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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Interim CMS Molecular Pricing Setting Off Alarms

Although the pricing on 114 molecular codes the Centers for Medicare and Medicaid Services (CMS) released last week are interim, fears are mounting in the lab sector they're precipitating a crisis that will be permanent.

Pathology and lab observers all said the same thing about the new pricing: The rates released by CMS are too low to cover the costs of performing the tests and represent a disaster in the making since the agency announced late last year it was placing new molecular pathology (MoPath) codes on the clinical laboratory fee schedule and leaving it up to regional Medicare administrative contractors (MACs) to determine prices.

The interim prices range from $41.41 in some regions for the Factor V Leiden test, CPT Code 81240, to determine a genetic tendency for deep vein thrombosis, to $8,792.88 for genetic testing for congenital long QT, CPT Code 81282. For some labs, the lower prices for many codes means they will have to stop performing certain tests. Labs that focus heavily on molecular testing may see their very survival jeopardized as a result of the low prices.

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LabCorp Prevails Over Quest in $250 Million Army Contract

Quest Diagnostics and LabCorp were so eager to provide laboratory services to the U.S. Army that they engaged in a years-long battle to secure the nine-figure contract.

When the plug was finally pulled on the legal seesawing early this month, LabCorp was on top.

A U.S. Court of Federal Claims ruling issued earlier this month awarded the contract to LabCorp, a decision that pivoted mostly on a picayune scoring process for their bids and how it was calculated and then rescored.

Quest was not mollified by this development, particularly since it had been declared the original winner of the five-year, $250 million pact

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■ **LabCorp Prevails Over Quest in $250 Million Army Contract**, *from page 1*

two years ago. That decision, court records say, was based in part by Quest offering the lowest price, one of five categories where the two lab giants were evaluated.

But LabCorp filed a protest with the Government Accountability Office (GAO) regarding the original award, resulting in a re-evaluation by the Army. That led to LabCorp wresting the contract from Quest, which in turn filed its own protest with the GAO, claiming LabCorp had too much leeway to make revisions in its bidding. Yet another re-evaluation by the Army did not change the result. Quest then sued in Federal Claims Court.

Such legal back-and-forth over a big and exclusive government contract is normal, "and in fact may escalate" in the future, said Jane Pine Wood, a member with the McDonald Hopkins law firm in Massachusetts, as national giants such as Quest and LabCorp find ways to grow flat revenues.

How both companies scored in the bidding is unknown, since their results were redacted before the Claims Court released its decision. But the court ruled that in the absence of specific restrictions, either party could make revisions to its bids as it saw fit. Quest was primarily focused on its technical volume capability during the rebidding and did not ask if it could make other changes in its proposal—something LabCorp inquired about and did. Quest also misinterpreted how its current interface with the Army's electronic health records would be evaluated, according to the ruling.

"We are disappointed by this decision. Quest Diagnostics is proud of our record of providing exceptional service to our nation's military families," said Quest spokesperson Wendy Bost. "We continue to believe we are the best provider for DOD."

A LabCorp spokesperson did not respond to a request for comment.

CAP Helps Develop Guidelines For Lung Cancer, Whole Slide Imaging

The College of American Pathologists (CAP) has issued new evidence-based guidelines for lung cancer testing and for the validation of whole slide imaging.

CAP joined with the International Association for the Study of Lung Cancer and the Association for Molecular Pathology to create evidence-based guidelines for lung cancer testing, while it compiled the whole slide imaging in-house.

The lung cancer guidelines include recommendations for two genetic-based tests for lung cancer. They include testing for mutations of the epidermal growth factor receptor, or EGFR, and the rearrangement of the anaplastic lymphoma kinase, or ALK. Both are considered reliable markers for lung cancer in molecular testing.

Officials say testing for these two biomarkers would make it easier to craft more effective therapies for treating the disease.

Lung cancer is the deadliest form of cancer in the United States, killing more than 160,000 Americans a year. Although the death rate has plateaued among men in recent years, the death rate for women continues to rise. More than 225,000 new cases are diagnosed annually. The five-year survival rate is just over 16 percent.

"Up to 20 percent of patients with lung adenocarcinoma, the most common type of lung cancer, will test positive for one of the two biomarkers," said Philip T. Cagle, M.D., medical director of pulmonary pathology in the department of pathology and genomic medicine at Methodist Hospital in Houston. "It is critical to identify these patients because they stand to benefit more from new targeted drugs than from conventional chemotherapy, and with fewer side effects."

