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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CAP ASKS CMS TO TOSS 2014 PAYMENT SCHEME

As everyone knows, the Centers for Medicare and Medicaid Services (CMS) has proposed to set a ceiling on pathology technical component rates paid under the Physician Fee Schedule (PFS) for 2014. Under the proposal, PFS rates for pathology technical component services in 2014 could be no higher than the rates that Medicare pays for the same services under the Outpatient Prospective Payment System (OPPS) fee schedule for 2013. (Note: This one-year lag is a critical issue—see page 4).

The proposal, if enacted, would cut Medicare payments to pathology labs by more than $500 million per year. Technical services related to flow cytometry, special stains, FISH and cytopathology would suffer rate reductions of more than 50%.

Armed with a legal opinion from the law firm Sidley Austin LLP, the College of American Pathologists contends that CMS's proposal violates Medicare statute 42 U.S.C. ß1848(c)(2)(C)(ii), which requires that PFS rates should be resource-based. CAP is urging CMS to withdraw the proposal. CMS's decision will be revealed in its Final Physician Fee Schedule Rule due out in early November.

The proposed cuts, if enacted, would likely result in a massive restructuring at the nation's 6,500 hospital, independent and physician-office-based labs that provide pathology services.

"We believe we've made a persuasive case in our response to CMS by emphasizing the impact these cuts would have on patient access to services, as well as by providing a thorough legal analysis of the statute, and we feel that CMS should withdraw the proposed rule. At this time, we do not know whether they will do so. Based on very productive conversations this week between CAP members and lawmakers and their staff on Capitol Hill, we also think that Congress appreciates their critically important oversight role. We feel they are paying attention to the issue and are poised to weigh in. There is little doubt that this rule would be devastating to patient care and, given the timeline of final rulemaking and implementation, there is no room to 'fix' this after the fact. CMS, with oversight from Congress, must get this right on the first pass. If they don't withdraw this precedent setting rule, patients will very quickly feel the unintended consequences of CMS's attempt to achieve 'cost-savings,'" says Kathryn Knight, MD, FCAP, Chair of CAP's Federal and State Affairs Committee. *Continued on page 4.*

RIEDEL DOGS QUEST AND LABCORP WITH MEDICAID LAWSUITS

Last month, Chris Riedel sold his California lab company, Hunter Laboratories, to Bio-Reference Labs for $14.4 million (see *LE*, August 2013, page 8). Now Riedel is focused on whistleblower lawsuits he has filed against the big labs in five states. The lawsuits allege that Quest and LabCorp overbilled for lab tests provided to each state's Medicaid program. *Continued on page 2.*

Contents

RIEDEL DOGS QUEST AND LABCORP (*cont'd from page 1*)

Riedel filed his first whistleblower lawsuit against Quest in California in 2005. This lawsuit was later expanded to include six other labs, including LabCorp, Health Line Clinical Laboratories, Physicians Immunodiagnostic Laboratory, Whitefield Medical Laboratory, Seacliff Diagnostics Medical Group and Westcliff Medical Laboratories.

The California Attorney General's office intervened in the lawsuit which resulted in settlement agreements reached in 2011. The seven labs paid a total of more than $300 million. Quest paid $241 million and LabCorp paid $49.5 million, although both labs denied all allegations. Riedel received more than $75 million of the settlement amounts and was named "Whistleblower of the Year" by the Tax Payers Against Fraud Education Fund.

Riedel has similar lawsuits underway in five states: Georgia, Massachusetts, Michigan, Nevada and Virginia. To date, Michigan is the only state that has intervened. But Riedel can still pursue his other whistleblower cases on his own. If the Government does not intervene, a whistleblower is entitled to a greater share of any proceeds (25% to 30%) than if the Government does intervene (15% to 30%). Riedel's law firm is Cotchett, Pitre & McCarthy (San Francisco), the same firm that represented him in California.

The stakes are high because the Affordable Care Act says that any healthcare provider convicted of billing fraud can be automatically excluded from all government programs.

Most recently, Riedel's whistleblower lawsuit in Virginia was unsealed. The lawsuit, which was originally filed in 2007, alleges that Quest and LabCorp "made false claims for payment of Medicaid-covered laboratory tests by falsely representing that the fees being charged were no greater than the maximum fees payable pursuant to Virginia regulations." The lawsuit contends that labs are required to bill the Virginia Medicaid program their most favorable rates. However, Quest and LabCorp allegedly billed the state's Medicaid program at its published fee schedule rates, while offering the same tests to physicians, hospitals, HMOs and GPOs at deeply discounted rates that were sometimes below cost.

