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COLA Earns Deeming Authority For California Laboratories

California has become the Golden State for COLA. After an arduous application process that lasted for nearly two years, COLA became the first private firm in the state's history to earn deeming authority for both federal as well as California state lab certification.

COLA, which was known as the Commission on Office Laboratory Accreditation when it was founded in 1988, also holds deeming authority for both state and federal inspections in five other states where there is a complimentary state inspection, including populous ones such as Florida and Pennsylvania. But California is the most populous state by far where it operates.

"This approval validates COLA's . . . commitment to patient safety," said Douglas Beigel, COLA's chief executive officer. "This is particularly important in California, where laboratories face a complex set of state laws and regulations concerning quality activities, as well as the personnel who can supervise and perform testing."

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Two National Labs Still Struggling With Bottom Lines

The first quarter of the year was hardly a heady one for the nation's two largest laboratories, but there appears much room for improvement for the remainder of 2014.

Pinched by lower reimbursements and bad winter weather, New Jersey-based Quest Diagnostics reported lower revenues for the seventh consecutive quarter. But this time it was also joined by North Carolina-based LabCorp, which has had a generally easier time of holding the line against revenue erosion.

Altogether, Quest's revenue of $1.75 billion was down 2.3 percent compared to the first quarter of 2013's $1.79 billion. But LabCorp's revenue was also down 1 percent, to $1.43 billion from $1.44 billion, taking a $42 million weather-related hit for the quarter.

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COLA Earns Deeming Authority for California Laboratories, *from page 1*

California lawmakers decided to farm out deeming authority to private operators after the Laboratory Field Services Division of the California Department of Public Health (CDPH) began to fall behind in its semiannual inspection and accreditation process. Although legislation to allow private organizations to take over the process was signed into law in 2009, the complexity of California's regulations and putting together a certification process for outside firms to obtain deeming authority took years.

Beigel said the organization also had to undergo the arduous process of cross-walking every facet of its accreditation program to California's set of existing laboratory regulations.

"It was an exhaustive list, probably the most detailed list of any state," Beigel said. "We had to ask ourselves how to write appropriate deficiencies. We talked about surveyor guidelines." He added that the organization's ISO 9000 certification was a big help in getting through the process.

Moreover, Beigel noted that California officials did not want to merely accept what he termed a "global statement" of how it would go about the deeming process. "They wanted to make sure we accepted their fundamental approaches to laboratory medicine," he said.

CDPH spokesperson Matt Conens confirmed that COLA is the first private organization in California to obtain deeming authority for labs. Applications have also been submitted by the College of American Pathologists, the Joint Commission, and the American Association of Blood Banks. Those applications remain pending.

The deeming process could prove fairly lucrative for COLA. In addition to the fees labs must pay to the CDPH to maintain their ongoing certification, COLA charges anywhere from $1,384 to certify a low test-volume lab to well over $5,950 for labs that perform more than 1 million tests annually.

A total of 432 labs in California have chosen COLA to conduct their federal accreditation inspections and reviews, and hundreds of others have the option of doing so in the future, according to a spokesperson with the organization. COLA has not yet hired any new employees to supervise the compliance process in California, Beigel said.

Under California law, COLA is also obligated to provide educational services to California's laboratories, the only requirement of its kind in the nation, according to Beigel. As a result, COLA will offer Web-based e-learning tools on issues such as safety and compliance, as well as ongoing webinars. The organization also held a summit in San Francisco late last month on laboratory medicine and its importance in patient outcomes.

"We are just getting started on getting the word out" regarding COLA's new role in California, Beigel said.

Takeaway: The most populous state is turning over laboratory accreditation duties to private entities, which will likely compete for this business over time.

Few Lab-Related Medical Errors Are Caused by Lab Operations

When an error occurs involving patient diagnostics, the laboratory itself is rarely at fault directly.

That is the finding of an extensive survey of diagnostic-related errors by the patient safety division of the ECRI Institute. The Pennsylvania-based medical quality think tank analyzed more than 2,400 incidents related to laboratories that occurred between 2011 and the middle of last year. They were categorized into 14 different types.

According to data gathered by ECRI, laboratory-related errors are the fourth-leading cause of medical errors, accounting for about 10 percent of the 287,000 reported to the organization by providers between 2009 and the middle of last year. However, they are the second most-cited error in medical malpractice lawsuits, with awards averaging more than $395,000 between 2008 and 2012.

