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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PALMETTO LEANS TOWARD MEDIAN PRICING FOR MDx TESTS

At recent meetings with California labs, Medicare carrier Palmetto GBA has suggested that it is reviewing median prices charged by labs using the old code-stack method of billing to determine the payment rates for 114 new molecular diagnostic test codes. Palmetto anticipates that it will publish these rates by the end of this month. Palmetto is the nation's largest Medicare carrier, processing claims in the J1 region (California, Nevada and Hawaii) and J11 region (North Carolina, South Carolina, Virginia and West Virginia). Other Medicare carriers are expected to follow Palmetto's lead. In the meantime, Palmetto and other carriers are delaying payment of claims for MDx tests. *Continued on page 6.*

COVERAGE DENIED FOR MOST MDx TESTS

Molecular labs around the country are waiting for Palmetto to release its payment rates for 114 new molecular diagnostic test codes. But a bigger issue has been Palmetto's strict coverage decisions for MDx tests. Reimbursement doesn't matter if an MDx test is not covered in the first place, observes *Laboratory Economics*.

Since July 2012, Palmetto has published coding guidelines and coverage updates for 22 tests under its Molecular Diagnostics Services Program (MolDx). Seventeen tests have been denied coverage and only five have received positive coverage decisions, according to an updated analysis by *LE*.

Many of the tests that have been denied coverage, such as UGT1A1 testing for colorectal cancer therapy selection, have been offered by the major national reference labs for years. *Continued on page 7.*

COURT REJECTS BOSTWICK'S REQUEST TO DISMISS WHISTLEBLOWER LAWSUIT

On December 18, a federal court in Ohio denied Bostwick Laboratories' motion to dismiss a False Claims Act (FCA) lawsuit regarding FISH bladder cancer testing.

The lawsuit was originally filed under seal in May 2008 by whistleblower Michael Daugherty, president of a competing lab company named LabMD (Atlanta). Daugherty filed an amended complaint (case: 1:2008cv00354) in Ohio Southern District Court on February 13, 2012.

Daugherty filed the lawsuit on his own behalf and on behalf of the United States as well as eight states to recover damages and penalties under the FCA. The Government, as well as the states, have declined to join the lawsuit. Nevertheless, Daugherty is pressing on. *Continued on page 2.*

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COURT REJECTS BOSTWICK'S REQUEST TO DISMISS (*cont'd from p. 1*)

Daugherty's lawsuit alleges that Bostwick Labs has defrauded the government by conducting expensive FISH bladder cancer tests without the ordering physician's consent and submitting these claims to Medicare and Medicaid. The lawsuit alleges that Bostwick had a policy of automatically performing reflex FISH tests on atypical urine cytology cases regardless of whether the treating physician ordered it or not.

Michael Daugherty

In addition, the lawsuit alleges that Bostwick Labs offered urology groups improper incentives to refer testing to Bostwick, in violation of the Stark Laws and the Anti-kickback Statute. Specifically, the lawsuit contends that Bostwick markets a program called "Tech 26" wherein Bostwick performs both the technical and the professional components of the FISH test but allows the urology group to bill for the professional component.

Daugherty's lawsuit quotes from a Bostwick marketing form titled "Tech 26 and FISH" that allegedly says:

> Basically, your clinic sends your FISH specimen to Bostwick Laboratories and we perform and bill for the technical component and then we send the report to your pathologist to sign off on and you bill for the professional component….There is no need to purchase a microscope, or anything else for that matter. The report includes a fluorescent photomicrograph of the FISH results and the initial diagnosis from our machine and cytotechs. There are no slides to store and you are able to bill Medicare.

Furthermore, the lawsuit alleges that Bostwick offers discounted billing for privately insured patients in exchange for referrals for Medicare business, routinely waives co-pays and deductibles for Medicare patients, and sets up and manages in-office pathology labs at below-market rates in exchange for referrals.

Bostwick filed a motion to dismiss, arguing that the lawsuit failed to specify any single allegedly false claim submitted to CMS.

In addition, Bostwick asserted that the testing services performed and billed were medically necessary and are not required to have physician's orders. As a general rule, Medicare only considers lab tests ordered by a treating physician to be "reasonable and necessary." However, Medicare has recognized exceptions to this rule that give pathologists discretion to order additional tests (e.g., special stains) that are necessary to report a complete and accurate diagnosis to the treating physician, noted Bostwick.