Riedel's case hinges on the interpretation of regulations from Virginia's Department of Medical Assistance Services that state "Payment for [laboratory services] shall be the lower of the state agency fee schedule…or actual charge (charge to the general public)." 12 VAC 30-80-30.

Riedel interprets this to mean that a lab can charge any customer (physician, hospital, HMO, GPO, etc.) a deeply discounted price for lab tests, so long as Medicaid gets the same price.

In a statement, Quest said: "The allegations have been made by Hunter Laboratories, a Quest Diagnostics' competitor. We believe these allegations lack merit, and our testing services are priced appropriately. We comply with the laws and regulations governing our business, including Medicaid pricing requirements, not only as a legal obligation, but also because it is the right thing to do. As always, Quest Diagnostics remains firmly focused on putting patients first and serving their needs."

Riedel's lawsuit cites specific examples of the wide variance in lab test prices. For example, the lawsuit says that Quest billed as much as $10.42 for an automated hemogram (CPT 85025), while charging other payers as little as $1.43.

Pricing Comparison: Medicare vs. Virginia Medicaid vs. Quest Diagnostics and LabCorp

Test Name	*CPT*	*Medicare Fee Schedule*	*Virginia Medicaid Fee Schedule*	*Quest Fee*	*LabCorp Fee*
CBC w Diff & Platelets	85025	$10.69	$8.59	$1.43	$3.62
Lipid Panel	80061	18.42	13.88	4.75	8.51
Comp. Metabolic Panel	80053	14.53	11.69	1.90	5.75
Ferritin	82728	18.73	15.06	2.85	3.68
TSH (ultra sensitive)	84443	23.10	18.57	5.70	6.44
Hemoglobin (A1C)	83036	13.34	10.74	4.51	5.52
PSA (Ultra-sensitive)	84153	25.29	20.34	5.86	5.52
Testosterone, Total	84403	35.49	28.54	14.25	7.36
Hepatitis C Antibody	86803	19.62	15.78	7.60	6.44
Progesterone	84144	28.68	23.06	14.75	10.12

Source: Medicare Part B Lab Fee Schedule 2013; Virginia Medicaid Lab Fee Schedule; Commonwealth of Virginia ex rel. Hunter Laboratories, LLC and Chris Riedel vs. Quest Diagnostics, et al. (case: 13-cv-01129)

A brief review of Riedel's four other known whistleblower lawsuits is listed below:

Georgia

In May 2013 Quest and LabCorp were each served with a False Claims Act lawsuit, *State of Georgia ex rel. Hunter Laboratories, LLC* and *Chris Riedel v. Quest Diagnostics Incorporated, et al.*, filed in the State Court of Fulton County, Georgia. The lawsuit (case: 13-cv-01838), originally filed by Hunter Labs in January 2008, alleges that Quest and LabCorp overcharged Georgia's Medicaid program. The case has been removed to the United States District Court for the Northern District of Georgia. The government has filed a notice declining to intervene in the case. Quest has filed a motion to dismiss and is awaiting a decision from the judge. The Georgia Medicaid program covers about 1.9 million beneficiaries.

Michigan

In January 2012, the State of Michigan intervened in a state false claims act suit filed against Quest Diagnostics, alleging that the company defrauded the state Medicaid program by overcharging for lab tests. The suit was originally filed in 2008 under the Michigan Medicaid False Claims Act by Riedel and Hunter Labs. Quest's motion to dismiss the complaint has been denied and the case is in the discovery phase. The Michigan Medicaid program covers about two million beneficiaries. LabCorp, which does no business with the Michigan Medicaid program, is not a defendant in this case.

Nevada

Riedel and Hunter Labs filed a whistleblower lawsuit against Quest in Nevada in December 2007. The state has not intervened. This lawsuit (case: CV07-02927) is scheduled to begin trial in November. LabCorp is not a defendant in this case. The Nevada Medicaid program covers about 341,000 beneficiaries.

Massachusetts

Riedel and Hunter Labs have also filed a whistleblower lawsuit against Quest in Massachusetts and discovery is ongoing. LabCorp is not a defendant in this case. MassHealth, the state's Medicaid program, covers 1.4 million beneficiaries.

Potential for Lawsuits in Other States?

