

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

MEDICARE TO SLASH TECHNICAL RATES

The reimbursement nightmare continues for pathology labs. Medicare Physician Fee Schedule rates for most high-volume technical services provided by pathology labs are set to be reduced by 50% or more next year, according to the 2014 Physician Fee Schedule Proposed Rule issued by CMS on July 8. The drastic reductions are the result of CMS's proposal to link payment for pathology services to the rates paid under Medicare's hospital outpatient prospective payment system, which are generally about 1/3 the rates paid under the PFS.

For example, the proposed rule would cut the technical component for CPT 88342 (immunohistochemistry) by 47% to \$38.45 effective January 1, 2014. And the technical fee for CPT 88185 (flow cytometry, add on) would be cut by 76% to \$12.93.

Meanwhile, professional component rates for most high-volume pathology services will be little changed next year. For example, the professional component rate for CPT

88305 (tissue exam) has been proposed at \$36.40, down 1% from its current rate of \$36.74. *Continued on pages 3-6.*

Technical Component Rates for 2014*

CPT Code	Proposed 2014 Rate	Change
88305-TC	\$30.96	-7%
88342-TC	\$38.45	-47%
88185-TC	\$12.93	-76%
88312-TC	\$23.82	-67%
88112-TC	\$23.82	-54%
88361-TC	\$38.45	-61%

*Proposed national rates unadjusted for geography. Assumes conversion factor remains at 34.023
Source: LE from CMS

CMS SEEKING RATE REVIEW FOR ALL LAB TESTS

CMS is proposing to review reimbursement rates for all 1,250 test codes paid under the clinical laboratory fee schedule (CLFS) with the intent of lowering payments to better align pricing with the cost of new and more efficient testing technologies. The initiative was likely supported by the recent OIG report published in June which showed that Medicare could save an estimated \$910 million per year by paying labs at the lowest rates paid by Medicaid plans and federal employee health plans (see LE, June 2013, pp. 1-2). *Continued on page 2.*

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CMS SEEKING RATE REVIEW FOR ALL LAB TESTS (*cont'd from p. 1*)

The proposal to review all tests on the CLFS was detailed in CMS's 2014 Physician Fee Schedule Proposed Rule. Most tests on the CLFS have not been reviewed for at least 20 years and there is currently no process to make adjustments to individual test codes.

CMS has proposed that, each year, it would review certain codes on the CLFS to decide whether payment for these codes should be adjusted due to technological change. Proposed payment rates for the first batch of test codes under review would be announced in the 2015 PFS proposed rule and the new rates would take effect January 1, 2016.

Inflation and productivity adjustments would continue to be applied to the CLFS each year.

CMS estimates that it would take at least five years to review all of the existing codes on the CLFS. The agency would start its review by examining the codes that have been on the CLFS the longest and then work forward. The proposal indicates that CMS would review an average of about 250 test codes per year.

Payment rates could be revised up or down. However, CMS said that it expects most payment amounts to decrease due to improvements in lab technology over the past 20+ years.

Following completion of its initial review, CMS has proposed that it would review test codes again every five years.

CMS is seeking public comment on its proposal as well as alternative suggestions for factoring technology improvements into lab test prices.

JUNE CPI-U POINTS TO 1% CUT TO 2014 CLFS

The Bureau of Labor Statistics has reported that the Consumer Price Index for Urban Consumers (CPI-U) was up 1.8% for the 12 months ended June 30, 2013. The June CPI-U will be utilized in the calculation of the 2014 adjustment to the Medicare Part Clinical Lab Fee Schedule (CLFS).

As per legislated methodology, the CLFS receives a CPI-U update each year minus a productivity adjustment (an estimated 1.1% for 2014). An additional 1.75% reduction is applied each year from 2011 to 2015 related to the Patient Protection and Affordable Care Act (aka Obamacare). Thus the CLFS will be cut an estimated 1.05% effective January 1, 2014.

Next year's estimated 1.05% cut follows the -2.95% update for 2013 and the 2% sequestration cut that took effect April 1, 2013.

Estimated 2014 Medicare CLFS Adjustment

CPI-U	1.8%
Productivity Adjustment	-1.10%
Mandated Cut (2011-2015)	-1.75%
Net Estimated Adjustment for 2014.....	-1.05%

Source: LE estimates

MEDICARE TO SLASH TECHNICAL RATES (*cont'd from page 1*)

In the proposed rule, CMS noted that the Practice Expense Relative Value Units (PE RVUs), which are supposed to capture expenses such as equipment, supplies and non-physician staff, for non-hospitals (e.g., independent pathology labs and physician-office labs) is based on cost data provided by those entities. It is difficult for CMS to validate that these reported expenses are correct and the data can be outdated (as technology costs rapidly decline). On the other hand, PE RVUs for hospitals are based on auditable hospital data, which is updated annually.

