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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PROPOSED HOSPITAL OUTPATIENT RULE SEEKS TO PACKAGE PATHOLOGY SERVICES

Medicare's Hospital Outpatient Prospective Payment System (OPPS) proposed rule for 2015 is seeking to package payment for all ancillary services for which the average cost is $100 or less. If finalized, nearly all outpatient pathology lab technical services will be packaged and no longer eligible for separate billing on the OPPS fee schedule.

Packaging refers to a decision not to pay for certain additional services for hospital outpatients if a major service is provided. The proposal seeks to make the OPPS system more similar to the inpatient hospital, in which a single payment is made for a patient's stay at the hospital, and less like the Physician Fee Schedule or the Clinical Lab Fee Schedule, in which each individual unit of service is paid. Last year, CMS packaged nearly all clinical lab tests so that they would not be paid separately if another service was provided to a hospital outpatient on the same day.

In the 2015 proposed rule, CMS plans to package ALL ancillary services for which the average cost is $100 or less. Noteworthy pathology and lab services on this list include phlebotomy (APC 0624), pathology technical services (APC 0342, including 88305-TC), and transfusion laboratory services (APC 0345).

Under the proposed rule, Medicare would continue to pay for ancillary services that cost less than $100 if they are the only ones provided to an outpatient on a given day (i.e., outreach lab services), but not if they are provided as part of the overall stay for a surgical patient, for example. The proposal would affect pathology technical services, but pathologists would still be able to bill separately for professional services provided to hospital outpatients. *Continued on page 3.*

FDA TO PHASE IN REGULATION OF LDTs

In a move strongly opposed by the lab industry, the Food and Drug Administration has announced plans to phase in regulation of laboratory-developed tests (aka homebrew tests). The FDA says that it is concerned about gaps in regulation of LDTs under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and in particular that CLIA does not assure the safety and effectiveness of LDTs, does not require adverse event reporting, nor require removal from the market of tests deemed unsafe. Furthermore, the FDA says the playing field is unbalanced with some companies going through the time and expense to win FDA approval of their tests, while others market similar tests without oversight. The FDA estimates that there are currently 11,000 LDTs being performed by 2,000 laboratories. *Continued on page 2.*

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FDA TO PHASE IN REGULATION OF LDTs (*continued from page 1*)
The FDA first proposed regulating certain lab-developed tests in 2006. But the agency ran into fierce opposition, particularly from the American Clinical Laboratory Assn. (ACLA).

ACLA has argued that the FDA lacks statutory authority to regulate LDTs and that LDTs are already regulated under CLIA. In addition, ACLA says that some testing currently performed at labs as LDTs will never generate the financial returns needed to justify the costs of obtaining FDA clearance or approval. Similarly, critical testing would be unavailable in the "lag time" between development of new tests and FDA authorization of them, according to ACLA.

But on July 31, the FDA notified Congress of its intent to regulate LDTs through a document titled "Framework for Regulatory Oversight of Laboratory Developed Tests." Under FDA's proposed risk framework, FDA will exempt "low-risk" (Class I devices) LDTs and LDTs intended for rare diseases and unmet needs from almost all regulations with the exception of:

- registration
- device listing
- adverse event reporting

FDA said these requirements would come into effect six months after the guidance is finalized.

High- and moderate-risk LDTs, however, will be subject to more rigorous regulatory requirements. In addition to needing to meet the above three requirements, moderate-risk LDTs (defined as Class II medical devices) will need to begin reporting adverse events within six months of the guidance being finalized, and will need to undergo premarket review (i.e. premarket notification, or 510(k) submissions) beginning five years after the guidance is implemented.

High-risk (Class III) devices will need to also begin reporting adverse events to FDA within six months of the guidance being finalized, and the "highest risk devices" will need to undergo review (i.e. premarket approval (PMA) application) starting 12 months after the guidance, while all other high-risk devices will be reviewed over a four-year time frame.

Devices would remain on the market during FDA's review. FDA said it will focus on reviewing LDTs which have the same intended use as FDA-cleared tests and devices, as well as LDTs meant to determine the safety or efficacy of blood and blood products.