So far, Medicaid lawsuits have been unsealed in five states. But there are at least six other states—Alaska, Arkansas, Florida, New Hampshire, New Jersey and Rhode Island—that have Medicaid regulations that require best pricing from providers. It remains to be seen if Riedel or anyone else has filed suits in these states.

CAP ASKS CMS TO TOSS 2014 PAYMENT SCHEME (*cont'd from p. 1*)

Meanwhile, in its comment to CMS Administrator Marilyn Tavenner, the American Clinical Laboratory Assn. (ACLA) noted that CMS has proposed linking the 2014 PFS rates to the 2013 OPPS fee schedule. Going forward, the proposed rule states that the PFS rates would always be locked at the lowest rate of either the PFS or OPPS fee schedule. This means that although OPPS fee schedule rates are set to rise substantially in 2014 (see *Laboratory Economics*, August 2013, p. 1), the PFS rates for the same services will be locked in at the lower 2013 OPPS fee schedule.

"The arbitrary nature of CMS's proposal is underscored by the fact that it would use this approach only to lower payments when the PFS rate is higher than the OPPS rate," commented ACLA.

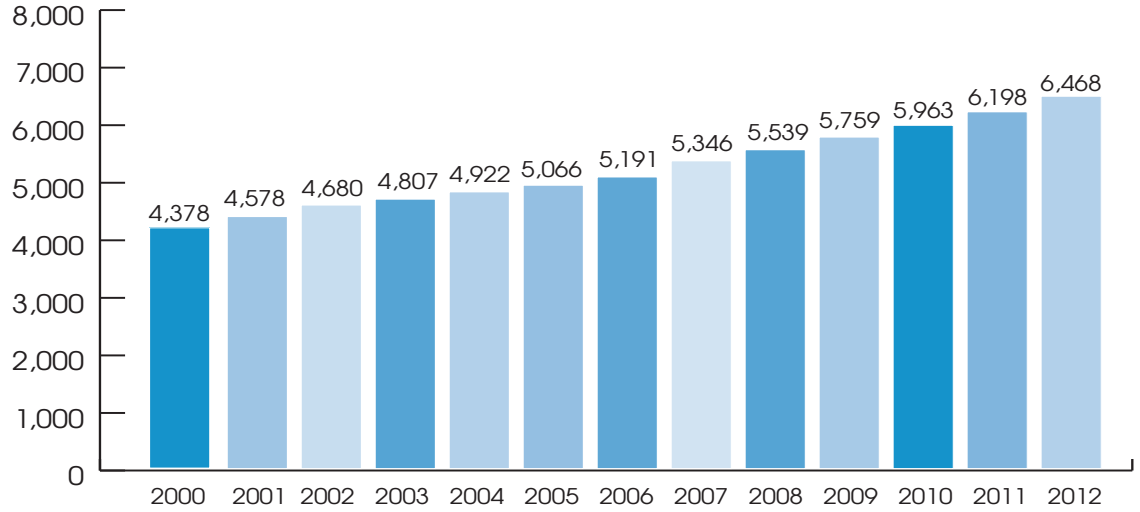
In addition, ACLA noted that CMS proposed to exclude "any service for which five percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services." This suggests that CPT codes 88120 and 88121, 88367 and 88368 (FISH testing) and 88184 and 88185 (flow cytometry) should be excluded from the proposal. CMS has informally indicated that CPT 88120, at least, should not have been included.

Furthermore, ACLA noted that the OPPS rates are unreasonable on their face given that they don't even cover the supply costs for some pathology tests. For example, ACLA cited CPT 88367, in situ hybridization, which is used to detect the HER2/neu gene, which is vital in determining breast cancer treatment. Under the proposed OPPS cap, the global payment for this test would be $99 (down from $258 in 2013). However, that's not enough to cover the required HER2/neu DNA probe kit costing $157, according to invoices from the manufacturer.

Finally, ACLA noted that for years CMS has described the procurement of OPPS data as an "imperfect" system, in which relative weights and payments are based on often flawed hospital reports and claims data. "There are very solid arguments against these cuts, but there is no way of handicapping the final rule and CMS has given no indication of which way they are leaning," says ACLA President Alan Mertz. CMS will release its final rule on or about November 1.

Number of Histopathology Labs* in U.S.

More than 2,000 CLIA-certified histopathology labs have opened over the past 12 years. A massive consolidation is likely to occur if the proposed Medicare rate cuts for 2014 are enacted.



*Includes all CLIA-certified U.S. labs with annual histopathology volume (specimen blocks prepared plus special stains) of 1,000 or more.

