new building will be devoted to accessioning. The whole floor is 50,000 square feet, but some of that will be left for infrastructure and future needs," he added.

Automation is such an important part of ARUP's processes that the new building will be connected via a footbridge and an automation line. "By bringing automation across the bridge, we can distribute specimens across the network of buildings," Genzen commented.

In ARUP's design, the third floor is devoted to automated testing and the fourth floor will be designated for mass spectroscopy testing. The first floor will include a cafeteria for employees and visitors, conference rooms, and an onsite machine shop and bioengineering support.

Double-Digit Growth

ARUP does not want to disclose the volume of tests it runs every year, said ARUP's President Andrew A. Theurer, CPA. "What I can say is that we've seen near double-digit growth for about five years now," he added. "And when you compound that growth every year, you end up with a significant jump in our overall test volume."

Like ARUP, Quest also is automating as many processes as possible for its new laboratory and has similar reasons for doing so—scalability and efficiency. In May, Quest learned that it would add more test volume when UnitedHealthcare announced that Quest would become a national in-network provider of lab testing. UHC has 49 million members nationwide. The anticipated volume Quest could get from the UHC deal is substantial. Quest also added volume from Horizon and BCBS of Georgia.

"We anticipated the need for more capacity and the need for increased turnaround time because—with those three contracts—we added 43 million additional lives to the testing we already do," said Scott Jeffers, Quest's VP of Enterprise Operations. "Those contracts were all new and effective as of January 1.

Millions of Tests Per Day

"Even before adding the volume from the new contracts, we currently manage about a quarter million patients a day in our patient service centers and from our in-office phlebotomy and other locations," he said. "Those patients generate about 2.5 million to 3 million tests a day.

"So, with the new lab facility we needed both additional capacity and increased efficiency," he added. "Of course, automation plays a significant role in all labs today, and it will have a bigger role in the years ahead."

Replaces Teterboro Lab

The lab in Clifton will replace Quest's lab in Teterboro, N.J. Also, Quest will convert facilities it has in Baltimore and in Horsham, Pa., into rapid response labs, Jeffers explained.

The new Clifton facility will be modeled on what Quest calls its lab-of-the-future in Marlborough, Mass., a facility that opened in 2015. "When we were designing the Clifton lab, we saw how important it was to get employees involved in the design," Jeffers commented. "In the months leading up to the announcement last fall, we called on employees from the region and staff from our Marlborough lab to offer suggestions about how to design this new facility.

Involving Lab Staff

"They were closely involved in reviewing the different designs and even in optimizing the workflow in the new lab," he added. "That's a lesson that smaller labs can take away from our experience because getting our team engaged up front to help design the best workflow within this new lab building was a terrific lesson for us. I expect we will enjoy the benefits of applying that lesson for many years to come."

Another design feature from Marlborough that Quest will adapt for the Clifton lab is a command and control center that Jeffers called "the eyes and ears and the brains, if you will, of the operation." Located above the analyzers and automation lines, the command center allows staff to monitor operations throughout the lab.

One other design attribute that Quest will bring from Marlborough is a plan to leave some floor space open for future expansion. "But that decision will depend on the volume we see over the next two to three years," Jeffers said. "From the start, we've had every intention of including space in this laboratory site for future expansion. But we won't know exactly how much extra space will be available until the lab opens in 2021.

"In the high-volume areas of the lab—meaning the general diagnostics areas—we plan to fill only about 70% of that space with automated equipment. But if volume rises faster than forecast, we may need to fill that added space with more capacity." TDR

—Joseph Burns

Contact ARUP at 800-522-2787 or Quest at 866-697-8378.

DaVita Builds New Lab in DeLand, Florida

IN AN ANNOUNCEMENT IN SEPTEMBER, DaVita Kidney Care said its clinical lab division opened a new 150,000 square-foot lab in DeLand, Fla. The new lab expands on one already in place in DeLand for more than 20 years and puts all lab operations under one roof, the company said.