The biggest political ally of the lab industry, Rep. Michael Burgess, MD (R-TX), has noted that the 60-day notification period he demanded of the FDA before it can officially release the LDT draft guidance may allow him to increase political pressure on the agency. Burgess, an Ob/Gyn physician, says FDA regulation of LDTs would be "redundant, will stifle innovation and will require additional taxpayer funding for the FDA." Burgess says a modernization of CLIA regulations would be preferable to FDA involvement. Burgess has received a total of $27,500 in contributions from ACLA, LabCorp and Quest Diagnostics over the past four years, according to the Center for Responsive Politics.

Supporters of FDA regulation include AdvaMedDx, the trade group that represents test kit manufacturers. AdvaMedDx says "FDA oversight of higher-risk diagnostic tests including companion diagnostics, regardless of the manufacturer, is essential to patient safety."

Given the existing political pressures, actual implementation of FDA regulation of LDTs is still uncertain and likely to be years away, notes *Laboratory Economics*.

PROPOSED HOSPITAL OUTPATIENT RULE (*cont'd from page 1*)
"Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item," stated CMS in the Proposed Rule for 2015. "Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner." *Laboratory Economics* interprets this to mean: Hospitals and physicians should expect billing challenges and reduced reimbursement for outpatient procedures in 2015.

Effective January 1, 2014, Medicare bundled the payment for nearly all outpatient clinical lab tests and a handful of add-on pathology tech services. This change eliminated nearly $3 billion per year in payments that hospitals had received from billing outpatient lab tests through the Clinical Lab Fee Schedule (*see details on page 5*).

The Proposed Rule for 2015 expands the bundling initiative to include nearly all pathology tech services. Outpatient pathology services slated to be bundled include APCs 342 & 433, which include the CPT codes for tissue exams (88304, 88305 & 88307), special stains (88312 & 88313), FISH testing (88365, 88367 & 88368), immunohistochemistry (G0461 & G0462), et al. If finalized, these services will no longer generate separate payment when provided in association with a primary procedure.

The Proposed Rule for 2015 states that CMS "with few exceptions, would consider all other services reported on a hospital Medicare Part B claim in combination with the primary service to be related to the primary service," regardless of any differences in the dates of service.

Under the Proposed Rule for 2015, only pathology tech services that are provided individually to hospital outpatients without additional services would be eligible for separate payment beginning January 1, 2015. In addition, as mentioned earlier, pathologists would still be able to bill separately through the Physician Fee Schedule for professional services provided to hospital outpatients.

For example, currently an Upper GI Endoscopy and Biopsy (CPT 43239) for a hospital outpatient with the average 2.2 tissue exams (CPT 88305-TC) is reimbursed by Medicare at $670 plus 2.2 x $36.53 for a total of $750.37. Under the Proposed Rule for 2015, the new OPPS reimbursement rate would be a single payment of $746.72.

The Part B Medicare reimbursement rate for the pathologist's interpretation in the example above is unchanged at approximately 2.2 x $38 for a total of $83.60 for the average GI biopsy. However, the new bundling system will tilt the financial incentive for the hospital toward performing fewer tissue exams, as well as special stains, for every outpatient biopsy procedure. Less utilization equals higher profit to the hospital under a bundled payment. It also means less professional interpretations for pathologists.

"Overall, the CY2015 OPPS Proposed Rule suggests that CMS is committed to transitioning outpatient hospital services to a more comprehensive bundled payment system in the near future. For hospitals and providers, this Rule, when combined with the Two Midnight Rule, may foretell the decline of the outpatient department as the ever-reliable profit center," according to an analysis written by healthcare attorney Laura Little from Arnall Golden Gregory LLP (Atlanta).

The Final Rule for 2015 will be issued on or around November 1.

PROPOSED OPPS RATES FOR KEY PATHOLOGY SERVICES FOR 2015

The proposed OPPS rates for 2015 are set to increase dramatically. However, most pathology tech services would no longer be eligible for separate payment.