The proposal would continue CMS' efforts to adjust payment rates for "mis-valued codes," by eliminating differentials in payment that, in the government's view, can create incentives to treat patients in higher-paying settings of care.

Laboratory Economics calculated the proposed rates for 2014 by taking the RVUs, unadjusted by geographic practice cost indices, multiplied by the current conversion factor of 34.023.

CPT 88305

Under the proposed rule, the technical component for CPT 88305, which was reduced by 52% this year, would go down by another 7% to \$30.96 effective January 1, 2014. The professional component for CPT 88305 would be cut by 1% to \$36.40 in 2014. The global payment would decline by 4% to \$67.37.

CMS rejected a proposal by the AMA RUC to create two new PE supply inputs for "specimen, solvent and formalin disposal cost" and "courier transportation costs" for six surgical pathology codes (CPT 88300, 88302, 88304, 88305, 88307 and 88309). CMS said these costs are already included in the PE RVUs through the indirect PE allocation.

Digital Pathology

The proposed rule reduces the technical component for CPT 88361 (tumor immunohistochemistry, computer-assisted image analysis) by 61% to \$38.45; the PC is being cut by 1% to \$56.82 and the global fee by 39% to \$95.26. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor. The reimbursement reduction is likely to slow growth of this fledgling technology.

FISH Bladder Cancer Testing

CMS cut reimbursement for FISH bladder cancer testing by approximately 50% in 2011. Reimbursement was then raised by more than 30% in 2013. Now CMS has flip-flopped again. Technical component reimbursement for CPT 88120 (FISH manual, 3-5 probes) is being cut by 72% to \$158.21; the PC will remain at \$56.48 and the global rate is being reduced 65% to \$214.69.

Computer-assisted FISH bladder cancer testing fared better. Technical component reimbursement for CPT 88121 (FISH computer-assisted, 3-5 probes) is being cut by 9% to \$462.37; the PC will be reduced by 1% at \$48.65 and the global rate is being reduced 8% to \$511.03.

Special Stains

The proposed rule reduces the technical component for CPT 88312 (special stains, group 1) by 67% to \$23.82; the PC is being cut by 1% to \$26.20 and the global fee by 49% to \$50.01.

The TC rate for CPT 88313 (special stains, group 2) is being cut by 57% to \$23.82; the PC will hold steady at \$11.91 and the global rate will fall 47% to \$35.72.