In the announcement, DaVita said its labs do more than 47 million laboratory tests annually and they employ some 450 employees in DeLand. "The campus is home to DaVita's newly designed, advanced automation lab, which aims to increase the volume of tests processed daily and provide enhanced test capacity and capabilities," the company said.

In the news release, DaVita Group Vice President Kenny Gardner said, "We expect our lab to touch an additional one million test tubes annually by 2023. Building this campus has enabled us to reimagine the lab and intentionally design a space outfitted for the future."

DaVita did not want to provide further comment beyond what it announced on Sept. 12.

Lower Prices, More Data in UHC's New Lab Network?

UnitedHealthcare aims to use data to improve patient care, say experts in managed care contracting

CEO SUMMARY: It's been a common strategy among managed care payers to seek the lowest prices for clinical laboratory testing when negotiating contracts with labs. However, lower prices may become less important over time as the health system moves away from fee-for-service payment toward value-based reimbursement. Now evidence is accumulating that at least some large health insurers are placing more value on contracting with labs that can provide more complete sets of lab data.

OVER THE PAST SEVERAL MONTHS, **UnitedHealthcare** (UHC) has sent termination letters to certain labs in its network in what one lab industry observer said reflected a wholesale shakeup of its contracting strategy.

"UHC is performing a house cleaning," said a lab industry executive who asked not to be named.

"The labs that received termination letters were getting paid at higher than market rates and had been in-network providers for UHC for a decade or longer. So, those higher rates were at least one reason why their network status was terminated. Plus, UHC likely had no need to renegotiate with those labs to reduce their rates—perhaps because there were duplicate or overlap providers who had more competitive rates. Therefore, the insurer could just remove them from the network because other labs could step in to maintain service."

This opinion is in response to changes in the lab contracting practices at several of the nation's biggest health insurers. As reported in THE DARK REPORT, UnitedHealthcare, **Aetna**, and **Horizon Blue Cross Blue Shield of New Jersey**, and **Blue Cross Blue Shield of Georgia** have added national lab companies to their provider networks for the first time in nearly a decade. All insurers want lower prices, of course, but today they also have an increased need for lab test data to help them manage patient outcomes, boost their star ratings, and fills gaps in care. *(See sidebar, "To Improve Care, UHC Wants More Lab Test Data," page 15.)*

To date, UnitedHealthcare seems to be most aggressive in its pursuit of lower costs and more data as the nation's largest health insurer has shown with three significant developments in how it contracts for clinical laboratory testing services.

Three Developments

First, as noted above, it has jettisoned smaller and regional laboratories from its provider network. *(See, "UnitedHealthcare Reportedly Cutting Ties with Regional Labs as Providers," TDR, Dec. 24, 2018.)*

Second, UHC made **Quest Diagnostics** a national network provider, effective Jan. 1, 2019, for its approximately 49 million members nationwide.

Laboratory Corporation of America was already an in-network provider for UHC's members, meaning this is the first time in 11 years that UHC has national contracts with both Quest and LabCorp. *(See "Big Insurers Seek Value-Based Deals with LabCorp, Quest," TDR, May 29, 2018.)*

Third, in its December network bulletin, UHC disclosed that it is changing its clinical lab contracting strategy by forming what it calls a preferred lab network.

Although the health insurer has not yet disclosed the criteria it will use to select labs for this network, it did say that it is continually evaluating the clinical laboratories that participate in its network so that it can innovate to serve the "ever changing healthcare environment" more efficiently. *(See "UnitedHealthcare Forming Network of Preferred Labs," TDR, Jan. 14, 2019.)*

Having watched UHC recently terminate labs from its provider network and add Quest so that both national labs are in its network, clinical lab executives are asking two questions.

Low Prices or Value?

First, is UnitedHealthcare pursuing a strategy of accessing the lowest prices for tests? If true, this would continue the practice of health insurers considering a lab test as a commodity item.

Second, will other large health insurers take similar steps to exclude regional and independent clinical labs from their provider networks in an effort to control lab test costs?

In the clinical lab industry, there's a common perception that the nation's largest health insurers consider lab testing to be a commodity. For this reason, UHC may cut labs from its network and shift that lab testing work to the nation's two largest clinical laboratories, where it pays much lower prices for those same tests.