Source: CMS/CLIA files

MEDICARE EXPENDITURES ON PATHOLOGY FELL 4.5% IN 2012

National Medicare Part B carrier payments for 12 high-volume pathology codes fell by 4.5% to $2.286 billion in 2012, according to data collected from CMS and the lab reimbursement consulting firm CodeMap LLC (Barrington, IL). Part B carrier spending on these 12 key pathology codes had increased by an average of 4.8% per year between 2007 and 2012.

Part B carrier spending on CPT 88305—the most frequently billed anatomic pathology procedure—decreased by 3.4% to $1.331 billion in 2012.

It appears that the expiration of the Centers for Medicare and Medicaid Services Technical Component Grandfather Clause (TC Grandfather) on June 30, 2012 was the cause of the decline in Medicare expenditures on pathology services. The TC Grandfather clause had allowed independent pathology labs to bill Medicare directly for the technical component of pathology services provided to hospital in-patients and out-patients. As a result of the regulatory change, since becoming effective July 1, 2012, independent pathology labs must now bill their hospital clients directly for these technical component services rather than Medicare.

The TC Grandfather expiration had its greatest effect on flow cytometry (CPT 88185) and special stains (CPT 88312 & 88313), which all saw Medicare spending decreases of greater than 10% in 2012.

Medicare Part B Carrier Spending on 12 Key Pathology Codes ($ millions)

Code (Description)	*2012*	*2011*	*1-Year Change*	*5-Year CAGR**
88305 (Level IV, tissue exam by pathologist)	$1,331.4	$1,377.9	-3.4%	3.2%
88342 (Immunohistochemistry)	268.7	278.5	-3.5%	11.8%
88185 (Flow cytometry, add on)	115.9	142.5	-18.7%	11.6%
84153 (Total PSA)	91.0	95.2	-4.4%	-0.7%
88112 (Cytopath cell enhance tech)	88.6	87.0	1.9%	7.4%
88312 (Special stains)	87.1	96.8	-10.1%	6.0%
88307 (Level V, tissue exam by pathologist)	80.7	84.9	-4.9%	0.7%
88313 (Special stains)	59.1	68.5	-13.7%	9.2%
88368 (FISH-manual)	53.5	58.6	-8.8%	8.0%
88120 (FISH-manual for UroVysion)	43.0	36.0	19.4%	NA
88331 (Pathology consult during surgery)	37.1	37.9	-2.2%	0.1%
88367 (FISH-computer assisted)	30.4	30.9	-1.7%	-1.7%
TOTALS	**$2,286.4**	**$2,394.7**	**-4.5%**	**4.8%**

*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: CMS and CodeMap LLC

CMS REVISES PROPOSED OPPS RATES FOR 2014

CMS has published a notice correcting technical errors that appeared in the July 19, 2013 proposed rule updating the Medicare Hospital Outpatient Prospective Payment System (OPPS) for 2014. The technical corrections resulted in changes to the proposed OPPS relative payment weights and conversion factor, which had the impact of reducing proposed payment rates by a small amount. However, even with the revisions, proposed OPPS rates for pathology technical services are set to skyrocket in 2014. See abbreviated table below:

Proposed OPPS vs. MPFS for Key Pathology Technical Services for 2014*

CPT/ HCPCS	Description	2014 Proposed APC	Proposed OPPS Rate	Proposed MPFS Rate	OPPS/ MPFS
88112-TC	Cytopath cell enhance tech	342	34.42	23.82	145%
88120-TC	FISH manual for urine sample	343	142.21	158.21	90%
88121-TC	FISH computer for urine sample	343	142.21	462.37	31%
88307-TC	Tissue exam by pathologist	343	142.21	60.90	234%
88342-TC	Immunohistochemistry	343	142.21	38.45	370%
88346-TC	Immunofluorescent study	344	273.40	38.45	711%
88367-TC	FISH-computer assisted	344	273.40	38.45	711%
88368-TC	FISH-manual	344	273.40	60.90	449%
88305-TC	Tissue exam by pathologist	433	57.55	30.96	186%
88312-TC	Special stains group 1	433	57.55	23.82	242%
88313-TC	Special stains group 2	433	57.55	23.82	242%
88331-TC	Path consult during surgery	433	57.55	23.82	242%
AVERAGE					***304%***

*Proposed national rates unadjusted for geographic wage differences; assumes conversion factor for MPFS remains at 34.023

Source: *Laboratory Economics* from CMS

Even with the revisions, Medicare reimbursement rates for technical pathology services paid under the OPPS are set to rise to an average of more than 3x the rates paid for the same services under the Medicare Physician Fee Schedule (MPFS).