The motion also said that claims regarding Bostwick's TC/PC arrangements should be dismissed because the issue of markups has already been debated in the news media and in government hearings. Therefore, Bostwick argued that the lawsuit does not clear the jurisdictional bar meant to prevent parasitic whistleblower suits that do not bring new allegations of fraud to light.

Daugherty has attempted to "manufacture an FCA claim through second-hand reports, innuendo and speculation about otherwise legitimate business practices," according to Bostwick's motion to dismiss.

But U.S. Senior District Judge Arthur Spiegel was not persuaded by Bostwick's arguments for dismissal. "Tests billed without a physician's order under the circumstances alleged in the complaint could plausibly be found to be medically unnecessary and thus fraudulent under the FCA, and that is the only question before the Court at this stage," wrote Judge Spiegel.

Daugherty is being represented by Morgan Verkamp LLC (Cincinnati), which specializes in False Claims Act litigation. Attorney Jennifer Verkamp says the lawsuit has moved to the discovery phase which is expected to last approximately one year. She confirmed that the federal government is being kept abreast of the lawsuit and has the option of intervening at any point in the future.

Daugherty's lawsuit confronts a number of controversial issues in pathology, including FISH test utilization, TC/PC arrangements and the pricing of management services provided to in-office pathology labs.

In a statement, Jerry Diffley, vice president and chief compliance officer at Bostwick Labs, said, "While disappointed in the ruling, the company recognizes that this decision comes at the initial phase of litigation and, as the Court made clear, is not based on the underlying merits of the litigation, but rather simply on the sufficiency of the allegations contained in the Amended Complaint. Bostwick denies any wrongdoing and intends to vigorously defend this lawsuit. Bostwick is committed to conducting its business with the highest degree of ethics and integrity and providing patients, physicians and the public with the utmost of care."

Bostwick Labs (Glen Allen, VA) is the largest uropathology lab in the nation. The company was founded by David Bostwick, MD in 1999. The private equity firm MetalMark Capital (New York City) acquired a majority stake in Bostwick Labs in November 2011. Following that deal, Dr. Bostwick moved from the role of chief executive to chief medical officer. He also continues to own a significant minority stake in the company.

Bostwick Labs had once been one of the fastest growing pathology labs in the nation. In 2008, the company filed plans for an initial public offering (IPO) seeking to raise as much as $100 million. The company's revenue grew by 60% to reach $163 million in 2008. By mid-2009, Bostwick Labs reported having more than 1,000 employees, including about 60 pathologists (see *LE*, September 2009).

But the IPO was never completed and Daugherty's lawsuit may have been a factor. Remember, the initial lawsuit was filed under seal in May 2008 just after Bostwick Labs had announced plans to go public.

Meanwhile, Bostwick Labs has encountered several reimbursement setbacks over the past few years including: 1) Medicare reimbursement for FISH testing was cut by 50% in 2011; 2) Medicare carrier Palmetto GBA, which processes claims in Bostwick Labs' home state of Virginia, effectively cut pathology reimbursement for prostate biopsies by 50% by making a coding change last year; and 3) CMS slashed technical component rates for CPT 88305 by 50% effective January 1, 2013.

There is probably no pathology lab in the nation that has been hit harder than Bostwick Labs by the three reimbursement cuts listed above, observes *Laboratory Economics*.

Bostwick Labs closed its labs in Nashville, Tennessee and Tempe, Arizona in mid-2011. In addition, the company is scaling back its lab operation in Florida. The company's executive vice president for sales, Jed Fulk, resigned in December.

Not much is known about the privately held LabMD. The company was founded by its president and sole shareholder, Michael Daugherty, in 1996. Before starting LabMD, Daugherty worked as a surgical sales rep at U.S. Surgical Corp. and Mentor Corporation.

Initially, LabMD operated as a urology health center under the name Southern Diagnostics & Treatment Inc. In 2000, the company received its CLIA certificate and began lab operations. From 2001 to 2003, the company referred patient specimens to Bostwick Labs. In 2003, Southern Diagnostics changed its name to LabMD, and became a full-service uropathology lab. LabMD currently has 42 employees, including two pathologists, and provides uropathology services nationwide.

MIRACA SUES POPLAR FOR "EMPLOYEE RAIDING"

Miraca Life Sciences (Irving, TX) has filed a lawsuit against Poplar Healthcare LLC (Memphis, TN) alleging that Poplar has engaged in a "massive scheme of employee-raiding" and has intentionally targeted Miraca's clients.

