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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Sonic Forms Joint Venture With ProMedica In Ohio

The new joint venture between Sonic Healthcare USA and ProMedica Health System (Toledo, OH) will operate under the name ProMedica Pathology Laboratories. Under the agreement, Sonic will contribute its Ohio lab business (known as Pathology Laboratories, Inc., or PathLabs) and an undisclosed amount of cash into the JV. ProMedica will contribute its existing outreach lab business. Sonic will own 49% and ProMedica will have a 51% stake in the JV. *Full details on page 5.*

OIG Points To Monetary Penalties To Encourage More Labs To Report PAMA Data

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently issued a report on the initial implementation of the new private-payer-based method for calculating lab test rates paid through Medicare's Clinical Laboratory Fee Schedule (CLFS).

The report, which was compiled using interviews with CMS and laboratory industry association staff, noted that CMS did not have the information necessary to identify all labs that were required to report their private-payer payment data. As a result, CMS used a significant portion of data from smaller labs that should not have reported, while missing information from many larger labs that failed to report.

OIG said that for future reporting periods, CMS could threaten labs that do not comply with reporting requirements with civil monetary penalties. *Continued on page 4.*

Bako Diagnostics Sues To Stop Former Dermpath Execs From Starting Competing Laboratory

Bako Pathology LP (dba Bako Diagnostics) has filed a lawsuit seeking an "emergency" injunction to block two ex-employee physicians from opening a competing lab, located just one mile from Bako Diagnostics' headquarters and lab in Alpharetta, Georgia, according to the filing.

The dispute centers on Bradley Bakotic, DPM, DO, a dermatopathologist and former Chairman and CEO at Bako Diagnostics, who left the company with co-founder Joseph Hackel, MD, in September 2017. Late last year, the pair filed a preemptive lawsuit (see *LE*, March 2018), seeking to invalidate their agreements not to compete against Bako Diagnostics for two years after departing. *Cont'd on page 2.*

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Bako Diagnostics Sues To Stop Former Dermpath Execs (*cont'd from p. 1*)
Drs. Bakotic and Hackel filed their lawsuit to clear the way for a new dermatopathology lab company, named Rhett Diagnostics, that they are forming. Their lawsuit argues that a provision of Delaware law bars contracts that restrict "the right of a physician to practice medicine."

Meanwhile, Bako Diagnostics' lawsuit accuses Bakotic and Hackel of copying the same marketing strategy they developed while at Bako Diagnostics in order to lure business away from their former company. In particular, Bako Diagnostics' alleges that Bakotic and Hackel have created a nonprofit foundation, named The Rhett Foundation for Podiatric Medicine Education, to promote their planned dermatopathology laboratory.

"Under the guise of 'giving back' through their 'nonprofit foundation,' defendants have begun running the exact same marketing playbook that was part of their job duties while at Bako Diagnostics in order to build 'Rhett' into a national brand," according to the lawsuit.

Bako Diagnostics says that the Rhett Foundation has begun sponsoring and speaking at podiatry and dermatology association events and created a fellowship program for podiatry students. "Defendants maintain these are 'altruistic educational endeavors' that do not compete with Bako Diagnostics, but in reality this marketing campaign (which defendants perfected while at Bako Diagnostics) is designed to do just that," according to the lawsuit.

The lawsuit says that since the start of 2018, the Rhett Foundation's website has announced 20 different podiatry and dermatology conferences that it will sponsor and/or have Dr. Bakotic speak at through the end of the year. "Whenever possible, defendants have not just offered sponsorship, but tried to replace and/or exclude Bako Diagnostics from such events."

For example, the lawsuit notes that Rhett Foundation recently acquired DERMFoot, an annual podiatry conference that attracts more than 300 attendees. The next DERMFoot conference in April 2019 will feature presentations from members of the Rhett Foundation, including Dr. Bakotic, and has excluded Bako Diagnostics from sponsoring or providing any speakers, according to the lawsuit.

Over the years, a number of commercial lab companies have found it difficult to keep hold of high-profile dermatopathologists.

The lawsuit filings show that Consonance Capital Partners (New York City) acquired a majority stake in Bako Diagnostics in January 2016 in a deal that valued the company at $242.5 million. As part of that transaction, Dr. Bakotic was paid $30.4 million in cash and stock, while Dr. Hackel received $14.4 million. As part of the deal, the defendants signed contracts agreeing not to compete with Bako Diagnostics until January 5, 2021. They also signed employment contracts that forbid them from competing with Bako Diagnostics for 24 months after leaving the company, according to the lawsuit.

