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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

WILL PAMA LAB TEST REPRICING BE DELAYED?

The Protecting Access to Medicare Act of 2014 (PAMA) gave CMS the authority to use private payer rates to reprice nearly all lab tests on the Part B Clinical Lab Fee Schedule effective in 2017. But CMS has not yet released crucial details for the repricing initiative through a Proposed Rule and this means that the agency is almost certain to miss the mandated deadline of June 30, 2015 for issuing a Final Rule. *Continued on page 8.*

OIG OPINION COULD STIFLE EXCLUSIVE ARRANGEMENTS; SHINES SPOTLIGHT ON WAIVER OF PAYMENT

A recent ruling by the Health and Human Services Office of Inspector General (OIG) could put the kibosh on exclusive arrangements between clinical laboratories and physicians, which some out-of-network labs may use to get access to certain patients they might not otherwise reach.

In a March 25 advisory opinion (No. 15-04), the OIG concluded that such exclusive arrangements could potentially generate prohibited remuneration under the anti-kickback statute and also subject the laboratory to certain administrative sanctions.

Not only does the opinion potentially stifle exclusive arrangements, it also shines a spotlight on waiver of payments, which has become a source of contention between healthcare providers and insurers. *Continued on page 3.*

QUEST AND QUINTILES TO FORM JV

Quest Diagnostics (Madison, NJ) and Quintiles Transnational Holdings (Research Triangle Park, NC) have agreed to form a joint venture business that will provide lab testing services to companies performing clinical trials for new drugs. The joint venture will be 60% owned by Quintiles and 40% by Quest. *Continued on page 2.*

AT PRESS TIME: President Obama is poised to sign legislation that will permanently repeal Medicare's sustainable growth-rate formula and avert a scheduled 21% cut to the Physician Fee Schedule (PFS). The legislation freezes payment rates under the PFS at current levels for 3 months (April – June) and then raises them by 0.5% for the last 6 months of calendar 2015. Over the long term, the new law contains measures that will pay doctors more for treating Medicare patients in alternative payment models (e.g., accountable care organizations) versus fee-for-service. More details in the next issue of *Laboratory Economics*.

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QUEST AND QUINTILES TO FORM JOINT VENTURE (*cont'd from page 1*)

The new business will pool the existing assets and revenue of the clinical trials lab testing businesses at Quintiles and Quest into one company. The joint venture would have generated revenue of about $575 million in 2014, making it the world's second-largest clinical trials lab-services company after LabCorp/Covance (which has ~$1+ billion in sales).

The deal is expected to close in the third quarter. The CEO of the new business will be Costa Panagos. Costa will come from Quintiles where he currently serves as the Global Head of Global Central Laboratories and Cardiac Safety Services. John Haydon, Vice President of Joint Ventures and Strategic Programs for Quest Diagnostics, will chair the joint venture's board of directors and play a leadership role in the integration.

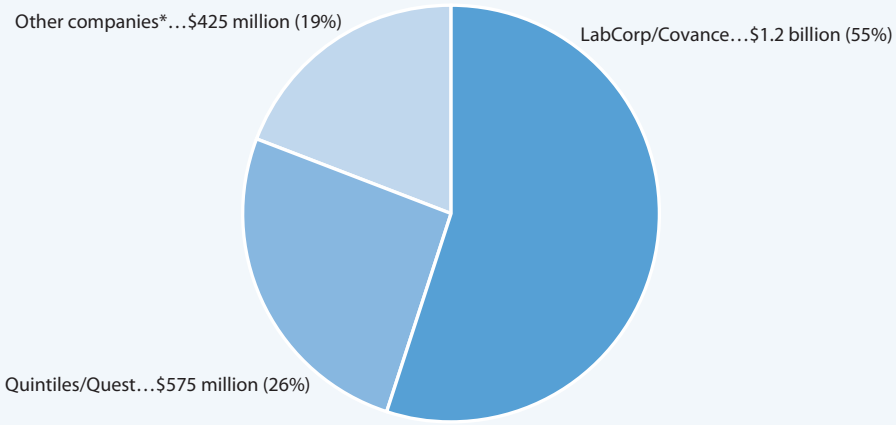
The joint venture will have about 2,000 employees worldwide. On a March 31 conference call, Quest CEO Steve Rusckowski said that, over time, the joint venture will integrate the two company's clinical trials lab businesses and reduce costs. Quest's largest clinical trials lab is located in Valencia, California. Quintiles' largest U.S. lab is in Marietta, Georgia, but it also has labs in Scotland, India, Japan, China and South Africa.