The original complaint was filed on December 5, 2012. An amended complaint (case: 2:12-CV-03047) was filed in U.S. District Court for the Western District of Tennessee on January 11.

Miraca is the nation's largest outpatient GI pathology practice, interpreting GI biopsies from over 350,000 patients per year. Miraca also provides dermatopathology, uropathology and hematopathology services. Miraca, formerly named Caris Diagnostics, was purchased by Miraca Holdings (Tokyo, Japan) for $725 million in cash in November 2011.

Poplar, formerly named GI Pathology, specializes in gastroenterology and has expanded into dermatopathology and hematopathology in recent years.

Miraca alleges that its problems started when its Director of Business Development, Mark Balsano, cashed in his stock incentive plan for $508,719 and then went to work for Poplar in October 2011. Balsano was the first in a "wave of employees" that left Miraca and joined Poplar, according to the lawsuit. Miraca claims that Balsano violated the "detrimental activity" provision of his stock incentive plan with Miraca when he joined Poplar and began recruiting other Miraca employees. "Poplar knew of Miraca's contractual relationships with its employees and encouraged Balsano to interfere with those relationships," according to the lawsuit.

Another former Director of Business Development at Miraca, Joshua Hobbs, went to work for Poplar in February 2012. In addition, two former Sales Directors, David Heddon and Karen Goldenson, joined Poplar in early 2012. In March 2012, two of Miraca's pathologists, Christopher Golembeski, MD, and Shawn Kinsey, MD, gave notice of their intent to resign and then went to work for Miraca.

Miraca alleges that its former sales executives and two pathologists violated their non-compete contracts when they went to work for Poplar and then solicited Miraca's clients. Miraca alleges that Poplar continues to actively recruit Miraca's employees and solicit its clients. Miraca is seeking actual and consequential damages, damages for unjust enrichment, as well as punitive and exemplary damages, and attorneys' fees.

Poplar has not yet filed a response to Miraca's lawsuit.

Miraca Sues Dr. Cohen and Dr. Horn

Separately, Miraca filed a lawsuit last year against two former dermatopathologist employees, Thomas Horn, MD and Lisa Cohen, MD, and their current employer MGPO Dermatopathology Associates (MDA). The lawsuit (case: 12-11024-RWZ) accuses the defendants of breaking non-compete contracts to unfairly establish a competing lab against Miraca.

Dr. Cohen started Cohen Dermatolopathology in 1997 and was later joined by Dr. Horn and Lisa Lerner, MD. Drs. Cohen and Lerner were the only shareholders of Cohen Dermatopathology. In May 2007, Cohen Dermatopathology was sold to Caris Diagnostics for $80 million cash; Drs. Cohen and Lerner each received approximately $40 million, according to the complaint. Caris was subsequently acquired by Miraca in 2011.

Cohen, Horn, and Lerner grew increasingly dissatisfied with the operation and management of Cohen Dermatopathology, and between mid-2011 and early 2012, all three doctors resigned and joined MDA, a dermatopathology outreach lab formed by Massachusetts General Hospital.

In its most recent motion, Miraca asked the court to grant a preliminary injunction preventing Drs. Cohen and Horn from working at MDA. On Jan. 2, 2013, District Judge Rya W. Zobel ruled that Miraca had not demonstrated a likelihood of success of its claim and denied the request for a preliminary injunction. Court proceedings for this case have been stayed, pending the conclusion of arbitration.

DR. COCKERELL TO FORM NEW INDEPENDENT DERM LAB

Clay Cockerell, MD, managing director of Cockerell & Associates (Dallas), owned by Quest's Dermpath Diagnostics, has announced that he is leaving to establish a new, Dallas-based, independent dermatopathology lab named Cockerell Dermatopathology.

Dr. Cockerell and Quest have reached an agreement that will result in the transition of services from Cockerell & Associates to Cockerell Dermatopathology. The transition of services to Cockerell Dermatopathology is expected to be completed during the summer of 2013.

AmeriPath originally acquired Dr. Cockerell's lab, formerly named Freeman-Cockerell Labs, in 1996. AmeriPath, a pathology practice management company, was then acquired by the private investment firm Welsh Carson and ultimately sold to Quest Diagnostics in 2007 for $2 billion.

NEW INDEPENDENT LAB IN NORTH CAROLINA

Two medical technologists, Sylvia Small, age 43, and Rhonda Outlaw, 50, have opened a new independent clinical lab in Aberdeen, NC (about 50 miles from Raleigh).