Bako Diagnostics says it will suffer irreparable harm if Bakotic and Hackel are allowed to open a competing lab. The suit, which was filed in Delaware Court of Chancery on July 18 (case no. 2018-0520), seeks fast-track treatment of its claims for breach of contract and tortious interference with business relationships.

Bako Diagnostics Hires New CEO
In separate news, Bako Diagnostics has hired Ted Hull as Chief Executive Officer, effective August 1. Hull succeeds Larry McCarthy, Chairman of Bako Diagnostics, who had been acting as interim CEO since August 2017 after the departure of Dr. Bakotic. Previously, Hull spent 15 years, from 2000-2015, at Genova Diagnostics (Asheville, NC), an independent clinical laboratory focused on chronic disease, where he served as Chairman and CEO.

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Bako Diagnostics Tops List of Largest Dermatopathology Labs

Bako Diagnostics was formed in 2008 when Drs. Bakotic and Hackel left Quest's AmeriPath to create their own competing lab company. Bako Diagnostics has become the largest independent dermatopathology lab in the nation based on its Medicare Part B revenue. In the three years ending December 31, 2016, Bako Diagnostics increased its Part B revenue by 25% per year to reach $26.6 million, according to Medicare Provider Utilization and Payment Data from CMS.

Top 25 Dermatopathology Labs Ranked by Medicare Part B Payments for 2016

Laboratory Name	*Location*	*Total Medicare Part B Payment Amount, 2016*	*Total Medicare Part B Payment Amount, 2013*	*3-Year CAGR % Change*
Bako Diagnostics	Alpharetta, GA	$26,590,787	$13,721,884	25%
Cockerell Dermatopathology	Dallas, TX	11,187,140	2,217,008	72%
Cohen Dermatopathology	Needham, MA	11,032,903	10,654,059	1%
Dermpath Diagnostics (Quest Diagnostics)	Port Chester, NY	9,159,110	9,170,172	0%
Dermpath Diagnostics (Quest Diagnostics)	Pompano Beach, FL	8,241,430	8,177,402	0%
Institute for Dermatopathology (Quest Diagnostics)	Newtown Square, PA	6,864,055	4,924,339	12%
UCSF Dermatopathology Service	San Francisco, CA	4,952,109	4,231,090	5%
Richfield Laboratory of Dermatopathology (Quest Diagnostics)	Cincinnati, OH	4,468,984	5,183,490	-5%
Boca Raton Outpatient Laser Center Pathology Services	Delray Beach, FL	4,380,678	4,136,827	2%
Dermatopathology Laboratory of Central States	Dayton, OH	4,195,042	4,248,913	0%
Dermpath Diagnostics (Quest Diagnostics)	Altamonte Springs, FL	2,952,163	3,843,479	-8%
Bethesda Dermatopathology Lab	Silver Spring, MD	2,821,296	2,304,293	7%
Ackerman Academy of Dermatopathology (Quest Diagnostics)	New York, NY	2,803,656	3,411,356	-6%
Dermpath Diagnostics (Quest Diagnostics)	Indianapolis, IN	2,621,312	2,567,929	1%
Gulf Coast Dermatopathology Laboratory	Tampa, FL	2,318,762	2,192,231	2%
Water's Edge Dermatology	Palm Beach Gardens, FL	2,145,035	1,278,689	19%
Dermpath New England (Quest Diagnostics)	Brighton, MA	2,000,434	1,701,877	6%
Finan Dermatopathology Laboratory	Atlanta, GA	1,845,017	1,579,724	5%
Aurora Diagnostics Laboratory of Dermatopathology	Woodbury, NY	1,514,667	1,539,300	-1%
Dermpath Diagnostics (Quest Diagnostics)	Oakwood Village, OH	1,497,567	1,197,163	8%
US Path Labs LLC.	Boca Raton, FL	1,318,924	753,204	21%
Dermpath Diagnostics (Quest Diagnostics)	Tucson, AZ	1,309,714	1,248,679	2%
Twin Cities Dermatopathology (Aurora Diagnostics)	Plymouth, MN	1,292,308	319,809	59%
Biopsy Diagnostics (Aurora Diagnostics)	Ridgeland, SC	1,243,583	2,033,948	-15%
Cleveland Skin Pathology Laboratory	Beachwood, OH	1,206,645	680,530	21%
Total, Top 25 Dermatopathology Labs		**$119,963,322**	**$93,317,395**	**9%**

Note: This list does not include dermatopathology divisions that are part of larger multi-specialty anatomic pathology labs owned by companies such as LabCorp, PathGroup, Sonic Healthcare, et al.

