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LABORATORY

INDUSTRY REPORT®



Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

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Congress Approves Bill Averting 'Fiscal Cliff'; Deal Prevents 27% Medicare Cuts for Docs

A bill passed by Congress on New Year's Day will delay for two months across-the-board spending cuts for defense and domestic agencies and block a 27 percent cut in Medicare reimbursement for physicians for one year. The two-month delay in the automatic sequester will put off the 2 percent cut to the clinical laboratory fee schedule until March 1.

The measure, expected to be signed by President Obama, would extend tax cuts on incomes up to \$400,000 for individuals and \$450,000 for couples. Earnings above those amounts would be taxed at a rate of 39.6 percent, up from the current 35 percent. It also extends Clinton-era caps on itemized deductions and the phaseout of the personal exemption for individuals making more than \$250,000 and couples earning more than \$300,000.

Under the agreement, estate taxes would be taxed at a top rate of 40 percent, with the first \$5 million in value exempted for individual estates and \$10 million for family estates. In 2012, such estates were subject to a top rate of 35 percent.

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Drug Abuse Issues Creating Niche for Testing Labs

The old proverb about a crisis creating an opportunity is being employed by laboratories that work within the niche of medication testing.

The crisis? Prescription drugs are being abused at historically high levels, particularly the powerful time-release opioids that were introduced by pharmaceutical makers in the 1990s. Such drugs have a variety of uses, from treating cancer patients to an aging population plagued by a growing number of aches and pains. And demand has been nearly insatiable: Sales of OxyContin grew sixfold from its introduction in 1997 to 2001, making it the best-selling pain reliever in U.S. history.

However, drugs such as OxyContin are also being regularly sold illegally or stolen, ground into powder to defeat its time-release

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Upcoming Conferences

Molecular Coding and Billing Workshop:

How to Get the Right Payment in 2013

Jan. 24, 2013

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Atlanta

www.G2Intelligence.com/codingworkshop

Volume to Value

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The Westin Beach Resort & Spa
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www.G2Labvalue.com

Pathology Institute

Grow Your Practice in Turbulent Times:

Pathology Business Models and Strategies That Work

Feb. 28-March 1, 2013

The Westin Beach Resort & Spa
Fort Lauderdale, Fla.

www.G2Path.com

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■ CONGRESS APPROVES BILL AVERTING 'FISCAL CLIFF,' from page 1

Taxes on capital gains and dividend income exceeding \$400,000 for individuals and \$450,000 for families would increase from 15 percent to 20 percent. The measure also addresses the alternative minimum tax and indexes it for inflation to prevent nearly 30 million middle- and upper-income taxpayers from being hit with higher tax bills averaging almost \$3,000.

The bill allows a two percentage point cut in the payroll tax for Social Security to lapse, which restores the tax to 6.2 percent. It also extends jobless benefits for the long-term unemployed for one year. 

Reference Testing Continues to Grow, Finds G2 Survey

Despite the lingering effects of the 2008 financial crisis and the great recession that followed, a new survey by G2 Intelligence concludes that the laboratory reference testing market experienced relatively solid growth in 2011.

The survey, *U.S. Laboratory Reference Testing: Market Profiles and Pricing Trends 2012*, queried 154 laboratory industry executives. More than 77 percent were affiliated with hospital laboratories, 15.6 percent were from independent or commercial labs, and the remainder were from physician office labs and pathology groups.

The survey concluded that the reference testing sector grew to \$6.9 billion in revenue in 2011, compared to \$6.2 billion in 2010. Both hospital and independent/physician lab testing grew at similar clips. Hospital testing volumes reached \$4 billion in 2011, compared to \$3.6 billion in 2010, while independent/physician lab testing grew to \$2.9 billion in 2011, up from \$2.6 billion in 2010.

However, there has been a growing reluctance for labs to refer their work to other labs for testing. The laboratories queried for the survey send out an average of 11.3 percent of their reference testing to other labs. Hospitals send out a similar amount: 11.1 percent. Physician office laboratories and pathology labs send out a significantly higher volume of their work: 24.3 percent. However, the total volume of work that is sent out dropped 0.3 percent between 2010 and 2011, and G2 Intelligence projects a similar volume drop for 2012. More than three-quarters of those surveyed attributed the drop in part to a campaign to widen their test menus and perform more esoteric assays in-house.

Additionally, the role of health care information technology is also growing, according to the survey data. Nearly 80 percent of the respondents said that IT capabilities are "very important" when choosing a lab. "Due to the rising cost of health care and an increasing demand by patients and insurers for better quality care, health care organizations are being driven to create and implement cutting-edge technology and IT solutions as they manage new mandates," the report concluded.