Proposed Opps Rates For Key Pathology Services

CPT/APC	Description	Proposed Bundled?	Proposed 2015 Rate	Final 2014 Rate	Percentage Difference
88104/450	Cytopath, smear	Bundle	$28.57	$19.84	44.0%
88108/450	Cytopath, concentrate tech	Bundle	28.57	19.84	44.0%
88112/342	Cytopath cell enhance tech	Bundle	54.43	36.53	49.0%
88120/433	FISH manual for urine sample	Bundle	181.66	61.47	195.5%
88121/433	FISH computer for urine sample	Bundle	181.66	179.67	1.1%
88172/342	Cytopath dx eval FNA 1st each site	Bundle	54.43	19.84	174.3%
88173/342	Cytopath eval FNA report	Bundle	54.43	36.53	49.0%
88177	Cytp FNA eval each additional	Bundle	Bundle	Bundle	NA
88184/433	Flowcytometry/tc, 1 marker	Bundle	181.66	36.53	397.3%
88185	Flowcytometry/tc, add-on	Bundle	Bundle	Bundle	NA
88187/661	Flowcytometry/read, 2-8	No	342.64	179.67	90.7%
88188/661	Flowcytometry/read, 9-15	No	342.64	278.23	23.1%
88189/661	Flowcytometry/read, 16 & >	No	342.64	36.53	838.0%
88300/450	Level I-surgical pathology	Bundle	28.57	19.84	44.0%
88302/450	Level II-surgical pathology	Bundle	28.57	19.84	44.0%
88304/342	Level III-surgical pathology	Bundle	54.43	36.53	49.0%
88305/342	Tissue exam by pathologist	Bundle	54.43	36.53	49.0%
88307/433	Tissue exam by pathologist	Bundle	181.66	61.47	195.5%
88309/661	Tissue exam by pathologist	No	342.64	179.67	90.7%
88311	Decalcification procedure	Bundle	Bundle	Bundle	NA
88312/342	Special stains group 1	Bundle	54.43	19.84	174.3%
88313/342	Special stains group 2	Bundle	54.43	19.84	174.3%
88314	Histochem stains add-on	Bundle	Bundle	Bundle	NA
88321/450	Microslide consultation	Bundle	28.57	19.84	44.0%
88331/433	Path consult during surgery	Bundle	181.66	36.53	397.3%
88332	Additional frozen section	Bundle	Bundle	Bundle	NA
88334	Intraop cyto path consult 2	Bundle	Bundle	Bundle	NA
G0461/433	Immunohisto/cyto chem 1st st	Bundle	181.66	36.53	397.3%
G0462	Immunohisto/cyto chem add	Bundle	Bundle	Bundle	NA
88346/433	Immunofluorescent study	Bundle	181.66	36.53	397.3%
88360/433	Tumor immunohistochem/manual	Bundle	181.66	36.53	397.3%
88361/433	Tumor immunohistochem/computer	Bundle	181.66	36.53	397.3%
88367/433	FISH-computer assisted	Bundle	181.66	36.53	397.3%
88368/433	FISH-manual	Bundle	181.66	36.53	397.3%

Source: *Laboratory Economics* from CMS

MEDICARE SPENDING ON HOSPITAL LAB TESTS TO DECLINE BY 60% IN 2014

Medicare Part B spending on clinical laboratory services paid through the Clinical Lab Fee Schedule (CLFS) to hospitals will plummet 60% to $1.837 billion this year, according to estimates from CMS's 2014 Medicare Trustees Report. The severe decline is due to the switch to bundled payment for lab tests provided to hospital outpatients which became effective January 1, 2014. As a result of the change, hospital labs are now essentially only reimbursed through the CLFS for their lab outreach testing.

Meanwhile, Part B spending for lab tests performed by independent labs and physician offices will total an estimated $5.277 billion in 2014, up 3.1% from $5.116 billion in 2013.

Total Medicare program spending in 2014 will be an estimated $611.7 billion, up 4.9% from $582.9 billion in 2013. The number of Medicare beneficiaries this year increased by 3.3% to 54 million.

Part B lab services will represent only 1.2% of overall Medicare program expenditures this year.

The Medicare Trustees Report is compiled by actuaries from the Centers for Medicare and Medicaid Services (CMS). This annual report is required by law and constitutes the government's official report on the status of the Medicare program.