Source: Medicare Provider Utilization and Payment Data from CMS for 2013-2016

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Quest's AmeriPath Reaches Settlement With Former Dermpaths

Quest's AmeriPath and two dermatopathologists have negotiated a settlement that resolves a non-compete agreement dispute (see *LE*, July 2018). The settlement, which was approved on August 1 by federal judge Cathy Seibel, stops the pair of doctors from competing against AmeriPath's laboratory in Port Chester, New York, until next year.

AmeriPath had sued Paul Chu, MD, former Executive Managing Director of the Port Chester lab, and Mark Jacobson, MD, a former Managing Director, in federal court in March to stop them from allegedly conspiring to open a competing dermatopathology lab in nearby Hawthorne, New York.

Under the settlement agreement, Chu may not be involved with any dermatopathology practice within 25 miles of AmeriPath's Port Chester lab through Jan. 31, 2019. And Jacobson is prohibited from soliciting any AmeriPath employees or clients through the end of 2018.

OIG Suggests CMS Threaten Monetary Penalties (*cont'd from page 1*)

Specifically, the OIG report noted: 1) Thirty-seven percent of reporting labs may not have met the low-expenditure threshold and should not have reported their pricing data; and 2) More than 20 high-volume labs should have, but did not report their data.

However, the OIG said that although some labs reported difficulty in interpreting the reporting requirements, CMS's modeling demonstrated that increased reporting from more labs would not have had a meaningful effect on 2018 payment rates.

Severe Penalties for Not Reporting

The PAMA statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day to laboratories for each failure to report or each misrepresentation or omission in reporting applicable information. CMS had stated that it did not intend to issue civil monetary penalties for the first data reporting period (January-May 2017).

However, the OIG seems to be prodding CMS toward using this authority for the next reporting period. The next reporting period is January-March 2020 for payment data collected from January-June 2019.

Potential to Require Hospital Outreach Labs to Report

Meanwhile, in its Proposed Medicare Physician Fee Schedule for 2019, CMS asked for comments on whether it should allow labs to use Form CMS-1450 bill type 14x or CLIA certificate numbers to determine if they are an applicable lab (see *Laboratory Economics*, July 2018). Doing so would allow nearly all hospital outreach labs to report their private-payer data in the next reporting period.

However, there is no guarantee that CMS will actually make this change when it issues its Final MPFS Rule in November. In addition, *Laboratory Economics* believes that most hospital outreach labs do not have the information systems in place that are needed to collect and report their private-payer rate data.

ACLA Still Waiting for Judge to Schedule Oral Arguments in CMS Lawsuit

Finally, *Laboratory Economics* notes that ACLA is still waiting for U.S. District Judge Amy Berman Jackson to schedule oral arguments for its lawsuit against CMS. The lawsuit, originally filed by ACLA in December 2017, charges that CMS wrongly excluded nearly all hospital outreach labs and relied too heavily on data from Quest and LabCorp when it calculated new market-based payments rates for the CLFS.

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Sonic Forms Joint Venture With ProMedica In Ohio (*cont'd from p. 1*)

Sonic's PathLabs is based in Toledo and performs roughly two million tests per year generating annual revenue of approximately $30 million. PathLabs will be closed after a transition period and its staff will transfer to ProMedica's new 83,000 square-foot core laboratory, which opened in April and is located in a separate building adjacent to ProMedica's flagship Toledo Hospital (722 beds).

ProMedica Pathology Labs at a Glance

Headquarters: .....Toledo, Ohio
Ownership: .....Sonic 49%/ProMedica 51%
Employees: .....200+
Core Laboratory: ..... 83,000 sq. ft.
Annual test volume: ... 4M outreach + 1.9M inpatient
Source: Sonic and ProMedica

Approximately two million annual outreach tests and another 1.9 million non-time-sensitive inpatient tests from ProMedica's 13 hospitals will also be consolidated at the core laboratory. In total, the JV's core laboratory will have more than 200 employees and initial volume of nearly six million tests per year. Noel Maring, Vice President of Hospital Affiliations at Sonic, says the JV will seek to grow volume by expanding throughout Ohio as well as southeast Michigan and part of Indiana.