PROPOSED PHYSICIAN FEE SCHEDULE RATES FOR 2014*

CPT Code	Modifier	Description	Physician Work RVUs	Non-Facility PE RVUs	Facility PE RVUs	Mal-Practice RVUs	Total RVUs for 2014	2014 Rate	2013 Rate	Percent Change
88108	Global	Cytopath concentrate tech	0.44	0.88	NA	0.02	1.34	\$45.59	\$78.93	-42.24%
88108	TC	Cytopath concentrate tech	0.00	0.69	NA	0.01	0.7	\$23.82	\$56.82	-58.09%
88108	PC	Cytopath concentrate tech	0.44	0.19	0.19	0.01	0.64	\$21.77	\$22.11	-1.52%
88112	Global	Cytopath cell enhance tech	1.18	1.16	NA	0.05	2.39	\$81.31	\$109.55	-25.77%
88112	TC	Cytopath cell enhance tech	0.00	0.69	NA	0.01	0.7	\$23.82	\$51.37	-53.64%
88112	PC	Cytopath cell enhance tech	1.18	0.47	0.47	0.04	1.69	\$57.50	\$58.18	-1.17%
88120	Global	Cytp urine 3-5 probes ea spec	1.20	5.05	NA	0.06	6.31	\$214.69	\$620.92	-65.42%
88120	TC	Cytp urine 3-5 probes ea spec	0.00	4.62	NA	0.03	4.65	\$158.21	\$564.44	-71.97%
88120	PC	Cytp urine 3-5 probes ea spec	1.20	0.43	0.43	0.03	1.66	\$56.48	\$56.48	0.00%
88121	Global	Cytp urine 3-5 probes cmptr	1.00	13.98	NA	0.04	15.02	\$511.03	\$557.98	-8.42%
88121	TC	Cytp urine 3-5 probes cmptr	0.00	13.58	NA	0.01	13.59	\$462.37	\$508.64	-9.10%
88121	PC	Cytp urine 3-5 probes cmptr	1.00	0.40	0.40	0.03	1.43	\$48.65	\$49.33	-1.37%
88173	Global	Cytopath eval fna report	1.39	1.72	NA	0.05	3.16	\$107.51	\$150.04	-28.34%
88173	TC	Cytopath eval fna report	0.00	1.12	NA	0.01	1.13	\$38.45	\$79.95	-51.91%
88173	PC	Cytopath eval fna report	1.39	0.60	0.60	0.04	2.03	\$69.07	\$70.09	-1.46%
88184	TC only	Flowcytometry/ tc 1 marker	0.00	0.69	NA	0.01	0.7	\$23.82	88.8	-73.18%
88185	TC only	Flowcytometry/ tc add-on	0.00	0.37	NA	0.01	0.38	\$12.93	\$54.10	-76.10%
88189	TC only	Flowcytometry/ read 16 & >	2.23	0.77	0.77	0.12	3.12	\$106.15	106.49	-0.32%
88304	Global	Tissue exam by pathologist	0.22	0.78	NA	0.02	1.02	\$34.70	44.57	-22.14%
88304	TC	Tissue exam by pathologist	0.00	0.69	NA	0.01	0.7	\$23.82	33.34	-28.57%
88304	PC	Tissue exam by pathologist	0.22	0.09	0.09	0.01	0.32	\$10.89	11.23	-3.05%
88305	Global	Tissue exam by pathologist	0.75	1.21	NA	0.02	1.98	\$67.37	\$70.09	-3.89%
88305	TC	Tissue exam by pathologist	0.00	0.90	NA	0.01	0.91	\$30.96	\$33.34	-7.14%
88305	PC	Tissue exam by pathologist	0.75	0.31	0.31	0.01	1.07	\$36.40	\$36.74	-0.91%
88307	Global	Tissue exam by pathologist	1.59	2.52	NA	0.05	4.16	\$141.54	\$297.36	-52.40%
88307	TC	Tissue exam by pathologist	0.00	1.78	NA	0.01	1.79	\$60.90	\$215.37	-71.72%
88307	PC	Tissue exam by pathologist	1.59	0.74	0.74	0.04	2.37	\$80.63	\$82.00	-1.67%

*Proposed national rates unadjusted for geography. Assumes conversion factor remains at 34.023.

Source: LE from CMS

CPT Code	Modifier	Description	Physician Work RVUs	Non-Facility PE RVUs	Facility PE RVUs	Mal-Practice RVUs	Total RVUs for 2014	2014 Rate	2013 Rate	Percent Change
88309	Global	Tissue exam by pathologist	2.80	5.93	NA	0.11	8.84	\$300.76	\$449.44	-33.08%
88309	TC	Tissue exam by pathologist	0.00	4.62	NA	0.03	4.65	\$158.21	\$304.51	-48.05%
88309	PC	Tissue exam by pathologist	2.80	1.31	1.31	0.08	4.19	\$142.56	\$144.94	-1.64%
88311	Global	Decalcify tissue	0.24	0.32	NA	0.08	0.64	\$21.77	\$20.41	6.69%
88311	TC	Decalcify tissue	0.00	0.21	NA	0.08	0.29	\$9.87	\$8.17	20.77%
88311	PC	Decalcify tissue	0.24	0.11	0.11	0.08	0.43	\$14.63	\$12.25	19.43%
88312	Global	Special stains group 1	0.54	0.91	NA	0.02	1.47	\$50.01	\$97.65	-48.78%
88312	TC	Special stains group 1	0.00	0.69	NA	0.01	0.7	\$23.82	\$71.11	-66.51%
88312	PC	Special stains group 1	0.54	0.22	0.22	0.01	0.77	\$26.20	\$26.54	-1.29%
88313	Global	Special stains group 2	0.24	0.79	NA	0.02	1.05	\$35.72	\$67.71	-47.24%
88313	TC	Special stains group 2	0.00	0.69	NA	0.01	0.7	\$23.82	\$55.80	-57.32%
88313	PC	Special stains group 2	0.24	0.10	0.10	0.01	0.35	\$11.91	\$11.91	-0.02%
88321	Global	Microslide consultation	1.63	0.96	0.69	0.10	2.69	\$91.52	93.22	-1.82%
88323	Global	Microslide consultation	1.83	1.73	NA	0.05	3.61	\$122.82	141.54	-13.22%
88323	TC	Microslide consultation	0.00	1.12	NA	0.01	1.13	\$38.45	58.52	-34.30%
88323	PC	Microslide consultation	1.83	0.61	0.61	0.04	2.48	\$84.38	83.02	1.63%
88331	Global	Path consult intraop 1 bloc	1.19	1.26	NA	0.02	2.47	\$84.04	\$99.69	-15.70%
88331	TC	Path consult intraop 1 bloc	0.00	0.69	NA	0.01	0.7	\$23.82	\$38.45	-38.06%
88331	PC	Path consult intraop 1 bloc	1.19	0.57	0.57	0.01	1.77	\$60.22	\$61.24	-1.66%
88342	Global	Immunohistochemistry	0.85	1.48	NA	0.04	2.37	\$80.63	115.34	-30.09%
88342	TC	Immunohistochemistry	0.00	1.12	NA	0.01	1.13	\$38.45	73.15	-47.44%
88342	PC	Immunohistochemistry	0.85	0.36	0.36	0.03	1.24	\$42.19	42.19	0.00%
88346	Global	Immunofluorescent study	0.86	1.46	NA	0.02	2.34	\$79.61	109.21	-27.10%
88346	TC	Immunofluorescent study	0.00	1.12	NA	0.01	1.13	\$38.45	67.37	-42.93%
88346	PC	Immunofluorescent study	0.86	0.34	0.34	0.01	1.21	\$41.17	41.85	-1.63%
88361	Global	Immunohistochem/comput	1.18	1.57	NA	0.05	2.8	\$95.26	156.51	-39.13%
88361	TC	Immunohistochem/comput	0.00	1.12	NA	0.01	1.13	\$38.45	99.35	-61.30%
88361	PC	Immunohistochem/comput	1.18	0.45	0.45	0.04	1.67	\$56.82	57.16	-0.60%
88367	Global	Insitu hybridization auto	1.30	1.54	NA	0.06	2.9	\$98.67	\$258.23	-61.79%
88367	TC	Insitu hybridization auto	0.00	1.12	NA	0.01	1.13	\$38.45	\$59.88	-35.79%
88367	PC	Insitu hybridization auto	1.30	0.42	0.42	0.05	1.77	\$60.22	\$198.35	-69.64%
88368	Global	Insitu hybridization manual	1.40	2.16	NA	0.05	3.61	\$122.82	\$232.04	-47.07%
88368	TC	Insitu hybridization manual	0.00	1.78	NA	0.01	1.79	\$60.90	\$170.46	-64.27%
88368	PC	Insitu hybridization manual	1.40	0.38	0.38	0.04	1.82	\$61.92	\$61.58	0.56%