Previously Small and Outlaw worked for Millennium Laboratories (Raleigh), a small independent lab that was acquired by LabCorp in 2011 and subsequently shut down. The transaction prompted the pair to become entrepreneurs and start their own lab company: Triune Laboratory.

Small says the biggest challenge was finding the initial financing of $300,000 to $350,000 needed to equip their new 2,200 square-foot lab. They raised most of the money from a pathologist in South Carolina, who wishes to remain anonymous, that they had both worked with before.

Triune started receiving patient specimens about nine months ago. The lab is currently processing about 600 tests per week and "business is steadily growing," according to Small. Triune's test menu includes chemistry, special chemistry, immunology, microbiology, hematology, and coagulation. The company has 11 full and part-time employees. Triune does some of its billing in-house and the remainder they vend out to Revenue Cycle Management LLC.

"We provide a personal service," says Small. "We are able to speak directly with our clients. We don't quite have a dedicated customer contact but we have a limited number of individuals who contact clients' offices once per week and make monthly visits. In addition, when you call, you speak to an owner."

Small says they plan to continue to focus on the local area (e.g., Sandhills, Aberdeen, Carthage, etc.) and then branch out to the Raleigh area. Triune aims to reach break-even in the first quarter of 2013.

PALMETTO LEANS TOWARD MEDIAN PRICING (*cont'd from p. 1*)

The American Clinical Laboratory Association (ACLA), which represents Quest Diagnostics, LabCorp and Myriad Genetics as well as 40 other lab companies, has been lobbying to have pricing for the 114 new MDx test codes set at the weighted median of the prices paid for these tests in the past. And it looks like Palmetto and other carriers will do just this.

Under this scenario, molecular labs that had priced their tests conservatively will see increased fees, while more aggressive labs will see reduced rates. For example, billing for Prostate Cancer Marker PCA3 (CPT 81479) at six labs has ranged from $80 to $165. Setting the price at the median of $132 would mean a price increase of 65% for the lowest priced lab and a decrease of 20% for the highest priced lab.

The table below shows hypothetical pricing for 20 key MDx tests, assuming that Palmetto and other carriers set rates for the new MDx codes at the median prices formerly charged by labs.

POTENTIAL PRICING FOR KEY MDX TESTS

Code	Lab Test	Sample Size	High Price	Median	Low Price
81200	Canavan Disease Mutation	5	$207	$152	$128
81206	BCR/ABL1 Quantitative	6	349	149	102
81210	BRAF Mutation	5	301	246	119
81223	Cystic Fibrosis	5	1,757	1,175	771
81225	CYP2C19 Genotype	13	731	386	178
81226	CYP2D6 Genotype	5	819	510	290
81227	CYP2C9 Genotype	7	641	344	88
81235	EGFR Mutation Analysis	6	1,722	646	296
81241	Factor V Mutation Analysis	5	117	70	65
81243	Fragile X DNA Test	5	135	87	46
81255	Tay-Sachs DNA Analysis	5	379	294	197
81270	JAK2 Mutation Analysis	5	88	70	65
81275	KRAS Mutation Analysis	6	637	290	256
81291	MTHFR DNA Analysis	6	146	82	52
81342	T-Cell Gene Rearrangement	5	273	201	106
81350	UGT1A1 Genotyping	6	313	58	58
81401	TPMT Genotype	5	130	117	82
81404	c-Kit Mutation Analysis	5	515	343	220
81479	Prostate Cancer Marker (PCA3)	6	165	132	80
86152	Circulating Tumor Cells	5	717	490	424

Source: *Laboratory Economics'* analysis of test code stacks

COVERAGE DENIED FOR MOST MolDx TESTS (*cont'd from page 1*)
Palmetto is denying coverage for most MDx tests because of insufficient evidence of clinical utility. In other words, Palmetto wants to see published studies demonstrating that physicians actually make clinical decisions based on test results.

Labs performing tests that have been denied coverage by Palmetto must seek payment from the patient's private insurance carrier or from the patient themselves.

Palmetto launched its ambitious MolDx earlier last year to "identify tests, determine coverage and determine reimbursement" for up to 1,500 molecular diagnostic tests.