In addition to clinical lab tests, the JV's core laboratory will perform Pap testing and technical services for anatomic pathology. Professional pathology services will continue to be provided by local pathologists, primarily Aurora Diagnostics' Consultants in Laboratory Medicine as well as pathologists contracted with PathLabs. Sonic's esoteric testing laboratory in Austin, Texas, will be the primary reference lab for the JV. ProMedica's 13 hospitals will each maintain rapid-response labs to perform urgent tests that require a turnaround time of four to six hours or less.

Maring says that the JV, which will commence operations on September 1, took nearly two years to negotiate. Rate cuts to the Medicare CLFS were part of the motivation for creation of the JV. "Both sides recognized the need for scale to reduce costs," he says. But Maring also points to opportunities for growth through geographic expansion. The largest competing labs in the region include LabCorp, Quest Diagnostics and Mercy Health's lab outreach business.

Maring says Sonic will manage the day-to-day operation of the JV and is currently searching for a General Manager.

ProMedica Pathology Laboratories is Sonic's fourth health system JV in the United States.

- In September 2017, Sonic partnered with NYU Langone Health to form a joint venture, NYU Langone Diagnostics, to grow NYU's outreach lab business.
- In April 2017, Sonic partnered with Baptist Memorial Health Care to establish a standalone microbiology laboratory in Memphis to serve Baptist's 17 hospitals in Tennessee, Mississippi and Arkansas, as well as Sonic's existing referrers in the mid-south.
- In April 2017, Sonic and Western Connecticut Health Network formed a joint venture, Constitution Diagnostics Network, to provide laboratory services throughout Connecticut.

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Large Hospital-Owned Independent Labs Growing By 3% Per Year

Overall, the nation's 25 largest hospital-owned independent labs grew their Medicare Part B collected revenue by a combined 3% per year from 2013-2016 to reach $259 million, according to a *Laboratory Economics* analysis of newly released Medicare Part B provider utilization and payment data. The fastest growing hospital-owned independent lab was **Northwell Health Laboratories** (Long Island, NY), which grew its Part B lab payments by 10.1% per year to $19.2 million from 2013-2016. Other fast growers included **Sonora Quest Laboratories** in Arizona, up 7.2% per year to $56.2 million, and **Tri-Cities Laboratory** (Kennewick, WA), now owned by LabCorp, which grew 7% per year to $4.5 million.

Large Hospital-Owned Independent Labs and Joint Ventures

Laboratory Name	*Location*	*Owner*	*Total Medicare Part B Payment Amount, 2016*	*Total Medicare Part B Payment Amount, 2013*	*3-Year CAGR % Change*
Sonora Quest Laboratories	Tempe, AZ	Banner Health and Quest Diagnostics	$56,246,257	$45,632,309	7.2%
ACL Services, LLC.	West Allis, WI	Aurora and Advocate	22,245,685	22,096,946	0.2%
Northwell Health Laboratories	Long Island, NY	Northwell Health	19,163,157	14,355,980	10.1%
Pathology Assoc. Medical Labs (PAML)	Spokane, WA	Purchased by LabCorp in 2017	14,908,989	14,853,771	0.1%
Diagnostic Laboratory of Oklahoma	Oklahoma City, OK	Integris Health and Quest Diagnostics	13,118,950	11,455,294	4.6%
Regional Medical Laboratory	Tulsa, OK	St. John Health System	11,811,474	11,236,326	1.7%
Health Network Laboratories	Allentown, PA	Lehigh Valley Health Network	11,685,880	10,257,164	4.4%
Diagnostic Laboratory Services	Aiea, HI	The Queen's Health Systems	9,880,099	8,930,154	3.4%
PeaceHealth Labs	Springfield, OR	Purchased by Quest in 2017	9,430,133	7,771,846	6.7%
Marshfield Clinic	Marshfield, WI	Marshfield Clinic	8,940,426	9,948,164	-3.5%
CompuNet Clinical Labs	Moraine, OH	Premier Health and Valley Pathologists	7,929,242	8,267,446	-1.4%
Mid America Clinical Laboratories	Indianapolis, IN	Local hospitals and Quest Diagnostics	7,902,342	7,402,500	2.2%
Scripps Health	San Diego, CA	Scripps Health	7,450,156	6,205,835	6.3%
Tricore Reference Laboratories	Albuquerque, NM	University of NM Health System and Presbyterian Healthcare	6,727,480	6,129,280	3.2%
Texas Health Physicians Group	Dallas, TX	Texas Health	5,794,513	5,385,888	2.5%
Mayo Clinic Jacksonville	Jacksonville, FL	Mayo Clinic	5,273,998	5,389,822	-0.7%
Associated Clinical Laboratories	Erie, PA	Local hospitals and Quest Diagnostics	5,250,305	5,154,370	0.6%
University Hospitals Laboratory	Cleveland, OH	University Hospitals of Cleveland	5,175,581	4,554,235	4.4%
Saint Francis Outreach Services	Tulsa, OK	Saint Francis Health System	4,904,710	4,583,664	2.3%
Tri-Cities Laboratory	Kennewick, WA	Purchased by LabCorp in 2017	4,474,821	3,654,619	7.0%
Affiliated Medical Services Laboratory	Wichita, KS	Via Christi Health System	4,249,175	3,562,410	6.1%
Sutter Valley Medical Foundation	Sacramento, CA	Sutter Valley Medical Foundation	4,200,636	6,824,088	-14.9%
NorDx	Scarborough, ME	MaineHealth	4,098,084	3,792,493	2.6%
Watson Clinic	Lakeland, FL	Watson Clinic	4,053,330	4,096,954	-0.4%
DMC University Laboratories	Detroit, MI	Detroit Medical Center	3,934,806	5,455,610	-10.3%
Total, top 25 labs			**$258,850,229**	**$236,997,170**	**3.0%**