In addition to the growth data, the report delves into the market share for the nation's largest laboratories, prices for the most common tests, turnaround times by lab, and which lab offers the best value.

The entire 54-page survey is priced at \$995. It may be obtained at www.G2Intelligence.com or by calling 800-401-5937. 

Automation Has Benefits but Also Poses Plenty of Risks

Growth in the laboratory business traditionally comes from consolidation and acquisitions. But can the automation of lab processes play a role in business expansion?

That was the question posed by pathologist Robert Boorstein, M.D., founder of the ClasGroup Co. and the former medical director of Enzo Chemical Labs, at G2 Intelligence's Lab Institute in Arlington, Va., last October.

The answer: It depends.

"Automation is here," Boorstein said. "The question is—how do you make it work?"

As Boorstein observed, automation can be a savings and efficiency boon for laboratories if it is done correctly. In one example, a lab was able to use automation to increase test volumes by 20 percent, cut turnaround times by 11 percent, and save \$100,000 in labor costs. In another, workloads all but doubled while staff was cut by about one-third.

But Boorstein noted that dramatic efficiencies can often be achieved just by streamlining operations rather than through automation. In short, automation is not a quick fix.

"You need to commit large amounts of resources in many areas," he said, noting that it requires space, retrofitting of space, information technology demands, and specific training of employees. He later added that "there is a tendency to go to an [automation] vendor and take what they sell" without assessing a laboratory and the parent health care organization's needs beforehand.

Some Efforts Disastrous

The results can be disastrous: In one instance, Boorstein cited a lab whose automation process was so troubled that it abandoned the project halfway through, selling equipment even before it had been used. Eventually, 300 people were laid off as the lab was forced to wind down operations. In another, a university medical center automated two labs but was forced to divert many tests to a third nonautomated lab.

Establishing Guidelines

Boorstein recommended developing guidelines for establishing whether automating is a success before undertaking such a project. That includes ensuring the automation is actually working and is state-of-the-art, ways to mark improved productivity and quality, and synergistic success—is the initiative dovetailing with and even driving the overall quality and efficiency goals of the health care organization?

Perhaps even more important is getting employees to buy in, particularly given some jobs may be at stake as the result of the automation. "You need clear leadership. You need to have a clear mission as to why you are moving forward. . . . [Y]our lab is not going to rise and fall on automation, but whether or not you can get the results to the doctors," he said. **G2**

PAML Purchases Minority Stake in CellNetix

Spokane, Wash.-based Pathology Associates Medical Diagnostics Laboratories (PAML) has entered into a letter of intent to purchase a minority share in Seattle-based CellNetix.

The companies, which announced the transaction last month, said it was the culmination of months of discussions prompted by recent changes in the health care industry. A joint statement issued by the companies remarked on a record number of partnerships, joint mergers, and other transactions in the health care industry. It did not disclose the terms of the transaction or how much of a stake CellNetix's management had agreed to sell.

PAML, which is a national laboratory that has been operating in the Pacific Northwest since the 1950s, is owned by two major hospital operators, Seattle-based Providence Health & Services and Catholic Health Initiatives in Englewood, Colo. It focuses primarily on mainstream testing. CellNetix, which has 45 pathologists on staff and provides services in Washington, Idaho, Alaska, and Oregon, focuses more on molecular diagnostics, although it offers a full suite of services.

"CellNetix and PAML have had a strong working relationship for many years. This investment by PAML strengthens our alliance, creates a tremendous opportunity, and provides a foundation for synergistic initiatives in a much wider arena," said Don Howard, M.D., CellNetix's chief executive officer.

CellNetix has been fairly aggressive in terms of pursuing deals and came close to acquiring Eastside Pathology in Bellevue, Wash., a few years ago. PAML has seen its volume of routine medical testing and associated revenues remain flat in recent years. PAML Chief Executive Officer Francisco Velazquez, M.D., has suggested the company would find ways to expand its menu of esoteric tests.

"For over 50 years, PAML has been a profitable and growing organization. But health care delivery is changing rapidly, so we are taking proactive steps to ensure continued expansion and success," Velazquez said. "The partnership between CellNetix and PAML is uniquely positioned to capitalize on the increasing needs of the integrated care market." 

OPKO Acquires OURLab for Prostate Cancer Platform

Miami-based pharmaceutical and diagnostics firm OPKO Health has acquired the controlling company for Oppenheimer Urologic Reference Laboratory, a Nashville-based laboratory owned by ProstData Inc. Terms of the transaction were not disclosed.