The catch is that the OPPS proposed rule for 2014 seeks to eliminate separate fee schedule payments to hospital outpatient departments for most clinical lab tests and anatomic pathology technical services. Instead, payment for clinical lab and pathology technical services would be merged into a single facility payment, much like the inpatient DRG. So the higher proposed OPPS rates would not apply to the majority of hospital outpatient pathology services, which would instead be bundled into a DRG-type payment.

The proposed OPPS rule, if enacted, would make hospital outpatient labs look more like cost centers as opposed to revenue generators, observes *Laboratory Economics*. As a result, many hospital outpatient labs would likely be consolidated into hospital inpatient labs or outsourced to lower-cost independent labs. *LE* further notes that while the shift toward bundled payments may reduce incentives to over-utilize test services, it could also reduce utilization of medically-necessary tests.

CMS TO PUBLISH FINAL GAP-FILL RATES FOR MDx TESTS

CMS is scheduled to release final gap-fill rates collected from Medicare carriers on September 30, which will be followed by a 30-day reconsideration period. The median rates from the carriers will be used by CMS to set the national limitation amounts (NLAs) which become effective January 1, 2014. Most private payers are expected to link their rates to the NLAs for the new molecular diagnostics test codes beginning in 2014 as well.

Medicare carriers released their initial rates for 114 new molecular test codes earlier this year. These initial rates were, on average, 25-30% lower than rates paid previously under the code stack method of billing. In addition, the initial rates for many molecular test codes were priced below the reagent and supply costs as measured by the American Medical Association's Relative Value Scale Update Committee (RUC) based on actual invoices submitted by the average midsize laboratory. For example, the AMA RUC calculated that the supply costs for BRAF Gene Mutation Analysis (CPT 81210) are $387.88 per test, but the median gap-fill reimbursement rate is currently set at only $89.95.

Molecular labs are hoping that CMS and the carriers have made significant upward adjustments to the initial rates announced earlier this year.

Meanwhile, molecular diagnostic labs continue to have difficulty getting paid by Medicare carriers for a number of MDx tests, especially Tier 2 tests and those related to pharmacogenomics testing, according to an informal survey of labs and billing companies by *Laboratory Economics*. On a more positive note, *LE* is told that carrier payments for most Tier 1 claims are currently being paid without delay.

MDx Test Price Comparison: Median Gap Fill vs. Supply Costs

Code	Lab Test	Median Gap Filled Amounts	Supply Costs*	Median GAP Fill as % of Supply Cost
81210	BRAF Gene Mutation	$89.95	$387.88	23%
81223	Cystic Fibrosis Full Sequence	1,554.46	4,160.43	37%
81225	CYP2C19 Genotype	187.92	208.89	90%
81226	CYP2D6 Genotype	298.80	208.89	143%
81227	CYP2C9 Genotype	111.17	208.89	53%
81256	Hereditary Hemachromatosis	70.20	57.89	121%
81270	JAK2 Mutation Analysis	82.88	197.19	42%
81275	KRAS Mutation Analysis	233.66	67.10	348%
81291	MTHFR DNA Analysis	92.92	188.95	49%
81301	Microsatellite Instability	320.84	244.2	131%
81350	UGT1A1 Genotyping	67.25	77.66	87%
81404	c-Kit Mutation Analysis	299.32	827.23	36%

*The median gap-fill rates calculated from initial rates issued early this year by the following MACs: Noridian, Novitas, WPS, NGS, First Coast, Cahaba, Palmetto, NHIC and Cigna

**Supply costs as published in CMS' Physician Fee Schedule Proposed Ruling for CY 2013.

Source: *Laboratory Economics* and CMS

MEDICARE SPENDING ON MDx TESTS SPIKES

National Medicare Part B carrier spending for the key pathology codes used to bill for molecular diagnostic tests increased by 77.6% to $187 million in 2012. Part B carrier spending on MDx tests increased by an average of 42.2% per year between 2007 and 2012. In an effort to reign in spending on MDx tests, CMS eliminated the stacking codes (CPT 83890-83914 and 88381-88386) and substituted 114 more specific new codes in their place effective January 1, 2013 (*see page 7*).