PALMETTO MOLDX COVERAGE DECISIONS (THROUGH JAN. 8, 2013)

Coverage Decision	Test Name	Manufacturer/ Marketer	Test Purpose
Denied	4q25-AF Risk Genotype	Quest's Berkeley HeartLab	Risk assessment for stroke
Denied	9p21 Genotype Test	Quest's Berkeley HeartLab	Assess risk of coronary artery disease and/ or heart attack
Denied	ApoE genotype	various labs	Assess risk of cardiovascular disease
Denied	BluePrint	Agendia	Guide therapy selection for breast cancer patients
Denied	KIF6 Genotype	Quest's Berkeley HeartLab	Assess risk of coronary artery disease
Denied	LPA-Aspirin Genotype	Quest's Berkeley HeartLab	Predicts increased CVD risk and event reduction during aspirin therapy
Denied	LPA-Intron 25 genotype	Quest's Berkeley HeartLab	Predict increased risk for coronary heart disease
Denied	Pervenio Lung RS	Life Technologies	Assess risk of early stage lung cancer
Denied	PreDx	Tethys Bioscience	Assess risk of type 2 diabetes
Denied	Prostate Markers (PTEN, ERG, HOXD3)	various labs	Molecular markers for prostate cancer
Denied	PTEN testing	various labs	For therapy selection in range of cancers
Denied	SLCO1B1 genotype	various labs	Assess effectiveness of statin therapy
Denied	UGT1A1 Gene Analysis	various labs	Guide therapy selection for colorectal cancer
Denied	Cytogenomic microarrays	various labs	Genetic screening test
Denied	Septin 9 Methylated DNA Test	various labs	Colorectal cancer screening test
Accepted	bioTheranostics CancerType ID	bioMerieux	Determine primary site of origin for metastatic cancer
Accepted	Vysis ALK Fish Test	Abbott	Guide therapy selection for patients with lung cancer
Denied	know error DNA Assay	Strand Diagnostics LLC	Track patient biopsy specimens
Accepted	Progensa PCA3 Assay	Gen-Probe	Identify patients with increased risk of prostate cancer
Accepted	BRAF V600 mutation test	Roche	Determines patient eligibility for Zelboraf for melanoma treatment
Accepted	Corus CAD Test	CardioDx	Diagnose coronary artery disease
Denied	OncoCee CTC Assay	Biocept	Detect metastatic disease for breast, prostate, lung and colon cancer

Source: *Laboratory Economics* from Palmetto GBA

MERGERS & ACQUISITION SUMMARY

Quest Diagnostics Buys Two Businesses from UMass

Quest completed its previously-announced deal to buy the UMass outreach lab. Under a new deal, Quest also acquired UMass' anatomic pathology outreach laboratory division. UMass pathologists will provide professional pathology services to Quest. Quest has finalized a 200,000-square-foot lease deal in Marlborough where it will build a lab over the next 18 to 24 months. Quest plans to move its acquired UMass lab operations there. In addition, Quest will consolidate its Athena Diagnostics business in Worcester as well as its Cambridge lab into the new facility.

Quest Sells OralDNA Labs to Access Genetics

As part of this transaction, OralDNA's testing services, now provided in Brentwood, TN, will be moved into Access Genetic's CLIA-certified lab in Eden Prairie, MN. The purchase price was not disclosed. Quest originally purchased OralDNA in mid-2009.

In addition, Quest has announced plans to sell its HemoCue point-of-care testing business. Quest says that it will record a loss of $89.5 million related to the sale of HemoCue and OralDNA Labs.

OPKO Completes Purchase of OURLab

OPKO Health Inc. (Miami) has completed its previously-announced deal to acquire Prost-Data Inc., doing business as OURLab (Nashville), for $40 million from its sole shareholder Jonathan Oppenheimer, MD. The transaction closed on December 17, 2012. The purchase price included $9.4 million in cash and $30.6 million in stock.

Lab21 Sells South Carolina Labs

Lab21 Limited (Cambridge, UK) has sold its South Carolina clinical labs (Greenville and Columbia) to the local management team led by Michael Bolick and South Carolina-based investors. The acquired labs have been renamed Selah Genomics Inc. The sale will remove a loss-generating business from Lab21, which now plans to focus on its diagnostic test kit business, according to CFO Susan Lowther.

PathCentral Sells Lab Business

PathCentral (Irvine, CA) has sold its small CLIA-certified lab to Ascend Clinical LLC (Redwood City, CA). Ascend, formerly named Satellite Laboratory, specializes in end-stage renal disease (ESRD) lab testing for dialysis clinics. With the sale, PathCentral plans to focus on its cloud-based technology, including its Anatomic Pathology Laboratory Information System (APLIS) and the PathCentral Online Professional Network.