CAP's pathology and laboratory quality center provided the process for creating the guidelines. The three organizations have also developed clinical tools and resources for pathologists and oncologists that distill the findings and recommendations.

Whole Slide Imaging Validation

The guidelines for whole slide imaging were developed to help pathologists and laboratories seeking confirmation for the accuracy of their imaging systems for the sake of diagnostics. Whole slide imaging allows practices and labs to digitize and archive images and use computer-aided diagnostic tools.

The guidelines include 12 recommendations, among them creating a validation process that emulates the clinical environment of the laboratory, using at least 60 routine cases for validation, and confirming that all material on the slide that has been scanned is included in the digital image.

"We developed the guideline in anticipation of wider adoption of WSI in clinical practice," said Liron Pantanowitz, M.D., associate professor in the pathology and biomedical informatics at the University of Pittsburgh and the lead author of the guideline. "The guideline marks a significant stepforward in demonstrating the value of this emerging technology for diagnostic use."

The Food and Drug Administration has not yet approved whole slide imaging for primary diagnoses, but the guidelines can be used for pathologists practicing abroad, according to CAP. Pathologists in the United States primarily use whole slide imaging for teaching, research, and remote consultations.

The lung cancer and whole slide imaging guidelines are available on the Web site of the *Archives of Pathology & Laboratory Medicine* at *www.archivesofpathology.org*.

NeoGenomics, Transgenomic Report Mixed Results

Two midsized players in the cancer-related molecular testing space reported mixed results for the first quarter, ending March 31, as they tried to expand sales for their products.

Both Fort Myers, Fla.-based NeoGenomics and Omaha, Neb.-based Transgenomic reported modest gains in revenue, but the former's net income narrowed while the latter's loss grew.

NeoGenomics reported net income of just $3,000 on revenue of $15.7 million for the quarter, compared to net income of $603,000 on revenue of $15.2 million for the first quarter of 2012. Transgenomic reported a loss of $3.6 million on revenue of $7.4 million for the quarter. That compares to a net loss of $2.7 million on revenue of $7.2 million for the first quarter of 2011. Operating expenses were up at both companies, primarily due to staff expansions.

Two Models for the Hospital Outreach Business: Dive In or Stay on Sidelines

The two biggest deals Quest Diagnostics has consummated in recent months involved hospital outreach laboratories. In October, it announced that it was acquiring the outreach business of the UMass Memorial Medical Center in Worcester, Mass., and that the two entities would build a combined regional lab.

Last month, Quest announced it was acquiring the outreach laboratory services of San Francisco-based Dignity Health, a large hospital system operating throughout much of California that was formerly known as Catholic Healthcare West.

But those deals may be the exception to the rule.

"Other than a few deals from Quest/LabCorp, the M&A market has basically been non-existent," said Brian Carr, chief executive officer of Regional Diagnostic Laboratories, a Nashville-based firm founded a year ago to focus on making hospital lab acquisitions and backed by $250 million in capital by Warburg Pincus. "For the most part, there are no buyers in the market."

Carr, who was out of the country earlier this month and responded to questions by e-mail, noted a variety of factors that are creating uncertainty in the market. They include recent steep cuts in the technical component of CPT Code 88305 by the Centers for Medicare and Medicaid Services, the acquisition of physician practices by large hospital systems in some markets, and the uncertainty of how laboratories will be integrated into the ever-growing number of accountable care organizations.

Deals Still Make Sense

Nevertheless, industry observers believe acquiring hospital outreach businesses makes sense.

As many as 30 million Americans are expected to gain insurance coverage over the remainder of the decade as large swaths of the Affordable Care Act (ACA) are enacted next year. Millions of baby boomers are also toddling toward Medicare eligibility and the consumption of even more medical services. Therefore, the overall market for basic lab testing is expected to grow, even though national labs such as Quest have struggled with flat revenues in recent years.

"Hospital lab strategies seem to be the path independent labs are heading down," said Piper Ellich analysts Kevin Ellich and Bradley D. Maiers said in a recent report. "While lab volumes have been weak for over 12 months, we believe the independent labs are focused on partnering and acquiring hospital labs and outreach programs."

But the strategy may be the best fit for national companies such as Quest and LabCorp, whose market power and cash hoards—nearly $1 billion combined—afford them a heap of patience.

