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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Seismic Shift in Managed Care Contracting for Labs?

RECENTLY TWO OF THE NATION'S LARGEST HEALTH INSURERS abandoned a managed care contracting strategy that they adopted 11 years ago. Back in 2007, **UnitedHealthcare** and **Aetna** each were willing to grant exclusive national provider status to a single lab company in exchange for deeply-discounted lab best prices. *(See TDRs, Oct. 16, 2006, Feb. 19, 2007, and May 29, 2018.)*

In these exclusive contracts, UnitedHealthcare's lab of choice was **Laboratory Corporation of America**. Aetna's lab of choice was **Quest Diagnostics**. This status quo held for more than a decade. Yet, in May, each health insurer announced it had signed agreements, effective this Jan. 1, that make both LabCorp and Quest national providers in their respective provider networks.

Around the country, labs that compete against LabCorp and Quest are wondering what this means. Back in 2007, the popular wisdom was that these two payers wanted the lowest prices they could negotiate. Thus, granting one lab exclusive status as a national lab provider (while excluding the other lab) was the mechanism they used to extract the lowest lab test prices possible.

The fact that the relationships launched in 2007 were allowed to continue through the end of 2018 can be seen as evidence that there was truth to the assumption that lowest price was a major goal of health insurers when contracting for lab testing services. So what is different in 2018 that caused the end of these exclusive national lab test contracts?

As you will read on pages 6-9 of this issue, multiple experts involved in managed care contracting for lab testing services believe that, at least in part, health insurers today need to develop reimbursement arrangements that reward providers for delivering value to the insurers' beneficiaries. Whereas, lowest price may be a prime objective when contracting in a fee-for-service system, in the coming era of value-based reimbursement, health insurers need to find hospitals, physicians, and labs that demonstrably produce improved patient outcomes in ways that measurably reduce healthcare costs.

If this is true, then local clinical labs and anatomic pathology groups now have the opportunity to demonstrate to payers how they contribute to improved patient care. As they do, they can regain network status with many of the national and regional health plans serving their communities. TDR

CMS Shows Its Hand in New Draft Rules for 2019

CMS proposed continuing to exclude hospital outreach lab prices from PAMA data collection

CEO SUMMARY: Publication of the draft Medicare Physician Fee Schedule on July 12 brought unwelcome news for the clinical lab industry, at least as it pertains to whether hospital lab outreach data should be included in the PAMA market study that the federal Centers for Medicare and Medicaid Services must conduct. In the draft rule, CMS again asserted that the intent of the PAMA statute does not encompass hospital labs and hospital outreach labs. Labs may now comment on the draft rule.

IN A PROPOSED RULE ISSUED JULY 12, the federal **Centers for Medicare and Medicaid Services** continued to push an interpretation of the Protecting Access to Medicare Act (PAMA) that will reduce still further what CMS pays for clinical laboratory tests.

In its proposed physician fee schedule for 2019, CMS said that it interprets PAMA in a way that excludes hospital laboratories and hospital outreach labs, both of which make up large and important segments of the clinical laboratory testing market. On the other hand, the rule could expand the number of labs that need to report data under PAMA by adding more independent labs and physicians' office labs, according to Amanda Murphy, an analyst with **William Blair & Company**, a financial services company in Chicago.

If approved as is, the proposed rule for the 2019 Physician Fee Schedule (PFS) would also cut what CMS pays for flow cytometry tests and would make some modest cuts in what it pays for some FISH tests and those cuts will be phased in over four years, Blair reported.

In a note to investors, Murphy further reported that CMS will pay more for some immunohistochemistry tests. The PFS affects tests Medicare covers when a physician is involved in the test.

The proposed rule also could change the definition of which clinical laboratories would be required to report data under PAMA. These labs are defined as "applicable labs" for data-reporting purposes. CMS seeks comments on a proposal to change the payment level used for labs that must report under the "Majority

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of Medicare revenues threshold" provision in PAMA.

The current level is $12,500 and CMS wants comments on the effect of lowering the threshold to $6,500 and raising it to $18,750. This would mostly affect physicians' office labs and independent labs.

In addition, CMS seeks comments from clinical laboratories and pathologists about how it could improve the data-collection processes it uses when setting clinical laboratory payment rates under PAMA. All comments are due to CMS by Sept. 10.

The most significant changes in the PFS could come under the revisions CMS is considering in the way labs must report data to CMS under PAMA. Since Jan. 1, when CMS began paying laboratories under PAMA, it reduced what it paid clinical labs for tests by an estimated 10%. Those rates were set under rules established under PAMA that are the subject of litigation in the U.S. District Court for the District of Columbia.

CMS Sued by ACLA

In December, the **American Clinical Laboratory Association** (ACLA) sued the federal **Department of Health and Human Services** (HHS), saying that the agency disregarded the requirement in PAMA that all applicable laboratories report relevant market-rate data about what private health insurers paid to clinical laboratories when it set the 2018 Clinical Laboratory Fee Schedule (CLFS). That lawsuit is pending. *(See TDRs, Jan. 2 and Mar. 5, 2018.)*

In an interview with THE DARK REPORT, Erin Will Morton, Senior Vice President of **CRD Associates**, a government relations firm in Washington, D.C., that represents the **National Independent Laboratory Association**, explained that the proposed PFS does not adequately address the problems with CMS' implementation of PAMA and continues to be flawed because it excludes the hospital lab market. CMS' interpretation of PAMA excludes hospital labs and hospital outreach labs from the data-collection processes, she said.

"CMS claims in the proposed 2019 Physician Fee Schedule rule that hospital labs and hospital outreach labs are not intended to be included in the PAMA statute," she said. "They are digging in by reiterating their own interpretation in the proposed PFS rule."