In addition to its laboratory, OURLab, which was founded in 1996, operates a network of 18 phlebotomy sites and also services hospitals. It focuses

primarily on prostate and bladder histologies but also performs several molecular pathology tests. The company's test volumes were unavailable.

OPKO has acquired a number of firms over the past year, although most have been in the pharmaceutical or research arena, and it has not acquired a laboratory in the past. It has a working relationship with Lab-Corp to complete the development of an Alzheimer's panel and market it as a laboratory-developed test.

Company officials said it would use the acquisition of OURLab as a platform to launch its 4KScore test, which uses biomarkers and algorithms to detect prostate cancer.

"We look forward to working together with OURLab's talented personnel," said Phillip Frost, M.D., OPKO's chairman and chief executive officer. 

OIG Permits Physician-Hospital Interface for Lab Testing

The Department of Health and Human Services' Office of Inspector General (OIG) has ruled that it would be appropriate for hospitals to allow a free electronic interface to physicians to order and obtain lab results and other patient information.

The OIG's ruling by its chief legal counsel, Gregory E. Demske, provides some clarity as to whether such interfaces violate anti-kickback laws under the Social Security Act by inducing a physician to make a patient referral to another provider.

According to the decision, the physicians in the community would not be receiving a kickback if they were allowed to use the interface, which permits disparate electronic health care record systems to communicate with one another. The OIG concluded that since the interface would only involve the transmittal and receipt of laboratory and other results, nothing of a specific monetary value was flowing between the hospital and the physicians.

In this instance, the interface would be available to all physicians, although the OIG believed that geography would limit the number of doctors who would actually use the interface.

The decision itself is not binding on other cases, Demske noted.

The OIG has been tough on recently proposed arrangements involving laboratory services and clinicians. In 2011, it rejected a proposed arrangement that would have permitted a laboratory to provide allergy testing services within a physician practice, noting that the as-needed basis of the arrangement, along with the collection of a percentage of revenues for the testing, would violate the law. 

■ DRUG ABUSE ISSUES CREATING NICHE FOR TESTING LABS, *from page 1*

element, and injected. As a result, a bottle of 100 OxyContin tablets can fetch \$3,000 or more. And that is just one pain-relieving drug being abused. According to the Centers for Disease Control and Prevention, deaths from prescription drugs now outnumber deaths from nonprescribed controlled substances. In 2009, the American Academy of Pain Medication recommended that urine drug testing become a routine part of pain care.

States Cracking Down

As a result, several states have been cracking down. For example, Tennessee recently passed stringent laws requiring physicians to input data into a centralized database on each pain medication each patient is receiving within seven days of writing a prescription.

“For the last two years, unintentional drug overdose is the number-one cause of death in Tennessee over motor vehicle accidents, homicides, or suicides,” said David Reagan, M.D., chief medical officer for the Tennessee Department of Health.

The opportunity? While growth for many traditional testing laboratories has been flat in recent years, prescription drug abuse trends have been a boon for medication testing labs.

Baltimore-based Ameritox, with 800 employees, is one of the largest businesses in this niche. It has two large labs in Midland, Texas, and in Greensboro, N.C., the latter opened in 2010. The company was founded in 2000 and originally focused on forensic toxicology but pivoted toward medication testing in 2004—a change that led to more private investors and rapid growth.

While Ameritox officials would not release revenue data, they say sales have been growing consistently, fueled by the ever-growing number of pain management medical practices that prescribe OxyContin and other powerful painkillers.

“There has been a growing trend of prescribed opiates, and with that has come an increasing specificity of clinical recommendations,” said Harry L. Leider, M.D., an Ameritox senior vice president and the lab’s chief medical officer. In Kentucky, for example, prescribing physicians are supposed to consult a computerized database to make sure their patients aren’t receiving duplicate prescriptions from other doctors. In Washington state, physicians are supposed to refer patients to pain specialists if their prescription dosages need to be increased. In Florida, which briefly drug-tested public assistance recipients for drugs, physicians who prescribe pain medications are strongly encouraged to have their patients undergo urinalysis.

Meanwhile, a 2009 study of nearly 1 million patient test results by Thomas Jefferson University researchers (which was funded by Ameritox through an unrestricted grant), 38 percent of patients had no detectable levels of the medication they had been prescribed, 27 percent had higher than expected levels of the prescribed drug in their system, and 29 percent had a nonprescribed drug present.

“Despite their skill and training, doctors are not always reliable detectors of how patients take their medication,” Leider said.