Beyond the immediate opportunity in lab testing services for clinical trials, Quintiles and Quest expect to collaborate in other areas. These include new ways to improve patient recruiting for clinical trials and faster development and commercialization of companion diagnostics. On the conference call, Quintiles CEO Tom Pike noted that nine out of the 41 new drugs approved by the FDA last year had biomarkers linked with them. And he said that more than half of new drugs now in development have a biomarker associated with them.

The joint venture announcement follows LabCorp's $6.1 billion acquisition of Covance Inc. completed earlier this year. Steve Rusckowski said the deal represents a "smart move" that allows Quest to "use its cash wisely for shareholders." Rusckowski said the deal will allow Quest to continue to make traditional clinical lab acquisitions.

Worldwide Market for Clinical Trials Lab Testing

The worldwide market for lab testing for clinical trials is estimated at $2.2 billion per year and is growing by 5% annually.



*Includes ICON, Clearstone/MDS, Pharma Product Development (PPD), Eurofins, Charles River Labs, et all.

Source: *Laboratory Economics*

OIG OPINION COULD STIFLE EXCLUSIVE ARRANGEMENTS *(cont'd from page 1)*

Background

The requestor is a multi-regional laboratory that provides clinical laboratory, anatomic pathology, and forensic pathology services to hospitals, long-term care and assisted living facilities, and physicians. The lab offers 45 patient service centers in multiple states. Typically, when the requestor's physician-practice clients order lab tests, their patients go to one of these patient service centers where the patient's blood is drawn, or other sample is collected, and then it is tested at the lab. The lab transmits the results back to the physician practice in the manner the physician requested (hard copy, facsimile, or electronically).

According to the lab, some physician practices have expressed a desire to work with a single laboratory for ease of communication and consistency in the reporting of test results. The lab notes, for example, that different labs use different reference ranges in reporting test results, and each lab requires a different interface for transmitting test reports electronically.

The lab certified that approximately 70 percent of its physician-practice clients have patients who are enrolled in insurance plans that require their enrollees to use a particular laboratory (exclusive plans), and physicians have indicated that between 10 percent and 40 percent of their patients are enrollees of exclusive plans. If the requestor is not the exclusive plan's designated laboratory, then the exclusive plan would not pay the requestor for any testing performed on the plan's enrollees (even as an out-of-network provider). The requestor certified that the exclusive plans do not include any individuals with federal health care program coverage as their primary insurance, but some plan enrollees could have federal health care program coverage as their secondary insurance.

Under the proposed arrangement, the requestor would enter into agreements with physician practices to provide all lab services required by that practice's patients, regardless of the patient's health plan coverage. If a physician whose practice has an agreement with the lab orders a test from the lab for an exclusive plan enrollee, the lab would not bill the patient, the physician practice, the exclusive plan, or any secondary insurer for the test. The lab would bill all other patients, whether privately insured or covered by a federal health care program, in accordance with fee schedules or contracted rates.

Under the written agreement between the parties, physicians would be required to represent that neither the physician nor the practice would receive any financial benefit from the lab's provision of laboratory services at no charge to exclusive plan enrollees, including any financial benefit by virtue or participating in an incentive plan that would pay the physician practice or the physicians a bonus or issue a penalty based upon the physician's practice or the physician's utilization of laboratory services. The lab certified that it would provide no items, services, or financial benefit, other than the limited-use interface, to physician practices in connection with the proposed arrangement.

OIG Analysis

According to the OIG, this arrangement potentially implicates the anti-kickback statute since the lab would provide free services to certain patients to secure all business, including federal health care program business, from physician practices. The OIG notes that its position on provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute.