Medicare Part B Spending on Lab Services, 2009-2014 ($ millions)*

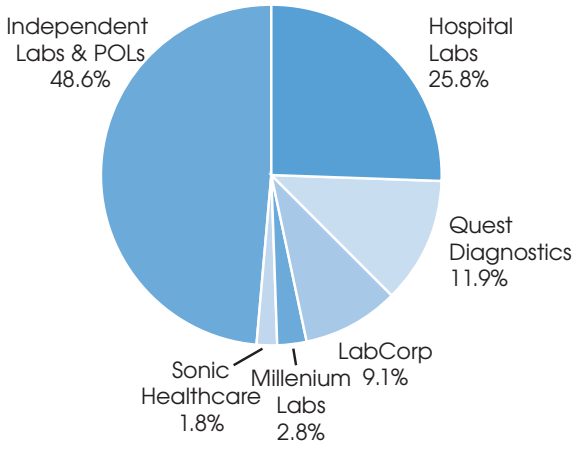
	2014E	2013	2012	2011	2010	2009	5-Year CAGR**
Intermediary Labs (hospitals)	$1,837	$4,630	$4,675	$4,420	$4,118	$3,983	-14.3%
Carrier Labs (independents & POLs)	5,277	5,116	5,102	4,579	4,808	4,671	2.5%
Total Part B Lab Spending	7,114	9,746	9,777	8,999	8,926	8,654	-3.8%
Total Medicare Expenditures	611,700	582,900	574,200	549,100	522,900	509,000	3.7%
Lab Spend as % of Medicare	1.2%	1.7%	1.7%	1.6%	1.7%	1.7%	NA

*Part B reimbursement amounts on a cash basis for the calendar year **CAGR=compound annual growth rate
Source: 2014 Medicare Trustees Report

Market Share for Medicare Part B Lab Spending in 2014

As a result of the new bundling payment rule for hospital outpatient lab testing, hospital labs' share of the Part B lab testing market has shrunk to 25.8% from approximately 50% previously. This market share change could have big implications in the calculations used by CMS to reprice the CLFS. CMS is currently in the rulemaking phase. The agency will collect pricing data from labs in 2016 and implement rate changes effective with the 2017 CLFS. The American Clinical Lab Assn. and its two largest members, Quest Diagnostics and LabCorp, are lobbying CMS to ensure that pricing surveys reflect the entire lab market and are not overweighted on the pricing from the two largest labs. Quest and LabCorp may have the lowest prices, but together they currently represent only 21% of Part B spending on lab tests paid through the CLFS.

Part B Lab Market Share



Source: *Laboratory Economics'* estimates based on data from CMS and company reports

TOP LABS RANKED BY MEDICARE PART B PAYMENTS

Altogether, the top 25 independent clinical labs received $3.2 billion in Medicare Part B payments in 2012, including payments made from both the CLFS as well as for pathology services paid through the Physician Fee Schedule. Quest Diagnostics, including AmeriPath and all other subsidiary labs, collected $1.1 billion, which accounted for approximately 15% of its overall $7.38 billion of revenue in 2012. LabCorp, including Dianon, Esoterix and all other subsidiary labs, collected $799 million in Part B payments, which represented 14% of its overall $5.671 billion of revenue in 2012.

Top 25 Clinical Labs Ranked by Medicare Part B Payments for 2012

Lab Company	*Medicare Payments*	*Medicare Patients*	*Avg. Payment Per Patient*
Quest Diagnostics	$1,129,596,458	8,072,915	$140
LabCorp	798,610,149	6,407,673	125
Millenium Labs of California	190,031,769	188,893	1,006
Sonic Healthcare	148,226,916	1,047,695	141
Health Diagnostic Lab	139,071,673	147,691	942
Bio-Reference Labs	105,565,117	384,912	274
AmeriTox Ltd.	99,553,259	140,313	710
Natural Molecular Testing Corp.	70,266,696	22,760	3,087
Miraca	65,947,920	232,077	284
Myriad Genetics	54,083,068	16,554	3,267
Genoptix	50,162,159	18,289	2,743
Genomic Health	49,334,918	14,335	3,442
Spectra	39,940,520	284,394	140
Aegis Sciences Corp.	36,150,368	66,583	543
Mayo Medical Labs	32,737,506	234,697	139
Clarient	32,496,485	38,917	835
Bostwick Labs	29,133,957	112,951	258
Physicians Choice Laboratory	24,879,615	29,537	842
ACL Laboratories	22,385,560	177,284	126
Trident USA Health	20,830,225	71,688	291
PAML	19,072,421	148,134	129
Visiting Physicians Assn.	18,698,173	37,895	493
Alere Toxicology Services	16,937,116	39,903	424
NeoGenomics	16,628,003	23,599	705
Atherotech	16,075,987	73,244	219
Total, 25 Labs	$3,226,416,040	18,032,933	$179

