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VOLUME 6, NO. 10 OCTOBER 2011

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

JAPANESE FIRM TO PAY $725M FOR CARIS DIAGNOSTICS

Miraca Holdings (Tokyo, Japan) is buying Caris Diagnostics, the anatomic pathology business of Caris Life Sciences (Irving, TX), for a price tag equal to 3.5 times its annual revenue of $207 million. The $725 million cash deal is expected to close in December.

Miraca is the largest commercial lab testing company in Japan and it also sells diagnostic tests through its subsidiary Fujirebio Inc. Miraca president Hiromasa Suzuki said the acquisition will allow Miraca to expand outside of the Japanese lab market, which is shrinking by about 1% per year. Miraca plans to expand its new U.S. pathology lab business, including through potential additional acquisitions.

Suzuki said the strength of the yen, which is trading near a record high against the dollar, was a factor in Miraca's decision to buy Caris. *More details on page 3.*

ANDREW BAKER STUBBORNLY PURSUING MEDICARE FRAUD LAWSUITS VS. QUEST AND LABCORP

It's been more than six years since whistleblower Andrew Baker filed a lawsuit in New York federal court against Quest Diagnostics alleging Medicare fraud. And Baker filed a similar lawsuit against LabCorp four years ago. These lawsuits allege that Quest and LabCorp subsidized below-cost lab test pricing to managed care companies (e.g. Aetna, Cigna, UnitedHealthcare) by overcharging the Medicare program.

However, to date, federal prosecutors have not joined either case. "This is exactly the same situation as with California Medi-Cal, where they [California Attorney General's Office] saw they had been duped out of money and did something about it….I am totally flummoxed why the U.S. Justice Department has done nothing," says Baker.

Nonetheless, Baker says he will continue with his lawsuits. "The Medicare program is being damaged….The way lab testing is priced is highly inefficient," he contends. *Continued on pages 5-7.*

DIGITAL PATHOLOGY MARKET POSTS SLUGGISH GROWTH

After several years of 10% to 15% annual growth, the U.S. clinical market for digital pathology has lost speed. Medicare Part B carrier spending on CPT 88361 (digital pathology for quantitative IHC) increased by only 4% to $18.9 million in 2010. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor. *Continued on page 2.*

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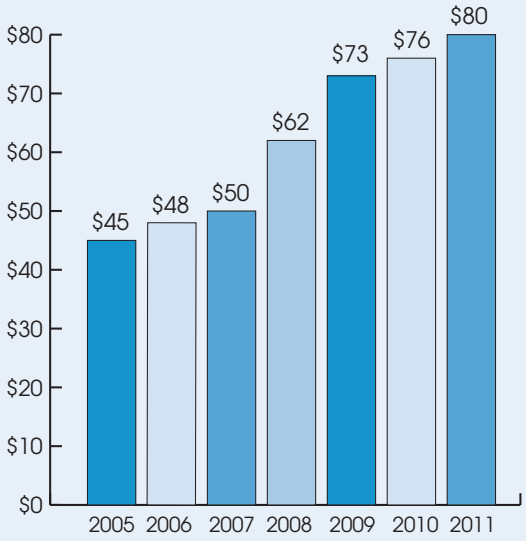
DIGITAL PATHOLOGY MARKET POSTS SLUGGISH GROWTH (*cont'd from p. 1*)

Laboratory Economics estimates the total U.S. clinical market for digital pathology is currently about $80 million (or about 4x the size of Part B carrier expenditures on 88361).

Approximately 500 academic medical centers, hospitals and independent labs have a digital pathology system in place. The market leaders are Aperio Technologies and BioImagene (owned by Roche-Ventana). At this point only the Aperio and BioImagene systems have FDA clearance for HER2 scoring. No vendor has received the Holy Grail: FDA clearance to use digital pathology as a primary diagnostic tool.

U.S. Clinical Market for Digital Pathology Services ($ millions)



Note: Estimates are for clinical market only and do not include digital pathology being used for non-clinical purposes such as clinical trials testing by pharmaceutical companies and use at academic medical centers for teaching purposes.
Source: *Laboratory Economics*

The lack of FDA clearance for primary diagnosis means no vendor can scale up so that prices can come down, according to Michael Farmer, principal at the IVD consulting firm McEvoy & Farmer (Seattle, WA). "At this point, a digital pathology system costs as much or more than an Xpress or Peloris or a Benchmark Ultra—and yet they are not viewed as being as essential as a high-throughput tissue processor or top-of-the-line IHC system at most of the labs," says Farmer.