Source: Medicare Provider Utilization and Payment Data from CMS for 2013-2016

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Hospital Outreach Labs Facing Strategic Crossroads

In the age of high-deductible health plans and greater price transparency, hospital outreach labs are faced with the choice of either reducing their rates and accepting a lower operating margin, or maintaining their premium prices and seeing volumes shift toward lower-priced commercial labs, according to Jeff Myers, Vice President of Consulting for Accumen Inc. (San Diego).

Myers believes large hospital outreach labs should be operated as a distinct business with their own NPI and control over billing. This will also allow them to offer a separate more competitive outreach lab fee schedule, while preserving their existing outpatient payer contracts.


Jeff Myers

Myers' comments came during *Laboratory Economics*' special teleconference on August 7, "Turbulent Times for Hospitals & Health System Labs." Below we summarize answers on other key topics from Myers as well as Stephen Finch, Director of Diagnostic Services at Rex Healthcare (Raleigh, NC) and John Waugh, Vice President for System Laboratories at Henry Ford Health System (Detroit, MI).

Will hospital outreach labs be capable of reporting their private-payer data to CMS if required to do so?


John Waugh

Waugh said that Henry Ford Health System was one of the twenty hospital-based outreach labs that reported its private-payer data to CMS in the first PAMA reporting period. "We were only able to do that because we outsource our outreach billing to a third-party biller. But the vast majority of hospital labs commingle their inpatient, outpatient and outreach billing and I don't know how they would untangle that."

What are the benefits of outsourcing your outreach billing?


Stephen Finch

"Many hospital billing departments feel it's not worth their time and effort to deal with the small-dollar lab test claims and they will summarily write off those claims if they are holding up payment for a $100,000 hospital claim….By outsourcing our outreach billing, we are not only collecting those small-dollar claims, but can also analyze data such as average collection per test and DSOs. It gives us the business intelligence we need to show the value of our lab outreach program when asking the C-suite for additional resources and investment," noted Finch.

How is your laboratory dealing with new prior authorization requirements from health plans?

"It's one of the most challenging areas we face. Patients don't understand it and physicians don't have the time for it," noted Waugh. Both Waugh and Finch said their health systems have central prior authorization teams that handle these requests for the laboratory and other departments.

In addition, Waugh noted the trend for large employers to bypass the insurance company middleman and contract directly with health systems. For example, Henry Ford recently signed a "direct-to-employer" healthcare contract with General Motors that will be open to 24,000 GM salaried employees and their families in Southeast Michigan this fall. These types of arrangements eliminate the whole issue of prior authorization, noted Waugh.

What are the advantages and disadvantages of either selling your outreach lab or having it managed by a commercial lab?

Myers advised hospital labs to enter any lab management discussions with a commercial lab from a position of strength. This is done by making sure their hospital lab has already wrung out all the

cost savings it can on its own, so that it can maximize the cost savings it negotiates with a commercial lab.