In addition, a clinical lab CEO said UHC's strategy is designed to move business away from high-cost hospital outreach programs and accomplish that by developing a preferred network that includes the nation's two largest clinical lab companies.

Labs with High Prices

Last year, UHC told Wall Street analysts that one component of its lab-contracting strategy and its deals with LabCorp and Quest was that it would develop ways to shift lab work away from hospital labs, either through redirecting testing or through acquisitions, according to another lab executive.

In addition to the contracts UHC has with LabCorp and Quest, it also has about 300 labs in its network and it added 25 labs in the past year, UHC told The Dark Report.

The creation of a new preferred lab network is consistent with a strategy UHC followed in Florida four years ago. In 2015, UHC required physicians to use its laboratory benefit management program administered by **BeaconLBS** when ordering 81 specified lab tests for its commercial members in the Sunshine State. A subsidiary of LabCorp, BeaconLBS had a network-within-a-network that UHC called "laboratories of choice."

Preferred Lab Network

With full details about UHC's new preferred lab network not yet known, lab executives experienced in managed care contracting say the primary goal of this network is for UHC to give better access to those laboratories willing to offer very low lab test prices.

"I don't know what number of labs will be in UHC's newest preferred network, but the health insurer will probably restrict or exclude higher-cost labs from this network," commented one clinical lab executive.

Another lab executive with experience in managed care contracting said UHC is applying lessons it learned when it

To Improve Patient Care, UnitedHealthcare Wants to Collect Richer Sets of Lab Test Data

HEALTH INSURERS HAVE LONG WANTED CLINICAL LABORATORIES TO KEEP COSTS LOW, but now payers seek more advanced ways to contain the overall cost of patient care. These new ways of contracting with labs go beyond a focus on lab-test prices, lab executives said. All labs may want to consider what Quest Diagnostics and Laboratory Corporation of America are doing to build lab test volume from health insurers, they added.

"There are two separate value streams for the national labs to deliver on," said one lab executive. "The first is reducing lab test costs—either by shifting testing from hospitals to the national labs or through an outright acquisition of a hospital's outreach operations.

"The other value stream is found in lab test data," he added. "UHC can use lab data to improve its numbers in Medicare's star ratings program."

The rewards are substantial. Last year, CMS paid $6.3 billion in quality bonus payments to Medicare Advantage (MA) plans under its star ratings program. UHC is the nation's largest Medicare Advantage insurer by far with 25% of the 20 million Medicare beneficiaries in Medicare Advantage plans, the **Kaiser Family Foundation** reported.

In a report last fall, the foundation showed that the average bonus payment was $321 per enrollee. That means, each year, for every 10,000 members that UHC has in MA plans that scored four stars or more, UHC could collect roughly $3.2 million.

"Another reason UHC places a high value on healthcare data is the work it does with its subsidiary, **Optum**," the executive added. "Lab data is probably a goldmine for Optum in that it not only sells that data, but it developed platforms designed to improve outcomes. In this regard, lab data would be huge."

Another executive also commented on UHC's work with Optum. "UnitedHealthcare has an increasing appetite for lab test data in part because of its Optum subsidiary," he said. "Optum is a health information technology company specializing in the use of data to manage costs and quality associated with certain disease states. This need for data is one reason UHC wants accurate and complete sets of lab test results on all of its beneficiaries."

More Nuanced Clinical Data

Optum, UHC, and other health insurers want clinical labs to provide more nuanced and detailed data on each patient's clinical condition, the executive added.

For example, since 2016, Quest has worked with **Inovalon**, a health technology company in Bowie, Md., to use real-time analytics at the point of care, he explained.

Quest said Inovalon integrates large datasets with some 600 electronic health record systems to help physicians align clinical management with quality, utilization, risk, and financial performance goals to support value-based care.

As a result of using Inovalon's data, Quest could be getting paid a separate fee for reporting member-based data services to UHC, as opposed to simply delivering the typical claims-based lab data that most labs deliver, the executive said.