Medicare Part B Carrier Spending on Molecular Dx Codes*

CPT Code	Short Description	Allowed Charges 2012	Allowed Charges 2011	1-Year Change	2007-2012 5 YR CAGR
83890	Molecule isolate	347,701	232,428	49.6%	32.3%
83891	Molecule isolate nucleic	2,845,040	2,165,841	31.4%	35.4%
83892	Molecular diagnostics	1,683,932	3,752,109	-55.1%	9.3%
83893	Molecule dot/slot/blot	405,952	370,340	9.6%	11.9%
83894	Molecule gel electrophor	437,426	332,389	31.6%	7.2%
83896	Molecular diagnostics	15,355,226	10,646,217	44.2%	34.5%
83897	Molecule nucleic transfer	12,038	3,840	213.5%	28.2%
83898	Molecule nucleic ampli, each	34,990,236	27,103,987	29.1%	26.4%
83900	Molecular diagnostics	8,739,525	4,612,551	89.5%	57.1%
83901	Molecular diagnostics	31,743,468	13,127,994	141.8%	97.9%
83902	Molecular diagnostics	1,161,296	1,135,829	2.2%	22.0%
83903	Molecule mutation scan	9,921,215	10,473,608	-5.3%	40.3%
83904	Molecule mutation identify	42,565,775	20,566,436	107.0%	35.8%
83905	Molecule mutation identify	17,078	7,873	116.9%	22.2%
83906	Molecule mutation identify	564	779	-27.6%	-30.0%
83907	Lyse cells for nucleic ext	1,468,789	989,565	48.4%	93.7%
83908	Nucleic acid, signal ampli	9,187,276	5,691,823	61.4%	90.2%
83909	Nucleic acid, high resolute	23,894,949	17,864,664	33.8%	118.8%
83912	Genetic examination	4,235,911	3,591,652	17.9%	23.8%
83913	Molecular, rna stabilization	298,717	261,914	14.1%	87.5%
83914	Mutation ident ola/sbce/aspe	101,167,530	12,647,125	699.9%	177.8%
88360	Tumor immunohistochem, manual	21,603,131	24,122,087	-10.4%	13.2%
88361	Tumor immunohistochem, computer	14,744,411	19,773,908	-25.4%	3.5%
88381	Microdissection manual	2,992,999	4,587,407	-34.8%	NA
88384	Array-based eval, 11-50 probes	130	167	-22.2%	35.0%
88385	Array-based eval, 51-250 probes	657,456	1,517,788	-56.7%	174.7%
88386	Array-based eval, 251-500 probes	1,785,304	1,466,403	21.7%	212.6%
	Part B Carrier Total	$332,263,075	$187,046,724	77.6%	42.2%

*Includes stacking codes 83890-83914, microarray codes 88384-88386 and HER2 scoring codes 88360-88361

**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: *Laboratory Economics* from CMS and CodeMap

RESPONSE GENETICS BUYS PATHWORK TISSUE OF ORIGIN TEST

Response Genetics (Los Angeles, CA) has purchased all the key assets of Pathwork Diagnostics, including its FDA-cleared Tissue of Origin Test for hard to identify tumors. Response paid a total of $1.3 million, including $200,000 in cash plus 500,000 shares of common stock valued at approximately $1.1 million.

Pathwork Diagnostics, which went out of business earlier this year, had raised more than $60 million from venture capital firms between 2006 and 2011. But the company burned through the cash, spending millions on getting FDA clearance for its test, sales and marketing, and the cost of operating its CLIA laboratory (now shutdown) in Redwood City, California. Reimbursement rates and coverage from private payers were also challenges.

Response will add the Tissue of Origin Test to its existing menu of cancer tests. The test could bring $5+ million in annual revenue to Response, which expects the deal to be accretive to earnings within one year.

PART B SPENDING ON DIGITAL IHC TUMBLES

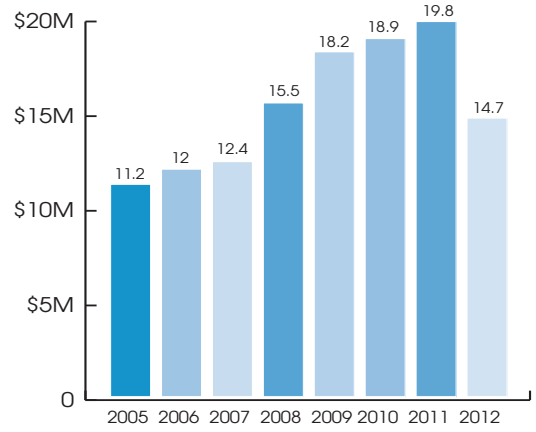
Medicare Part B carrier spending on CPT 88361 (digital pathology for quantitative IHC) fell by 25% to $14.7 million in 2012. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor. The number of submitted Part B claims also fell by 25% to 190,767 claims in 2012. This is the first year in which Part B spending and submitted claims for 88361 have fallen, following several years of 10-15% annual growth.