Source: *Laboratory Economics* from CMS Medicare utilization data for 2012

LABCORP MID-YEAR 2014: ACQUISITIONS BOOST REVENUE

LabCorp (Burlington, NC) reported net income of $254.4 million for the six months ended June 30, 2014, down 15% from $299.2 million in the same period for 2013. LabCorp's reported revenue increased by 1.3% to $2.947 billion in first-half 2014. *Laboratory Economics* estimates that LabCorp's organic revenue was flat after adjusting for the revenue added from numerous acquisitions, including Bendiner & Schlesinger Inc. (May 2013), Genesis Clinical Outreach Lab (June 2013), MuirLab (November 2013), et al. On July 18, the company held a conference call with analysts and investors to discuss its year-end results. Here's a summary of some key topics:

Molecular Test Reimbursement

Dave King, Chairman and CEO, said that LabCorp continues to have difficulty in getting paid for some molecular tests from some payers. Molecular testing represented $52 million of nonpayments for LabCorp in 2013, with Tricare representing a significant portion. Tricare began restoring payment for 40 commonly-ordered genetic tests, including cystic fibrosis, in July. Tricare had stopped covering many laboratory-developed genetic tests in January 2013 because the elimination of the molecular diagnostics CPT codes led Tricare to place the tests on the government's "no pay" list. In addition, King noted the rapid growth in the Medicaid population, but said that Medicaid payment policies tend to be very restrictive for molecular testing. "We started getting paid by some payers that were not paying us last year. But we've not seen any material overall improvement in the landscape," said King.

LabCorp Mid-Year Financial Summary ($ millions)

	6 months 6/30/2014	6 months 6/30/2013	% Chg
Total revenue	$2,947	$2,909	1.3%
Operating cash flow	350	336	4.1%
Capital expeditures	105	91	15.6%
Free cash flow	245	245	-0.1%
Pretax income	420	491	-14.5%
Net income	254	299	-15.0%
Diluted EPS	$2.94	$3.18	-7.5%
Total debt	3,008	2,510	19.8%
Cash & securities	480	111	330.8%
Shareholders' equity	2,656	2,663	-0.3%
Bad debt %	4.7%	4.3%	9.3%
Days sales outstanding	49	50	-2.0%
Number of requisitions	67.5	64.9	4.0%
Est'd revenue per requisition	$43.65	$44.81	-2.6%

Source: LabCorp

Bad-Debt Expense

LabCorp's bad-debt expense increased to 4.7% of revenue in first-half 2014 versus 4.3% in first-half 2013, driven by increased cost shifting to patients. King noted that more people were getting healthcare coverage under the ACA, but the average deductible before the patient gets $1 of benefit in a silver plan, for example, is about $3,000.

BeaconLBS

King said that LabCorp's lab test utilization management system, BeaconLBS, will begin rollout in Florida this fall for United Healthcare's fully-insured commercial members. Among other things, BeaconLBS directs physicians to order certain lab tests, including anatomic pathology and Pap tests, to a small network of labs dominated by LabCorp.

Texas Medicaid Under Investigation

LabCorp's latest 10K and 10Q revealed that in October 2013 the company received a civil investigative demand from the State of Texas Office of the Attorney General requesting documents related to its billing to Texas Medicaid. LabCorp said it is cooperating with the request. In addition, LabCorp faces a Medicaid pricing lawsuit in Florida, where the State Attorney General's Office has intervened as a plaintiff.

QUEST DIAGNOSTICS MID-YEAR 2014: ACQUISITIONS BOOST REVENUE

Quest Diagnostics (Madison, NJ) reported net income of $237 million for the six months ended June 30, 2014, down 21% from $301 million in the same period for 2013. Quest's reported revenue increased by 1.3% to $3.648 billion in first-half 2014. Recent acquisitions (Steward Health outreach lab, Summit Health, Solstas, ConVerge Diagnostic, et al.) added approximately 5% to Quest's reported revenue growth. On July 24, the company held a conference call with analysts and investors to discuss its year-end results. Here's a summary of some key topics discussed as well as info from the company's 10Q Report:

Anatomic Pathology

Quest CEO Steve Rusckowski said that given the substantial pathology reimbursement cuts over the past two years, Quest has made some deliberate choices to reduce its pathology practices in "some areas that we thought were not in the best interest of building value over time."

Affordable Care Act

Rusckowski said that Quest was beginning to see increased Medicaid patient volume as a result of the Affordable Care Act.

