

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

OMB REVIEWING CMS PROPOSED RULE FOR PAMA CLINICAL LAB TEST PAYMENT POLICY

CMS is finally making progress toward implementing the Medicare clinical lab test payment reforms mandated by the Protecting Access to Medicare Act of 2014 (PAMA). Under PAMA, CMS must base Medicare payment rates for clinical lab tests on private payer rates starting January 1, 2017. The statute requires that CMS publish a Final Rule that details the parameters for collecting private payer payment data from labs no later than June 30, 2015—a deadline that CMS missed.

On August 31, 2015, CMS submitted its Medicare clinical diagnostic laboratory test payment system Proposed Rule to the White House Office of Management and Budget (OMB) for regulatory clearance—the last stop before publication in the *Federal Register*. The text of the proposed rule is not yet available, but should be published in the *Federal Register* sometime in the next few weeks. More details expected in next issue of *Laboratory Economics*.

SONORA QUEST LABS STARTS DIRECT ACCESS TESTING PROGRAM

Sonora Quest Laboratories (Tempe, AZ) has launched a direct-access-testing service aimed at taking advantage of a new Arizona law, effective July 3, that lets consumers order their own lab tests without a physician’s prescription. Despite little advertising, demand for the new service has been “stronger than expected and steady” over the first two months since being launched, according to Christina Noble Reiff, Vice President of Business Development at SQL. She says that initial marketing has been limited to e-mails to existing Sonora Quest patients with chronic conditions. *Continued on page 4.*

FLORIDA MEDICAID PRICING LAWSUIT COULD RESULT IN HUGE SETTLEMENT

A Medicaid pricing lawsuit in Florida has received zero media attention (outside of *Laboratory Economics*) but is now likely headed toward a settlement that could potentially cost Quest Diagnostics and LabCorp tens of millions of dollars, or much, much more. Earlier this year, Florida Circuit Court Judge Angela Dempsey denied separate motions by Quest and LabCorp to dismiss the case. The lawsuit (*State of Florida, Hunter Laboratories and Chris Riedel vs. Quest Diagnostics and LabCorp; case #2007-CA-003549*) is now in the discovery phase. *Continued on page 2.*

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FLORIDA MEDICAID PRICING LAWSUIT (*cont'd from page 1*)

Discovery in these types of cases usually lasts about one year, according to Riedel's lawyer Niall McCarthy from Cotchett, Pitre & McCarthy, LLP. The depositions on the case begin this month and the defendants will now testify under oath about their billing practices in Florida, according to McCarthy. "We believe our complaint alleges a very strong case that Florida taxpayers were overcharged. We look forward to presenting the case on the merits," says McCarthy.

Riedel initially filed his whistleblower lawsuit in 2007. As a result, the Florida Attorney General's Office began an investigation into Quest and LabCorp's pricing and billing practices as they relate to Florida's Medicaid program. In November 2013, the State of Florida intervened as a plaintiff in the lawsuit.

The lawsuit contends that Florida Medicaid regulations require labs to bill their lowest rates for services provided to Medicaid patients. Instead, the lawsuit alleges that Quest and LabCorp billed Medicaid some of their highest rates, and were paid the maximum Florida Medicaid fee schedule amounts for lab tests, while deeply discounting their prices to other customers.

Florida Attorney General Pamela Jo Bondi contends that the alleged overcharges were collected from Florida's Medicaid Program over the past 15 years. Quest receives approximately \$25 million per year from Florida's Medicaid program, while LabCorp receives approximately \$17 million per year.

Status of 7 Medicaid Whistleblower Lawsuits Initiated by Chris Riedel

<i>State</i>	<i>Medicaid Enrollment</i>	<i>Whistleblower Lawsuit Filed</i>	<i>State Intervene?</i>	<i>Defendants</i>	<i>Status</i>
California	12.5M	2005	YES	Quest, Lab-Corp and 7 smaller labs	Settled in 2011. Quest paid \$241M. LabCorp paid \$49.5M.
Florida	3.5M	2007	YES	Quest, LabCorp	Florida AG intervened in November 2013; now in discovery phase.
Georgia	1.8M	2008	NO	Quest, LabCorp	Settled with Quest in March 2014. Lawsuit vs. LabCorp continues.
Massachusetts	1.6M	2007	NO	Quest	Settled in 2013 for undisclosed amount.
Michigan	2.3M	2008	YES	Quest	Settled for an undisclosed amount in early 2015.
Nevada	563,000	2007	NO	Quest	Settled in 2013 for undisclosed amount.
Virginia	1.0M	2007	NO	Quest, LabCorp	Both lawsuits dismissed in 2014.