"In the proposed PFS rule, CMS seeks comments on possible changes to improve the data collection process," she added. "But, while, CMS says it is interested in hearing comments from stakeholders on ways to increase the volume of data it uses to establish the new rates, the agency also claims that the statute—meaning PAMA itself—excludes hospital labs and hospital outreach labs."

CMS makes this claim in the PFS when it states, "We believe Congressional intent [in PAMA] was to effectively exclude hospital laboratories as applicable laboratories, which was apparent from the statutory language, in particular, the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the [PAMA] Act.

"CMS goes further in the proposed PFS, stating that if the CMS-1450 14x bill is used to define applicable laboratories, then all hospital outreach laboratories will meet the majority of Medicare revenues threshold," she adds. "And then CMS states, 'At this time, we believe that this approach would be inconsistent with the [PAMA] statute.'"

Inconsistencies Cited

The issue of inconsistency raises the question of whether the PAMA statute itself is clear. "Indeed, the statute is clear in its definition of an applicable lab," Morton said. The statute requires that 50% or more of a lab's revenue must come from the physician fee schedule (PFS) or from the Clinical Laboratory Fee Schedule (CLFS) if a lab is to be considered an applicable lab.

"The statute does not exclude hospital labs." Morton said. "The problem comes

ACLA Lawsuit Says CMS Lab Data Collection Was Flawed From Start, Did Not Follow Law

BASED ON ITS CALCULATIONS before the 2018 CLFS went into effect, the federal Centers for Medicare and Medicaid Services predicted that its payments to laboratories would decrease by $390 million during 2018.

But because the methods CMS used to collect the market-rate data under the Patients Access to Medicare Act of 2014 (PAMA) were so flawed, reimbursement decreased by $670 million this year, according to documents filed in a lawsuit the American Clinical Laboratory Association (ACLA) brought against Health and Human Services Secretary Alex M. Azar. This amount is about 10% of the $6.8 billion that CMS paid under Medicare Part B for lab tests in 2016.

In its lawsuit, ACLA and other associations that represent labs and support the ACLA's lawsuit, outlined several ways the PAMA data-collection methods were flawed. The **Advanced Medical Technology Association** (AdvaMed) said, for example, that the way CMS implemented PAMA, it excluded hospital outreach laboratories and physician office laboratories (POLs) because hospital outreach labs generally do not have a separate National Provider Identification (NPI) number and because most POLs do not get at least $12,500 of their Medicare revenue from the CLFS, the brief said.

The ACLA also was critical of the way CMS collected lab test payment data under PAMA. It said in a news release earlier this month that it would urge CMS and Congress to address problems in the way CMS collects payment so that care for the nation's most vulnerable seniors is not jeopardized.

The data-collection methods were flawed because CMS collected data from less than 1% of laboratories nationwide, ACLA said. "By excluding more than 99% of the nation's laboratories, CMS violated the statute and undermined Congress's goal of protecting beneficiaries and supporting value-based care delivery," the association added.

from CMS' interpretation of the statute to define an applicable laboratory by its National Provider Identifier (NPI) number under Medicare Part B, and its exclusion of hospital labs as part of this interpretation."

Some members of congress were clear that the intent of PAMA was to collect data from all sectors of the laboratory business, Morton recalled. To support this claim, she quoted a statement from the *Congressional Record* by U.S. Senator Richard Burr (R-North Carolina) who, on May 8, 2014, said this about PAMA:

'It is my understanding that the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule.'"

Morton also added a quote from Senator Orrin Hatch (R-Utah) on the same day. Hatch said the following about the intent of PAMA: 'The Senator [Burr] is correct…[T]he intent is to ensure that Medicare rates reflect true market rates, and that commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

After citing these quotes, Morton said, "The senators' comments make clear that, at the least, hospital outreach labs should be included in the data collection. But that's not what CMS says in the proposed Physician Fee Schedule for 2019." TDR

—Joseph Burns

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New Aetna, UHC Contracts Create Openings for Labs

Experts say regional laboratories have opportunity to be in-network if they market their strengths

CEO SUMMARY: New national lab contracts that LabCorp and Quest announced in May could disrupt the lab testing market in ways regional labs can exploit, experts said. Health plans entered these new contracts after realizing that the exclusive network contracts do not work, one lab consultant explained, adding that large national labs will compete with hospital outreach programs. Also, local labs may be able to provide services in areas where the health insurers have coverage gaps.

AFTER A DECADE OF SOLE-SOURCE LAB TEST NATIONAL CONTRACTS, both **Aetna, Inc.**, and **UnitedHealthcare** (UHC) announced the end to that strategy in May. Each of the two major health insurers said new national contracts that include both **Laboratory Corporation of America** and **Quest Diagnostics Inc.** would be effective on Jan. 1.

The fact that both payers made the same decision at about the same time signals that the healthcare system in 2018 is significantly different than it was in 2007. Ten years ago, financial analysts and lab experts said Aetna and UnitedHealthcare were trading exclusive national laboratory provider status for rock bottom lab test prices.

But now, 11 years later, fee-for-service is on the way out and value-based reimbursement is gaining momentum. This means health insurers need their providers—including clinical labs—to deliver more than low prices.

Instead, health insurers want to contract with those clinical laboratories and other providers that can improve patient outcomes, help physicians reduce unnecessary utilization, and lower the cost of care. All of these goals are positive for smaller regional clinical laboratories that do not have the volume to match the low test prices of the billion-dollar national lab companies.

Local Access Needed

What independent clinical labs and hospital lab outreach programs often have is more convenient local patient access, faster turnaround times for reporting results, pathologists and clinical chemists who know the local doctors and individual patients, and the ability to maintain a complete lab test record for inpatient, outpatient, and outreach results using the same methodologies and reference ranges.