Insurers also have opposed waivers of out-of-pocket expenses for patients. In October 2014, Cigna Corp. sued Health Diagnostic Laboratories (Richmond, VA) for $84 million for its practice of "fee forgiving," which Cigna said circumvented standard procedures for holding down health care costs. And increasingly insurers are sending letters to providers warning that if they discount the amount that patients owe, then they also discount the amount the insurers owe.

Also at issue in this case is remuneration. Even though the lab certifies that physicians and physician practices would receive no financial benefits under the proposed arrangement, the OIG maintains that the potential savings on electronic medical record interfaces combined with reduced administrative cost associated with not using multiple laboratories essentially amounts to remuneration.

Finally, the OIG believes the proposed arrangement could violate the federal government's "substantially in excess" provision, which is designed to prevent individuals and entities from charging the Medicare and Medicaid programs substantially more than their usual charges to other payers for the same items or services. Typically this is only a concern if a provider is discounting close to half of its non-Medicare or non-Medicaid business, which the OIG believes could be likely in this scenario.

What's the Upshot for Labs?

Karen Lovitch, an attorney with Mintz Levin in Washington, D.C., believes this advisory opinion is somewhat confusing for labs since its analysis seems to hinge on remuneration to physicians tied to at least one item that is non-quantifiable (i.e., administrative cost savings from consistent reference ranges) and another that may or may not exist in every case (elimination of monthly maintenance fees associated with multiple interfaces). Oddly, in a footnote to the opinion, the OIG acknowledged that any remuneration offered to patients through the proposed arrangement presents a low risk of fraud and abuse under the anti-kickback statute due to the lack of connection to services payable by a federal health care program.

Karen Lovitch

"It's unclear what the OIG's take on a laboratory's decision not to bill would be if these two factors didn't exist, or if the arrangement weren't exclusive," Lovitch tells *Laboratory Economics*.

The opinion cannot necessarily be extrapolated to other labs, adds Lovitch, noting that the proposed arrangement is "not your typical laboratory services arrangement." Labs that are contemplating the same or similar arrangements should consult with legal counsel before proceeding, she advises.

Robert Mazer, an attorney with Ober|Kaler (Baltimore) says that it's important to recognize that the OIG did not announce this new policy on its own initiative, but addressed this issue only in response to a request for an advisory opinion. "Nonetheless, it appears that the OIG disfavors these arrangements when they result in any financial benefit to referring physicians." Mazer finds it surprising that this opinion does not even mention a 1994 special fraud alert issued by the OIG on which laboratories frequently relied in believing that such arrangements were permissible.

Robert Mazer

Jane Pine Wood, an attorney with McDonald Hopkins (Boston) agrees that this proposed arrangement is specific to the lab requesting the opinion and thus the ruling may not necessarily apply to other labs. The key issue, however, is that labs need to be aware that any waiver of patient balances carries a certain amount of risk, both from federal and private payers.

Jane Pine Wood

"Labs are caught between a rock and a hard place because most labs are out-of-network with major payers, but doctors don't necessarily want to triage the lab work," she says. "If labs waive patient payment, they implicate federal and state laws, and if they don't, they may find it difficult to compete."

Advisory opinion No. 15-04 is available at *http://oig.hhs.gov/fraud/docs/adviso-ryopinions/2015/AdvOpn15-04.pdf.*

ARE PATHOLOGISTS OVERUTILIZING SPECIAL STAINS?