CMS's Repricing of the Clinical Lab Fee Schedule

Rusckowski said that CMS is in the middle of the rule-making process that will be used to develop a median market-based price approach to the Clinical Lab Fee Schedule. "And I will share with you that the trade association [ACLA] that I am now the Chair of is actively engaged in this, so I will tell you my colleagues that sit on the Board with me are also very actively engaged." Lobbying is focused on making sure that CMS includes all labs in its price sampling, including hospital outreach labs, which generally have the highest prices, according to Rusckowski. CMS is scheduled to collect pricing data from labs in 2016 and then reset pricing for the CLFS effective in 2017.

Medicaid Pricing Lawsuits

Earlier this year, Quest settled Medicaid pricing lawsuits filed against it by Hunter Laboratories in Massachusetts, Nevada and Georgia and reached an agreement in principle to settle a similar case in Virginia. Quest reported legal settlement costs of $11 million in the first half of this year. Quest still faces Medicaid pricing lawsuits in Michigan and Florida, where each State Attorney General's Office has intervened as a plaintiff.

Quest Diagnostics Mid-Year Financial Summary ($ millions)

	6 months 6/30/2014	6 months 6/30/2013	% Chg
Total revenue	$3,648	$3,602	1.3%
Operating cash flow	364	255	42.7%
Capital expeditures	117	105	11.4%
Free cash flow	247	150	64.7%
Pretax income	405	453	-10.6%
Net income	237	301	-21.3%
Diluted EPS	1.63	1.92	-15.1%
Total debt	3,958	3,497	13.2%
Cash & securities	144	148	-2.7%
Shareholders' equity	4,119	3,939	4.6%
Bad debt %	4.1%	3.9%	5.1%
Days sales outstanding	47	47	0.0%
Est'd number of requisitions	153	147	4.3%
Est'd revenue per requisition	$44.04	$45.17	-2.5%

Source: Quest Diagnostics and requisition estimates from *Laboratory Economics*

AURORA DIAGNOSTICS REFINANCES DEBT

Aurora Diagnostics (Palm Beach Gardens, FL) has entered into a new five-year loan agreement with Cerberus Business Finance LLC. (New York City), a private lending firm. The deal, which became effective July 31, 2014, includes a $165 million term loan, a $30 million revolving credit line and a $25 million delayed draw term loan. The loans are secured on a first-priority basis by a lien on substantially all of Aurora's tangible and intangible assets. Minimum interest on the loans is 8.25% per year.

Aurora says that approximately $145.6 million of the proceeds under the new loan agreement have been used to pay down the company's existing revolver and secured loan (which had been due to expire in May 2015 and May 2016, respectively). The balance of the proceeds, including the availability of the revolving credit line, will be used for potential future acquisitions and for general operational needs, according to Aurora.

Aurora now has total debt of approximately $350 million. In addition to the new Cerberus loan, Aurora has $200 million in unsecured notes outstanding that have an annual interest rate of 10.75% and come due in January 2018.

News of the refinancing puts to bed rumors of an imminent bankruptcy for Aurora, which started with a *Wall Street Journal* article late last year.

Aurora recently completed two acquisitions: Mid-Atlantic Pathology Services and Hallmark Pathology. In a press release, Aurora's CEO Dan Crowley said the company has an attractive pipeline of other potential acquisitions. "It is nice to have a financial partner like Cerberus, who worked with us to construct the credit facility to support our acquisition strategy," said Crowley.

Cerberus Business Finance LLC is a unit of Cerberus Capital Management LP (New York City), a private investment firm that specializes in distressed assets and securities.

SKINPATH PATHOLOGIST CLAIMS VICTORY IN LAWSUIT

After more than four years of legal filings, depositions, mediations and discovery, the 11th Circuit Court of Appeals in Northern Georgia has affirmed a summary judgment in favor of R. Wesley Wetherington, MD, in his legal battle with Quest Diagnostics' AmeriPath.

In brief, the legal saga started in April 13, 2010, after Quest officials showed up at the Dermpath Diagnostics' lab in Marietta, Georgia and escorted its Medical Director, Dr. Wetherington, out of the building because of rumors that he was considering leaving the company to start a competing lab. The next day Dr. Wetherington filed a lawsuit claiming his non-compete contract with AmeriPath was invalid because he was terminated without cause. Then on April 15, 2010, Dr. Wetherington formed his own lab company named SkinPath Solutions (Smyrna, GA). Quest's AmeriPath then filed a lawsuit against Wetherington claiming he violated his non-compete contract.