Some experts who advise labs on working with health insurers have said that the new managed care contracts the large health plans have with national lab companies will create opportunities for nimble local labs. For example, health insurers still need regional labs to fill gaps in their lab networks.

"It is reasonable to assume that those health plans—and even the national lab companies themselves—may be interested in signing contracts with small and regional labs," stated Steve Stonecypher and Andrew Stimmler, Managing Partners with **Shipwright Healthcare Group LLC**, in Greensboro, N.C.

A Time to Exploit Turmoil

The contracts LabCorp and Quest announced in May could create turmoil in the market for clinical lab services that regional laboratories can exploit, Stonecypher and Stimmler added.

On May 24, UnitedHealthcare announced that it signed new long-term contracts with Quest and LabCorp and that, in those contracts, it would collaborate on value-based contracting. *Forbes* reported that, as part of the new contracts, UHC will bring to lab services the same aligned incentives and enhanced patient experience that UHC has with more than 1,100 hospitals and 110,000 physicians in accountable care organizations.

In these new deals, UHC was renewing an existing contract it has with LabCorp. Under that contract, LabCorp remains as UHC's exclusive national laboratory provider until the end of this year. On Jan. 1, UHC will begin a new long-term partnership with LabCorp that also allows Quest Diagnostics to be an in-network lab for all UHC plans covering its 48 million beneficiaries.

Contract Terms Expanded

The next day, Aetna and LabCorp announced extended and expanded contracts they originally signed in 2007. Under the new agreement effective Jan. 1, LabCorp would become a preferred national laboratory for almost all Aetna members. The expanded agreement will provide about 20 million eligible members with in-network access to LabCorp's testing. LabCorp was already an in-network lab for several million Aetna members in certain markets, the companies said in a joint press release.

One publication characterized the Aetna and UHC deals as opening up their lab contracts in a way that suggests that the health insurers no longer favor exclusive contracts. Exclusive deals are not worth the limits they impose on members, said *AIS Health*, a newsletter company.

One lab expert THE DARK REPORT interviewed agreed, although he also said he could not comment on the record about the specific contracts. "What many labs don't see is that health plans are realizing that the exclusive network contracts do not work," he said. "They just end up with leakage costs and access issues from the excluded national lab company.

"That's why Aetna and UHC are bringing in both national lab companies," continued the executive. "That way, their members have choice that allows the plans to work steerage mechanisms against the more expensive hospital laboratory outreach programs.

Outreach: The Coming Battle

"It's sad to say, but it's true, many smaller labs are struggling," he added. "That means the next real battle will be between the biggest lab companies and the hospital lab outreach programs."

This comment is similar to what the *AIS Health* newsletter reported when it said that health insurers might be more interested in seeing how competition between the two national lab companies could improve care for Aetna and UHC members. Under the new national deals, the lab companies will compete on quality metrics to prove they can serve health plan members well, the newsletter said.

Another lab executive who asked not to be named said his company questions how Aetna and UHC will view the contracts they have with hospitals in light of these agreements. "Will they leverage the new agreements to lower fees from hospitals or eliminate some of the hospital

agreements?" he asked. "Do these new deals have the potential to affect hospitals' decisions about whether to remain in the outreach lab business?"

As part of the new contracts, *Forbes* reported that UHC executives said they would collaborate with the diagnostic test companies on a variety of value-based programs while aligning incentives, and improving patients' experience.

A Chance to Fill Gaps in Care

"For all these reasons, regional labs have an opportunity," commented Stonecypher and Stimmler. "Payers have always had gaps in their coverage for clinical lab services," Stonecypher said. "Even when Quest and LabCorp had their previous contracts with UHC and Aetna, there were gaps. So, there also will be gaps in patient access after these contracts become effective on Jan. 1.

"Each one of those gaps is an opportunity for a regional laboratory because Quest, LabCorp, UHC, and Aetna are going to need to backfill those gaps in their coverage," he added.

In addition, he commented, the large national clinical labs provide what health plans want: data to support the delivery of value-based care. If regional labs can't provide that test-result data, then health insurers may not be interested in working with them, he said.

"Every national payer that we've talked to emphasizes that they prefer to send work to the national labs because those labs have the data, the scale, and the price they want," Stonecypher said. "Also, the national labs offer one-stop shopping.

"This means that, if LabCorp and Quest don't have what a health insurer needs in certain areas, then the insurer will contract with regional labs," he added. "However, it remains administratively complicated and costly to manage multiple contracts. That's why big health insurers have national contracts and are paring down their networks.

"Some regional labs are providing the data that payers want and some are not providing it," Stonecypher explained. "But the big labs are providing those results routinely. That's what health plans want and need."

Stimmler added that regional labs may provide the data, but it may not be in a format the health plans can use. "The data could be spotty or difficult to decipher," he said. "Or it could just be a small amount of data versus what the larger labs can provide."

To take advantage of any opportunities that exist to fill gaps in the large national contracts, regional labs and hospital outreach labs should evaluate their strengths to see where they might be able to support Aetna and UHC, Stimmler recommended.

"Ask yourself what your lab is doing differently that the national labs are not doing," he said. "Once you know that, make sure the payers know it too. Don't expect the payers to be aware of that or to know who you are.

Outreach: The Coming Battle

"Identify what your lab can do well operationally that Quest Diagnostics or LabCorp can't do," continued Stimmler. "Identify the things that your lab has that it can use to advantage to win managed care contracts with payers."