Mislabeled specimens were the leading cause of the incidents, occurring 31 percent of the time. The largest number of errors, 626, or 26 percent of the total, took place in inpatient general care areas of hospitals, particularly in the emergency department.

"Strategies to reduce diagnostic errors involving laboratory testing must entail all phases of the laboratory testing process and engage all stakeholders in that process."
—Karen P. Zimmer, M.D., Medical Director, ECRI's patient safety operations

Of the laboratory-related incidents, only 4 percent—or fewer than 100—occurred within the physical walls of the laboratory. Most of the errors—74 percent in total—occurred during the preanalytic phase, when tests are being ordered and specimens are being collected and transported.

Data on how much harm the errors caused to patients were incomplete, with the impact of only 42 percent of the events recorded. Among those fully traced incidents, four were harmful enough to lead to a patient's hospitalization. Another 24 resulted in temporary harm that required medical intervention.

The report recommended a variety of ways to reduce errors, most of them related to technology. They included using standardized measures for identifying patients and specimens and keeping them aligned through the use of electronic bar coding and radio frequency identification tags.

As for less technologically oriented solutions, the report recommended that labs build a process map or flowchart to understand the sequence of events required to test a specimen and that it be used in conjunction with root cause analysis to pinpoint the origin of any issue.

To that end, the report recommended that staff be educated regarding compliance and patients be reminded about the importance of their involvement in the testing process. It also suggested creating a series of team-building exercises designed to break down barriers between the laboratory and patient care staff.

"Strategies to reduce diagnostic errors involving laboratory testing must entail all phases of the laboratory testing process and engage all stakeholders in that process," said Karen P. Zimmer, M.D., medical director of ECRI's patient safety operations.

Takeaway: Although they can be extremely costly, laboratory-related errors rarely take place within the four walls of a laboratory, and most do not rise to the level of causing patient harm.

CCLA Files Suit Over MAC Local Coverage Determinations

The ongoing friction between providers and Medicare Administrative Contractors (MACs) was elevated by a lawsuit filed last month by a leading laboratory lobby claiming the local coverage determination (LCD) process is arbitrary and restrictive.

The lawsuit, filed April 18 against the U.S. Department of Health and Human Services (HHS) in federal district court in the District of Columbia by the California Clinical Laboratory Association (CCLA), comes as the lab sector continues to be pressured by a combination of reimbursement cuts and claims denials—a trend some in the lab sector say originates with the MACs.

The MACs, which serve as regional administrators for the Centers for Medicare and Medicaid Services (CMS), have been the focus of provider ire for several years. Another service many MACs perform, recovery audit contracting, is being aggressively questioned by hospitals, particularly over the payment of claims for patients who are only hospitalized for a day or two.

However, the LCD issue with labs is in a way more existential in nature—the venue where the care is being delivered is not being debated, but whether assays should be employed and paid for at all.

"It seems to be a process with complete unilateral authority to ignore . . . scientific evidence to understand these issues, and our folks have finally decided something has to be done to address the problem," said CCLA President Michael Arnold.

The suit pivots on a patient denied access to lab testing: an 82-year-old retired nurse and Medicare Part B enrollee who suffers from chronic illnesses that require an extensive drug regimen—drugs that at times have caused allergic reactions so severe that she has contacted the Food and Drug Administration (FDA) to obtain more information on their potential side effects.

The suit claims that Palmetto GBA, the MAC that leads the way in approving coverage for molecular diagnostics through its MolDx program, began unilaterally denying such testing under an LCD it approved in March. That's despite the fact the FDA received more than 210,000 reports regarding serious adverse events to therapeutic drugs in 2012 alone. The suit claims that the LCD is in conflict with the Medicare edict that providers should be able to provide reasonable and necessary services in order to treat their patients.

Arnold calls the woman, whose identity was kept confidential, the "perfect person" to serve as a plaintiff. Her age and situation renders her immediately sympathetic, and Medicare enrollees are a potent political force in the United States. The type of testing she requires—which falls under the mantle of

personalized medicine—is considered crucial to the future growth of the laboratory sector. Moreover, she requires molecular testing—another type of assay crucial to the sector's future—and one that the MACs have been systematically denying, according to the suit and industry observers.

Francisco Velázquez, M.D., chief executive officer of Spokane, Wash.-based PAML, noted that the MACs have been targeting molecular tests for LCD-based denials in part because of their costs, which can easily climb into the four figures.