Meanwhile, Allen Gown, MD, chief pathologist at PhenoPath Laboratories (Seattle, WA), believes glass slides will remain the principal media for pathologists for the next 10 years. "No digital image will ever be as efficient for ease of use as a glass slide," he told pathologists in a presentation at the Med3000-PSA conference in Palm Springs, California, September 21-23. Gown said the biggest problem is the storage of digitized images. "The technology gets obsolete very quickly, but I can still look at glass slides from 100 years ago." Over time, Gown thinks digital pathology's principal use will be for telepathology at remote locations and possibly quantification of IHC and FISH stains. "But we're waiting for more quantification tools," he added.

Medicare Part B Carrier Claims Data for CPT 88361, 2005-2010

CPT 88361 (digital pathology)	*2005*	*2006*	*2007*	*2008*	*2009*	*2010*	*1-Year Change*	*5-Year CAGR**
Total tests submitted	118,333	128,098	135,222	165,605	192,442	206,567	7.3%	11.8%
Amount submitted ($ mill)	NA	NA	$34.9	$46.3	$55.5	$58.1	4.7%	NA
Amount allowed ($ mill)	$11.2	$12.0	$12.4	$15.5	$18.2	$18.9	4.1%	11.0%

*CAGR=five-year compound annual growth rate.

Note: Data is for Medicare Part B carriers for CPT 88361, including global, technical-only and professional-only claims and expenditures. Source: CodeMap LLC (Schaumburg, IL)

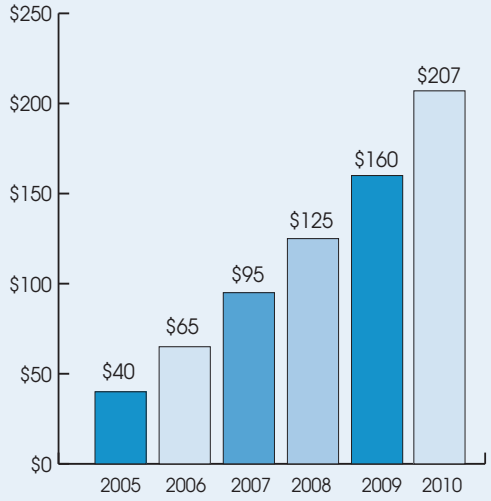
JAPANESE FIRM TO PAY $725 MILLION FOR CARIS (*cont'd from page 1*)

Caris Life Sciences (CLS) is majority-owned by entities that are controlled by its chairman and chief executive, David Halbert. Halbert's private equity firm, Caris Ltd., bought Caris Life Sciences (formerly named Pathology Partners) in May 2005 for $120 million. Another private equity firm, J.H. Whitney & Co. has a minority interest in Caris Life Sciences.

Miraca is buying CLS' primary business, Caris Diagnostics (CarisDx), which processes and analyzes biopsies from approximately 1 million patients per year. CarisDx employs 760 people, including 70 pathologists and more than 100 sales reps, at three labs in Dallas, Phoenix and Boston. CarisDx was founded in 1996 with a focus on gastrointestinal pathology. Over the past five years, the company has expanded into dermatopathology, hematopathology and uropathology. CarisDx had operating income of $34 million on revenue of $207 million in 2010.

The sale to Miraca will not include CLS' molecular profiling test unit, Caris Target Now, or its Carisome subsidiary, which is developing blood tests for cancer. These businesses will be combined and spun off into a separate company.

Revenue at Caris Diagnostics ($ millions)



Source: Miraca and Caris Life Sciences

Miraca has annual revenue of approximately 168.2 billion yen (USD $2.2 billion). As of March 31, 2011, the company held cash and securities of 33.5 billion yen (USD $438 million). Miraca says it will help finance its purchase of CarisDx with up to 50 billion yen (USD $650 million) in bank loans.

CarisDx increased its revenue by an average of 30% per year between 2007 and 2010. This growth occurred despite the histology lab insourcing trend at specialty groups (urology, gastroenterology and dermatology). Even so, at 3.5x annual revenue, Miraca is paying a steep price to enter the competitive U.S. anatomic pathology market.