These new developments in the lab testing marketplace demonstrate how healthcare's ongoing transformation creates new challenges for health insurers. More attention is being placed on improving patient outcomes and reducing the cost of care. Local labs and hospital outreach labs should seize this opportunity by showing health insurers how they can deliver more value from their lab testing services. TDR

—Joseph Burns

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LabCorp, Quest Diagnostics Outline Steps to Provide Value-Based Care to Insurers

IN THEIR RESPECTIVE CONFERENCE CALLS WITH WALL STREET ANALYSTS, executives from both Quest Diagnostics and Laboratory Corporation of America outlined how they will deliver value-based care under the new managed care contracts with UnitedHealthcare (UHC) and Aetna in the coming years.

LabCorp CEO David King said he expects the net result of the contracts for LabCorp to have a negative effect on revenue and profit next year because LabCorp will lose some patients as customers. "I will say that, just as we have said from the beginning, given the number of covered lives in each of those plans, it is highly likely that we'll lose more in United than we'll pick up in Aetna," he commented. Not only are there more covered lives in the UHC contract that could move to Quest, but LabCorp has a larger percentage of those lives than Aetna has, he explained.

To make both contracts work, LabCorp will use the data it has from patient test results and integrate that data from its **Covance** subsidiary and from its contracts with **Walgreens** where it is adding lab testing in retail stores, he added. In the second quarter, LabCorp had operations in 16 Walgreens stores, he said.

After meeting with health insurers recently, King explained what they want from clinical labs. Payers want to know how their patients are doing, where there are gaps in care, and they want LabCorp to identify opportunities to treat patients more efficiently so that the insurers can receive bonus payments under Medicare's Star Ratings system, he explained.

"They (insurers) also want to know in a health system, for example, how is my patient cohort performing against comparable patient cohorts," King added. "How are my physicians performing against comparable physicians both internally and externally?"

This is the information that LabCorp aims to deliver to health plans and other labs should do the same.

Quest Chairman, President, and CEO Steve Rusckowski had similar comments, saying Aetna and UHC are partnering with Quest to reduce laboratory spending and bring down the overall cost of care.

In addition, Quest CFO Mark Guinan explained what Quest aims to deliver under the UHC contract. In general, the UHC arrangement is a traditional fee-for-service contract, he said, but there are incentives for Quest if it can reduce the cost of care. What Quest gets paid will vary depending on its performance, he added.

"When we talk about value-based contracting, as I referenced earlier, there are incentive payments that we can earn by saving them money," stated Rusckowski. "When I say saving them, I'm talking about not just United but obviously, the healthcare system and especially the patient."

Managing Patient Care

In addition, Quest will aim to reduce costs by how it helps physicians and other providers manage patient care. "So price is one thing, but the level of activity for a patient with a given condition is also a driver," he said. Some labs might have lower prices per test but the work of those labs might end up costing health insurers more because physicians and hospitals have to provide more care for patients with some conditions, he explained.

Therefore, Quest will focus on the total cost per interaction with a patient and aim to save money "by doing things that are medically appropriate at a good price," he added.

"And to the extent this saves money for the system and overall stakeholders, some of that will come back to us," commented Rusckowski. "So there are incentives for Quest Diagnostics."

CEO SUMMARY: In the Province of Québec, an ambitious project is underway to consolidate the clinical laboratory testing of 123 laboratories into 11 centralized lab clusters. It is one of the largest lab consolidation projects now happening in the world. Among the goals of this project is to improve quality and efficiency while incurring no additional costs. A unique benchmark for tracking improved productivity and lower costs is the weighted unit per hour, or WU/hour. The lab clusters will need to boost this productivity measure by only 16% to achieve the targeted savings.

Optilab Québec to move 123 labs into 11 lab groups

Québec's Laboratory Consolidation Plan Aims to Save $13.5M

In the province of Québec, one of the world's largest clinical laboratory consolidation projects is underway. The provincial health system wants to consolidate 123 clinical laboratories in the province into 11 groups (clusters) of labs. Each lab group, or cluster, will have a central laboratory facility.

The goal of the project is to generate substantial cost savings and improve quality by funneling all of the province's lab tests into 11 large test centers while also standardizing lab test menus and methodologies throughout the province. Perhaps most ambitious of all, Ralph Dadoun, PhD, Project Director for **Optilab Québec**, plans to accomplish the consolidation without adding costs.

In a presentation at the Frontiers in Laboratory Medicine (FiLM) conference in Birmingham, England, in January, Dadoun explained that—just by standardizing equipment within the clusters—the financial objective of the project is to save at least US$9 million annually, and possibly as much as US$13.5 million. Currently $1 Canadian is worth about 75¢ in U.S. currency.

Whether the savings are modest or significant will hinge on the successful modernization of each of the 11 lab clusters. This will be achieved by standardizing instruments and test menus. Plans are to optimize the use of equipment over two shifts (which is not the case today) by using standardized equipment and an increased focus on efficiency and workforce productivity. The primary goal is to wring enough savings so that the entire project is done on what Dadoun calls "a zero budget."

The projected savings must offset the costs of a new laboratory information system (LIS) to be deployed throughout the province, all renovation and transition costs, and full accreditation to ISO 15189, Dadoun said. Money to fund all of these expenses at "no cost" means that most of the savings will need to come from improved productivity, reduced costs of reagents and normal staff attrition, he added.

"Our mission at Optilab is to develop an integrative clinical lab testing system—a common operational template—for physical laboratories to follow," noted Dadoun. "The strategic plan is to increase efficiency, particularly in the biggest consolidated lab facilities, to such an extent that we achieve these objectives at zero cost."

Pathologists and clinical laboratory directors may ask why anyone would attempt to accomplish such a Herculean task. But for Dadoun, there is no other way for the province to deliver laboratory services and maintain state-of-the-art technology to benefit Québec's population of 8.2 million.