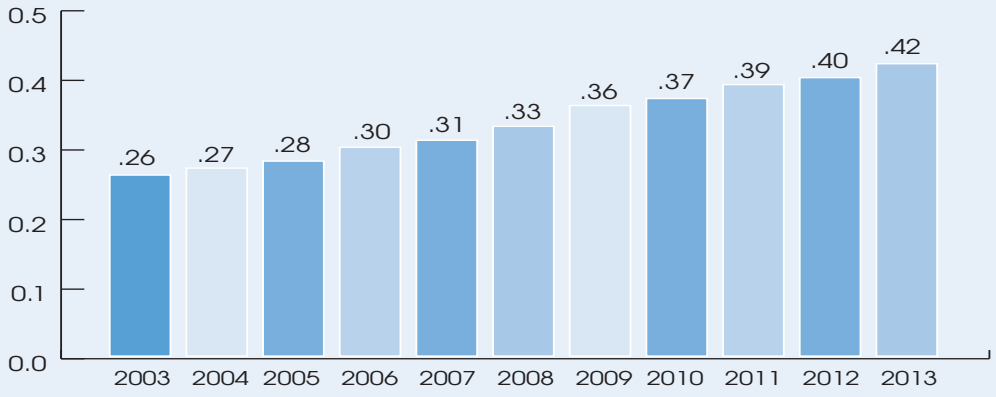
Medicare claims processor Noridian has chosen to follow the lead of Palmetto GBA and has issued a proposed local coverage decision (LCD) that will set limits on when a pathologist can order special stains and IHC stains. In brief, the LCD would require pathologists to first review an hematoxylin and eosin (H&E) stain prior to ordering special stains for most cases.

If adopted, the coverage policy will affect Medicare beneficiary services in Jurisdiction E (CA, HI and NV) and Jurisdiction F (AK, AZ, ID, MT, ND, OR, SD, UT, WA and WY). Noridian issued the proposed LCD on February 5 and the comment period ended March 30. This same LCD has already been finalized by Palmetto for Jurisdiction 11 (NC, SC, VA and WV) effective March 16. And other Medicare contractors could potentially follow Palmetto's lead.

Palmetto and Noridian say that limits are necessary because pathologists are overutilizing special stains. According to Medicare Part B claims data, the ratio of submitted claims for special stains and IHC stains (CPT 88312, 88313 and 88342) to submitted claims for tissue exams (CPT 88305) has been rising steadily for the past 10 years.

For example, in 2003 there was a national total of 4.17 million combined Part B claims submitted for CPT 88312, 88313 and 88342 versus 15.926 million submitted claims for CPT 88305. This represented a ratio of approximately one to four (i.e., 4.17/15.926 = 0.26). Fast-forward 10 years later and the ratio has risen to 0.42.

Ratio of Special Stains & IHC to Tissue Exams



Source: CMS Part B claims data (submitted claims for all modifiers), 2003-2013

Palmetto and Noridian believe that the increased volume of claims for special stains and IHC represents overutilization that may be driven by the following scenarios:

- Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist.
- Use of special stains and/or IHC stains without clinical evidence that the stain is actionable or provides the treating physician with information that changes patient management.
- Use of stains when the diagnosis is already known based on morphologic evaluation.
- H&E staining is included in the billing CPT code and is not a separately billable service.

The College of American Pathologists (CAP) has opposed the LCD because it says base evidence is unsubstantiated and the policy encroaches on pathologist medical judgment. The LCD "comprises assertions about the expected utilization of special stains over the course of time as might be seen on a retrospective analysis of aggregated claims" and is of "no practical use to a pathologist at the point of making any particular diagnosis or determining the billable service(s) for an individual patient," according to CAP's comment letter to Noridian. Furthermore, CAP noted that LCDs are intended to define when a service is reasonable and necessary as opposed to "scenarios that might be driving medically unnecessary over-utilization."

Meanwhile, *Laboratory Economics* asked Palmetto why it doesn't do a claims audit of those providers that appear to be overutilizing special stains and IHC.

"The primary objective of the LCD is educational—what is reasonable and necessary for billing these services. The policy established Medicare's expectation under which a [billing] review may be conducted," responded Elaine K. Jeter, MD, MolDx Medical Director for Palmetto GBA.

AURORA DIAGNOSTICS DELAYS FILING OF ANNUAL REPORT

Aurora Diagnostics (Palm Beach Gardens, FL) has notified the Securities & Exchange Commission that its independent public accounting firm, McGladrey LLP (New York City), has resigned effective March 26, 2015. As a result, Aurora was unable to meet the March 31 deadline for filing its 10-K Annual Report for 2014. Aurora says that it remains committed to filing its 10-K at the earliest possible time.

Aurora says that the resignation of its accounting firm was the result of its identification of a prohibited relationship between an associated entity of McGladrey with an entity under common control of Aurora. The prohibited relationship began during the period ended June 30, 2013.