Significant Pathology Lab Transactions ($ millions)

Date	Buyer	Target	Purchase Price*	Acquired Revenue	Price/ Revenue
Pending	Miraca Holdings	Caris Diagnostics	$725	206	3.5
Feb 2011	Novartis	Genoptix	330	195	1.7
Dec-10	LabCorp	Genzyme Genetics	925	370	2.5
Nov-10	Sonic Healthcare	CBLPath	124	85	1.5
Oct-10	GE Healthcare	Clarient Inc.	580	115	5.0
Oct-07	Aurora Diagnostics	Greensboro Pathology Consultants	145	35	4.1
Jun-07	Quest Diagnostics	AmeriPath	2,000	760	2.6
Mar-03	Welsh Carson	AmeriPath	839	485	1.7
Feb-03	LabCorp	Dianon	544	190	2.9
Jun-01	Dianon	UroCor	180	56	3.2
AVERAGE					2.9

*Purchase prices include assumed debt

Source: *Laboratory Economics*

MORE ON CAP ACCREDITATION OF IN-OFFICE LABS…

In the last issue of *Laboratory Economics* we noted the inconsistency of the College of American Pathologists' vigorous lobbying efforts against in-office histology labs, given the fact that many of these labs are attaining CAP accreditation (see *LE*, September 2011, page 1). Here is CAP's response to the article:

> *In regard to in-office laboratory business arrangements, the CAP's fundamental concern is that under the Stark in-office ancillary services self-referral exception, the incentive—regardless of accreditation—is to order and provide more testing services than are necessary, leading to overutilization of services and higher costs to the system. The incentives in these arrangements are misaligned, as is made clear by Congress's current efforts to move away from these types of payment incentives.*
>
> *The CAP accreditation process focuses on ensuring that every lab we accredit meets the highest possible standards for operation under the law. Through the process, we verify what testing and services are provided, and ensure that they comply with CLIA. However, the accreditation process does not include scrutinizing or collecting information on a lab's business arrangements.*
>
> *Due to the requirement that CAP-accredited labs provide like-teams to participate in the accreditation of other labs, it is rare for an in-office lab to qualify for CAP accreditation. However, it can happen if the lab meets all of CAP's requirements, or if CAP review is requested by CMS, which does happen from time to time.*

GULF COAST DERMATOLOGY OPENS LABS AND HIRES PATHOLOGIST

First it was urology groups, then gastroenterology and now dermatology practices are opening in-office histology labs. *Laboratory Economics* first reported the new dermatology group trend in February 2011. And now the trend is in full swing.

Gulf Coast Dermatology (Panama City, FL) is one of the most recent groups to open its own histology lab. Previously, the group sent its skin biopsies to an outside pathology lab.

The group, which has five dermatologists, has also hired a staff pathologist, Scott Schlauder, MD. Schlauder comes to Gulf Coast Dermatology after completing a residency in pathology at the University of South Florida and a fellowship in dermatopathology at the Tufts University School of Medicine in Boston.

Gulf Coast Dermatology's new lab is also offering histotechnology certification and has three students. The students are paid employees of the group. The training includes video conferencing and projects from the Indiana University School of Medicine's curriculum.

IOP CELEBRATES ITS 50TH IN-OFFICE LAB WITH FREE iPAD PROMO

The consulting firm In-Office Pathology LLC (IOP—Lake Forest, IL) recently completed the installation of its 50th histology lab. The company, which is run by Joe Plandowski and Bernie Ness, is celebrating this milestone by offering new specialty group clients a 50% discount off its list fees if they sign on to build an in-office lab. In addition, IOP is offering a free iPad 2 to the first five group managing partners that it talks with about opening a lab.

ANDREW BAKER STUBBORNLY PURSUING LAWSUITS (*cont'd from page 1*)

Fair Laboratory Practice Associates vs. Quest Diagnostics (case 1:05-cv-05393-RPP)

During the 1990s, Andrew Baker, Richard Michaelson and Mark Bibi were executives at California's largest lab company, Unilab. Baker was chairman and chief executive from 1993 through the end of 1996. Michaelson was chief financial officer from 1993 to 1997. And Bibi was general counsel, responsible for all legal affairs, between 1993 and the spring of 2000. Unilab was purchased by Quest Diagnostics in February 2003.


Andrew Baker

The three former Unilab executives created a general partnership, Fair Laboratory Practice Associates (FLPA), in late 2004 specifically to sue Quest Diagnostics for allegedly violating anti-kickback laws. The original *qui tam* (aka whistleblower) complaint was filed under seal in June 2005. An amended complaint was unsealed in 2009.

The lawsuit alleges that, since 1996, Quest/Unilab has been providing illegal kickbacks in the form of below-cost lab tests, to Aetna, Cigna and other managed care companies. Per-member per-month fees were as low as $0.50 for some contracts, according to the lawsuit. In exchange for the low rates, the suit says, managed care companies pressured physicians in their networks to send lucrative Medicare tests to Quest/Unilab.

The complaint quotes numerous Quest executives. For example, a Quest managed care manager is alleged to have told Quest employees: "Follow the Medicare. If we are not getting the capitated HMO crap, we are certainly not getting the Medicare pull-through. We need to button down these accounts that are leaking."