"Why did we embark on the Optilab project?" he asked. "The reason is simple: Our provincial health system doesn't have any more money to inject. Almost 50% of the provincial budget is allocated to healthcare.

Status Quo Is No Option

"In clinical laboratories, we're all in the same situation: With no funding, the status quo is not an option if we want to benefit from the latest diagnostic technologies," Dadoun explained. "By that, I mean it would cost way too much money to reinvest in the present structure in most of the province's clinical labs with no added value.

"Therefore, we need to have all new equipment in each of the 11 central lab clusters and we need to have a complete standardization of equipment," he said. "It might take some time to achieve complete standardization, but all the recurring savings generated by the standardization will be re-injected into the project."

One unusual element of the project is how the labs will measure productivity. Dadoun explained that the success (or failure) of the initiative will be assessed using a measure of clinical laboratory test volume called the weighted unit per hour or WU/hour.

"The WU/hour includes all the components of each test—whether the test is in biochemistry, hematology, microbiology, or pathology," stated Dadoun. "This metric includes all costs needed to run each test, including reagents and labor needed to run the test, time on the testing equipment, overhead in the lab, and the cost to deliver the test result to the ordering physician."

Using weighted units per hour allows each of the consolidated lab organizations to compare their productivity to all 11 centralized lab facilities in Québec.

Early this year, Dadoun used the WU/hour metric to assess the average productivity in every lab in each of the 11 clusters. From this assessment, he found that productivity ranged from an average low of 44 WU/hour in cluster 2 to an average high of 72 WU/hour in cluster 11.

Using the beginning of this year as the baseline, this existing level of productivity showed that the average of all labs in the province amounted to 66 WU/hour. When the transition to the new system is complete in three to five years, Dadoun expects the average productivity of all province labs to hit 76 WU/hour, which he called the 90th percentile of productivity today.

Realistic Productivity Target

"This level of productivity is a goal perceived as being realistic even in the lab community," he commented.

Last year, Dadoun began implementing the consolidation plan in earnest. "One first step in this project was to make significant investments in two major labs, both in Montréal," he said. "One of those labs is at **McGill University Health Centre**. MUHC is a new hospital with a new lab that just opened late last year.

"The other is at the **University of Montréal Hospital**, on the French side of the city," he explained. "In that hospital, we have a new lab as well.

"Each central lab in the 11 lab clusters will be evaluated on its ability to process a high throughput of tests over 16 hours for every day of the year, and the cluster will be asked to achieve a productivity at the actual 90th percentile," he said.

The goal of reaching the 90th percentile is not a firm target. "There is some flexibility, but we will ask them all to aim for this level of productivity," commented Dadoun.

"The reason for the flexibility is that it's important to acknowledge that each lab has different particularities," he added. "Some smaller labs handle lower volume than the larger labs and the weighted unit per hour (WU/hour) will account for that variation.

One Size Does Not Fit All

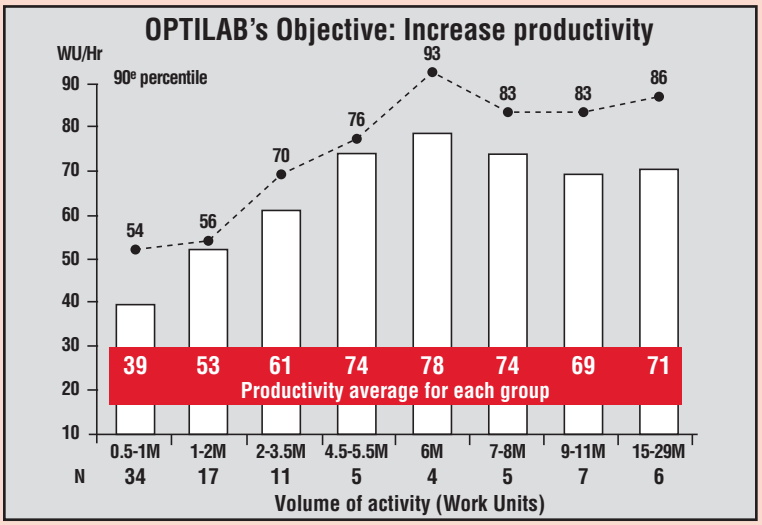
"The beauty of this model is that it takes into consideration the geographical environment and the particularities of each cluster," he said. "In other words, one size does not fit all."

During his presentation at FiLM, Dadoun showed slides that explained how the WU/hour metric is used to assess the productivity of each lab cluster.

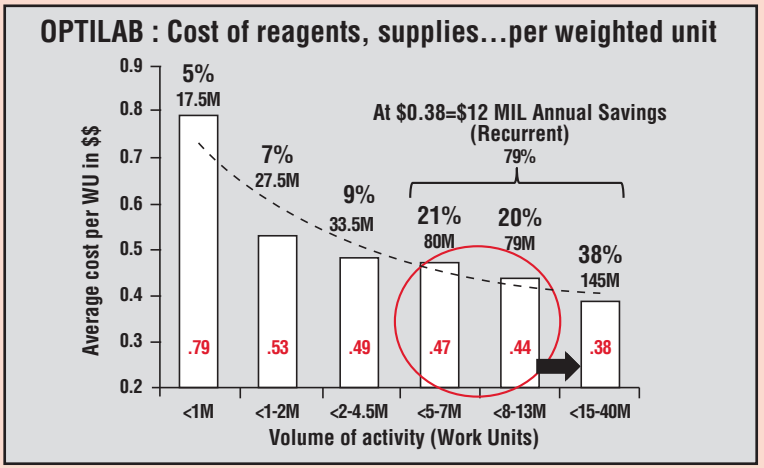
One slide showed that lower-volume labs had less productivity than higher-volume labs. Productivity ranged from 39 WU/hour in labs running fewer than 1 million WU per year to a high of 78 WU/hour for labs running 6 million WU/hour per year. For labs running more than 7 million WU/year, productivity was slightly lower, ranging from 69 million WU/hour to 76 WU/hour. *(See sidebar on page 13.)*

With these numbers, Dadoun calculated that the average level of productivity per day for the 11 lab clusters in Québec currently is 66 WU/hour. Then he calculated that, if optimal productivity would be at the 90th percentile, it is feasible to have each lab cluster aim to achieve productivity at their 90th percentile level.