When evaluating an outreach lab sale, Myers warned that potential commercial lab buyers will discount a hospital lab's projected revenue to reflect the commercial lab's significantly lower fee schedules as well as future cuts to the Medicare CLFS.

Finally, Myers noted that he has seen both successful and unsuccessful hospital-commercial lab partnerships. He cautioned that some of these have been in existence for twenty or thirty years, and can be very difficult to unwind.

Has your outreach lab benefited from health system acquisitions of physician practices?
Both Waugh and Finch noted that their outreach lab volumes have benefited from health system acquisitions of physician practices. Finch said that acquired practices are converted to the health system's EHR, which allows them to seamlessly order their lab tests. "But we want them to choose our outreach lab services, rather than be forced to choose us."

How do the sales and marketing staff at hospital outreach labs stack up?
"Many hospital outreach programs will speak as though they have a dedicated sales force. However, in reality, the majority of their 'sales reps' function more like field service representatives, spending the majority of their time attending to specific needs of existing client offices in order to maintain the laboratory business. A professional sales team that is focused on obtaining new clients and revenue is vital to the success of a hospital outreach program," noted Myers.

Spotlight Interview with Catholic Health Initiatives' Timothy Murray


Tim Murray

Catholic Health Initiatives is an Englewood, Colorado-based health system that operates 581 CLIA-certified laboratories across the country. *Laboratory Economics* recently spoke with Tim Murray, MS, MT (ASCP), CHC, National Director of Laboratory Compliance, about the organization's approach to laboratory compliance.

What is the breakdown on CHI's 581 laboratories?
About 77% of the 581 are physician office laboratories that perform testing at the waived complexity level. Approximately 109 of those laboratories are hospital-based, and the remaining laboratories serve large physician groups. Our system's hospital laboratories perform about 40 million billable tests each year.

Describe your compliance program.
CHI's compliance team reports to leadership at our national Englewood, Colorado, office, not to our individual hospitals. When I became part of CHI's national compliance team, I was tasked with developing a national laboratory compliance plan, and in order to accomplish that goal I needed to formulate and lead a national compliance committee that provided much assistance. We mirrored our laboratory compliance plan after the OIG Model Compliance Plan issued in 1998 and in it, attempted to cover all aspects of laboratory compliance. Our committee reviews the plan annually and makes any updates as regulations change. Additionally, the committee assigns a specific annual monitor to each moderate and above complexity laboratory by considering laboratory compliance "hot buttons" focusing on any concerns or actions taken by the OIG in the past year. It is a real team effort.

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Every CHI laboratorian or other healthcare professional performing moderate, complex or above testing is required to take two online education courses where the first reviews all aspects of the compliance plan and another that focuses on proficiency testing protocols. Each laboratorian or other testing personnel must complete this education within 30 days of hire and then annually thereafter.

What compliance issues are most concerning to you?
The sheer volume of regulations is overwhelming to laboratorians trying to provide the highest quality patient care. Correct and appropriate laboratory coding and billing is a major risk. Lab professionals do their best to ensure correct codes are applied for billing purposes, but sometimes the code descriptions are not clear, potentially resulting in unintentional assignment errors.

How do you ensure that laboratory staff are using the correct codes?
First and foremost, we address the importance of correct coding in our Laboratory Compliance Plan. This document is a must-read where understanding and competence demonstration is required by each new laboratory employee upon hire and annually thereafter. Our National Laboratory Compliance Committee reviews new and any clarified guidance from regulators and assists in providing feedback to our laboratory leaders when questions are raised.

Another important strategy is to continually communicate compliance informational updates to our laboratory directors and local compliance officers. That information is then used to educate and as a basis to initiate immediate corrective action when appropriate.

We also work through regional and national laboratory compliance teams who provide correct coding input. For example, this past year the OIG was concerned about drug screen coding. We reviewed our coding for that specific testing throughout our system to make certain those tests were coded correctly.

What do you see as your biggest challenge in ensuring compliance with federal and state laws?
It is the number of laws and regulations out there and the fact that sometimes federal, state and accrediting agencies requirements differ. CMS and the accrediting agencies are coming more and more in alignment with each other. CMS is being very intentional about making certain the accrediting agencies are following their standards at a minimum. It makes my job less complicated when I go onsite to one of our laboratories to perform a CLIA compliance review. CMS recently put out a request for information regarding modernizing CLIA regulations. Laboratory professionals and organizations representing them were finally able to give input on the inconsistencies and the modernization of these regulations.