Source: *Laboratory Economics* from lawsuits

Riedel patterned his Florida lawsuit after a similar case he filed against the big lab companies in California. In 2011, Quest and LabCorp entered separate settlement agreements totaling \$290.5 million with the State of California to resolve allegations of overcharging that state's Medicaid program, which goes by "Medi-Cal." As whistleblower, Riedel received more than \$70 million from the California settlements in 2011.

Riedel had also filed Medicaid lawsuits against Quest and/or LabCorp in five other states (Georgia, Massachusetts, Michigan, Nevada and Virginia) in 2007 and 2008. However, nearly all of these cases have been either dismissed or settled out of court for relatively small sums. The one exception is Riedel's lawsuit versus LabCorp in Georgia. In May 2015, the U.S. District Court for Northern Georgia dismissed Riedel's anti-kickback claim and remanded the remaining state law claims to the State Court of Fulton County. In July 2015, LabCorp filed a motion to dismiss these remaining claims.

Riedel's Medicaid lawsuits must be particularly confounding to Quest and LabCorp, notes *Laboratory Economics*. After all, both companies are paid Florida Medicaid's maximum fee schedule amount for lab tests provided to the state's Medicaid recipients, the same amount paid to other independent labs. Both labs have argued that their Medicaid billing is in accordance with established industry practice and has not caused Florida to pay out sums it otherwise would not have paid. Note: Florida's Medicaid Lab Fee Schedule is currently set at approximately 70% of the national Medicare Clinical Lab Fee schedule.

However, Riedel and the Florida Attorney General say that the big labs billed and accepted lower rates from non-Medicaid Florida customers. Their lawsuit contends that Florida law requires labs to bill the state's Medicaid program the lower prices they offer to non-Medicaid Florida payers.

For example, under a contract with the U.S. Dept. of Veterans Affairs, Quest charged \$3.00 for CPT 80053 (basic metabolic panel) and LabCorp charged \$3.18, but each company receives \$8 from Florida Medicaid for the same test, according to the lawsuit.

The plaintiffs are seeking treble damages, or three times the amount of actual financial losses suffered by the State of Florida starting from January 2000 through the present. In addition, the plaintiffs demand that Quest and LabCorp each be assessed civil penalties of \$10,000, for each and every false claim they submitted and pay all attorneys' fees.

"We are aware of the allegations made in this case and the Attorney General's decision to intervene. The allegations are without merit, and we look forward to presenting our case. As always, Quest Diagnostics remains firmly focused on putting patients first and serving their needs," according to a Quest spokesman.

And LabCorp says, "The company will vigorously defend the lawsuit."

The case is being litigated in the Second Judicial Circuit in Leon County, Florida. *Laboratory Economics* reached out to the Florida's Attorney General's Office for comment. "As litigation is ongoing, and a protective order has been issued for the discovery, it would not be appropriate to comment any further at this time," answered a spokesman for the Florida AG.

There is additional risk for Quest and LabCorp if the lawsuit goes to trial because the Affordable Care Act says that any healthcare provider convicted of billing fraud can be automatically excluded from all government programs.

SONORA QUEST LABS STARTS DIRECT ACCESS TESTING (*cont'd from page 1*)

The new service, which has been branded My Lab ReQuest, includes a limited menu focused on wellness health profiles, including screening for allergies, diabetes and cardiovascular health. SQL Medical Director Robert Stern, MD, notes that SQL's test menu includes over 1,000 tests, "but just because you can perform a test, doesn't mean you should offer it to consumers."

"If people are going to order tests for themselves, then they should do it from a lab with an established long-term track record," says Stern. He notes that all direct access tests offered by Sonora Quest are FDA approved.

Consumers can order tests either online or at any of Sonora Quest's 70 patient service centers, which are located primarily within medical office complexes, throughout the state. Test prices are clearly indicated and results are available within 2-3 days either online, by e-mail or regular mail, according to Noble Reiff.

Stern is aware that many lab companies, including Quest Diagnostics, have tried without success to develop the direct-access testing market over the past 10 years. "They may have been too early. Today might be the right time for this. We'll see."

Meanwhile, on a July 23 conference call with investors, Quest Diagnostics' CEO Steve Rusckowski suggested that Quest might offer direct access testing in other states if it succeeds in Arizona. "We are encouraged by the initial results from what we see in Arizona and we do believe this is a trend we're on top of, and we're very well positioned."