Lab Consolidation Program in Québec Intends to Pursue Two Key Productivity, Cost Measures



GRAPH ONE (above): In the first phase of this lab consolidation project in Québec, the goal is to achieve 76 weighted units per hour (WU/Hr) within each cluster, compared to the existing productivity of 66 WU/Hr, a targeted increase of 16%. For eight of the clusters, this graph shows the existing productivity as bars and the target WU/Hr for each cluster as points in the line. In successive phases, the plan is for all labs in Québec to have productivity in the 90th percentile.



GRAPH TWO (above): Another factor to support the lab clusters working toward the 90th percentile of productivity is to standardize test menus, lab equipment, and install a common laboratory information system and specimen tracking system. This chart shows how, at different test volumes (and economies of scale), these standardized, uniform systems will contribute to reducing the average cost of weighted units per hour (WU/Hr).

If all the labs raise their productivity at the 90th percentile, the provincial productivity will go from 66 WU/hour to 76 WU/hr, a 16% increase in productivity, he added.

Once this is achieved, it is possible to assess how much each lab within a cluster would need to raise its productivity to further boost the average level of productivity in that cluster, Dadoun said. To do so:

- the smallest labs (those running fewer than 1 million tests per day) would need to raise their daily productivity level from 39 WU/hour to 54 WU/hour;
- those labs doing 6 million tests per day would need to increase their productivity from 78 WU/hour to 93 WU/hour; and,
- those labs running 15 million to 20 million tests per day would need to raise their productivity from 71 WU/hour to 86 WU/hour.

90th Percentile Productivity

In the succeeding phase of this ongoing lab consolidation project—after introducing the new LIS along with full interoperability and standardized equipment—the next goal would be to have each lab cluster raise its productivity to the 90th percentile level, enabled by these changes.

For example, boosting productivity to the 90th percentile level would mean productivity would need to go up to 62 WU/hour in lab cluster 1 and increase to 79 WU/hour in lab cluster 11, said Dadoun, adding, "Here we are referring to the performance of the cluster. A cluster is composed of many different size labs. One cluster could have eight labs composed of three labs at 1 million WU per year, four labs at 4 million WU, and the central lab at 15 million WU per year.

"Another cluster could have 16 labs between 1 million and 1.5 million WU per year and a central lab at 18 WU million per year," he said. "We will not ask these two clusters to have the same performance level, but both will reach their 90th percentile productivity.

"That's the beauty of a system which takes into consideration the particularities and composition of the lab clusters," he added. "That's why I emphasize that one size does not fit all. And that's why Optilab will focus on the performance of the cluster.

Saving Time and Money

"If all labs in all 11 clusters can raise their productivity to their 90th percentile level, then all labs in the province will have reduced annual work time by approximately 700,000 hours," he said. "The vast majority of the labor reduction, if not all of it, will be through normal attrition."

Now that the metrics for measurement are in place, Dadoun explained that the next part of the laboratory consolidation project involves elements most clinical lab directors know well. One is to buy, test, and validate a laboratory information system (LIS) for all 11 lab clusters. The second is to develop, test, and validate a specimen-transportation system that allows the labs to trace the location of all patients' specimens.

"The health minister wants one LIS for the entire province," he said. In December, the ministry requested—and the province is evaluating—those bids," added Dadoun. "The decision is expected by the end of this year."

Same LIS in All Clusters

The planned implementation of the LIS is within five years, he said. "In the meantime, some lab clusters are in a transition phase and implementing a middleware approach," he added. "Currently, three clusters—including one that has a university teaching hospital laboratory—are in the process of implementing some middleware. Two other lab clusters are running the same LIS that was recently upgraded.

"Because this is an operation running at what we call zero cost, each cluster needs to provide a 10-year auto-financing plan," Dadoun said. "The auto-financing plan includes all costs that Optilab incurs, including those for the LIS, the cost of a transitional LIS (if needed), the cost of all renovations, and the cost of implementing ISO 15189.

"The objective is that all savings will come within three to five years from a variety of sources, including more efficient use of reagents and supplies, and a decrease in the numbers of older lab-testing equipment used throughout the province," he added. "It's possible, however, that we could see some variation from cluster to cluster.

Auto-Financing of a Cluster

"To date, each of the 11 lab clusters has submitted an auto-financing plan and those plans are being reviewed and revised," he explained. "The auto-financing plans will be reviewed every year and adjusted, if needed, to hit the budgeted goals while adapting to new realities."

Within 24 months of the Ministry of Health and Social Services' approval of the financing plans, Dadoun expects that the first three lab clusters will be fully operational and as many as five clusters might be fully operational.

In conclusion, Dadoun explained, that while all of these steps are significant, perhaps the most significant is the goal of achieving full accreditation to ISO 15189: Medical Laboratories, for all 11 lab clusters. Recently, health ministry officials signed the contract and implementation will begin in early next year.

"At this early stage, if we have only three lab clusters fully operational, then, ideally I would like one of them to include a major university hospital with all the complexity of a university teaching hospital," stated Dadoun. "And I would like one to be from one of the largest regions in the province that has small labs spread widely."