Other Players

Other significant players in the medication testing space are AIT Laboratories in Indianapolis, Calloway Labs in Woburn, Mass., and Dominion Diagnostics in North Kingstown, R.I. All are privately held. Along with pain medication monitoring, many of the labs also monitor for amphetamines; designer drugs such as Ecstasy, bath salts, and synthetic marijuana; and anti-anxiety medications such as benzodiazepines.

There have been some major management shifts at some of the labs in recent months. Last September, Ameritox appointed a new chief executive officer, A. Scott Walton, a Harvard MBA who was a former LabCorp executive vice president and chief of its esoteric testing business. In October, AIT announced CEO Ron Thieme was stepping down, after just seven months in the position.

And even though there are several larger labs in the space, AvuTox, based in Rocky Mount, N.C., has grown from its founding in early 2009 to 25 employees and 5 million tests a year. Chief Executive Officer Philip Radford said the company focuses on providing quicker turnaround times on toxicology tests than national laboratories. He noted that some labs take up to 21 days to deliver results.

“The doctors are frayed, under a lot of stress, and need quick data,” Radford said.

Additionally, Radford, who holds a doctorate degree in analytical chemistry, noted that the recent advances in linking mass spectrometry with liquid chromatography also provided what he believed was an opening.

About 60 percent of Ameritox’s client base is physicians or small physician practices, with most specializing in pain management. AvuTox, which deals primarily with psychiatrists in North Carolina, New York, and Puerto Rico, can lease in-office testing equipment to practices—charging per test that is run—or perform the tests on its own. The majority of physicians still prefer the latter, according to Radford, because of the potential for complicating reimbursement issues with Medicare and Medicaid. Although the company can provide test results electronically, about half of the clientele prefers to receive results by fax machine.

Despite its growth, the sector is not without its concerns. Medicaid has been cutting down on the number of tests it is willing to perform on enrollees, which has been putting pressure on future revenue growth, according to Radford. And Leider acknowledged there has been a fair amount of litigation between medication labs, the result of what he described as “the amount of entrants in the market.”

Indeed, Ameritox sued AvuTox last year over alleged intellectual property infringement. The case was quickly settled, and both companies say they have moved on. Radford even considered the litigation as a badge of honor.

“When I saw that lawsuit, it was kind of a feeling of ‘wow, we have made it to the big leagues,’” he said. 



INDUSTRY BUZZ

Quest, LabCorp Begin Using Heart Failure Assay

The nation's two major clinical laboratory companies have signed agreements with a San Diego-based firm to use its assay to determine the prognosis of patients with chronic heart failure.

Quest Diagnostics and LabCorp have both agreed to use the presage assay developed by Critical Diagnostics, which focuses specifically on developing tests for cardiac patients.

The assay Quest and LabCorp will use gauges the levels of the interleukin receptor ST2, which is an indicator that a patient's heart is under stress and losing its effectiveness in circulating blood. According to studies, higher soluble levels of the ST2 receptor in a patient's body are linked to a three-times greater risk of being rehospitalized within 30 days of an inpatient discharge, as well as higher mortality rates.

Chronic heart failure, also known as congestive heart failure, is a growing problem in the United States. It is often linked to obesity and other lifestyle issues. Six million Americans have been diagnosed with the condition, according to the American Heart Association, with another 600,000 new cases being diagnosed each year.

"We are extremely proud to be associated with these two exceptional organizations," said James Snider, Critical Diagnostics' president. "The Quest/Berkeley HeartLab and LabCorp collaborations, in addition to our existing clinical lab relationships, mean that physicians nationwide will now have access to Presage ST2 testing to help guide and improve heart failure patient outcomes."

Starting in November 2012, the management of heart failure patients and their readmission rates began to determine in part incentive payments or penalties to hospitals that participate in the Medicare program. The program is one of the cost-management components introduced by the Patient Protection and Affordable Care Act.

Speaking at G2 Intelligence's Lab Institute in Arlington, Va., last October, Quest Diagnostics Chief Executive Officer Steve Rusckowski noted that labs will have to focus on providing cost savings for acute care and other providers as a way to build greater volumes of business.

The companies did not disclose how many ST2 tests are expected to be ordered in the coming months or how it would be marketed to providers.

References

Ameritox 888-494-2165	CellNetix 206-215-5960	OPKO Health 305-575-4100
AIT Laboratories 800-875-3894	ClasGroup 917-312-3786	PAML 509-755-8600
AvuTox 252-443-6502	LabCorp 800-845-6167	Quest Diagnostics 800-222-0446

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Email: customerservice@G2Intelligence.com

Mail to: G2 Intelligence
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Fax: +1-603-924-4034

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Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher
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