Sonora Quest Labs is a joint venture between Banner Health System (51% owner) and Quest Diagnostics (49% owner) that was formed in 1997. Sonora Quest operates a major independent lab facility in Tempe and manages the inpatient labs at 13 Banner Health hospitals in Arizona. Sonora Quest has approximately 3,000 employees and performs more than 57 million tests per year. Dave Dexter, President of Sonora Quest, tells *LE* that his lab is on track to record test volume growth of approximately 4.4% to 5% in 2015.

Sonora Quest Sample Direct Access Test Prices

CPT	Description	Price
85610	Prothrombine Time	\$7
82465	Total Cholesterol	\$8
85025	CBC	\$11
83036	Hemoglobin A1C	\$16
80061	Lipid Panel	\$21
84443	TSH	\$26
84153	PSA	\$29
82306	Vitamin D	\$36
NA	STD Screen (GC/chlamydia, herpes, syphilis, HIV)	\$210
NA	Expanded Health Profile (lipid panel + comprehensive metabolic panel + glucose test)	\$210

Source: Sonora Quest Laboratories

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INDUSTRY GROUPS RECOMMEND NEW APPROACH TO MEDICARE PAYMENT FOR DRUG TESTING

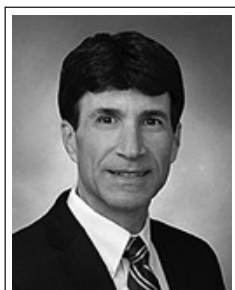
Industry groups and test manufacturers are recommending that Medicare take a different approach to how it pays for drug testing.

In June, CMS proposed to use only two G codes to cover all drug-of-abuse (DOA) testing, one for presumptive testing (GXXX1) and one for definitive testing (GXXX2). The agency said it believed this approach would help counter what it viewed as unnecessary and inappropriate DOA testing. Pricing for the two proposed codes has not yet been determined. Industry groups and IVD companies largely opposed the proposal, saying that two codes are not sufficient to adequately reimburse for legitimate DOA testing ordered by physicians.

At the August 26 inaugural meeting of the Medicare Advisory Panel on Clinical Laboratory Diagnostic Tests, several commenters recommended that CMS take a different approach. “There appears to be unanimity among stakeholders, as well as advisory panel members, that the system proposed by CMS is not workable,” Julie Khani, senior vice president for the American Clinical Laboratory Association (ACLA), tells *Laboratory Economics*.

The Drug Testing Coalition, a group consisting of drug test manufacturers including Alere, Beckman and Siemens Healthcare Diagnostics, recommended that CMS use two G codes for presumptive testing: GXXX3, for tests capable of being read by direct observation, and GXXX4, for tests performed on instrumented test systems. GXXX3 would be crosswalked to existing code G0434 (\$19.79), and GXXX4 would be crosswalked to G0431 (\$98.96).

For definitive drug testing, the coalition recommended a tier-based approach, similar to the current practice for automated, multi-channel chemistry testing panels

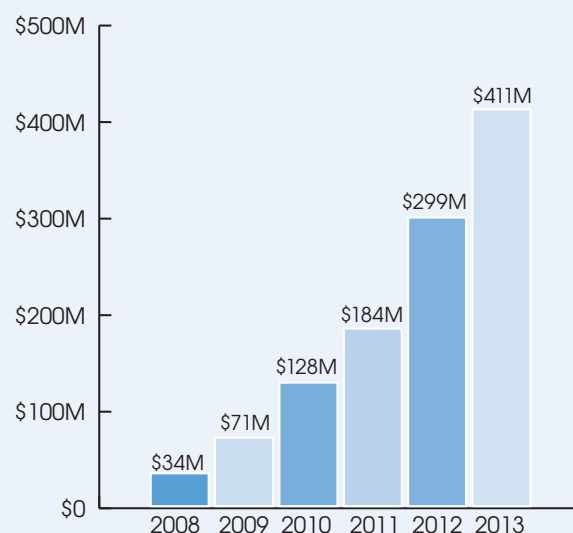


Paul Radensky

under which laboratories would bill using the CPT codes, and CMS would implement a payment edit grouping numbers of tests within certain payment tiers. In the first tier, for example, tests one through seven would be paid individually, with payment crosswalked to CPT code 82542 (\$24.58). Payment for the next three tiers would be bundled and discounted, with 8 to 14 tests paid at \$196.64, 15 to 21 tests paid at \$245.80, and 22 or more tests paid at \$294.96, according to Paul Radensky, MD, JD, a principal with McDermott+Consulting, an affiliate of the law firm of McDermott Will & Emery (Washington, D.C.). Radensky represents the Drug Testing Coalition.