*Proposed national rates unadjusted for geography. Assumes conversion factor remains at 34.023.

Source: LE from CMS

GAUGING THE REVENUE LOSS TO PATHOLOGY GROUPS AND LABS

The technical component rate reductions proposed by CMS for 2014 will result in an estimated revenue loss of \$571 million in Medicare payments to pathology groups and labs next year. This estimate is based on Part B spending on the top 20 pathology codes in 2013 multiplied by the proposed rate reductions for 2014. *LE's* estimate of \$571 million in lost Medicare revenue is equal to an overall 25% reduction in Medicare payments to pathology groups and labs. Our estimate is in line with CMS's estimate of minus 26%.

In addition, the Medicare rate changes will also influence rates paid by commercial third-party payers. Many, if not most, private insurance payers base their rates on a percentage of the Medicare Physician Fee Schedule. Some private insurance payers' rate schedules will automatically reset to the lower rates effective January 1, 2014. Other contracts will be reset over the course of the next 1-3 years as these contracts come up for renewal.

This year's 52% cut to 88305-TC combined with the proposed technical component cuts for next year may force many independent pathology labs and in-office labs to sell or shut down.

Medicare Annual Expenditure Estimates for Key Pathology Codes

Code (Description)	Estimated Part B Spending 2013 (\$ millions)	2014 Global Rate Change	2014 Revenue Impact (\$ MM)
88305 (Level IV, tissue exam by pathologist)	\$1,008.66	-3.9%	-\$39.3
88342 (Immunohistochemistry)	\$323.94	-30.9%	-\$100.1
88185 (Flow cytometry, add on)	\$164.02	-76.1%	-\$124.8
88307 (Level V, tissue exam by pathologist)	\$113.55	-52.4%	-\$59.5
88312 (Special stains)	\$107.77	-48.8%	-\$52.6
88112 (Cytopath cell enhance tech)	\$99.04	-25.8%	-\$25.5
88313 (Special stains)	\$75.41	-47.2%	-\$35.6
88368 (FISH-manual)	\$65.59	-47.1%	-\$30.9
88120 (FISH-manual)	\$49.73	-65.4%	-\$32.5
88331 (Pathology consult during surgery)	\$43.47	-15.7%	-\$6.8
88121 (FISH-computer assisted)	\$41.43	-8.4%	-\$3.5
88309 (Level VI, tissue exam by pathologist)	\$34.58	-33.1%	-\$11.4
88173 (Cytopath eval FNA)	\$33.99	-28.3%	-\$9.6
88367 (FISH-computer assisted)	\$32.36	-61.8%	-\$20.0
88346 (Immunofluorescent study)	\$25.12	-27.1%	-\$6.8
88304 (Level III, tissue exam by pathologist)	\$23.93	-22.1%	-\$5.3
88321 (Microslide consultation)	\$20.16	-1.8%	-\$0.4
88189 (Flow cytometry, read 16+)	\$20.08	-0.3%	-\$0.1
88108 (Cytopath, concentrate tech)	\$16.57	-42.2%	-\$7.0
88311 (Decalcify tissue)	\$10.39	6.7%	\$0.7
Total	\$2,309.8	-24.8%	-\$571.1