The 11th Circuit Court of Appeals affirmed a summary judgment that ruled that Wetherington was terminated and therefore AmeriPath's non-compete contract was unenforceable. The Circuit Court also affirmed a summary judgment that found the non-compete to be overly and unreasonably broad. In July 2014, Quest reimbursed Dr. Wetherington about $700,000 for his legal expenses.

"It is a great win for an individual who stood up to a major corporation. I am glad to have this nightmare behind us," Dr. Wetherington tells *Laboratory Economics*. He says that SkinPath Solutions currently has 33 employees with two board-certified dermatopathologists who will process roughly 80,000 patient cases this year.

GTCR BUYS BILLING FIRM XIFIN

The private equity firm GTCR (Chicago) has acquired XIFIN, Inc. (San Diego) for an undisclosed sum. XIFIN develops and markets financial management systems to anatomic pathology, radiology, hospital outreach, and independent clinical labs. XIFIN has more than 250 employees and the company's systems process more than $7 billion in claims annually.

Lâle White, who founded XIFIN in 1997, will remain Chief Executive at XIFIN. "We are excited to partner with Lâle and her team to acquire XIFIN," said Dean Mihas, Managing Director at GTCR. "GTCR looks forward to investing in the business and building a leading company within the healthcare information technology industry."

XIFIN's owners included White and the private equity firms Windward Ventures, Enterprise Partners and Boulder Ventures.

CAREDX RAISES $40 MILLION FROM IPO

CareDx (Brisbane, CA), formerly named XDx Inc., raised $40 million in a downsized IPO by offering 4.0 million shares at $10, well below the initial expected range of $15 to $17 per share. The company originally planned to raise $50 million by offering 3.1 million shares (see *LE*, August 2014, p. 11). CareDx trades on the NASDAQ under the symbol CDNA. Piper Jaffray and Leerink Partners acted as lead managers on the deal.

CareDx markets a proprietary laboratory-developed test ("AlloMap") that helps to determine the risk of rejection of a new heart in transplant candidates. All testing is performed at the company's CLIA-certified laboratory in Brisbane, California. The list price of AlloMap is $3,600.

The company said in its SEC filing that it had a $1.3 million net loss on revenue of $5.9 million for the three months ended March 31, 2014. That compares with a loss of about $1.35 million on revenue of $5 million in the same period a year ago. The volume of delivered tests was 2,800 tests in first-quarter 2014 versus 2,200 tests in first-quarter 2013. Since being formed in 1998, CareDX has accumulated losses totaling $161.5 million.

At the IPO price of $10 per share, CareDx has a current market value of $116 million, or approximately five times its annualized revenue of $23.6 million.

CareDx's biggest shareholders after the IPO include the private equity firms Kleiner Perkins Caufield & Byers, whose 9.1% stake is worth about $10.6 million, and TPG Biotechnology Partners, whose 8.8% stake is worth about $10.3 million. CareDx's CEO Peter Maag owns a 1% stake worth about $1.2 million.

CANCER GENETICS BUYS GENTRIS FOR $4.75 MILLION

Cancer Genetics Inc. (Rutherford, NJ) has acquired Gentris Corp. (Morrisville, NC) for $4.75 million, comprised of $3.25 million in cash and $1.5 million in Cancer Genetics stock. Gentris owners are also eligible for up to $1.5 million in performance-based payments that are tied directly to revenue milestones. Gentris operates a CLIA-certified 24,000-square-foot lab in Research Triangle Park that specializes in pharmacogenomics testing for cancer drug clinical trials. Gentris has 45 employees, $5-6 million in annual revenue and $1.5-1.8 million in net losses. Cancer Genetics plans to keep the lab open and Gentris founder Michael Murphy will serve as General Manager.

FDA CLEARS NEW AT-HOME DNA-BASED COLORECTAL CANCER TEST

The FDA has approved Cologuard, the first noninvasive DNA screening test for colorectal cancer. Priced at $599 per patient, Cologuard is designed to detect red blood cells and abnormal DNA in a patient's stool, and is intended for at-home use by adults age 50 and older. The test has been proven to find 92% of cancers and 69% of the most advanced precancerous polyps in average-risk patients.

David Ahlquist, MD, a gastroenterologist and professor of medicine at Mayo Clinic, is the inventor of the Cologuard technology, which has been licensed to Exact Sciences Corp. (Madison, WI). Under that licensing agreement, Mayo Clinic and Dr. Ahlquist share in equity and royalties. In addition, FDA approval has triggered a $500,000 milestone payment to Mayo Clinic.