In April 2011, Judge Robert Patterson dismissed the case, ruling that Bibi, by participating in a lawsuit against his former employer, had disclosed confidential information in violation of state ethics rules (attorney-client privilege).

Baker and Michaelson tried to convince the court to let the lawsuit continue without Bibi, but Judge Patterson said that all three men and their lawyers were tainted by the wrongly disclosed confidential information. Furthermore, the judge ruled that Baker, Michaelson and Bibi are disqualified from filing future actions against Quest.

Baker says the ruling did not address the substance of FLPA's case against Quest/Unilab, but was dismissed based on a technicality. FLPA is appealing this ruling and will file its first brief on October 31.

Meanwhile, in July 2011, the U.S. District Attorney for the Southern District of New York announced its decision not to intervene in this whistleblower case.

Notes: The False Claims Act provides incentives to whistleblowers by granting them up to 30% of any settlement plus reimbursement of legal fees. Under the structure of the FLPA general partnership, Baker would receive 57% of any potential settlement, Bibi would get 29% and Michaelson would get 14%. Indeed, the FLPA partners stand to gain as much as $300 million, or 30% of the $1 billion of alleged damages.

Baker is currently chairman and chief executive of Life Sciences Research Inc., which is the parent company of Huntingdon Life Sciences (HLS). HLS is a contract animal testing company focused on pharmaceutical, food and veterinary research. Michaelson is chief financial officer and Bibi is general counsel.

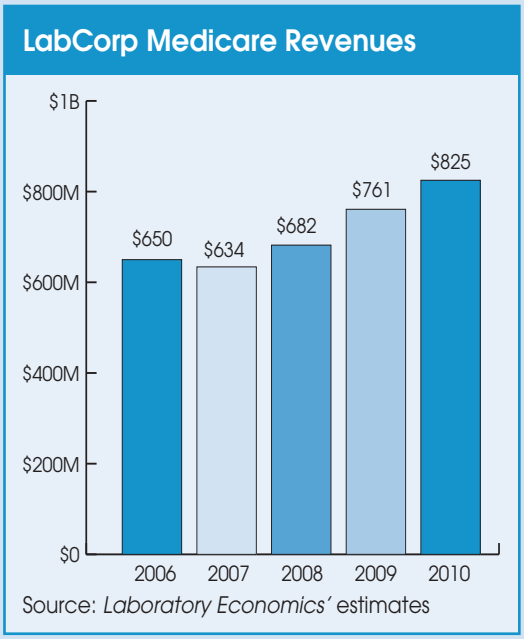
NPT Associates vs. LabCorp (case 1:07-cv-05696-GBD)

For this lawsuit, Andrew Baker formed a general partnership named NPT Associates. NPT Associates has two partners, Baker and an undisclosed individual. *Laboratory Economics* thinks the unnamed partner may be a former LabCorp executive. The original whistleblower complaint was filed under seal in June 2007. An amended complaint was unsealed in September 2011.

The lawsuit alleges that LabCorp entered into a 10-year contract with UnitedHealthCare, effective January 1, 2007, in which LabCorp gave UHC deeply discounted lab test prices in exchange for UHC requiring its network doctors to refer their Medicare patients to LabCorp. By doing so, LabCorp increased its Medicare revenue to nearly $1 billion per year, according to the suit.

To get this business, the suit says, LabCorp charged UHC less than one-half of what it charged Medicare for the same tests. In early 2008, LabCorp received approximately $7.43 for each test performed for in-network UHC physicians, which was below its cost, according to the suit.

The lawsuit cites a LabCorp National Awards Dinner held at the Four Seasons Hotel in Philadelphia in late 2007 or early 2008. At this dinner, Don Hardison, former chief operating officer at LabCorp, allegedly said that LabCorp did not enter into the contract to obtain UHC business; it entered into the contract to obtain Medicare business. Hardison allegedly said that if LabCorp did not obtain the Medicare pull-through business, "the company would lose its shirt and would not even be able to turn on the lights."



The suit claims that UHC threatened its contracted physicians who used out-of-network labs with financial penalties and ultimately with expulsion from UHC's networks.

The exchange of LabCorp's below-cost lab test pricing for UHC pressuring its physicians to send all their lab tests to LabCorp violates anti-kickback law and the False Claim Act, according to FPT's complaint.

Baker believes that labs are required to provide "best price" based on Section 1128(b)(6)(A) of the Social Security Act, which permits the Secretary of Health and Human Services to exclude a healthcare provider from the Medicare program if that provider has "submitted or caused to be submitted bills or requests for payment...under title XVIII [Medicare] or a state healthcare program containing charges...for items or services furnished substantially in excess of such individual's or entity's usual charges...for such items or services."