Sterling Reference Labs (Tacoma, WA) Buys Two Drug Testing Labs on the East Coast

Sterling acquired SECON of New England (Worcester, MA) and Graham-Massey Analytical Labs (Shelton, CT). SECON operates a CLIA-certified lab that provides drug testing services to clients in Massachusetts, Connecticut, Pennsylvania, Florida, Georgia, Indiana, Louisiana, North Carolina, Rhode Island and Texas. Graham-Massey operates a CLIA-certified lab that provides drug testing and low-price routine clinical lab testing under the brand ThriftyLab. Sterling is owned by the private equity firm Waud Capital Partners (Chicago).

Visiopharm Acquires Digital Pathology Consultants

Denmark-based Visiopharm has acquired the consulting firm Digital Pathology Consultants LLC (Westminister, CO). Amanda Lowe, founder and president of DPC, has become Visiopharm's Director of Marketing for the Americas. Visiopharm markets digital pathology systems to biopharmaceutical companies and clinical researchers.

DRUGS-OF-ABUSE TESTS ARE FASTEST-GROWING PART B TESTS

Three tests for drugs of abuse rank at the top for Medicare Part B carrier spending growth between 2008 and 2011. Part B carrier spending on tests for opiates (CPT 83925) and benzodiazepines (CPT 80154), which are typically performed to monitor patients on chronic pain medication, grew at respective annual rates of 92% and 75%. Spending on marijuana testing--cannabinoids (CPT 82542)--grew by 54% per year. Expenditures on vitamin D tests (CPT 82306) increased by 38% per year. CPT 84999 (unspecified chemistry test) grew by an average of 31% per year. This code is being used for a variety of new tests that have not received specific CPT codes.

MEDICARE PART B CARRIER SPENDING ON TOP 30 CLINICAL LAB TESTS

CPT Code	2011	2008	3-Year CAGR*
84443 (TSH)	$355,253,940	$322,710,635	3.3%
85025 (CBC)	340,823,447	337,339,715	0.3%
80053 (metabolic panel)	322,272,358	295,251,361	3.0%
80061 (lipid panel)	306,032,877	298,552,579	0.8%
82306 (vitamin D)	225,065,643	85,683,525	38.0%
83036 (A1C)	175,994,402	156,344,160	4.0%
85610 (prothrombin time)	115,243,109	119,027,090	-1.1%
84153 (PSA)	95,176,565	95,007,665	0.1%
80048 (metabolic panel)	90,546,835	93,792,696	-1.2%
83925 (opiates)	77,922,525	10,984,425	92.1%
82607 (vitamin B12)	72,591,743	57,384,019	8.2%
83970 (parathormone)	68,014,528	182,934,759	-28.1%
84999 (unspecified chemistry test)	56,738,467	25,364,100	30.8%
87086 (urine culture)	54,628,400	47,385,679	4.9%
84439 (thyroxine, free)	54,044,400	43,388,133	7.6%
83880 (BNP)	52,202,329	49,133,551	2.0%
82728 (ferritin)	46,545,951	73,882,795	-14.3%
82746 (folate)	42,373,305	35,012,180	6.6%
82542 (cannabinoids)	37,382,667	10,168,433	54.3%
84403 (testosterone, total)	34,482,832	20,551,031	18.8%
82570 (creatinine)	34,024,377	24,648,383	11.3%
87186 (MIC)	32,146,272	23,333,833	11.3%
85027 (CBC)	31,674,305	24,993,906	8.2%
81001 (urinalysis)	31,136,974	27,493,977	4.2%
83898 (molecule nucleic ampli, each)	27,104,485	15,671,344	20.0%
87088 (urine culture)	26,494,587	25,241,231	1.6%
83550 (TIBC)	24,932,507	46,306,107	-18.6%
86235 (nuclear antigen antibody)	24,731,938	19,281,890	8.7%
83540 (iron)	23,605,960	43,810,630	-18.6%
80154 (benzodiazepines)	23,476,043	4,385,900	74.9%
Total, 30 Tests	**$2,902,663,768**	**$2,615,065,733**	**3.5%**

*CAGR=compound annual growth rate

Source: *Laboratory Economics* from CMS's Part B Extract and Summary System (BESS), 2008-2011

PATHOLOGY CLAIMS VOLUMES GROWING BY 3.6% PER YEAR

Submitted claims to Medicare Part B carriers for 30 key anatomic pathology and serum cancer marker codes increased by an average of 3.6% per year between 2008 and 2011, according to data collected by *Laboratory Economics* from CMS. Submitted claims for CPT 88305 grew by a modest 3.2% per year. Claims volume grew fastest for CPT 88275 (cytogenetic analysis), up 15.7% per year, and CPT 88342 (immunohistochemistry), up 12% per year.