In May, when UnitedHealthcare announced it would add Quest as a preferred lab provider, the health insurer said its lab services contracts "will include a broad range of value-based programs," and that it will use lab test data "to drive more personalized care support."

introduced the BeaconLBS program in Florida. Although pathologists, ordering physicians, and clinical laboratory directors were highly critical of BeaconLBS, the lab-test ordering program has remained in place since then.

Under the BeaconLBS program, if a physician didn't notify UHC about the pending test order, the lab would not get reimbursed.

"Today, I believe UHC is applying what it learned in Florida by putting some of the fundamentals of the BeaconLBS program in place nationwide," observed a lab executive who knows the Florida market well and who asked not to be identified. "In order to be considered for participating in the new preferred network, labs likely will need to accept lower rates in exchange for a favored position in UHC's list of preferred providers.

"That's what happened in Florida," the executive added. "Laboratory of choice labs were easiest for physicians to locate on the list of labs those doctors could access. But these labs had to agree to accept less-than-competitive rates from UHC to join that network."

Factors Under Negotiation

Could UnitedHealthcare's announcement of its new preferred lab network be a strategy to drive down the average rates it pays for lab tests?

"That would be my guess, since lowest price continues to be the major driver in negotiating a managed care contract for lab testing," the executive continued.

"UHC could give preferred labs some kind of marketing push so that any physician ordering one of those 81 or so tests will be directed to the preferred labs.

"The trade-off for any preferred network labs is that they will get consistent reimbursement rates from UHC," she noted. "That could be a big deal because it helps labs meet preauthorization requirements in ways that give them confidence those lab claims ultimately will be paid.

"While we don't know what UHC will pay its preferred labs, we can assume it's likely to be a deep discount off what Medicare pays, meaning something well below 100% of Medicare," stated a vice president of managed care contracting for an independent lab company who asked not to be named.

"Those clinical laboratories that got termination letters were getting paid well, and that's likely one reason why UHC carved them out of its provider network."

Geographical Coverage

In addition to accepting lower rates from UHC, clinical labs also will need to serve a wide geographic area—either a state or a region—several executives said.

"Any lab serving a big area will have an advantage over smaller labs, but you'll also need to have an edge on what Quest and LabCorp offer," commented one executive.

"UHC is not likely to have much overlap in any areas where Quest and LabCorp have patient service centers.

"In fact, your lab may need to be a national player to be included in this new preferred network," added another executive. "I don't think regional labs will even be considered."

In addition, the two national labs will be paid for other value they deliver through a bonus program and through getting the increased test volume that comes with contracting with the nation's largest health insurer, a lab executive said.

An insight that developed from these conversations with executives is that each said a primary goal behind UHC's changes in how it contracts for lab tests is to lower what it spends on lab tests.

But a secondary goal is to contract with those laboratories that have enriched data sets in a form the insurer finds useful. In addition, UHC may want to include labs in its provider network if they can show that they collaborate with clinicians to improve patient outcomes and can reduce the overall cost of care.

—Joseph Burns

Legal Update

California Lab Company Closes After Negative Medicare Decision

With each new ruling about coverage for a proprietary diagnostic assay, Medicare officials send a message to the entire clinical laboratory industry that any lab company with a proprietary test needs to submit adequate clinical evidence that demonstrates two positive aspects of the test.

First, that the assay accurately measures the biomarkers that it says it measures. Second, that the results of the assay will help a physician make a decision that contributes to better care for the patient, compared with current clinical practice.

CardioDx, of Redwood City, Calif., is the latest example of what happens to a lab with a proprietary test that does not invest the resources to gather clinical data to make a compelling case for the test's clinical utility. Questions about the clinical utility of CardioDx were an issue in two federal whistleblower cases filed against the company in 2015 and 2018.

Negative Coverage Decision

The final nail in the CardioDx coffin, however, is believed to be a negative ruling for coverage of the company's Corus CAD test from the Medicare program. In November, Medicare Administrative Contractor **Palmetto GBA** issued a local coverage determination saying, "Since initial coverage of the assay, the manufacturer has failed to demonstrate that testing resulted in improved patient outcomes or that testing changed physician management to result in improved patient outcomes."