Proponents of digital pathology point out that digital IHC represents only a portion of the market. They say the market is being driven more by non-reimbursed services, such as education and training, second opinions and archiving specimens.

Nonetheless, the digital pathology market is evolving much more slowly than experts had predicted a few years ago. Barriers to greater adoption include: cost, speed and limited FDA clearance.

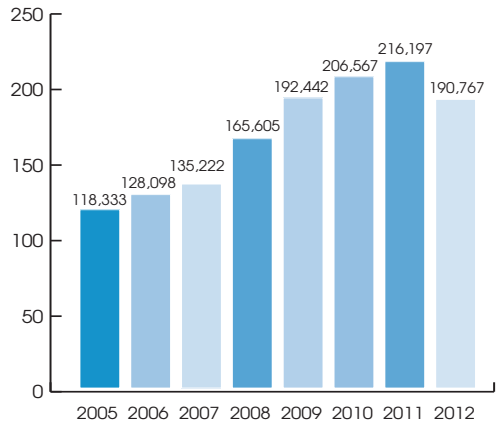
Reimbursement is also a concern. Under the proposed Physician Fee Schedule Rule for 2014, the Medicare Part B global payment for CPT 88361 would decrease by 39% to $95.26, including a 61% decrease in the technical component rate to $38.45 and a 1% decrease for the professional component rate to $56.82.

Medicare Part B Carrier Expenditures for CPT 88361



Source: *Laboratory Economics* from CMS

Medicare Part B Submitted Claims for CPT 88361



Source: *Laboratory Economics* from CMS

BOSTWICK PAYS $500K TO RESOLVE FRAUD ALLEGATIONS

Bostwick Laboratories (Glen Allen, VA) has agreed to pay the United States $503,668 to resolve allegations its sales reps used a clinical study to induce certain physicians to use its testing services, according to an August 20 press release issued by the United States Attorney's Office for the Eastern District of New York.

The Bostwick-sponsored study was called "Determination of the Accuracy of PCA3Plus Urine Assay for the Detection of Prostate Cancer."

PCA3Plus is the brand name of a urine test performed by Bostwick that is based on reagents made by Hologic Gen-Probe. The test is usually performed when a patient has previously had a negative prostate biopsy, but their PSA levels remain high or continue to rise. The test aids physicians in determining if a repeated biopsy is necessary.

The Bostwick study required that for each patient enrolled, the physicians were obligated to send both the PCA3Plus urine specimen and prostate biopsy specimen—which otherwise could have been sent to any number of labs—to Bostwick for analysis. As a result, the government alleges that Bostwick paid those physicians to steer their prostate biopsy specimens to its labs. Bostwick then submitted claims to Medicare and Tricare for reimbursement for both the prostate biopsy analysis and the PCA3Plus test, even though the prostate biopsy was the "gold standard" and the PCA3Plus test was not medically necessary in such situations, according to the government.

The government's investigation began in late 2009 after a Bostwick sales rep asked a New York City urologist, Robert Gluck, MD, to participate in the PCA3Plus study. Gluck then filed a whistleblower complaint against Bostwick on behalf of the United States in the Eastern District of New York. Under the federal False Claims Act, Gluck will receive a share of the recovery (approximately 20%).

In settling the matter, Bostwick Labs did not admit any wrongdoing. "This settlement resolves a four-year old government investigation, and enables us to focus on the future of our company rather than the past. We remain strongly committed to compliance with federal rules and regulations governing our business practices and continue to have a strong compliance program in place," according to Jerry Diffley, Vice President and Chief Compliance Officer at Bostwick.

Restructuring at Bostwick Labs

Separately, *Laboratory Economics* notes that Bostwick Labs, like many other pathology lab companies, has undergone a deep restructuring. Over the past few years, Bostwick has closed labs in Arizona, Maryland, Tennessee and London, England, and cut staff at its remaining labs in Virginia, Florida and Long Island, New York. The company's workforce has shrunk from approximately 1,000 employees in 2010 to its current 550 employees, including about 25 pathologists.

New VP of Sales

In other news, Bostwick recently hired Robert Phillips as Vice President of Sales. Phillips was formerly Vice President of Sales at LabCorp's Integrated Oncology division. He replaces Jed Fulk, who resigned from Bostwick Labs in December 2012.