"Labs have played games to avoid this section by establishing unrealistically expensive patient fee schedules, which are much higher than the Medicare fee schedule, that they then point to as proof that they are not charging Medicare substantially in excess of their usual charges," according to Baker.

An initial pretrial conference for this case is scheduled for January 3, 2012. LabCorp has not yet filed a response to NPT's complaint and the company did not respond to *LE's* request for a comment.

ARE LABS SUPPOSED TO GIVE MEDICARE THEIR "BEST PRICE?"

Laboratory Economics posed this simple question to billing expert Lale White, chief executive of Xifin (San Diego, CA). Here is her condensed answer:

No, labs are supposed to bill Medicare their "usual charge." CMS has tried to redefine this term (usual charge) on three separate occasions without success. The last attempt was a draft issued in 2003 that tried to define "usual charge" as the average received from all fee for service non-Medicare/Medicaid payers, as well as prices billed to physicians and capitated rates. Charging Medicare more than 120% of this amount would have been considered "substantially in excess" of usual charges and thus a basis for exclusion from the Medicare program. However, this guidance was revoked in 2007.

Prior to 2003, the Office of Inspector General (OIG) had indicated that the "usual charge" was considered to be the standard "list" price routinely billed (not contracted reimbursement) to patients and other insurers (not direct physician billing).

It is important to note that the two reasons the OIG gave for withdrawing the proposed rule were: 1) the agency did not have sufficient data to establish a fixed benchmark for "substantially in excess" that could be applied for all healthcare services equitably; and 2) a concern for the unintended consequence of increasing healthcare costs by causing providers to raise prices to other payers as a result of the rule, rather than lowering prices to Medicare.

In the absence of this clarification, we would fall back on the prior interpretations. However, there is an advisory opinion on "Discount Arrangements Involving Clinical Labs" which also signals the percentage at which OIG would consider labs to have discounted at a rate that would alter the "usual charge." Here is the relevant excerpt from the advisory opinion published in April 2000:

> *Section 1128(b)(6)(A), which permits exclusion of providers that submit claims to Medicare or Medicaid for amounts substantially in excess of the provider's usual charges, is not a blanket prohibition on discounts to private pay customers. Section 1128(b)(6)(A) addresses a much narrower issue: tiered pricing structures that set one price for Medicare or Medicaid and a substantially lower price for most other customers. Given the statutory language, we do not believe that the section 1128(b)(6)(A) is implicated unless a provider's charge to Medicare is substantially in excess of its median non-Medicare/Medicaid charge. In other words, a provider need not even worry about section 1128(b)(6)(A), unless it is discounting close to half of its non-Medicare/Medicaid business. In addition, the statute contains an explicit exception permitting a charge differential where "the Secretary finds there is good cause" for the disparate treatment. Within these parameters, providers are free to negotiate discounts, so long as the discounts are not tied to unlawful referrals of Federal healthcare program business.*

Nonetheless, I think Medicare pricing regulations are much clearer than Medicaid regulations, particularly the regulations in California. California does not require lowest cost, but simply chooses to misinterpret their own language every couple of years. They could choose to clarify the language at any time, but they do not. There have been a couple of legal cases on this matter (e.g., Duz-Mor and Physicians & Surgeons). Both of those cases were lost by Medi-Cal, specifically because the Medi-Cal language is NOT lowest cost language. The recent qui tam settlements have done absolutely nothing to clarify the language and most certainly do not set a legal precedent. Meanwhile, Medicare has defined usual and customary. There is also plenty of documentation to indicate that neither lowest cost nor direct client/physician billing is included in the definition of usual and customary.

CPT 88305 TC FACES POTENTIAL DEVASTATING CUT

The Centers for Medicare and Medicaid Services has requested the AMA's Relative Value Upscale Committee (RUC) to review the direct practice expense (PE) and work values for the technical component of CPT 88305. CMS thinks the code may be overvalued.