A whistleblower who worked in sales at CardioDx brought the case to the attention of the federal **Department of Justice**, said Justin T. Berger, a partner with the law firm **Cotchett, Pitre, and McCarthy** in San Francisco. In an interview with The Dark Report, Berger said the whistleblower, Bryan Barnette, had worked at CardioDx as a sales manager when he learned that the test did not identify patients that could be "ruled out" for heart disease, as the company had claimed.

In 2015, Berger filed the case under seal in the U.S. District Court for the Northern District of California. Since then, the DOJ has investigated the case, he added. A second whistleblower filed a similar case that corroborated Barnette's claims, but that second case was dismissed because it was the second one filed, Berger said.

In the initial court filing, lawyers for Barnette said, "Since 2012, Defendant CardioDx has fraudulently sought reimbursement for medically unnecessary, excessive, and ineffective cardiovascular tests. Contrary to Cardio's declarations to Medicare and private insurance companies, Cardio's test provides no benefit to Medicare covered men and less than marginal benefit to Medicare covered women.

"Despite this reality, Cardio fraudulently induced Medicare to approve the Corus CAD test for Medicare reimbursement to the tune of $1,095 per test," court documents showed. "Additionally, to further increase ordering of the Corus CAD test, Cardio developed and implemented several kickback schemes to induce physicians and their staff to refer business to it."

CardioDx conspired with **Phlebotek Corporation**, a phlebotomy services company in Oakland Park, Fla., to implement a kickback scheme that caused thousands of false claims to be submitted to Medicare and private insurers, the court filing added.

CardioDx either submitted, or caused to be submitted, thousands of false claims to Medicare and private insurers in California by engaging in five schemes, the complaint alleged. Those schemes are as follows, the court documents showed:

- "Fraudulently inducing Palmetto GBA to approve the Corus CAD test for Medicare payment by making false representations of Cardio's "rule out" capability;
- "Conspiring with Phlebotek to engage in an illegal kickback scheme by providing physicians and medical assistants illegal remuneration for submitting specimens to Cardio;
- "Creating an illegal registry kickback scheme that provided physicians illegal remuneration for submitting patient data;
- "Organizing unlawful 'free screening days' for Medicare patients, resulting in claims for medically unnecessary and excessive tests; and,
- "Providing unlawful kickbacks by waiving patients' co-pays and deductibles."

A 'Rule-Out' Test

In the local coverage determination (LCD), Palmetto reproduced about five pages of evidence that CardioDx submitted to support its claims that physicians could use the assay "as a 'rule out' test for stable non-diabetic patients presenting to a primary care physician with the new onset of symptoms suggestive of coronary artery disease."

Nevertheless, the LCD stated that "The vendor has provided no evidence that use of the test results in improved patient outcomes (clinical utility). Thus, this test does not meet Medicare's reasonable and necessary criteria for coverage. A number of the published papers have stressed that physician behavior has changed on the basis of the test.

"However, clinical utility is not established by clinician referrals to cardiology or for further cardiac evaluation," the LCD noted. "These articles provide no defined treatment protocol(s) to manage patients with a GES of any value. Furthermore, clinicians are left to interpret the test results as they see fit.

"The test is neither a 'rule out' or 'rule in' test and is marketed to primary care and cardiologists without providing value to the patient or physician management of the patient," Palmetto GBA said. "Finally, the Corus CAD test is not included in any professional society management or treatment guidelines."

In an article about CardioDx in *The San Francisco Chronicle*, staff writers Sophia Kunthara and Catherine Ho reported that their analysis of Medicare records showed CMS paid $52 million for the test since 2012. They also reported that the company notified state officials in December that closing the company would result in laying off 110 employees.

Since the company was founded in 2003, CardioDx raised about $297 million, they added. During its most recent pitch for venture funding in January 2017, it raised $22.5 million, they wrote. "Soon after it received the green light for Medicare coverage, the company brought in $58 million from prominent venture capital firms, including **GE Capital**, **Intel Capital**, and **Kleiner Perkins**, Kunthara and Ho reported. The three venture capital firms declined to comment for the *Chronicle's* article.