The lawsuit notes that Palmetto, which makes LCDs in several populous states, issued a directive earlier this year that bars coverage of any molecular tests unless it gives its explicit approval, whether through an LCD or another process.

But aside from molecular testing, far less pricey assays are also being curbed, according to Velázquez.

> ***"We are seeing overall general payers being somewhat more restrictive."***
> ***—Francisco Velázquez, M.D., Chief Executive Officer, PAML***

"We have seen more restriction on testosterone and vitamin B testing as well," he said.

According to the suit, various MACs have also adopted inconsistent LCDs regarding testing for illicit drugs or prescription drug abuse, which has been another growth segment for laboratories, although it is unclear how large a market exists among the Medicare population. In some regions, a negative result from a more basic drug test bars the use of more sophisticated testing.

The lawsuit also claims that the LCDs promulgated by one MAC may have a national impact because it may regulate a lab operating within a specific jurisdiction but govern how they perform testing throughout the United States.

OIG Cites LCD Inconsistencies

HHS may not be completely unsympathetic to the laboratory sector. Its Office of Inspector General published a report last January concluding that LCDs create inconsistencies in Medicare coverage. "The presence of . . . LCDs was unrelated to the cost and utilization of items and services," a portion of the report read. "Furthermore, LCDs limited coverage for these items and services differently across states. LCDs also defined similar clinical topics inconsistently." The OIG recommended that CMS create a new plan to create more consistency between LCDs by region and that its evaluation of LCDs take into account how they impact coverage for patients nationally.

Labs are not completely powerless regarding the LCDs, but their ability to push back against them is fragmented. Currently, they must appeal

each claim denial individually. The appeals process can go through five separate steps, including a hearing in front of an administrative law judge, whose backlogs often last for months, if not years. And if certain filing deadlines are not met in contesting a denial, the labs are completely barred from pursuing them.

The process can be so cumbersome that hospitals have dedicated staff or law firms specifically assigned to appeal claims denials. Labs, which tend to be much smaller than hospitals—and are likely contesting claims of a smaller monetary amount—may not have the resources to do so.

Moreover, the MAC-issued LCDs have a tendency to seep into the policies of commercial payers, the lawsuit claims and Velázquez has confirmed.

"We are seeing overall general payers being somewhat more restrictive," Velázquez said. This has placed labs like PAML in the curious position of "whether we should do the test [at all], or risk getting paid very little, or do we have to put more burden on the patients," he added.

And there is connective tissue between the MACs and private payers. Palmetto is owned by Blue Cross of South Carolina. WellPoint, a large national insurer, owns another MAC, Noridian.

Partly a result of noncoverage policies, PAML recently launched a pilot project of inserting a new patient financial responsibility form into the testing process. Such forms—which communicate that the patient's insurer may not pay for their assays and therefore they may have to foot the bill instead—are being distributed at three PAML testing centers in Washington state, a first in the lab's 59-year history.

The initial results have not been encouraging. "Patients were not happy they had to read another form. And they are concerned that the test is expensive, and they are wondering how they are going to pay for it," Velázquez said.

That these issues have bored in on labs made the CCLA lawsuit all but inevitable, Arnold said, but he added that it is also a "last resort."

A trial date for the lawsuit has not been set, but it is likely being utilized more as a tool to get HHS and the MACs to enter negotiations about the setting of LCDs for lab testing.

If the lawsuit does eventually lead to change in that process, it is likely to take years. Hospitals and HHS have been tussling for well over a year over rules intended to clarify what constitutes a short inpatient stay subject to an audit by MACs. A resolution on that issue is not yet in sight.

Takeaway: The lab sector has entered into what it considers a "last resort" battle over the use of local coverage determinations by the Medicare program's fiscal intermediaries. G2

■ Two National Labs Still Struggling With Bottom Lines, *from page 1*

In a conference call with analysts, Quest Chief Executive Officer Steve Rusckowski said the unusually harsh winter weather cut into revenues by about 2 percent, or about $35 million. However, he was fairly upbeat for the remainder of the year.

"While the slow start to this year clearly is a challenge, we are confident that progress we have made on growth initiatives, particularly as a result of acquisition activities, will enable us to meet our commitments," he said, adding that he was committed to "restoring growth."

Test volumes for Quest were down 2.8 percent, and revenue per requisition was down by the same amount. Quest has made two major acquisitions in recent months, including Solstas Lab Partners and Summit Health, and the just announced acquisition of the hospital outreach operations for Steward Health Care.