According to Piper Ellich, the bottom-line gains for the two Quest deals are relatively small: up to $80 million a year for the Dignity Health business and $30 million to $40 million for the UMass deal. That would represent a 1.7 percent bump in annual revenues based on Quest's 2012 numbers.

Moreover, Ellich and Maiers reported that volume at the UMass lab are down between 10 percent and 20 percent since the deal was announced—the kind of numbers Quest will be challenged to build back up over the coming years.

Long Timelines

Meantime, those looking for quicker gains may not find the market as attractive, observers say.

"Quest is a global company. They plan on staying in the business for the long term, they have lots of money, and they are looking for hospital outreach to really grow their business and survive during health care reform," said Susan Stegall, a laboratory consultant in Youngstown, Ohio.

That may be why Quest—which did not respond to a request for an interview—has been diving into the hospital outreach market, while other seemingly big players for hospital outreach labs have been decidedly more hesitant to do so.

"It's a long-term strategy because there is still uncertainty in the larger market as to where this is going—there's so much experimentation in new delivery models," said Dennis Weissman, president of Dennis Weissman & Associates, a laboratory consulting firm in Washington, D.C., and founder of G2 Intelligence. "More providers are at risk, and there is a pretty strong sense that the industry is moving toward further realignment, and no [specific] sense in terms of where we're going to end up."

However, that tends to play to the advantage of hospitals, according to Stegall. No matter how the ACA unfolds, they need capital to invest in health care information technology systems to deal with the influx of new patients and to meet many of the new quality care mandates. In California, systems such as Dignity Health have been spending billions of dollars to meet tough seismic standards that were introduced in the mid-1990s—in many cases, building replacement hospitals because it's easier than retrofitting.

"In this environment, with the reimbursements down, they can buy labs for cheap," Stegall said.

"A hospital CFO has to weigh the possible returns for the diagnostic area and where they can get more of a return," Weissman said. "One of the options is to sell the lab if they can use the money for better returns."

Financial considerations or not, hospital labs tend to be toward the bottom of the hierarchy when considering strategic moves involving capital projects. Even for a relatively minor job such as redesigning the emergency room, it's often recommended that hospitals scrap their existing lab space for the new project, according to Phillip Monteleoni, a veteran hospital architect who worked for decades in New York City before retiring several years ago.

It is those factors, in part, that have been driving Regional Diagnostic Laboratories to take a decidedly different tack than Quest and LabCorp.

On the Sidelines

Carr admitted that his company "is on the sidelines" for now based on the current market conditions. The company Web site, which has been contracted to a single landing page, is being redesigned, he added. However, he dismissed whispers that the venture is being shut down.

"It is our intention that this is temporary," Carr said. "Warburg Pincus has a long time horizon and remains committed to me, RDX and the laboratory diagnostic space."

Carr told *Laboratory Industry Report* last fall that Regional had backed away from closing two deals, including one so close to completion that job postings for the lab were on the company's old Web site. Regional has since backed away from additional opportunities, Carr noted, a decision he said was "wrenching" but would have led to the company owning assets that would now be worth substantially less than what they would have paid for them (due in part to the differences in payment for hospital laboratory services versus services provided by independent labs).

"Our experience in the laboratory business over the last 25 years allowed us to see the early indications of a business downturn in the diagnostic laboratory industry," Carr said. "We believed that laboratories would be challenged to navigate/counter the predicted trends we were foreseeing over the next 12 to 24 months."

Although Carr is optimistic that eventually the market will be primed for hospital outreach acquisitions, the time horizons envisioned by Regional, Carr, and Warburg Pincus may not be the same as Quest and LabCorp, according to Stegall.

"(Carr) has a reputation of buying up labs and flipping them," Stegall said. "His perspective and what he is trying to do is really different from what Quest is doing. He's in it for the short term. He wants to get in there, fix up the asset, sell it off, and make money for his investors. I see it as two different strategies in this era of health care reform."

■ Interim CMS Molecular Pricing Setting Off Alarms, *from page 1*

A group of nine trade organizations related to the laboratory sector—including the College of American Pathologists (CAP), the American Clinical Laboratory Association, and the California Clinical Laboratory Association (CCLA)—last week asked CMS to hold off on finalizing the prices as planned in September after a 60-day public comment period that commenced last week as well. It also asked the agency to hold open-forum sessions to address the lab sector's questions and concerns.

"The whole process has gone awry. It's really quite difficult at this point," said Michael Arnold, executive director of the CCLA.