Because CMS staff indicated they could not implement the new tier system

Medicare Part B Spending on Drugs of Abuse Testing*



*Total spending on six codes (CPT 80102, 80154, 82145, 82542, 83840 & 83925).

Source: *Laboratory Economics* from CMS

for definitive testing by Jan. 1, 2016, the coalition is recommending that the agency move forward with the recommendation on presumptive testing but maintain the status quo for definitive drug testing until CMS is able to implement the tiered payment system, Radensky tells *Laboratory Economics*. The recommendations are supported by a number of industry groups, including ACLA, the College of American Pathologists and AdvaMedDx.

Preliminary determinations on pricing of these codes could be published by CMS as early as the next few weeks. Final determinations on pricing should be released by the end of the year.

The debate over how to price drugs of abuse tests follows explosive growth in Medicare Part B expenditures on these tests. During the five year period 2008-2013, Part B spending on drugs of abuse testing, as measured by six codes (CPT 80102, 80154, 82145, 82542, 83840 & 83925) grew by an average of 64% to reach \$411 million.

Meanwhile, in addition to discussing drug testing codes and other proposed code changes, the panel also voted to continue pricing of Medicare's current crosswalk pricing of \$492.72 for Cologuard, a test for colon cancer developed by Exact Sciences Corp. (Madison, WI). The panel approved the current pricing despite efforts by Cable Car Capital, an investment firm, to lower the price. Cable Car disclosed at the July clinical laboratory fee schedule meeting that it held a short interest in Exact Science's stock, which means it would benefit if the stock fell.

The list of new codes and codes up for reconsideration on the CLFS are available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Clinical-Lab-Codes-for-CY-2016.pdf>.

DRUG TEST FIRMS AVERAGE 34 TESTS PER MEDICARE PATIENT

The top 30 drugs-of-abuse testing lab companies performed an average of 33.8 tests per Medicare patient they served in 2013, according to data analyzed by Laboratory Economics from the Medicare Part B program. On average, the 30 labs received \$751 in Medicare payments for each Medicare patient they served in 2013.

The biggest outlier is Confirmatrix Laboratory, which is based in the Atlanta area. Confirmatrix performed an average of nearly 120 tests per Medicare patient it served in 2013. The company received a total of \$9.1 million in Part B payments for an average of \$2,406 per Medicare patient. Confirmatrix is a urine toxicology lab formed by Khalid Satary. Mr. Satary founded the company after he was released from federal prison in 2008 following a three-year sentence for running the largest counterfeit compact disc operation in U.S. history.

Nexus Lab 2.0 LLC (Danville, KY) performed an average of nearly 70 tests per Medicare patient it served in 2013. The Medicare billing privileges of Nexus 2.0 were revoked effective October 24, 2013. Medicare contractor CGS Administrators revoked the company's billing rights after discovering that Nexus 2.0 had been submitting Part B lab test claims using the company's national provider ID (NPI) as both the "rendering" and the "referring" NPI.

At the other end of the spectrum was MedTox Laboratories (St. Paul, MN). MedTox performed an average of only 9.9 tests per Medicare patient it served in 2013. The company received a total of \$3.6 million in Part B payments for an average of \$265 per Medicare patient. LabCorp acquired MedTox for \$241 million in July 2012.