MEDICARE PART B CARRIER SUBMITTED CLAIMS FOR KEY PATHOLOGY CODES

CPT Code	2011	2008	3-year CAGR*
88305 (Level IV, tissue exam by pathologist)	20,717,354	18,833,168	3.2%
88342 (Immunohistochemistry)	4,810,717	3,428,438	12.0%
84153 (PSA total)	4,420,305	4,472,707	-0.4%
88185 (Flow cytometry, add on)	2,968,824	2,384,535	7.6%
88313 (Special stains)	1,708,880	1,373,282	7.6%
88312 (Special stains)	1,642,291	1,449,015	4.3%
88112 (Cytopath cell enhance tech)	1,256,358	985,547	8.4%
88304 (Level III, tissue exam by pathologist)	1,235,850	1,228,700	0.2%
88307 (Level V, tissue exam by pathologist)	969,758	932,868	1.3%
82378 (CEA)	823,434	876,191	-2.0%
88331 (Pathology consult during surgery)	604,447	601,920	0.1%
86300 (CA 15-3)	471,622	459,734	0.9%
88108 (Cytopath, concentrate tech)	396,418	404,919	-0.7%
88173 (Cytopath eval FNA)	366,188	331,575	3.4%
88368 (FISH-manual)	330,034	343,395	-1.3%
84154 (Free PSA)	328,648	285,328	4.8%
88346 (Immunofluorescent study)	319,552	237,484	10.4%
86304 (CA 125)	255,514	265,952	-1.3%
88321 (Microslide consultation)	210,364	203,037	1.2%
88189 (Flow cytometry, read 16+)	191,015	161,029	5.9%
88367 (FISH-computer assisted)	189,036	412,434	-22.9%
88309 (Level VI, tissue exam by pathologist)	177,331	188,617	-2.0%
82105 (AFP)	176,090	143,057	7.2%
88271 (Cytogenetics, DNA probe)	170,338	143,772	5.8%
82232 (B2M)	165,522	169,728	-0.8%
88184 (Flow cytometry, 1 marker)	142,821	126,745	4.1%
86301 (CA 19-9)	127,878	117,367	2.9%
86294 (Immunoassay for tumor antigen)	85,532	134,149	-13.9%
84432 (Thyroglobulin)	82,970	60,420	11.2%
88275 (Cytogenetic analysis, 100-300 cells)	81,907	52,828	15.7%
Totals	**45,426,998**	**40,807,941**	**3.6%**

Note: Claims volume totals are sum of submitted claims for TC, PC and global services
*CAGR=compound annual growth rate
Source: *Laboratory Economics* from CMS's Part B Extract and Summary System (BESS), 2008-2011

NATIONAL HEALTH SPENDING UP 3.9%

U.S. healthcare spending reached $2.701 trillion in 2011, or $8,680 per person, according to the annual report that the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) released Jan. 7. Healthcare expenditures grew 3.9% in 2011, the same rate of growth as in 2009 and 2010. Healthcare spending as a share of Gross Domestic Product (GDP) has remained stable from 2009 through 2011, at 17.9%.

• **Hospital Services:** Increased by 4.3% to $850.6 billion in 2011 compared with 4.9% growth in 2010. The slower growth in 2011 was influenced by a slowdown in price growth and continued low growth in the use of hospital services.

• **Physician and Clinical Services:** Up 4.3% to $541.4 billion in 2011, accelerating from 3.1% growth in 2010. Although growth in prices slowed, non-price factors such as use and intensity of services increased faster in 2011. Spending by private health insurance and Medicare, the two largest payers of physician and clinical services, both accelerated in 2011.