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>
> ***—Steve Rusckowski, Chief Executive Officer, Quest Diagnostics***

"M&A will be a key component of growth" in the coming months, wrote analyst Michael Cherny of ISI Group in a recent report.

In addition to the acquisitions, which Rusckowski believes will boost revenues, he also said the addition of newly insured lives in late 2013 and early 2014 as a result of the rollout of the Affordable Care Act is also expected to generate growth.

Meanwhile, both companies also reported sharply lower net income. Quest's was $104 million, down nearly 24 percent from the $136 million it reported during the first quarter of last year. Much of that drop—$27 million—it attributed to ongoing restructuring costs. LabCorp's net was also down, to $113.5 million from the $147.2 million it reported in the year-ago quarter—a drop of 23 percent. Like Quest, LabCorp also took a charge for restructuring, to the tune of $7.6 million.

But LabCorp Chief Executive Officer Dave King was also upbeat. "We delivered a quarter with solid volume growth and strong earnings despite the greatest weather impact in our company's history," he said in a statement. The weather eroded LabCorp's revenue even more than Quest's, causing it to drop 2.9 percent overall. The company maintained its forecast of revenue growth of 2 percent in 2014, despite the down quarter. Test volumes were up 3.3 percent, but revenue per accession was down 3.3 percent.

Darren Lehrich, an analyst with Deutsche Bank, trimmed LabCorp's full-year revenue estimates to $5.93 billion from $5.94 billion but still noted that would represent a 2.2 percent year-over-year growth. However, he continues to project the company will post 2015 revenues of nearly $6.2 billion, which would be a 5 percent gain.

As for both labs, Lehrich believes that the new patch in the sustainable growth rate payment formula recently approved by Congress and some near-term resolution regarding pricing for molecular testing should help their bottom lines further into the year.

Takeaway: Quest and LabCorp had downbeat first quarters, but both expect improvements before year's end.

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INDUSTRY BUZZ

PCLS Moves Into Hospital-Acquired Infections Testing

Physicians Choice Laboratory Services (PCLS), the South Carolina-based toxicology and pharmacogenomics lab, is inching into new territory: Hospital-acquired infections (HAIs).

PCLS has acquired San Diego-based MultiGEN Diagnostics for undisclosed terms. Although a relatively tiny operation, MultiGEN has developed a platform that uses the Sanger sequencing method with up to 20 genetic targets in a single analysis, up from two to four targets in past iterations of this test. It also lowered the reagent price point for such an analysis from about $20 an assay to about $2, according to Joe Wiegel, PCLS's president.

The MultiGEN acquisition is currently being fused with a minority stake PCLS recently took in HealthCure, a Michigan-based company that consults with providers on reducing their rate of HAIs. Most of MultiGEN's staff has been relocated to PCLS headquarters in order to better integrate the operations of the two firms. Several technicians and technologists will be added to its existing staff.

"We have an initiative to expand our service offerings to allow us to work closely with hospitals, and HAIs really hit hospitals hard in the pocketbook," Wiegel said. According to a 2013 study in the *Journal of the American Medical Association*, HAIs cost hospitals at least $10 billion annually to combat and treat. The Centers for Disease Control and Prevention concluded that HAIs such as methicillin-resistant Staphylococcus aureus and C. difficile infect about 2 million patients a year, killing about 100,000 of them.

Wiegel envisions integrating MultiGEN assays into HealthCure's overall product offerings, which includes a focus on long-term suppression of bacteria colonization in hospital settings. He suggested they could be used as part of HealthCure's environmental assessment of a hospital to determine where harmful bacteria is most highly concentrated. It could also be used to screen incoming patients to determine if they are bringing potentially harmful bacteria into the hospital. Turnaround time for such screenings could be less than one day, he added.

For the moment, MultiGEN-HealthCure will focus on community hospitals, but Wiegel observed that "there is nothing necessarily limiting us to a specific type of hospital."

Takeaway: Physicians Choice Laboratory Services is using strategic acquisitions to expand its testing portfolio.

References

California Clinical Laboratory Association
916-446-2646

California Department of Public Health
916-558-1784

COLA
800-981-9883

ECRI Institute
610-825-6000

HealthCure
313-743-2357

LabCorp
336-229-1127

PAML
509-927-6250

Physicians Choice Laboratory Services
855-900-2927

Quest Diagnostics
800-222-0446

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