Upon FDA approval, Exact Sciences also received a proposed coverage memorandum from CMS. The agency has proposed coverage for the Cologuard test once every three years for Medicare beneficiaries who are 50 to 85 years old who show no signs or symptoms of colorectal disease. A final National Coverage Determination is expected to be posted in October or November of this year, following a public comment period.

Through their physician, patients order a Cologuard kit mailed directly to their home. Patients then collect a stool sample via the Cologuard Collection Kit, then send the kit back to the Exact Sciences' CLIA-certified lab for testing. Exact Sciences reports a single test result—positive or negative for the presence of precancerous polyps or cancer—back to the patient's physician. Patients with positive test results are advised to undergo a diagnostic colonoscopy.

Cologuard is not the first DNA-based colorectal cancer test from Exact Sciences. The company previously marketed a laboratory-developed test named PreGen-Plus. On October 11, 2007, the FDA sent a warning letter to Exact Sciences, indicating that PreGen-Plus was a Class III medical device that required premarket approval. Shortly thereafter, Exact Sciences and its marketing partner at the time, LabCorp, stopped offering PreGen-Plus.

Exact Sciences is hoping that the combination of FDA approval, CMS coverage and a lower price will make Cologuard successful in the marketplace, observes *Laboratory Economics*.

Since being formed in 1995, Exact Sciences has accumulated losses totaling $243 million.

AETNA SUES LAB TO RECOVER $15 MILLION IN FRAUDULENT CLAIMS

Aetna Health Inc. has filed a 45-page civil complaint in Camden County Superior Court against Biodiagnostic Laboratory Services (BLS-Parsippany, NJ), three of its owners, and more than a dozen doctors who have admitted pocketing bribes from BLS in return for lab tests referrals.

The suit comes more than a year after the FBI arrested company officials and a group of doctors practicing in New Jersey/New York, and charged them with participating in a long-running bribes-for-referral scheme that generated more than $100 million in revenue for BLS.

The physicians "accepted bribes from BLS to induce their referrals of patients, including Aetna members, to BLS for lab tests rather than to an in-network laboratory provider," according to the lawsuit. Aetna says the scheme, which began at least as early as 2006, resulted in about $15 million in damages to Aetna. To date, at least 29 people, including the defendant doctors, have pleaded guilty to paying or accepting bribes to refer lab tests to BLS.

LAB STOCKS UP 10% YTD

Fourteen lab stocks increased an average of 10% year to date through August 13. In comparison, the S&P 500 Index is up 5.7%. The top-performing lab stock so far this year is Enzo Biochem, up 80%, followed by Myriad Genetics, up 72%,. LabCorp is up 13% and Quest Diagnostics is up by 14%.

Company (ticker)	Stock Price 8/13/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$32.09	$25.54	26%	$889	22.9	1.2	3.1
Cancer Genetics Inc. (CGIX)	9.85	13.78	-29%	91	NA	13.5	2.1
CombiMatrix (CBMX)	2.00	2.30	-13%	22	NA	3.2	1.7
Enzo Biochem (ENZ)	5.25	2.92	80%	230	NA	2.4	6.1
Foundation Medicine (FMI)	25.75	23.82	8%	726	NA	20.5	5.9
Genomic Health (GHDX)	27.56	29.27	-6%	869	NA	3.1	5.9
LabCorp (LH)	103.66	91.37	13%	8,801	16.8	1.5	3.3
LipoScience (LPDX)	3.00	4.25	-29%	46	NA	0.9	1.0
Myriad Genetics (MYGN)	36.04	20.98	72%	2,623	15.7	3.5	3.7
NeoGenomics (NEO)	4.88	3.62	35%	245	119.0	3.4	10.8
Psychemedics (PMD)	14.50	14.69	-1%	78	20.7	2.7	6.1
Quest Diagnostics (DGX)	61.15	53.54	14%	8,831	11.2	1.2	2.1
Response Genetics (RGDX)	0.67	1.16	-42%	26	NA	1.4	10.6
Sonic Healthcare (SHL.AX)	17.92	16.58	8%	7,183	19.6	2.0	2.4
Unweighted Averages			10%		32.3	4.3	4.6

Source: Bloomberg and Zacks

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