Optilab Québec's Accomplishments to Date

LAST YEAR WAS SIGNIFICANT for the Optilab Québec project because it accomplished several significant milestones in the effort to consolidate 123 lab operations in the province into 11 lab clusters, said Ralph Dadoun, PhD, Project Director for Optilab Québec.

For example, in March 2017, "buy in" from the leaders of the province's laboratory community had been achieved.

By April 1, 2017, all human resources and payroll functions had been transfered from the associated labs in the province to the central laboratory. In effect, this step meant that all lab employees had a change of employer and were now working for one employer in the province, he explained.

At the same time, the operational, equipment, and capital budgets for the 11 lab clusters were approved.

By the end of June 2017, the province had created a province-wide Department of Laboratory Medicine and the department appointed administrative and medical directors for the province.

There are several novel concepts in this province-wide lab consolidation endeavor. First, use of the weighted units per hour (WU/hour) as a productivity measure makes it possible to compare labs of all sizes and economies of scale in a consistent and equitable manner.

Second, Dadoun and his leadership team have created an objective and fair way to compare the predicted productivity goals versus the actual productivity attained in each cluster. This is a benefit to the provincial health authority because it makes it possible to publicly show performance against goals. TDR

—Joseph Burns

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IT Update

Computer Hackers Attack LabCorp, Company Shuts Entire IT Network

FOR ALL CLINICAL LABORATORIES AND PATHOLOGISTS, the hacking problems **Laboratory Corporation of America** experienced earlier this month are a reminder that unwanted IT attacks are not a matter of if, but when. It is an accepted fact that labs and other medical providers are at higher risk of such attacks because computer hackers value patients' medical data higher than they do other hackable data.

This is why IT security experts advise all healthcare providers to have cybersecurity insurance coverage, at a minimum. As a result of having such coverage, LabCorp minimized the costs it incurred to investigate and stop the attack on its systems over the weekend of July 14 and 15, according to LabCorp Chairman and CEO David P. King.

During that weekend, staff at LabCorp detected suspicious activity in the company's computer systems. In a statement issued following the discovery of the activity, LabCorp said that it took its systems offline—a step that affected test processing and customer access to test results.

By Monday, July 16, the company said it was working to restore full system functionality as quickly as possible. It added that testing operations had substantially resumed and that other systems would be restored within several days.

Ryan Parry, West Coast correspondent for the UK's *DailyMail.com*, reported on July 16 that hackers had breached LabCorp's IT and that a company insider said senior managers were informed that the company's entire computer network was shut down across the entire United States on the morning of Sunday July 15.

During a conference call with Wall Street analysts 10 days later, on July 25, David P. King addressed what he called "the recent ransomware event," saying operations had returned to normal.

When IT staff detected suspicious activity on its network, the company took certain systems offline to protect patients' private information, he said. "This decision was the right one, although it led to a disruption in service which required approximately one week for recovery."

Working with independent forensic IT experts, LabCorp found no evidence of theft or misuse of data, he said. "We believe the financial impact will not be significant and the company has cyber insurance coverage," he added.

The data analytics company **Veriphyr** reported in May that, for hackers, a single patient's personal health information is worth $50 on the black market. That is why hackers are targeting patients' healthcare data. For comparison, the company said Social Security numbers are worth only $3 each; credit card information, $1.50; date of birth, $3; and mother's maiden name, $6.

"One reason for the high value is that a person cannot cancel their own medical history, but they can always cancel a stolen credit card number," the company said. "This makes it much harder to prevent stolen medical data from being used by criminals." TDR

—Joseph Burns

Lab Market Update

Quest, Sonic Issue Statements about Pap Test Issues in Ireland

To date, news reports say at least 221 women got false negative Pap results and 18 women have died

PROBLEMS WITH CERVICAL CANCER SCREENING IN IRELAND continue to make headlines in the Irish newspapers and roil the Irish health system. Caught up in this story are two billion-dollar lab companies that performed cervical cancer screening under contract to the **Irish Health Service**.

THE DARK REPORT provided its first coverage of these developments in its previous issue. *(See: "Pap Test Errors in Ireland, Attributed to Quest, CPL," July 9, 2018.)* We asked both **Quest Diagnostics** and **Sonic Healthcare**, which owns **Clinical Pathology Laboratories**, for a comment on this matter.

In response, a Quest spokesperson provided the following statement:

We understand the deep and abiding trauma experienced by cancer patients and sympathize sincerely with them and their families. In the case of Ms. Mhic Mhathúna, we, together with the Irish Health Services, we (sic) have provided her and her family with significant financial redress which we hope will provide security for her family. The relative contribution of the various providers to this settlement will be decided at a later date.

Quest Diagnostics has been providing cervical cancer screening services for the Irish government since 2008. As a result of the cervical cancer screening program, cervical cancer rates in Ireland have dropped 7% in every year since 2010. Prior to Quest's involvement in 2008, there was no Irish national screening program, women waited many months for results, and cervical cancer rates were actually increasing at about 4% per year.

We note that the June 30 CBS report, as well as reporting from other media outlets, have conveyed either explicitly or implicitly that cervical cancer screening is a diagnostic test. This is incorrect. A Pap smear is designed to identify individuals with cellular markers which may indicate future disease potential. The primary objective of any screening program is risk reduction and there are a number of steps in the screening process, including physician examination, consideration of personal and familial history, smear-taking, cytopathology, colposcopy, and/or histopathology.

The Irish government and health services have repeatedly stated that Quest's performance is in accordance with both their requirements and international standards, a statement with which we fully agree. Moreover, Quest adheres to the rigorous U.S. standards, which include regulation by federal and state health authorities.

When asked for comment, officials at Sonic Healthcare referenced a statement they provided to the *Austin American-Statesman*, which reads:

What has happened to Mrs. Phelan and her family is tragic, and we deeply regret the outcome. We hope this settlement will allow Mrs. Phelan to gain additional treatment and an improved prognosis and quality of life.