Aurora says that it has hired Crowe Horwath LLP (Chicago) as its new principal independent accounting firm.

Aurora Diagnostics does not have publicly-traded stock listed on the NYSE, AMEX or Nasdaq. However, it does have publicly-traded debt outstanding. As a result, Aurora is required to file quarterly and annual financial reports with the Securities & Exchange Commission.

As of April 10, Aurora's senior debt (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at approximately 88 cents on the dollar with a yield to maturity of 15%.

The resignation of Aurora's independent accounting firm follows the recent departure of board member Peter J. Connolly (see *LE*, March 2015, p. 5).

AURORA AP MANAGER ARRESTED FOR ALLEGEDLY STEALING $370,000

Jessica Hess, 42, of Port St. Lucie, Florida, has been arrested and is accused of stealing more than $370,000 from Aurora Diagnostics during her three years of employment, according to the *Palm Beach Post*.

Hess faces fraud, larceny and embezzlement charges in connection with making false book entries at Aurora's corporate office where she worked as an accounts payable manager from March 2011 to July 2014. Hess allegedly created and altered documents in order to transfer money into her bank accounts.

The company was first tipped off about the suspected thefts last June after receiving an anonymous phone call that claimed that Hess was bragging about stealing funds from Aurora, according to police reports. She was fired by Aurora in July 2014. Hess was arrested on April 8, 2015, and released from the Palm Beach County Jail the following day on $44,500 bail.

HDL AND SINGULEX TO PAY $48.5 MILLION TO SETTLE KICKBACK CHARGES

Health Diagnostic Laboratory (Richmond, VA) and Singulex Inc. (Alameda, CA) have agreed to pay $47 million and $1.5 million, respectively, to settle civil allegations filed by the Justice Department that they paid doctors for patient specimens and billed Medicare for medically unnecessary testing.

Under the settlement agreements, HDL and Singulex denied wrongdoing and have been removed from liability. Each company will still be permitted to bill Medicare and Medicaid. Settlement terms also include corporate integrity agreements with the Office of Inspector General of the U.S. Department of Health and Human Services.

However, HDL's former chief executive Latonya Mallory and its former marketing contractor, BlueWave Healthcare Consultants (Hanceville, AL), have not been let off the hook. The DOJ has intervened in whistleblower lawsuits against Mallory as well as BlueWave and its two owners, Floyd Calhoun Dent and J. Bradley Johnson.

In addition, the DOJ has joined a lawsuit against Berkeley HeartLab Inc., owned by Quest Diagnostics. Quest bought Berkeley in 2011; Berkeley stopped paying doctors' processing and handling fees soon after that.

HDL, Singulex and Berkeley market cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels). As alleged in the lawsuits, HDL, Singulex and Berkeley induced physicians to refer patients to them for tests by paying them processing and handling fees of between $10 and $17 per referral and by routinely waiving patient co-pays and deductibles.

In addition, the DOJ says that HDL and Singulex allegedly conspired with BlueWave to offer these inducements on behalf of HDL and Singulex. BlueWave had contracted to provide sales and marketing support to HDL and Singulex. BlueWave was founded in 2010 by Dent and Johnson, each of whom had previously worked at Berkeley.

The lawsuits were filed by whistleblowers Dr. Michael Mayes, Scarlett Lutz, Kayla Webster and Chris Reidel under the qui tam provisions of the False Claims Act. The whistleblowers' share of the settlements has yet to be determined.

Layoffs at HDL

Separately, *Laboratory Economics* notes that HDL had been one of the fastest growing labs in the nation. After being formed in 2008, HDL quickly grew its revenue to $383 million in 2013, including 41% from Medicare. However, over the past six months, the company has laid off more than 200 employees, shrinking its workforce down to about 700 employees.

More Payers Deny Coverage for Cardiovascular Risk Testing

LE also notes that following the increased scrutiny of cardiovascular disease risk testing, more payers are issuing non-coverage decisions for them on the basis that they are unproven and considered not medically necessary. Among the payers that have recently issued non-coverage decisions for cardiovascular disease risk testing are UnitedHealthcare (12/1/2014), BlueCross BlueShield of Mississipi (1/9/2015) and Premera Blue Cross (1/28/2015).