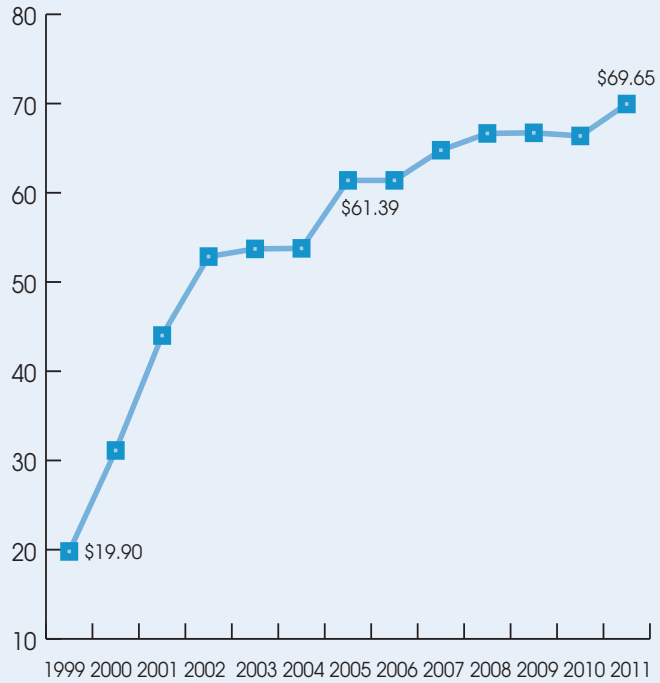
The agency's concern was outlined in its proposed physician fee schedule rule for 2012 released on July 1, 2011. On page 42795 of the proposed rule, CMS stated, "A stakeholder informed us that the direct PE inputs associated with a particular tissue examination code [CPT 88305] are atypical….The stakeholder claims that in furnishing the typical service, the required material includes a single block of tissue and 1-3 slides. The stakeholder argues that the typical cost for the service amount is approximately $18, but the PE RVUs for 2011 result in a national payment rate of $69.65 for the technical component of the service."

CMS has requested that AMA RUC review CPT 88305 "as soon as possible."

The little-known AMA group, which is comprised of 29 doctors, has a powerful influence on Medicare payment rates. Since 1991, the RUC has submitted more than 7,000 recommendations to CMS on the value of physician work. CMS has overwhelmingly rubber-stamped RUC recommendations, accepting more than 94%, according to AMA numbers.

The potential for a review and cut in CPT 88305 reimbursement was "a huge topic of discussion for the top brass" at the recent College of American Pathologists' annual conference in Dallas, Texas, according to a pathologist who attended CAP executive meetings but wishes anonymity.

Medicare Reimbursement for CPT 88305 Technical Component*



*National payment unadjusted for geographic practice cost differences.
Source: Medicare physician fee schedules, 2001 to 2011

In an August 30, letter to CMS Administrator Donald Berwick, MD, the trade group said, "CAP disagrees with the request to review the work RVU of this code based on the most recent extensive review conducted by the RUC over a prolonged process to validate the work RVU for CPT code 88305 as well as other codes in this family." CAP said the review of these codes, completed in April 2010, had between 84 and 165 survey respondents for each code and concluded that the current work values were accurate.

Laboratory Economics notes that CPT 88305 is the bread and butter procedure for pathologists. Medicare reimbursement for the technical component of CPT 88305 has risen by an average of 11% per year since 1999. Any significant cut in Medicare reimbursement for this code would be devastating to pathologists and labs.

MEDICARE PAYMENT TRENDS FOR PATHOLOGY

National Medicare Part B carrier payments for 12 high-volume pathology codes increased by 7.8% to $2.3 billion in 2010, according to data collected by the lab reimbursement consulting firm CodeMap LLC (Barrington, IL).

Medicare Part B carrier spending on CPT 88305—the most frequently billed anatomic pathology procedure—increased by 4.5% to $1.278 billion in 2010.

However, growth was much stronger in FISH testing, immunohistochemistry (IHC), special stains and flow cytometry.

Spending on CPT 88367 (FISH using computer assisted technology) grew by 34% in 2010. CPT 88367 is the primary code used to bill for Abbott's UroVysion bladder cancer test. Effective January 1, 2011, CMS created new CPT codes that drastically cut reimbursement for UroVysion bladder cancer testing (see *LE*, December 2010, page 1). The reimbursement change will slow the growth in Part B spending on FISH testing.

Part B carrier spending on CPT 88342 (immunohistochemistry), which is used to diagnose the type of cancer and origin, increased by 18% in 2010.

CPT 88313 (special stains) increased by 15% in 2010. Special stains are ordered by pathologists to assist in diagnosing particularly difficult cases.

CPT 88185 (flow cytometry-technical component only) increased by 12.5% in 2010. Flow cytometry is a method of counting cells that is routinely used to determine the type of leukemia, lymphoma or myeloma cells that are present.