The CCLA has been instrumental in lobbying Palmetto GBA, the regional MAC for California, to raise the prices on some tests. Palmetto was among the first contractors to announce its initial MoPath pricing, and many other contractors have used those rates as a basis for setting their prices. Palmetto agreed last month to adjust pricing for eight higher-volume tests, raising them a nonweighted average of 75 percent.

Molecular Prices, Codestacking vs. New Interim CMS Prices

Code	Test	Code Stacking Price	New Mean Price	Difference
81200	Canavan Disease Mutation	$213.00	$99.68	-$113.32
81225	CY2C19 Genotype	$290.00	$223.10	-$66.90
81235	EFGR mutation analysis	$302.00	$184.90	-$117.10
81241	Fragile X mutation analysis	$136.00	$72.77	-$63.23
81275	KRAS mutation analysis	$911.00	$233.97	-$677.03
81291	MTHFR DNA analysis	$130.00	$86.55	-$43.45
81350	UGT1A1 Genotyping	$83.00	$74.02	-$7.98

Source: XIFIN, CodeMap, Piper Jaffray

However, the increases did not cover another 106 tests. And the rationale accompanying CMS's decision-making process noted that the MACs were permitted to collaborate with one another on their pricing and that several became reliant on Palmetto's lead.

Early Stages

Jonathan Myles, M.D., chairman of the CAP economic committee, preferred to take more of a long view. "We are in the early stages of the gap-fill process," he said. "It is important that the various stakeholders and payers realize this is not final."

But Myles, who serves as the CAP's liaison to the American Medical Association's committee that helps set pricing for medical procedures, said the actual cost data for performing the tests has not been closely scrutinized by the MACs or CMS. "If they converted that into real dollars, they would be significantly greater than the posted prices," he said.

Myles added that the comment period is likely to encourage some upward adjustments on the prices. However, he noted that the process for the price setting has not been appropriately open to all the parties—a concern shared by others.

"We have to yet to see any real rationale or transparency to the gap-fill process," said Rina Wolf, vice president of commercialization strategies, consulting, and industry affairs for XIFIN, a San Diego-based revenue cycle management firm. Wolf has been actively tracking developments in pricing of molecular pathology tests.

INDUSTRY BUZZ

Sloan-Kettering, Foundation Enter Into Test Development Pact

Memorial Sloan-Kettering Cancer Center in New York City has entered into a deal with Foundation Medicine to develop a new molecular-based diagnostic test to optimize the treatments for hematologic cancers.

The deal is intended to accelerate Foundation's product development in molecular diagnostics. The company, which is based in Cambridge, Mass., and operates a CLIA-certified laboratory there as well, currently has a single product on the market. FoundationOne provides genomic profiles on solid tumors. The $5,800 test provides oncologists information to determine more specific clinical pathways for treating their patients.

The primary hematologic cancers include leukemia, lymphoma, and myeloma. There are about 48,000 cases of leukemia diagnosed in the United States every year, while another 1 million patients are battling various forms of lymphoma and myeloma.

"We are partnering with Foundation Medicine to develop a best-in-class assay for hematologic cancers because we view achieving this goal as an extension of our mission as a comprehensive cancer center: Making it possible for all patients to be treated with the therapy that is matched with their individual cancer," said Craig B. Thompson, M.D., Sloan-Kettering Cancer Center's president and chief executive officer. Sloan-Kettering is the largest private cancer research institution in the United States.

Under the terms of the deal, Sloan-Kettering researchers will focus on RNA and DNA sequencing to develop a new test to help craft more focused treatments for hematologic cancer patients. Foundation will contribute technology and computational algorithms, as well as market and distribute the test.

"Our approach is to collaborate with leaders like Memorial Sloan-Kettering across all areas of clinical oncology and cancer genomics and seek partners who are equally committed to the changing paradigm of cancer care," said Michael J. Pellini, M.D., Foundation Medicine's chief executive officer. "This is the ideal partnership to support the development of our new product for patients with hematologic malignancies."

A Sloan-Kettering spokesperson did not respond to a request for comment as to whether the deal contains a revenue-sharing component.

The new test is expected to be available by the end of 2013, officials said.

References

California Clinical Laboratory Association
916-446-2646

College of American Pathologists
800-323-4040

Foundation Medicine
617-418-2200

LabCorp
800-845-6167

Memorial Sloan-Kettering Cancer Center
212-639-2000

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Quest Diagnostics
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615-577-5888

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