Bostwick Labs is owned by the New York City-based investment firm Metalmark Capital.

LABCORP TO BUY MUIRLAB IN NORTHERN CALIFORNIA

John Muir Health has signed a definitive agreement to sell its clinical lab outreach business (provided through MuirLab) to LabCorp. In 2012, MuirLab processed more than 2.7 million lab tests. Assuming average collected revenue of $15 per test, *Laboratory Economics* estimates that MuirLabs had annual revenue of more than $40 million per year.

The transaction is scheduled to close in early November. The purchase price has not been disclosed.

Terms of the deal call for LabCorp to take over the operation of MuirLab's 26 patient service centers (PSCs) throughout Northern California. LabCorp is also purchasing the client list of office-based physicians and hospitals served by MuirLab. In addition, LabCorp will be the preferred provider of reference lab services for John Muir Health.

John Muir plans to shut down its relatively new 56,000-square-foot core lab that serves outreach clients. This lab was opened in April 2008 and cost more than $30 million to construct. It featured one of the largest custom Beckman lab automation systems in the United States. LabCorp is likely to transfer MuirLab's testing services to its largest lab in California, in San Diego.

Also, as of November, John Muir will no longer provide lab services to skilled nursing facilities. MuirLab currently provides lab services to more than 300 nursing homes in northern California. Nursing home clients had comprised a significant portion of MuirLab's outreach business. LabCorp is not buying MuirLab's nursing home business.

Approximately 540 lab employees will lose their jobs, although LabCorp may hire about 150.

The transaction with LabCorp does not affect John Muir Health's two hospital-based labs in Walnut Creek (570 beds) and Concord (300 beds), which will continue to be owned and operated by the health system.

"Physicians and patients have frequently complained about MuirLab's pricing. This agreement will lower patients' out-of-pocket expenses and advance John Muir Health's efforts to deliver high-quality care at an affordable cost," said Calvin Knight, President and Chief Executive of John Muir Health, in a press statement.

Knight indicated that MuirLab had been operating at a loss. "These decisions allow us to redirect financial resources that were needed to support MuirLab into other strategic initiatives that position us for future growth and help us meet the short- and long-term needs of our patients and the communities we serve," said Knight.

John Muir is currently in the process of investing tens of millions of dollars to construct new regional outpatient care centers. The first center (70,000 square feet) is expected to open in Walnut Creek in January 2014.

MuirLab will be the second hospital lab outreach program that LabCorp has purchased in the San Francisco area. In August 2008, LabCorp purchased Stanford Hospital's clinical lab outreach business.

LAB STOCKS UP 3% YTD

Thirteen lab stocks are, on average, up 3% in price year to date through September 19. In comparison, the S&P 500 Index is up 16%. The top-performing lab stocks so far this year are Response Genetics, up 47%, and Cancer Genetics, up 27%, followed by Genomic Health, up 23%. Quest Diagnostics is up 6% and LabCorp is up 15%.

Company (ticker)	Stock Price 9/19/13	Stock Price 12/31/12	2013 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$28.82	$28.63	1%	$803	17.0	1.2	3.1
Cancer Genetics Inc. (CGIX)	12.65	10.00	27%	74	NA	13.9	NA
CombiMatrix (CBMX)	2.91	5.28	-45%	13	NA	2.3	1.8
Enzo Biochem (ENZ)	2.50	2.70	-7%	100	NA	1.0	2.8
Genomic Health (GHDX)	33.62	27.24	23%	1,030	843.5	4.2	7.3
LabCorp (LH)	99.76	86.62	15%	9,060	14.7	1.6	3.5
LipoScience (LPDX)	5.09	9.00	-43%	76	NA	1.4	1.4
Myriad Genetics (MYGN)	25.69	27.25	-6%	2,070	14.7	3.4	2.9
NeoGenomics (NEO)	2.64	2.48	6%	129	NA	2.2	7.0
Psychemedics (PMD)	12.91	10.75	20%	69	22.6	2.7	6.0
Quest Diagnostics (DGX)	61.81	58.27	6%	9,390	15.0	1.3	2.5
Response Genetics (RGDX)	2.05	1.39	47%	63	NA	3.1	7.2
Sonic Healthcare (SKHCY)	13.71	13.69	0%	5,486	NA	NA	NA
Unweighted Averages			3%		154.6	3.2	3.8

Source: Zacks

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