*Proposed national rates unadjusted for geography. Assumes conversion factor remains at 34.023.

Source: CMS and *LE* estimates for Part B spending in 2013

GAO CALLS FOR ACTION ON SELF-REFERRED PATHOLOGY SERVICES

Self-referring physicians order more anatomic pathology services (88305s) per biopsy procedure for Medicare beneficiaries than those that use an outside lab, according to a new report from the Government Accountability Office (GAO). For example, self-referring urologists referred an average of 12.5 CPT 88305s per biopsy procedure for diagnosis of elevated prostate specific antigen, while those that used an outside lab referred an average of 8.5, based on the GAO’s analysis of claims in 2010.

The GAO report was titled: *Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer*. The report was made at the request of Senators Max Baucus (D-MT) and Chuck Grassley (R-IA) and Representatives Sandy Levin (D-MI), Henry Waxman (D-CA) and former Rep. Pete Stark (D-CA).

Average Number of Billed 88305s per Biopsy Procedure for Medicare Claims in 2010			
	Self-Referring Physicians*	Non-Self-Referring Physicians	Percentage Difference
DERMATOLOGY			
Neoplasm of uncertain behavior of skin (ICD-9 238.2)	1.8	1.6	13%
Other malignant neoplasm of skin (ICD-9 173.3)	1.6	1.4	14%
Actinic Keratosis (ICD-9 702.0)	1.7	1.5	13%
GASTROENTEROLOGY			
Benign neoplasm of colon (ICD-9 211.3)	2.2	1.9	16%
Atrophic gastritis (ICD-9 535.10)	2.2	1.9	16%
Unspecified gastritis and gastroduodenitis (ICD-9 535.50)	2.7	2.0	35%
UROLOGY			
Elevated PSA (ICD-9 790.93)	12.5	8.5	47%
Malignant neoplasm of prostate (ICD-9 185)	8.5	6.1	39%
Malignant neoplasm of bladder (ICD-9 188.9)	1.8	1.7	6%

*Self-referring physicians include those who have an ownership stake in a clinical lab, but more commonly, those who prepare and/or evaluate specimens at an in-office pathology lab.
 Source: GAO Report, June 2013

The GAO report found that referrals for anatomic pathology services by dermatologists, gastroenterologists and urologists substantially increased the year after they began to self-refer. For example, urologists that began self-referring in 2009 increased their orders for 88305s by an average of 58.5% in 2010 compared to 2008, the year before they began self-referring.

GAO estimates that in 2010, self-referring providers likely ordered over 918,000 more 88305s than if they had referred specimens to an outside lab. These additional orders for 88305 cost Medicare an estimated \$69 million.

GAO also reviewed special stains (CPT codes 88312, 88313 and 88342) and found that the utilization of special stains substantially increased the year after a physician began to self-refer.

The report brings pathologists one step closer toward their goal of having anatomic pathology removed from the In-Office Ancillary Services (IOAS) exception, observes *Laboratory Economics*. The IOAS exception allows physicians to bill for certain medical services where an ownership interest exists. It was intended to apply to services provided at the time of an office visit as a convenience to patients.

GAO recommended three steps that CMS can take to eliminate unnecessary increases in these biopsies:

- Develop a self-referral flag on Medicare Part B claims for physicians to indicate if pathology services are self-referred or not.
- Implement an approach to ensure the appropriateness of biopsy procedures performed by self-referring physicians.
- Limit financial incentives that go along with referring a higher number of 88305s for biopsy procedures.

HHS's response to Recommendation 1 offered some hope to pathologists. HHS noted that the President's Fiscal Year 2014 Budget proposal included a provision to exclude certain services from the IOAS exception to the Stark Law. These services included diagnostic imaging, radiation therapy and physical therapy. Anatomic pathology was not mentioned, but HHS's response noted that AP services "may share some characteristics with the services mentioned in the President's proposal."