Can you give me some examples of the input you have given to CMS regarding CLIA?
We recommended modernizing CLIA regulations to match current technology levels and practice regarding histocompatibility testing. In terms of personnel requirements, we stated that a nursing degree does not equate to a clinical laboratory degree for certain testing personnel qualifications. On the issue of proficiency testing, we recommended that CMS consider intent before taking any actions or making determination/classification of a violation of PT referral. In addition, we recommended that technical competency assessment be transferable across CLIA locations within the same health system.

Have you seen a difference in enforcement over the past two years?
Yes, proficiency testing has been more strictly enforced over the past few years. There's been a lot of attention paid to regulation enforcement because it's a very serious issue. The proficiency testing regulations are pretty black and white. The stringent regulatory enforcement and the consequences of not being compliant caused CHI to add its comments in response to CMS' CLIA request for information – intent needs to be considered in determining applicability and enforcement of PT referral regulations.

LabCorp Mid-Year 2018 Review

LabCorp (Burlington, NC) reported net income of $407 million for the six months ended June 30, 2018, up 11% from the $368 million in the same period for 2017. Overall, LabCorp's reported half-year revenue was up 16% to $5.7 billion.

Looking specifically at LabCorp's lab testing business: revenue was up 6.6% to $3.6 billion, including 3.5% gained from acquisitions (e.g., PAML and Mount Sinai outreach lab). On July 25, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

UnitedHealthcare and Aetna
LabCorp CEO Dave King said the biggest opportunity available from its new contract with Aetna (effective 1/1/2019) and its renewed contract with UnitedHealthcare was in capturing market share from high-cost lab providers. "The reality is we cannot do this ourselves. There are many reasons why lab work goes to higher-cost providers. Many health systems are very insistent that their doctors send their work to their own captive laboratories. They do things like telling us that we can't have an interface to return results electronically, so everything has to go back on fax, which is inconvenient for the doctor in terms of putting that information into the medical record."

LabCorp Mid-Year Financial Summary ($ millions)

	Six Months Ended 6/30/18	Six Months Ended 6/30/17	% Change
Total revenue	$5,714.6	$4,941.9	16%
LabCorp Diagnostics	3,584.2	3,360.8	7%
Covance Drug Development	2,132.6	1,581.7	35%
Operating cash flow	522.0	536.4	-3%
Capital expenditures	159.7	141.5	13%
Free cash flow	362.3	394.9	-8%
Pretax income	554.2	544.4	2%
Net income	407.0	367.8	11%
Diluted EPS	$3.94	$3.54	11%
Est'd number of requisitions	80	75	6.4%
Est'd revenue per requisition	$44.76	$44.81	-0.1%

Source: LabCorp and *Laboratory Economics'* estimates

In addition, King noted structural obstacles in plans that have an out-of-network benefit. "So if I'm an employer and I have a plan that pays 50% of billed charges or 70% of usual and customary for out-of-network and you have non-compliant behavior by out-of-network labs where they're willing to write off patient responsibility, they can do pretty well at 50% of billed charges and writing off the balance. And until we have changes in benefit design, there is really nothing that we or Quest or anybody else can do to bring that work into the network."

"It's going to require a sustained effort on the part of the managed care industry, employers and healthcare providers to encourage compliant behavior and to encourage benefit design and structural setups that reward patients for bringing their work into the network," said King.

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Hospital Lab Management & Acquisitions

We are interested in broad strategic partnerships with key anchor systems, such as Providence St. Joseph, Novant, Mount Sinai and PAML. "These are deals that take time to materialize but they're more than just 'We take over a lab and manage the laboratory.' These are deals that include data, they include pathology, they include reference testing, and a whole range of services. And we have a significant number of health system opportunities on the table in front of us, but it's difficult to predict what the timing is….And I think we're seeing that people are seeing the consequences of PAMA and they are thinking about what their strategic options might be with their lab assets," said King.