Top 30 Drugs-of-Abuse Testing Labs by Medicare Part B Payments

<i>Company</i>	<i>Location</i>	<i>Number of Patients</i>	<i>Services Performed</i>	<i>Avg. Services Per Patient</i>	<i>Total Paid by Medicare (\$ mill)</i>	<i>Avg. Paid Per Patient</i>
Millennium Health LLC.	San Diego, CA	211,035	9,656,984	45.8	\$211.0	\$1,001
Ameritox Ltd.	Greensboro, NC	113,921	3,646,976	32.0	85.2	748
Aegis Sciences Corp.	Nashville, TN	79,692	2,477,672	31.1	49.6	622
Physicians Choice Laboratory	Rock Hill, SC	37,353	1,426,920	38.2	33.5	896
Alere Toxicology Services	Austin, TX	42,279	583,808	13.8	15.0	354
AvuTox LLC	Rocky Mount, NC	9,611	515,392	53.6	12.9	1,343
PremierTox	Russell Springs, KY	9,463	479,663	50.7	11.4	1,210
American Institute of Toxicology	Indianapolis, IN	29,955	366,126	12.2	10.3	345
Dominion Diagnostics	North Kingston, RI	23,316	414,125	17.8	9.6	413
Rocky Mountain Tox	Denver, CO	13,671	416,581	30.5	9.3	677
Confirmatrix Laboratory	Lawrenceville, GA	3,792	453,335	119.6	9.1	2,406
Compass Laboratory Services	Memphis, TN	6,127	366,404	59.8	8.1	1,320
Universal Oral Fluid Lab	Jeannette, PA	6,254	220,675	35.3	6.8	1,093
Castle Medical	Smyrna, GA	6,638	348,947	52.6	6.8	1,026
Nexus Lab 2.0 LLC	Danville, KY	3,816	262,884	68.9	6.6	1,722
Essential Testing LLC	Collinsville, IL	9,565	332,235	34.7	6.2	643
Elab Solutions Inc.	Sandy Springs, GA	10,879	518,059	47.6	6.1	561
Infiniti Labs Inc.	Tampa, FL	5,703	226,202	39.7	5.3	935
Calloway Laboratories	Woburn, MA	13,424	173,303	12.9	4.8	357
DrugScan Inc.	Horsham, PA	13,826	184,762	13.4	4.3	311
Peachstate Health Management	Gainesville, GA	6,650	215,274	32.4	4.1	623
Logan Laboratories	Tampa, FL	2,921	168,702	57.8	4.0	1,370
LabCorp/MedTox Laboratories	St. Paul, MN	13,714	136,306	9.9	3.6	265
Ameritox Ltd.	Midland, TX	7,827	165,321	21.1	3.6	455
American Forensic Toxicology	Huntington, NY	7,367	155,574	21.1	3.6	481
American Clinical Solutions	Ruskin, FL	11,295	159,869	14.2	3.5	313
AmeriDrug Laboratories	Loveland, CO	2,554	187,671	73.5	3.4	1,326
Choice Laboratory Services	Dallas, TX	7,519	135,656	18.0	3.2	422
Medicus Laboratories LLC	Plano, TX	14,249	103,070	7.2	3.0	208
Hill Country Toxicology	San Antonio, TX	3,280	113,875	34.7	2.6	791
Total 30 Labs		727,696	24,612,371	33.8	\$546	\$751

Source: 2013 Medicare Fee-for-Service Provider Utilization & Payment Data

MILLENNIUM MIGHT BE FORCED TO RESTRUCTURE MASSIVE LOAN

Investors in debt issued by Millennium Health LLC (San Diego, CA), the biggest drug-testing lab in the U.S. and biggest recipient of Medicare drug-testing payments, have suffered substantial losses following news that the company is near finalizing a \$250 million settlement with the U.S. Justice Department. The settlement would resolve allegations that Millennium overcharged the Medicare program for lab tests.

In 2013, for example, Millennium received \$211 million in Part B payments by providing an average of nearly 46 tests per Medicare patient served (*see table on page 7*).

In addition, Millennium faces increased scrutiny, lower rates and potential settlement payments with commercial health insurance companies. And CMS is in the process of reconfiguring its method of paying for drugs-of-abuse testing in an effort to discourage overutilization (*see pages 5-6*).

As a result, Millennium's \$1.775 billion senior secured term loan due in 2021 (cusip #60038CAFO) is now trading at approximately only 50 cents on the dollar. That puts the loan at price levels similar to those issued by firms that are either in default or facing bankruptcy.

Millennium took the loan out in early 2014. Rather than fund productive investments, Millennium used the money to pay a \$1.27 billion dividend to the company's management team and TA Associates, which own the company. It also paid off \$195 million of debt that TA Associates held.