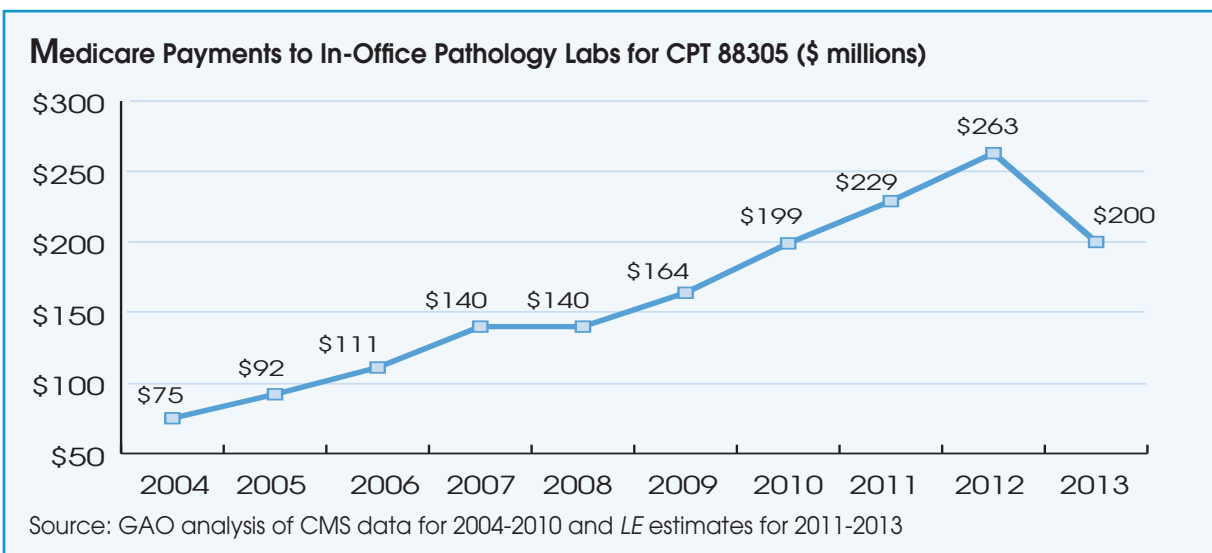
HHS said that Recommendation 2 would involve too many claims reviews to be practical.

HHS concurred with Recommendation 3 and noted that it reduced payment for the technical component of CPT 88305 by approximately 50% this year, thereby reducing the financial incentives associated with self-referral for this code. In addition, *LE* notes that the technical component rates for nearly all the other AP codes are set to be dramatically reduced in 2014, according to the recently released 2014 Physician Fee Schedule Proposed Rule.

"The analysis suggests that financial incentives for self-referring providers is likely a major factor driving the increase in referrals for these services," Rep. Waxman said in a joint statement from the legislators. "As Congress looks to rein in unnecessary spending, my colleagues and I should explore this area in greater depth," he said.

LE notes that removing AP services from the IOAS exception would shift millions of dollars from in-office pathology labs back to traditional independent pathology labs and hospitals.

The GAO report calculated that Medicare expenditures for self-referred AP services (as measured by CPT 88305) increased from about \$75 million in 2004 to \$199 million in 2010. *LE* estimates that these expenditures will total \$200 million in 2013, even after accounting for this year's 50% cut to 88305-TC.



AETNA CLARIFIES NEW NATIONAL LAB FEE SCHEDULE

As previously reported, Aetna modified its national lab fee schedule effective July 1. The changes resulted in clinical lab and anatomic pathology rates that are equal to only 45-50% of the national Medicare Clinical Lab Fee Schedule. Aetna's new national rates only apply to its national contracts with Quest Diagnostics and about 50 other commercial labs, including Bio-Reference Labs, Bostwick Labs, Clariant, Enzo Clinical Lab, Miraca Life Sciences, NeoGenomics, Sonic Healthcare, et al. The new basement rate contract does not apply to physicians contracted under Aetna's local market fee schedule or other non-national laboratory arrangement. If your lab did not receive a letter from Aetna announcing the change, you are not subject to it.

FORMER DERMATH DOC STARTS NEW LAB

Lynn Cooper, MD, former Medical Director for Quest's Dermath Diagnostics in Atlanta, has formed a new lab company named LDC Dermatopathology LLC based in Marietta, GA (just north of Atlanta).

Cooper joins a growing list of dermatopathologists that have left Dermath Diagnostics to form their own lab companies.