Quest Diagnostics Mid-Year 2018 Review

Quest Diagnostics (Madison, NJ) reported net income of $396 million for the six months ended June 30, 2018, up 11% from $357 million in the same period for 2017. Overall, Quest's reported half-year revenue increased by 3.3% to $3.8 billion. Looking specifically at Quest's lab testing business: revenue was up 3.7% to $3.6 billion, including 3.4% gained from acquisitions and 0.3% from organic growth. On July 24, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

Test Volume Trends

Excluding acquisitions, Quest's lab testing volume growth was only 0.2% in the six months ended June 30, 2018. Quest attributed this to three factors: 1) a slowdown in prescription drug monitoring due to policy changes introduced by some payers to limit definitive testing after screening; 2) a decline in hepatitis C genotype testing due to the rapid acceptance of AbbVie's Mavyret drug which works for all HCV patients irregardless of their genotype; and 3) a slowdown in vitamin D testing due to increased coverage denials.

New UnitedHealthcare Contract

"An awful lot of United's lab testing is going to high-cost providers, including hospitals, physician-owned labs and regional independent labs," said Quest CFO Mark Guinan. He suggested that United will begin actively steering physicians and patients toward a preferred lab network of low-cost labs next year. "We believe that, around the middle of next year or maybe a little ahead of that, United will talk about their preferred [lab] network and what some of the conditions are to be a preferred provider." He said that United may also introduce new plan benefit designs that provide "financial incentives for patients and others in the decision-making process to drive things towards that preferred [lab] network because that preferred network will be at the highest quality and the best value of any of the options within their network."

Hospital Lab Management

Quest CEO Steve Rusckowski said he expects to announce several new professional laboratory services (PLS) relationships with health systems later this year. "It is a business that has lower revenue per req because of the unique nature of what it is. It's basic testing done for hospital in-patients, where typically, we have fewer tests per req and more basic testing."

Quest Diagnostics' Mid-Year Financial Summary ($ millions)

	Six Months Ended 6/30/18	*Six Months Ended 6/30/17*	*% Change*
Total revenue	$3,803	$3,681	3%
Lab testing	3,638	3,506	4%
Other revenue	165	175	-6%
Operating cash flow	503	490	3%
Capital expenditures	151	107	41%
Free cash flow	352	383	-8%
Pretax income	493	538	-8%
Net income	396	357	11%
Diluted EPS	$2.84	$2.53	12%
Est'd number of requisitions	84	82	2%
Est'd revenue per requisition	$43.18	$42.76	1%

Source: Quest Diagnostics and *Laboratory Economics'* estimates

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Lab Stocks Up 37% Year To Date

Prices for 17 publicly-traded lab stocks are up 37% on an unweighted average basis through August 10. In comparison, the S&P 500 Index is up 6.5% year to date. The top-performing lab stocks so far this year are Natera, up 181%, and CareDx, up 131%. At the two largest public labs, LabCorp is up 13% and Quest Diagnostics is up 10%.

Company (ticker)	Stock Price 8/10/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$0.95	$1.85	-49%	$26	NA	0.9	1.3
CareDx (CDNA)	16.99	7.34	131%	599	NA	11.8	17.9
Enzo Biochem (ENZ)	4.14	8.15	-49%	195	NA	1.8	2.3
Exact Sciences (EXAS)	49.93	52.54	-5%	6,130	NA	17.4	8.2
Foundation Medicine (FMI)	137.00	68.20	101%	5,090	NA	28.4	267.6
Genomic Health (GHDX)	54.25	29.39	85%	1,950	NA	5.4	8.6
Interpace Diagnostics (IDXG)	1.07	1.02	5%	30	NA	1.7	0.8
Invitae (NVTA)	9.95	9.08	10%	669	NA	6.2	4.9
LabCorp (LH)	179.59	159.51	13%	18,370	14.2	1.7	2.6
Myriad Genetics (MYGN)	42.53	34.35	24%	2,970	22.0	3.8	3.1
Natera (NTRA)	25.22	8.99	181%	1,490	NA	6.7	NA
NeoGenomics (NEO)	12.50	8.57	46%	1,020	NA	3.8	6.2
Opko Health (OPK)	5.42	4.90	11%	3,030	NA	3.0	1.7
Psychemedics (PMD)	21.43	20.56	4%	118	19.5	2.8	6.5
Quest Diagnostics (DGX)	108.53	98.49	10%	14,830	18.7	1.9	2.8
Sonic Healthcare (SHL.AX)	26.01	21.40	22%	11,050	23.8	2.1	2.8
Veracyte (VCYT)	12.00	6.53	84%	473	NA	5.9	16.0
Unweighted Averages			37%	$68,040	19.6	6.2	22.1

Source: Capital IQ

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