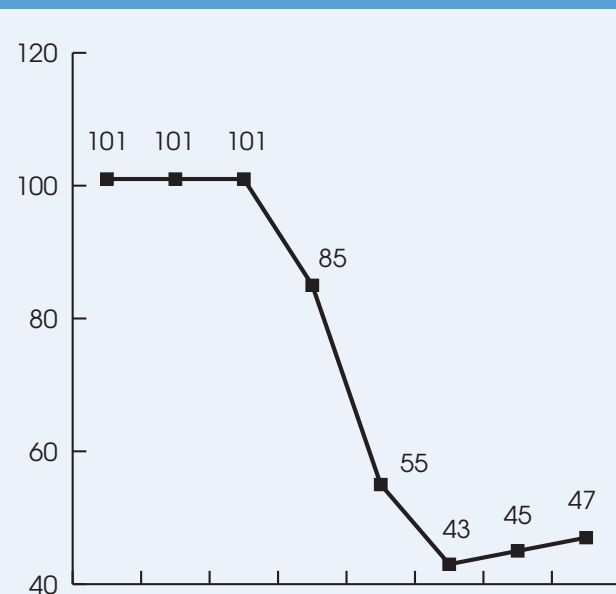
The loan transaction was managed by JPMorgan Chase & Co., which sold portions of the debt to institutional investors, including Oppenheimer Funds, Fidelity Investments and Franklin Resources. These institutional investors then put part of their Millennium loan investment into their mutual funds owned by retail investors.

Earlier this month, Standard & Poor's lowered its rating on Millennium's loan to CCC+ from B and revised its recovery rating on this debt to "4" from "3" reflecting its expectation for average (30% to 50%) recovery in the event of a payment default. S&P said that high litigation settlement costs and declining profits as a result of falling revenue per specimen "likely make Millennium's existing capital structure unsustainable over the long term."

In the fourth quarter of 2014, Millennium recorded EBITDA (earnings before interest, taxes, depreciation and amortization) of \$87 million, down from \$92 million in fourth-quarter 2013; revenue was flat at \$167.3 million versus \$168 million.

Millennium has reportedly hired Lazard Ltd. and law firm Hogan Lovells to advise it on potential negotiations with creditors to reduce its debt.

Millennium Health's Senior Secured Loan Value*



*Cents on each dollar of loan face value
Source: *Laboratory Economics*

NEW TEXAS LAB TO BUY HDL FOR \$37.1 MILLION

TTrue Health Diagnostics LLC (Frisco, TX) has agreed to pay \$37.1 million for Health Diagnostics Laboratory (Richmond, VA). HDL has been operating under Chapter 11 bankruptcy protection since June 7. True Health is a new clinical lab company focused on testing for cardiovascular disease and diabetes. The transaction is expected to close by the end of the month.

HDL filed for Chapter 11 about two months after agreeing to pay \$49.5 million to the federal government to settle allegations that it paid kickbacks to physicians in the form of a \$20 per specimen process and handling fee.

True Health is expected to keep HDL's massive 283,000 square-foot headquarters and lab in downtown Richmond in operation. HDL has about 570 employees.

The \$37.1 million purchase price is equal to about 1/10 of HDL's peak sales of approximately \$380 million in 2013. HDL's annual revenue has dropped by almost 50% since it stopped providing P&H payments to physicians in mid-2014.

NC LAB CHOICE AMENDMENT KILLED IN COMMITTEE

An attempt by a North Carolina state congressman to allow physicians to choose which clinical laboratories to use was shot down recently after insurers testified against the provision.

Rep. Paul "Skip" Stam, a Republican from Wake County, offered the provision as an amendment to House Bill 287, which would amend state insurance laws. The amendment would have allowed doctors and patients to choose the lab they wanted to use, even if not in-network with an insurer, as long as the lab agreed to participate in the health benefit plan according to terms offered by the insurer.

Stam told members of the House Judiciary II Committee that the measure would increase competition, which could lead to better outcomes for patients. However, representatives from at least two insurers lobbied against the amendment, and the measure was voted down in committee.

"We think this actually will impede competition," Chris Evans, director of regulatory affairs for Blue Cross Blue Shield of North Carolina, told wral.com, adding that her company selects labs based on both quality and price.

Don d'Ambrosi, research assistant for Rep. Stam, said the provision was modeled after that state's "pharmacy of choice" statute, which went into effect in 2000.

The lab choice provision was initially included as part of HB 287 but was pulled from the bill in order to allow the bill to move from one committee to the next, d'Ambrosi tells Laboratory Economics. After the original lab choice provision was pulled, Stam's office recommended to the lab supporters that they seek to include it as a study item with recommendations presented prior to the next legislative session.

"The advocates for the measure still thought it could be moved through this session. However, when it was provided as a formal amendment to the same bill, it was soundly defeated. For that reason, it is my opinion that it is dead for the remainder of this session," says d'Ambrosi.

"It could still be studied by the agency and a recommendation brought back to the next session IF the agency wants to do it," he adds. "I have my doubts this late in the session that it could be handled as a study bill." D'Ambrosi says he is not aware of any laboratories in North Carolina lobbying against the provision.