These include Clay Cockerell, MD, who is in the process of opening a new independent dermatopathology laboratory in Dallas named Cockerell Dermatopathology. Dr. Cockerell is former Managing Director at Dermath Diagnostics in Dallas.

Others competing dermatopathology labs created by ex-Quest/Dermath pathologists include Bako Pathology (Alpharetta, GA), Skin Diagnostics (Birmingham, AL) and Skinpath Solutions (Smyrna, GA).

ACCELPATH CANCELS DIGIPATH ACQUISITION

AccelPath, Inc. (Gathersburg, MD) and DigiPath Solutions LLC (Spring, TX) have canceled an acquisition agreement signed late last year (see *LE*, October 2012, page 9). Under that agreement, AccelPath was to acquire DigiPath from its sole shareholder, Rishi Reddy, for approximately \$2 million. That deal was recently canceled and all parties were restored to their status before the purchase agreement was executed.

Founded in 2010, DigiPath Solutions markets a combination of in-office pathology lab development services to physician practices with digital pathology interpretations by contracted pathologists.

AccelPath is a small publicly-traded company focused on providing digital pathology services and professional interpretations to in-office labs at physician practices and other histology labs. In the six months ended December 31, 2012, AccelPath reported a net loss of \$1.1 million on revenue of \$191,706. The company had a working capital deficit of \$2.1 million as of December 31, 2012.

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QUEST ANTITRUST LAWSUIT DISMISSED

A California federal judge has dismissed a lawsuit that accused Quest Diagnostics of allegedly negotiating illegal agreements with Aetna, Blue Shield of California and the Blue Cross Blue Shield Assn. that make it impossible for independent labs to compete. U.S. District Judge Jon Tigar in San Francisco dismissed the case in its entirety saying the allegations “fall short” of stating a claim. However, Judge Tigar has given the plaintiffs until August 25 to file an amended complaint.

The lawsuit (case 4:12-cv-05847) had originally been filed in November 2012 by four independent labs in California, including Hunter Laboratories (Campbell, CA), Rheumatology Diagnostics Laboratory (Los Angeles), Pacific Breast Pathology Medical Corp. (Novato, CA) and Surgical Pathology Associates (Los Gatos, CA).

The four California labs alleged:

- Quest conspired with BCBSA to formulate a new policy requiring labs to submit Blue Card members’ claims to the BCBS plan in whose state the patient is insured. The policy has made it difficult for molecular and specialty labs operating from a single location to compete on a national basis and has driven volume to Quest. The lawsuit alleged that the American Clinical Lab Assn. (ACLA) had drafted a strong protest to the new Blue Card policy. However, Quest, the largest contributor to ACLA’s funding, vetoed the transmittal of the letter of protest.
- Quest has systematically contracted with IPAs on a below-cost capitated basis in order to lock out competition and induce the referral of lucrative Medicare and Medi-Cal business.
- Quest has bargained for right-of-first-refusal contracts with Aetna. These contracts require Aetna to contact Quest before entering new contracts with other labs. Quest must agree to the plan before Aetna may consider adding the lab to its network.
- Quest gave Blue Shield of California a 10% discount on lab test fees in return for kicking two competitors (Westcliff Labs and Hunter Labs) out of its network.
- Quest has been illegally capping patient payments or waiving all patient co-pay and deductible charges in California and making up for the losses with “pull-through” business from Medicare and Medicaid.

The plaintiffs allege that Quest’s anticompetitive behavior excludes new competitors from entering the market and has given Quest a 70% market share in the Northern California physician outpatient market.

In response, Blue Shield of California had argued that all the lawsuit showed was that Blue Shield shifted business from one competitor (Hunter Labs) to another (Quest), to obtain lower prices for its health plan members.

Quest said the lawsuit merely described a competitive market that lowers costs for patients.

Aetna said that exclusive contracts are lawful unless they foreclose a big share of the market to competition. But Aetna only covers about 9% of the U.S. population.

“Parties such as BCBSA should not be hauled into court and forced to undergo the potentially

massive investment necessary to defend against antitrust claims when presented with pleadings as skimpy and implausible as these are,” according to the reply from the BCBSA.

In his June 25 ruling, Judge Tigar noted that the lawsuit’s allegations were too vague. For example, the lawsuit provided little details on Quest’s “below-market” pricing or the percentage of labs denied entry into the market because of Quest’s contracts.

“The court’s ruling is consistent with our position that the plaintiffs’ allegations were entirely without merit, lacking both a factual basis and legal foundation,” according to Wendy Bost, Director of Media Relations at Quest.