Medicare Part B Carrier Spending on 12 Key Pathology Codes, 2005-2010 ($ millions)

Code (Description)	2005	2006	2007	2008	2009	2010	1-Year Change	5-Year CAGR*
88305 (surgical pathology)	$1,067	$1,117	$1,140	$1,182	$1,223	$1,278	4.5%	3.8%
88342 (immunohistochemistry)	122	138	154	180	205	241	17.7%	14.6%
88367 (FISH-computer assisted)	2	13	33	65	100	134	34.4%	131.9%
88185 (flow cytometry)	43	47	67	94	115	129	12.5%	24.6%
84153 (PSA)	84	87	94	95	98	96	-2.1%	2.7%
88312 (special stains)	54	60	65	72	80	86	8.0%	9.8%
88307 (surgical pathology)	83	83	78	78	79	81	2.7%	-0.5%
88112 (special stains)	47	59	62	68	70	79	12.4%	10.9%
88368 (FISH-manual)	13	27	36	54	68	70	2.6%	40.0%
88313 (special stains)	32	32	38	47	52	60	14.9%	13.4%
88304 (surgical pathology)	31	29	28	28	28	30	5.4%	-0.7%
88361 (digital pathology)	11	12	12	16	18	19	4.1%	11.0%
TOTALS	$1,590	$1,704	$1,808	$1,979	$2,136	$2,302	7.8%	7.7%

*CAGR=compound annual growth rate

Note: Data is derived from analysis of the Physician Supplier Procedure Summary Master File (PSPSMF) which includes data from all Medicare Part B carriers. This data represents procedure-specific billing data for all physician/supplier services rendered to all Medicare beneficiaries during the calendar year named and processed by the carriers through the six months of the following year. Part B claims processed by fiscal intermediaries are not included.

Source: CodeMap LLC (Schaumburg, IL)

MARKET SHARE TRENDS IN PATHOLOGY

A closer look at the Medicare Part B carrier claims data for the two top codes (88305 and 88342) shows that a major shift continues to take place in the locations where pathology services are being provided.

The number of inpatient claims barely grew in 2010, while claims from office-based physicians, outpatient hospitals and independent labs grew the fastest.

Overall, submitted Medicare Part B claims for CPT 88305 grew by 4.8% to 19.8 million in 2010.

Part B claims submitted for CPT 88305 by office-based physicians increased by 8.5% to 6.4 million in 2010.

Inpatient hospital claims were flat at 1.7 million.

Submitted Medicare Part B Carrier Claims for CPT 88305 by Place of Service

Place of Service	2005	2006	2007	2008	2009	2010	1-Year Change	5-Year CAGR*
Physician office	4,953,745	5,190,639	5,509,048	5,745,995	5,919,071	6,419,605	8.5%	5.3%
Outpatient hospital	4,551,707	4,832,341	4,469,417	4,382,305	4,274,271	4,451,086	4.1%	0.5%
Independent lab	5,650,491	8,784,007	6,454,707	6,834,210	6,943,696	7,169,480	3.3%	4.2%
Inpatient hospital	1,921,458	1,969,847	1,795,664	1,776,258	1,702,436	1,705,958	0.2%	2.4%
Ambulatory surgery center	59,022	54,411	76,032	73,761	77,802	76,694	-1.4%	5.4%
Other locations	39,872	30,531	31,273	20,639	17,516	23,991	37.0%	9.7%
Totals	17,176,295	20,861,776	18,336,141	18,833,168	18,934,792	19,846,814	4.8%	2.9%

*CAGR=five-year compound annual growth rate. Note: Claims equal total submitted to Medicare Part B carriers for CPT 88305, including global, technical-only and professional-only claims. Source: CodeMap LLC (Schaumburg, IL)

Overall, Medicare Part B claims for CPT 88342 (immunohistochemistry) grew by a solid 11.5% to 4.3 million in 2010. Growth was strongest for outpatient hospital claims, which grew 14.3% to 1.3 million claims. Growth was weakest for inpatient claims, which increased by 8.6% to 898,307.

Submitted Medicare Part B Carrier Claims for CPT 88342 by Place of Service

Place of Service	2005	2006	2007	2008	2009	2010	1-Year Change	5-Year CAGR*
Outpatient hospital	769,266	908,076	924,753	1,036,643	1,139,250	1,302,464	14.3%	11.1%
Physician office	316,539	359,369	412,537	494,489	541,358	609,169	12.5%	14.0%
Independent laboratory	676,161	883,714	926,558	1,107,772	1,289,819	1,421,215	10.2%	16.0%
Inpatient hospital	596,477	669,510	696,914	777,784	826,842	898,307	8.6%	8.5%
Ambulatory surgery center	3,809	4,408	7,505	6,214	19,884	25,913	30.3%	46.7%
Other locations	6,034	5,359	7,046	5,536	4,791	5,630	17.5%	-1.4%
TOTALS	2,368,286	2,830,436	2,975,313	3,428,438	3,821,944	4,262,698	11.5%	12.5%

*CAGR=five-year compound annual growth rate. Note: Claims equal total submitted to Medicare Part B carriers for CPT 88342, including global, technical-only and professional-only claims. Source: CodeMap LLC (Schaumburg, IL)

NEW CANCER CASES RISING BY 3.6% PER YEAR

The number of new cancer cases in the United States grew by an average annual rate of 3.6% between 2008 and 2011, according to the American Cancer Society (ACS). That's higher than the average 2% per year growth in the age 65 and over population in the United States, according to figures from the U.S. Census Bureau.