Cigna Lawsuit Against HDL

Finally, *LE* notes that Cigna filed an $84 million lawsuit against HDL late last year alleging that HDL engaged in a "fraudulent 'fee forgiving' scheme" that undermines the insurance system by unfairly promising free services to out-of-network patients. HDL is seeking to have the suit dismissed on the grounds that Cigna has not specifically detailed the "who, what, when, where, and how," necessary to plead fraud.

WILL PAMA LAB TEST REPRICING BE DELAYED? *(cont'd from page 1)*

Proposed regulations will provide details for exactly which types of labs will need to report the pricing data that CMS will use to calculate weighted median prices. The American Clinical Laboratory Assn. (ACLA), as well as its two biggest members, Quest Diagnostics and LabCorp, have all been lobbying to ensure that hospital lab outreach programs and large physician-office-based labs be required to report their test pricing.

ACLA President Alan Mertz says his organization has requested that the Proposed Rule be issued as soon as possible. Labs will need time to assemble the pricing data and related quality assurance procedures before submitting the information to CMS, notes Mertz. He says that CMS has given no indication as to when it will release the proposed regulations.

After the proposed regulations are issued, labs will have 60 days to comment on them. It will then take CMS at least several weeks to analyze the comments and issue a Final Rule. This means that the June 30 deadline for issuing the final regulations is almost certain to be missed.

As a result, *Laboratory Economics* thinks that the scheduled start date (1/1/2017) for the new pricing might also be pushed back. A delay in the start date would be welcome news for the lab industry.

Timing and Implementation (as required by PAMA)

- CMS must issue proposed regulations with 60-day comment period
- CMS scheduled to release final regulations by June 30, 2015
- Rate reporting to begin January 1, 2016
- Weighted medians calculated and effective January 1, 2017

PUBLICLY-TRADED LABS GREW 1.5% IN 2014

On a combined basis, 18 publicly-traded labs grew their revenue by 1.5% to $16.8 billion in 2014 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 16 publicly-traded labs grew by 12% last year (after adjusting for acquisitions).

Revenue growth was fastest at five cancer-testing lab companies—Foundation Medicine (up 111%), Cancer Genetics (up 54%), Combimatrix (up 26%), Myriad Genetics (up 25% after adjusting for acquisitions) and NeoGenomics (up 24% after adjusting for acquisitions). In addition, Sequenom Laboratories, which specializes in prenatal genetic testing, increased its revenue by 27%.

Acquisition-adjusted revenue for Quest Diagnostics was down 3% last year, while LabCorp's revenue was up 1.7%. The third largest U.S. lab company, Bio-Reference Labs, had estimated revenue growth of 15% (after adjustments for acquisitions).

Revenue Growth at 18 Publicly-Traded Lab Companies ($000)

Company	Revenue 2014	Revenue 2013	Reported Change	Pro Forma Change*
Quest Diagnostics	$7,435,000	$7,146,000	4.0%	-3.0%
LabCorp	6,011,600	5,808,300	3.5%	1.7%
Bio-Reference[1]	832,282	715,354	16.3%	15.0%
Myriad Genetics[2]	778,216	613,165	26.9%	25.0%
Sonic Healthcare USA[3]	699,689	705,340	-0.8%	-0.8%
Genomic Health	275,706	261,595	5.4%	5.4%
Miraca Life Sciences USA[4]	240,400	226,300	6.2%	0.0%
Sequenom Laboratories	151,569	119,556	26.8%	26.8%
NeoGenomics	87,069	66,467	31.0%	24.0%
Foundation Medicine	61,079	28,990	110.7%	110.7%
Enzo Clinical Labs[5]	58,689	55,889	5.0%	5.0%
LipoScience[6]	39,000	52,400	-25.6%	-25.6%
Psychemedics	29,205	26,870	8.7%	8.7%
CareDx	27,306	22,098	23.6%	23.6%
Response Genetics	16,720	19,801	-15.6%	-15.6%
Cancer Genetics Inc.	10,199	6,610	54.3%	54.3%
Combimatrix	8,042	6,367	26.3%	26.3%
Aurora Diagnostics[7]	NA	NA	NA	NA
Total, 18 companies	$16,761,772	$15,881,102	5.5%	1.5%
Total, 16 companies (excluding Quest and LabCorp)	$3,315,172	$2,926,802	13.3%	12.0%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]Bio-Reference's revenue is for fiscal year ended October 31, 2014; [2]Myriad Genetics' revenue is for fiscal year ended June 30, 2014; [3]Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2014 (using constant exchange rate of 1 AUD = 0.9417 USD; [4]Miraca's revenue is for U.S. lab business for fiscal year ended March 31, 2014; [5]Enzo's revenue is for lab services only for fiscal year ended July 30, 2014; [6]LipoScience 2014 revenue figures from company projections from Proxy Statement filed with SEC on October 20, 2014. [7]Aurora Diagnostics has not yet filed its annual report for 2014 Source: *Laboratory Economics* from company reports