OPKO HEALTH COMPLETES ACQUISITION OF BIO-REFERENCE LABS

Opko Health Inc. (Miami, FL) completed its purchase of Bio-Reference Labs Inc. (Elmwood Park, FL) on August 20. Shareholders of Bio-Reference received 2.75 shares of Opko common stock for each share of BRLI common stock. The deal was initially valued at \$1.47 billion or \$52.58 per share of BRLI common stock, when first announced on June 4. However, shares of Opko steadily declined after the deal was announced. As a result, Opko wound up buying Bio-Reference for only \$1 billion, or \$34.61 per share. This price valued Bio-Reference at approximately 1x its estimated revenue of \$927 million and 8.3x its EBITDA (earnings before interest, taxes, depreciation and amortization) of \$121 million for the fiscal year ending October 31, 2015.

In a filing with the Securities & Exchange Commission, Bio-Reference said that it began a serious review of strategic options, including a potential sale of the company, in early 2014. During the 2014-2015 period, Bio-Reference entered into confidentiality and due diligence agreements with 12 potential suitors, including five strategic companies and seven private investment firms. Bio-Reference says it did not approach either Quest Diagnostics or LabCorp because of antitrust regulatory concerns.

Comparison of Lab Acquisition Valuations Based on Annual Revenue (\$ millions)

Lab Type	Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/Revenue
Pathology-National	May-07	Quest Diagnostics	AmeriPath	\$2,000	\$752	2.7
Routine	Aug-99	Quest Diagnostics	Smithkline Beecham Clinical Labs	1,187	1,590	0.7
Routine	Feb-03	Quest Diagnostics	Unilab	1,000	425	2.4
Routine/Esoteric	Aug-15	Opko Health	Bio-Reference Labs	1,000	927	1.0
Routine	Apr-95	LabCorp	Roche Biomedical Labs	950	730	1.3
Routine	Nov-05	Quest Diagnostics	LabOne	947	500	1.9
Pathology-National	Dec-10	LabCorp	Genzyme Genetics	925	370	2.5
Pathology-National	Mar-03	Welsh Carson	AmeriPath	839	480	1.7
Esoteric	Apr-11	Quest Diagnostics	Athena Diagnostics	740	110	6.7
Pathology-National	Nov-11	Miraca Holdings	Caris Diagnostics	725	207	3.5
Routine	Jul-02	LabCorp	Dynacare	685	238	2.9
Pathology-National	Jan-03	LabCorp	Dianon	600	190	3.2
Pathology-National	Nov-10	GE Healthcare	Clariant Inc.	585	117	5.0
Routine	Jul-93	Quest Diagnostics	Damon Corp.	575	330	1.7
Routine	Mar-14	Quest Diagnostics	Solstas Lab Partners	563	390	1.4
Routine	Mar-02	Quest Diagnostics	American Medical Labs	500	300	1.7
Routine	Nov-99	Kelso & Co.	Unilab	450	285	1.6
Routine	Nov-05	Sonic Healthcare	Clinical Pathology Labs	380	187	2.0
Esoteric	Mar-11	Quest Diagnostics	Celera Corp	341	128	2.7
Esoteric	Jan-06	AmeriPath	Specialty Laboratories	330	152	2.2
Pathology-National	Feb-11	Novartis	Genoptix	330	195	1.7
Esoteric	Jul-94	Quest Diagnostics	Nichols Institute	325	280	1.2
Esoteric	Jun-06	Fisher Scientific	Athena Diagnostics	283	55	5.1
Esoteric	Feb-14	Myriad Genetics	Crescendo Biosciences	259	40	6.5
Drug Test	Jul-12	LabCorp	Medtox Scientific	241	110	2.2
Overall Average For 25 Deals						2.6

Source: Laboratory Economics

PUBLICLY-TRADED LABS GROW 3% IN FIRST-HALF 2015

On a combined basis, 20 publicly-traded labs saw their revenue increase by 3% to \$8.5 billion during the first six months of 2015 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 18 publicly-traded labs grew by 5.8% in first-half 2015 (after adjusting for acquisitions).

Revenue growth was fastest at Invitae Corp., up 623%; Cancer Genetics, up 190%; and Foundation Medicine, up 61%.

Acquisition-adjusted revenue for Quest Diagnostics increased by 0.8% in first-half 2015, while LabCorp's revenue was up 4.2%. The third largest U.S. lab company, Bio-Reference Labs (now part of Opko Health) had revenue growth of 13.1%.