CPL is one of two U.S., and two Irish laboratories, that have provided Pap smear testing for the Irish cervical screening program since 2008. These screens have been performed through manual examinations of individual slides, without the benefit of computer-based imaging and a separate HPV test, which together comprise the clinical standard in the U.S. and many other countries for cervical cancer screening.

Since 2008, more than three million screening tests were performed by the four laboratories contracted by the Irish Health Service Executive. This testing was performed to the highest quality standards in order to ensure the best possible outcomes for the women participating. Despite this, it is internationally recognized that no screening program is 100% effective and all have an inherent margin for error.

The results of cervical cancer screens conducted by our lab and three others are well above the accepted accuracy rate for the type of screening specified by the Health Service Executive in Ireland and have been continuously monitored and repeatedly endorsed by Irish health authorities as well as U.S. laboratory accrediting agencies.

Clinical Pathology Laboratories [a division of Sonic Healthcare] has a lengthy history of reading and evaluating Pap smears and performing other medical tests. We adhere to the highest clinical standards and are regularly reviewed by the appropriate U.S. governmental and private accrediting agencies, and have maintained continued accreditation for more than 20 years.

The Irish news media have published articles about women who have filed lawsuits against the labs and the Irish Health Service, saying their cervical cancer went undetected. Typically, these are mothers with young children who have only months to live because their cancer is untreatable.

It is possible that these failures are result of what could be systemic errors in the design and implementation of Ireland's national cervical cancer screen program, called CervicalCheck, that was launched in 2008. Since then, more than 200 women reportedly got false negative reports and some have been diagnosed with cervical cancer.

Earlier this month, *CBC News* in Canada reported that as of July 9, 221 women in Ireland had been diagnosed with cervical cancer after receiving false negative results on Pap tests. Of these women, 18 had died.

Quality Control Audit in 2014

Since 2008, CervicalCheck reported that some 3,000 women in Ireland have been diagnosed with cervical cancer. During a routine quality control audit in 2014, CervicalCheck said it identified 221 women, who, "on look-back, the screening test could have provided a different result or a warning of increased risk or evidence of developing cancer." Stated differently, at least some of their Pap screen test(s) were false negatives.

In implementing CervicalCheck, Irish health officials issued a series of tenders. By 2010, **Quest Diagnostics** and **Sonic Healthcare, Ltd.** were each performing about half of the 300,000 or so cervical cancer screenings done on behalf of Irish women each year.

Sonic built a lab in Ireland, **MedLab Pathology**, to do some of this testing and sent the balance to its **Clinical Pathology Laboratory** (CPL) division in Austin, Texas. Quest Diagnostics performed its share of Irish cervical cancer screening in its labs in the United States. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Clinical labs and physicians can soon say goodbye to "meaningful use." Federal officials are proposing a significant change to the Medicare and Medicaid EHR Incentive program for certified EHRs that has been in existence since 2011. In a press release issued last spring, the **Centers for Medicare and Medicaid Services** (CMS) issued a proposed rule. It said, "The proposed rule proposes updates to Medicare Payment policies and rates under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) to reflect the changing needs of the Meaningful Use program."

MORE ON: *Meaningful Use*

CMS says the meaningful use program will be renamed as "Promoting Interoperability." The program will now have several goals, such as "making the program more flexible and less burdensome, emphasizing measures that require the exchange of health information between providers and patients, and incentivize providers to make it easier for patients to obtain their medical records electronically." Lab managers should also note that, in the press release, CMS states it wants the program to "achieve greater price transparency and interoperability—essential components of value-based care."

AUSTRALIA REGULATES LDTS

Laboratory-developed tests (LDTs) are an issue in Australia, just as they are in Europe and the United States. In May, Australia's **Therapeutics Goods Administration** issued guidance on how labs must handle *in vitro* diagnostic (IVD) tests that are "manufactured and/or modified in-house" for clinical use. Among the changes is one that limits a laboratory network to "a group of laboratory organisations that operate under a single quality management system (QMS)."

TRANSITIONS

• **Bako Diagnostics** of Atlanta, Ga., appointed Ted Hull as Chief Executive Officer, effective Aug. 1. Hull has held executive positions with **Ramble Ventures**, **Eurofins Scientific**, **Genova Diagnostics**, **Quest Diagnostics**, **Nichols Institute**, and **Deloitte**.

• **Sonora Quest Laboratories** named Sonny Varadan as its new Chief Information Officer. Previously, Varadan served at **Nichols Management Group, PAML**, **Providence Healthcare**, and **Getronics**.

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 researchers at the **Tufts University School of Engineering** developed a tooth-mounted sensor that monitors glucose, salt, and alcohol in foods as they enter the body, with wireless transmission of the data.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 20, 2018.

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ESSENTIAL SESSION | **CMS, CAP, COLA, Joint Commission, A2LA To Present at Special Session on Compliance**

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To help you prepare your lab for tougher inspections and new regulatory requirements, *Lab Quality Confab* brings together all the organizations that accredit laboratories: CMS, The Joint Commission, CAP, COLA, and A2LA.

This panel has the essential knowledge you need to keep your lab "inspection ready" at all times. This session is valuable for another reason: many hospitals and health systems operate labs accredited by different organizations and in this one session you can hear, learn, and ask questions of the leaders from all the lab accreditors. Each panelist will share the 10 lab deficiencies identified most often during lab inspections.

Heather Hurley
The Joint Commission

Kathy Nucifora
COLA

Nora Hess
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- ***Can Uber/Lyft Technologies Also Revolutionize Specimen Transport Systems Used by Labs?***