CLIA UPDATE 2015: Q&A WITH ACTING DIRECTOR OF CMS DIVISION OF LABORATORY SERVICES

Karen Dyer

Karen Dyer, MT (ASCP), DLM, has her hands full since taking over as acting director of the Division of Laboratory Services at the Centers for Medicare and Medicaid Services (CMS) at the beginning of this year. Dyer, a medical technologist with decades of experience in the industry, now is charged with overseeing more than 250,000 clinical and anatomic pathology laboratories registered in the United States under the Clinical Laboratory Improvement Amendments (CLIA).

On March 24, Dyer discussed ongoing CLIA initiatives during a teleconference sponsored by *Laboratory Economics*. Among topics addressed were proficiency testing, individualized quality control protocols, CLIA interpretive guidelines, off-label use of blood glucose meters, and a new requirement that labs be required to provide completed test result reports directly to patients.

Here are some highlights from the Q&A portion of the teleconference:

Q: Could you elaborate on the difference between when a laboratory developed test (LDT) is properly classified and regulated under CLIA versus when a test crosses the line and should be cleared by the Food and Drug Administration (FDA)?
A: The FDA issued its draft guidance on LDTs [in October], and we will be working with the FDA to provide better guidance for laboratories. The LDTs that are developed by a lab and that do not go outside of the laboratory and are used just for that facility's patients would fall under CLIA. We would come in and look at what you're doing. We would look at your performance specs to make sure you are testing correctly. When a lab decides to market the test and broaden its usage, the labs will have to provide data to the FDA to get clearance. CLIA only looks at the analytic validity of the test, but the FDA actually looks at the clinical validity—it looks to see if the test is actually measuring what the lab says it's measuring when the test was developed. That test would then have to go through the FDA clearance.

Q: What if a lab develops a test and that lab has locations in 12 other areas of the country, can that lab offer that lab-developed test at other labs that they own in other parts of the country?
A: My interpretation is that no, they wouldn't. If a lab in Baltimore has developed a test, it's developed for the population in Baltimore and cannot be used in other labs.

Q: [Under the patient access rule that became mandatory last October], are there any limits on the type of test results that must be made available directly to patients?
A: Under CLIA, we look at all lab test results being included (including historical data). In terms of HIPAA, patient access is to a designated record set, and that record set can have a variety of information in it— it could have medical history, it could have billing information, it could have radiology, so a patient can actually say I want everything, and the hospital or facility would have to provide everything. A patient can pretty much ask for anything in their medical record from a facility.

Q: Does pathology fall under the patient access rule? In other words, can patients require a pathology report (with diagnosis) be sent to them? Can it be delayed until the referring provider receives it and perhaps talks with the patient?
A: Pathology reports do fall under patient access and a patient can request them. [In terms of delaying the response], that wasn't the intent of the rule. If the report is available, the patient should be able to get it. The lab has up to 30 days to provide the report to the patient.

Q: Regarding external quality control, if the manufacturer says that for a waived test you should perform a positive and a negative quality control, what do you do?
A: You can't do anything less than what the manufacturer says, so if it says perform positive and negative, that's what you must do.