Revenue Growth at 20 Publicly-Traded Lab Companies (\$000)

Company	First-Half 2014	First-Half 2013	Reported Change	Pro Forma Change*
Quest Diagnostics	\$3,764,000	\$3,648,000	3.2%	0.8%
LabCorp (diagnostics only)	3,047,000	2,866,600	6.3%	4.2%
Bio-Reference ¹	432,820	382,635	13.1%	13.1%
Myriad Genetics ²	369,900	371,700	-0.5%	-0.5%
Sonic Healthcare USA ³	361,200	350,700	3.0%	3.0%
Genomic Health	138,771	137,479	0.9%	0.9%
Aurora Diagnostics	124,039	117,829	5.3%	0.0%
Sequenom Laboratories	70,572	76,843	-8.2%	-8.2%
NeoGenomics	47,396	38,852	22.0%	11.0%
Foundation Medicine	41,753	25,951	60.9%	60.9%
Enzo Clinical Labs ⁴	30,547	28,707	6.4%	6.4%
Veracyte	23,126	16,153	43.2%	43.2%
CareDx	14,344	12,700	12.9%	12.9%
Psychemedics	13,757	14,739	-6.7%	-6.7%
Transgenomic	13,553	13,015	4.1%	4.1%
Exact Sciences	12,385	0	NA	NA
Cancer Genetics Inc.	8,555	2,942	190.8%	190.8%
Combimatrix	4,878	3,763	29.6%	29.6%
Opko Health Inc.	3,857	4,003	-3.6%	-3.6%
Invitae Corp.	3,030	419	623.2%	623.2%
Total, 20 companies	\$8,525,484	\$8,113,030	5.1%	3.0%
Total, 18 companies (excluding Quest and LabCorp)	\$1,714,484	\$1,598,430	7.3%	5.8%

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

¹Bio-Reference's revenue is for the six months ended April 30, 2015; ²Myriad Genetics' revenue is for six months ended June 30, 2015; ³Sonic Healthcare USA's revenue is for six months ended June 30, 2015; ⁴Enzo's revenue is for lab services only for six months ended January 31, 2015.

Source: *Laboratory Economics* from company reports

LAB STOCKS DOWN 7% YTD

Sixteen lab stocks have declined by an unweighted average of 7% year to date through September 16. In comparison, the S&P 500 Index is down 2.9%. The top-performing lab stocks so far this year are NeoGenomics, up 61%; Cancer Genetics Inc., up 41%; and Myriad Genetics, up 21%. Meanwhile, Quest Diagnostics is up by 1%.

Company (ticker)	Stock Price 9/16/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/Sales	Price/Book
Bio-Reference (BRLI)*	\$34.61	\$32.13	8%	\$963	19.0	1.4	2.9
Cancer Genetics Inc. (CGIX)	9.45	6.68	41%	93	NA	6.0	3.5
CombiMatrix (CBMX)	1.20	1.29	-7%	15	NA	1.7	1.8
Enzo Biochem (ENZ)	2.98	4.44	-33%	137	NA	1.4	4.0
Exact Sciences (EXAS)	19.76	27.44	-28%	1,900	NA	136.9	7.8
Foundation Medicine (FMI)	22.28	22.22	0%	766	NA	10.8	2.9
Genomic Health (GHDX)	25.48	31.97	-20%	828	NA	3.0	5.6
Invitae (NVTA)	10.33	16.00	-35%	329	NA	78.0	1.8
LabCorp (LH)	119.89	107.90	11%	12,120	25.9	1.7	2.5
Myriad Genetics (MYGN)	41.30	34.06	21%	2,830	38.2	3.9	4.2
NeoGenomics (NEO)	6.73	4.17	61%	407	NA	4.2	6.7
Psychemedics (PMD)	10.21	15.15	-33%	56	25.9	2.0	4.6
Quest Diagnostics (DGX)	67.92	67.06	1%	9,750	19.9	1.3	2.2
Response Genetics (RGDX)**	0.03	0.32	-91%	1	NA	0.1	NA
Sonic Healthcare (SHL.AX)	19.05	18.50	3%	7,662	21.2	1.8	2.3
Veracyte (VCYT)	8.68	9.66	-10%	240	NA	5.5	3.8
Unweighted Averages			-7%		25.0	16.2	3.8

*Bio-Reference Labs was sold to Opko Health Inc. on August 20. **Response Genetics filed for Chapter 11 bankruptcy in early August 2015 and has an agreement to sell its assets to Cancer Genetics Inc. Source: Capital IQ

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