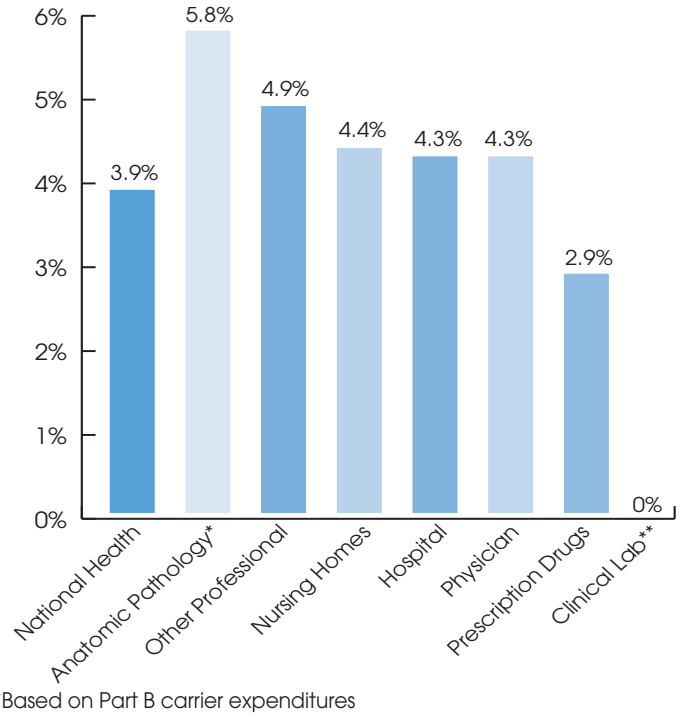
In comparison, Medicare Part B expenditures on **Anatomic Pathology Services** grew by 5.8% to $2.7 billion in 2011. And Medicare Part B spending on **Clinical Lab Tests** was flat at $8.9 billion.

• **Retail Prescription Drugs:** Grew by 2.9% to $263 billion in 2011, following a historically low growth rate of 0.4% in 2010. The acceleration in 2011 was partly due to both faster growth in prescription drug prices, partially for brand-name and specialty drugs, and increased spending on new brands. However, the relatively low rate of growth in 2011 continued to be influenced by slower growth in the number of prescriptions dispensed, increased use of generics, and continuation of patent expirations for brand-name drugs.

• **Nursing Homes:** Increased by 4.4% to $149.3 billion, an acceleration from growth of 3.2% in 2010. The faster growth in 2011 was primarily due to a one-time sharp increase in Medicare spending for skilled nursing facilities.

• **Other Professional Services:** Up 4.9% to $73.2 billion in 2011—slightly faster than 4.6% in 2010. This category includes physical therapy, optometry, podiatry and chiropractic medicine.

Comparison ofHealthcare Spending Growth Trends for 2011



*Based on Part B carrier expenditures
**Based on Part B carrier and fiscal intermediary expenditures
Source: *Laboratory Economics* from CMS

LAB STOCKS ROSE 25% IN 2012

Ten lab stocks rose by an unweighted average of 25% in 2012. However, the combined market capitalization for the group was down 1% to $21.8 billion. In comparison, the S&P 500 Index was up 12% and the Nasdaq was up 14% in 2012. The top-performing lab stocks in 2012 were Medtox Scientific (which was acquired by LabCorp in July 2012), up 92%, followed by NeoGenomics, up 77%, and Bio-Reference Labs, up 76%. LabCorp shares were up 1% and Quest Diagnostics was unchanged.

Company (ticker)	Stock Price 12/31/12	Stock Price 12/30/11	2012 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$28.63	$16.27	76%	$793	19.1	1.2	3.5
CombiMatrix (CBMX)	5.28	20.00	-74%	6	NA	1.1	2.1
Enzo Biochem (ENZ)	2.70	2.24	21%	106	NA	1.0	2.3
Genomic Health (GHDX)	27.24	25.39	7%	838	93.9	3.7	5.7
LabCorp (LH)	86.62	85.97	1%	8,194	12.7	1.5	3.1
Medtox Scientific (MTOX)*	27.00	14.05	92%	242	16.6	2.1	NA
Myriad Genetics (MYGN)	27.25	20.94	30%	2,218	19.9	4.3	3.5
NeoGenomics (NEO)	2.48	1.40	77%	112	NA	1.9	12.2
Psychemedics (PMD)	10.75	9.10	18%	57	17.9	2.3	4.9
Quest Diagnostics (DGX)	58.27	58.06	0%	9,263	12.5	1.2	2.2
Unweighted Averages			25%	$21,828	27.5	2.0	4.4

*Medtox was acquired by LabCorp in July 2012 for $27 per share.

Source: Zacks Investment Research

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