Chris Riedel, Chief Executive at Hunter Labs, says, “Dismissal with leave to amend is common in antitrust cases. We will be filing an amended complaint with more specific information. The same thing happened in the California Qui-Tam case. Ironically, in the Qui-Tam amended complaint Quest had a fit when more specific information was included and filed a motion requesting that much of it be redacted from the complaint released to the public.”

Based on CLIA data from CMS, *Laboratory Economics* estimates that Quest has a 46% share of the independent lab market in California. LabCorp has a 20% share. Next are two dialysis-related testing labs: Spectra Labs (Milipitas, CA), 5% share, and Ascend Clinical LLC (Redwood City), 3% share. Physicians Automated Lab (Bakersfield and Burbank), which is owned by Sonic Healthcare USA, has a 2% share.

Riedel is being represented by Cotchett Pitre & McCarthy LLP. The is the same law firm that helped Hunter Labs and the State of California negotiate a \$290+ million Medicaid pricing lawsuit settlement from Quest (\$241 million) and LabCorp (\$49.5 million) in 2011.

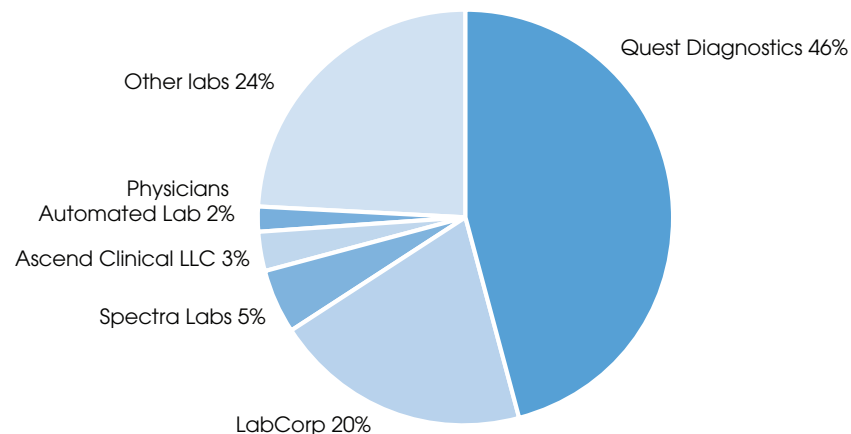
Laboratory Economics notes that Hunter Labs has filed whistleblower lawsuits against Quest and LabCorp in at least four other states. Lawsuits that have been unsealed include Michigan, Massachusetts, Georgia and Nevada. These lawsuits allege that Quest and LabCorp have overcharged Medicaid for lab tests.

To date, Michigan is the only state that has intervened.

The Nevada case is scheduled to begin trial in November.

Hunter Labs is also believed to have filed similar lawsuits in several other states, including Florida and Virginia. However, these cases have not been unsealed.

California Independent Lab Market Share*



*Based on annual test volume reported on CLIA forms
Source: CLIA Database of Independent Labs, January 2013

LAB STOCKS UP 4% YTD

Thirteen lab stocks are, on average, up 4% in price year to date through July 15. In comparison, the S&P 500 Index is up 14%. The top-performing lab stocks so far this year are NeoGenomics, up 35%, followed by Genomic Health, up 31%. Quest Diagnostics is up 3% and LabCorp is up 12%.

Company (ticker)	Stock Price 6/17/13	Stock Price 12/31/12	2013 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	\$27.09	\$28.63	-5%	\$749	16.6	1.1	3.1
Cancer Genetics Inc. (CGIX)	11.60	10.00	16%	50	NA	11.6	NA
CombiMatrix (CBMX)	3.04	5.28	-42%	11	NA	0.7	4.5
Enzo Biochem (ENZ)	2.24	2.70	-17%	90	NA	0.9	2.5
Genomic Health (GHDX)	35.72	27.24	31%	1,079	178.6	4.5	8.3
LabCorp (LH)	97.34	86.62	12%	9,043	15.5	1.6	3.3
LipoScience (LPDX)	6.71	9.00	-25%	98	NA	2.1	1.7
Myriad Genetics (MYGN)	31.80	27.25	17%	2,530	20.1	4.4	3.9
NeoGenomics (NEO)	3.36	2.48	35%	164	NA	2.7	8.6
Psychedics (PMD)	10.99	10.75	2%	58	19.3	2.3	5.1
Quest Diagnostics (DGX)	59.89	58.27	3%	9,460	14.1	1.3	2.2
Response Genetics (RGDX)	1.74	1.39	25%	57	NA	2.5	5.4
Sonic Healthcare (SKHCY)	13.22	13.69	-3%	5,250	NA	NA	NA
Unweighted Averages			4%		44.0	3.0	4.3

Source: Zacks

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