The fastest growing number of new cancer cases is occurring in prostate cancer, up 8.9% per year between 2008 and 2011. The next fastest growing area is thyroid cancer, up 8.8% per year, followed by breast cancer (8% per year) and liver (7%). Pancreas cancer cases are growing by 5.3% per year and uterine cancer by 5% per year.

The ACS says 569,490 people in the United States will die from cancer in 2011. The leading cause is lung cancer—an estimated 157,300 people will die from the disease this year. The next leading cause is colorectal cancer (51,370 deaths), followed by breast cancer (40,230 deaths).

Estimated New Cancer Cases, 2008-2011

	2011	2010	2009	2008	3-YearCAGR*
Bladder	69,250	70,530	70,980	68,810	0.2%
Breast	232,620	209,060	194,280	184,450	8.0%
Cervical	12,710	12,200	11,270	11,070	4.7%
Colon & Rectum	141,210	142,570	146,970	148,810	-1.7%
Kidney & Renal	60,920	58,240	57,760	54,390	3.9%
Leukemia	44,600	43,050	44,790	44,270	0.3%
Liver	26,190	24,120	22,620	21,370	7.0%
Lung & Bronchus	239,320	240,610	236,990	232,270	1.0%
Lymphoma	75,190	74,030	74,490	74,340	0.4%
Myeloma	20,520	20,180	20,580	19,920	1.0%
Oral	39,400	36,540	35,720	35,310	3.7%
Ovary	21,990	21,880	21,550	21,650	0.5%
Pancreas	44,030	43,140	42,470	37,680	5.3%
Prostate	240,890	217,730	192,280	186,320	8.9%
Skin	76,330	74,010	74,610	67,720	4.1%
Thyroid	48,020	44,670	37,200	37,340	8.8%
Uterine	46,470	43,470	42,160	40,100	5.0%
Other	157,010	153,530	152,630	151,360	1.2%
All Cases	1,596,670	1,529,560	1,479,350	1,437,180	3.6%

*CAGR=compound annual growth rate Source: American Cancer Society

PLUS DIAGNOSTICS TO OPEN HOUSTON LAB

Plus Diagnostics (Union, NJ) plans to open a new pathology lab in Houston, Texas, by the end of the year. The new lab will initially focus on gastroenterology and urology, with plans to expand into dermatology and women's health. The company has existing labs in New Jersey and California.

LAB STOCKS DOWN 10% YEAR TO DATE

Ten lab stocks have fallen by an unweighted average of 10% so far this year through October 10. The combined market capitalization for the group is currently $18.8 billion. In comparison, the S&P 500 Index is down 8% and the Nasdaq is down 6.5%. The top-performing lab stocks so far this year are CombiMatrix, up 15%, followed by Genomic Health, up 6%. Meanwhile, the stock price of LabCorp is down 9% and Quest is down 12%.

Company (ticker)	Stock Price 12/31/10	Stock Price 10/10/11	2011 Price Gain	Market Capitalization ($ millions)	Earnings Past 12 Months	Price-to-Earnings Ratio
Bio-Reference (BRLI)	$22.18	$19.00	-14%	531	1.23	15.4
CombiMatrix (CBMX)	2.15	2.47	15%	26	-0.87	NA
Enzo Biochem (ENZ)	5.28	2.63	-50%	101	-0.35	NA
Genomic Health (GHDX)	21.39	22.78	6%	672	0.25	91.1
LabCorp (LH)	87.92	79.63	-9%	8,074	5.72	13.9
Medtox Scientific (MTOX)	13.10	12.87	-2%	115	0.47	27.4
Myriad Genetics (MYGN)	22.84	19.90	-13%	1,693	1.11	17.9
Neogenomics (NGNM)	1.30	1.06	-18%	46	-0.09	NA
Psychemedics (PMD)	8.20	7.77	-5%	41	0.61	12.7
Quest Diagnostics (DGX)	53.97	47.38	-12%	7,501	2.88	16.5
Averages			-10%	18,800		27.9

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