CardioDx did not respond to multiple requests for comment, but attorney Jeffrey M. Berman who represents Phlebotek said, "Phlebotek vehemently denies that it violated any healthcare law or that it conspired with CardioDx, Inc. in any way, and believes plaintiff's claims against Phlebotek in that action will fail under controlling law in the Ninth Circuit. Phlebotek is aggressively defending the lawsuit and looks forward to challenging plaintiff's conclusory and baseless allegations." TDR

—Joseph Burns

Contact Justin Berger at 650-697-6000 or jberger@cpmlegal.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

More than 63 healthcare and medical service organizations signed a letter asking officials at the federal **Centers for Medicare and Medicaid Services** (CMS) to reconsider their latest interpretation of a National Coverage Determination (NCD) on the subject of next-generation sequencing (NGS). *Clinicalomics* wrote that "the final NCD also included repeat testing when a new primary cancer diagnosis is made by the treating physician and the patient meets other clinical criteria—but removed coverage with evidence development for tests not authorized by the FDA."

MORE ON: *NGS*

In the letter to CMS, the undersigned organizations wrote, "It is our understanding that despite the NCD being requested for a somatic-based test, CMS has instructed Medicare Administrative Contractors (MACs) to apply the terms of the NCD to both somatic and germline NGS-based testing for patients with cancer. The implication of this interpretation is that both germline and somatic tumor NGS-based testing will become 'non-covered' for Medicare beneficiaries with early-stage cancer. Our organizations believe that the inclusion of NGS-based testing for germline mutations represents significant policy overreach by CMS that will have unintended consequences on the care delivered to Medicare beneficiaries."

HEALTHNETWORK BUYS GENETIC LAB

On Jan. 14, **Health Network Laboratories** (HNL) of Allentown, Penn., announced its purchase of **Connective Tissue Gene Tests, LLC** (CTGT), of Allentown, Penn. CTGT offers diagnostic tests for inherited genetic disorders.

TRANSITIONS

- **Metabolon** of Morristown, N.C., announced that Michael Rasche is its new President of International Business. Rasche previously held executive positions at **Definiens**, **AYOXXA Biosystems GmbH**, **Dako**, **Roche Diagnostics**, and **Bayer Diagnostics**.
- **InReach Community Dx**, of Seattle selected Francisco R. Velázquez, MD, SM, to be its Chairman of the Board. Velázquez has held executive positions at **PAML** and **Quest Diagnostics**.
- John Lubniewski will be the new CEO at **HTG Molecular Diagnostics**, of Tucson, Ariz., where he is currently President and COO. Lubniewski has previously worked at **Roche Diagnostics**, **Ventana Medical Systems**, and **Corning Incorporated**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how the **Food and Drug Administration** cleared **23andMe** to report results of its direct-to-consumer pharmacogenetics test to customers without a physician's order, thus bypassing doctors and clinical laboratories.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, February 25, 2019.

SPECIAL SESSION

Why Supporting Patients as They Become Consumers Helps Our Lab Grow Profitably

Peter E. Fisher, MD, MBA
President and CEO, Health Network Laboratories
Allentown, Penn.

Our Strategies for Access and Care Collaborations to Integrate Care Improve Outcomes, Add Value

Patient-centered care is becoming a reality in healthcare today as health networks and physicians recognize the value of informed patients who make choices as consumers of medical services. This is why the team at Health Network Laboratories (HNL) is in the forefront of anticipating and meeting the needs to today's patient-as-consumer.

In this information-rich session, you'll learn HNL's master strategy to support its parent health network, to deliver enriched lab testing services to physicians, and to provide patients with a high-touch lab testing experience.

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- ***New Successes with Lab Test Utilization: Helping Doctors Order Better to Improve Patient Care.***
- ***Increase Lab Revenue by Using Digital Tools That Help More Patients Provide Specimens.***