Q: If a facility is using the Roche Inform II [blood glucose] meter within a hospital environment, is the facility required to define "critically ill" so it would not be considered using the glucometer as "off label?" In this case, glucometers would not be allowed to be used on the facility defined "critically ill" patient; samples would be sent to the main laboratory for testing.
A: If the manufacturer says not to use it on critically ill patients, it's up to the facility to define what "critically ill" is. Populations are very different; there are different definitions of "critically ill" among different facilities.

ARIZONA EXPANDS DIRECT ACCESS TESTING

Arizona Governor Doug Ducey has signed legislation that will allow Arizonans to get any lab test directly from licensed labs without a doctor's order.

Arizona already allows individuals to receive a number of common lab tests, including those for cholesterol, blood glucose and the prostate-specific antigen (PSA), without a physician's written authorization. The new law, "Laboratory Testing Without Order," will expand that universe to all lab tests effective in early July.

The new law specifies that individuals must receive their results directly from labs. It also says that healthcare providers are not subject to liability or disciplinary action for failing to review or act on the results of tests not ordered by that provider.

The new law requires individuals to pay for tests that they order. And it prohibits clinical labs from submitting claims for reimbursement for tests conducted without a healthcare provider's request or written authorization.

Elizabeth Holmes, founder and CEO of Theranos (Palo Alto, CA), lobbied for the change (see *LE*, March 2015, p. 3). Theranos operates draw sites at about 40 Walgreens stores in the Phoenix area and is in the process of opening a CLIA-certified lab in Scottsdale. Governor Ducey signed the legislation at the Theranos lab in Scottsdale.

Theranos Searching for Laboratory Director
Separately, *Laboratory Economics* notes that Adam Rosendorff, M.D., resigned from his position as Theranos' laboratory director for its CLIA-certified labs in Newark, California and Scottsdale, Arizona in December 2014. Rosendorff is now working as a laboratory director at Invitae Corp., which operates a genetic testing lab in San Francisco and recently raised $102 million from an IPO (see *LE*, March 2015, p. 5). Theranos has not yet found a replacement for Rosendorff and is currently advertising the laboratory director position on its website. The company is also searching for a administrative lab director for its Newark lab.

In related news, Theranos recently promoted Christian Holmes to the position of director, commercial operations. Christian Holmes, the younger brother of CEO Elizabeth Holmes, was previously director of product management at Theranos.

LAB STOCKS UP 19% YTD

Fourteen lab stocks have increased by an unweighted average of 19% year to date through April 13. In comparison, the S&P 500 Index is up 2% and Nasdaq is up 5.5%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 120% on news that Roche is buying a majority stake in the company. Meanwhile, Quest Diagnostics is up by 13% and LabCorp is up 16%.

Company (ticker)	Stock Price 4/13/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$35.51	$32.13	11%	$986	19.6	1.1	3.0
Cancer Genetics Inc. (CGIX)	9.29	6.68	39%	91	NA	9.0	2.6
CombiMatrix (CBMX)	1.89	1.29	47%	24	NA	3.0	3.0
Enzo Biochem (ENZ)	2.88	4.44	-35%	131	NA	1.4	3.8
Foundation Medicine (FMI)	48.98	22.22	120%	1,430	NA	23.2	16.0
Genomic Health (GHDX)	30.93	31.97	-3%	995	NA	3.7	6.9
LabCorp (LH)	125.18	107.90	16%	12,560	21.2	2.1	3.8
Myriad Genetics (MYGN)	35.02	34.06	3%	2,490	24.2	3.5	3.7
NeoGenomics (NEO)	4.97	4.17	19%	299	NA	3.6	5.2
Psychemedics (PMD)	16.59	15.15	10%	89	27.7	3.0	6.9
Quest Diagnostics (DGX)	75.50	67.06	13%	10,900	19.8	1.5	2.6
Response Genetics (RGDX)	0.39	0.32	23%	15	NA	1.0	NA
Sonic Healthcare (SHL.AX)	20.95	18.50	13%	8,422	22.0	2.1	2.6
Veracyte (VCYT)	8.31	9.66	-14%	187	NA	4.7	4.5
Unweighted Averages			19%		22.4	4.5	5.0

Source: Bloomberg

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