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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CALIFORNIA LABS SEEING MEDI-CAL CUTS OF UP TO 30%

Clinical laboratories in California are caught in a web of cumulative cuts to Medi-Cal (Medicaid) payments, with labs experiencing a 20% to 30% cut for many testing codes effective July 1, 2015.

The move to reduce lab payments was inspired in part by the 2011 state settlements with Quest and LabCorp over charges that Medi-Cal overpaid for lab testing services, according to Kristian Foy, legislative advocate for the California Clinical Laboratory Association. Also contributing to the cuts is the state's ongoing budget crisis, she says.

"California now has over 12 million people enrolled in Medi-Cal. It just keeps growing," she notes. "The state is really worried about the cost." *Full details on page 4.*

IS NEW CMS ADVISORY PANEL READY TO PRICE LAB TESTS?

After missing a Jan. 1, 2015 deadline, CMS finally released the names of the individuals it has selected for its Advisory Panel on Clinical Diagnostic Laboratory Tests. This panel, which includes 15 people and a Chair, is charged with providing input to CMS on the establishment of payment rates for new lab tests. Importantly, this panel will also provide advice to CMS on the use of private-payer rates for the repricing of existing tests on Medicare's Clinical Laboratory Fee Schedule (CLFS). The panel is stacked with doctors and scientists from academic medical centers, but seems lacking in business and finance experience, notes Dennis Weissman, President of the lab consulting firm Weissman & Associates LLC (Washington, DC). *Continued on page 3.*

ARE YOU READY FOR ICD-10? OCT. 1 DEADLINE LOOMS

Anyone expecting a delay in the transition to ICD-10 this October should stop holding their breath. It's unlikely to happen. While several bills are pending in Congress that would provide a grace period, extended transition, or even outright repeal, experts say they believe the transition to ICD-10 will proceed as scheduled effective Oct. 1, 2015. "I don't expect any delay," Charles Root, CEO of CodeMap (Schaumburg, IL), tells *Laboratory Economics*. *Continued on page 2.*

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ARE YOU READY FOR ICD-10? (*cont'd from page 1*)

On a positive note, at least for pathologists and other physicians, the Centers for Medicare and Medicaid Services (CMS) said in July that for one year it would not deny physician or other practitioner claims that use the wrong ICD-10 code as long as they are from the correct code family. However, JoAnne Glisson, vice president of the American Clinical Laboratory Association (ACLA), said it's not clear that this policy will apply to labs, and even if it did it would not apply to claims paid on the Clinical Lab Fee Schedule. ACLA is seeking clarification on this point from the Centers for Medicare and Medicaid Services.

According to a July 7 letter sent to providers, for 12 months after ICD-10 implementation, Medicare contractors will not deny physician or other practitioner claims billed under the Part B physician fee schedule through either automated medical review or complex medical record review based solely on the specificity of the ICD-10 diagnosis code, as long as the physician/practitioner used a code from the right family. However, a valid ICD-10 code still will be required on all claims starting Oct. 1, 2015.

In addition, Medicare contractors will not subject physicians or other eligible professionals to the Physician Quality Reporting Systems, Value-Based Modifier, or Meaningful Use Penalties during primary source verification or auditing related to the additional specificity of the ICD-10 diagnosis code, as long as the physician or professional used a code from the correct family.

Rocky Beginning

While Root believes most labs should be prepared for the transition, he does note that the beginning could be a little rocky as coders determine specific codes under ICD-10. Because ICD-10 offers more specificity than ICD-9, there will be many more codes to choose from (69,000 vs. 14,000).

For example, under ICD-9, there was one code for venom (989.5). Under ICD-10, there are 50 new codes for venom, ranging from T63.0 (toxic effect of snake venom) to T63.082 (toxic effect of other African or Asian snake, intentional self-harm).

As is often the case, labs' ability to submit properly coded claims depends in large part on referring physicians. If a physician submits a requisition with an ICD-9 code after Oct. 1, the lab coder will need to translate it to an ICD-10 code. In instances where one ICD-9 code translates to many different ICD-10 codes, the lab coder will need to contact the referring physician to determine which code is accurate.

"The issue for labs is the ordering provider," notes Glisson. "Some providers don't provide an ICD-9 code today, so it's unclear how many are prepared to provide ICD-10 codes." In these cases, labs will need to determine the appropriate code based on any narrative or will need to contact the ordering provider.

Coders can use online mapping tools to help make the conversion from ICD-9 to ICD-10 (a Google search turns up a number of them that are readily available). CMS also offers general equivalence mappings (GEM) on its website at https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html. In addition, a number of specialty associations have developed cheat sheets that list the top 50 codes in that specialty cross-walked from ICD-9 to ICD-10.

Another concern raised by Glisson relates to local coverage determinations (LCDs) or national coverage determinations that reference specific ICD-10 codes. Even if CMS provides the same flexibility to labs, labs will likely need to provide the specific code, not simply one from the same code family, she says. In several meetings with CMS officials and in subsequent letters, ACLA has shared its concern that Medicare administrative contractors effectively may have altered their coverage policies for certain laboratory services in the course of the transition to ICD-10 by not including the full range of ICD-10 codes that map to existing ICD-9 codes in LCDs.

One drawback of submitting non-specific codes from the same code family is that this could result in imprecise documentation in the electronic health record, notes Diana Voorhees, president of DV & Associates (Salt Lake City). "This may label patients somewhat permanently with information that is incorrect," she says.

IS NEW CMS ADVISORY PANEL READY TO PRICE LAB TESTS? (*cont'd from p. 1*)
In addition, Weissman notes that none of the panel members represent small independent labs or nursing home labs. These are the very labs that will get hit the hardest if the CLFS repricing results in large rate cuts for routine lab tests, he adds. Among those selected to the advisory panel are:

- **Steve Phurrough, MD,** Panel Chair, CMS Medical Officer
- **Geoffrey Baird, MD, PhD,** Assistant Professor in the Department of Laboratory Medicine at the University of Washington and Director of Clinical Chemistry at Harborview Medical Center
- **Vicki Baselski, PhD,** Professor, Pathology and Laboratory Medicine, University of Tennessee Health Science Center
- **Stephen N. Bauer, MD,** Medical Director at Path Logic, a division of NeoGenomics, former CAP President; and current member of the CAP Economic Affairs Committee
- **William Clarke, PhD, MBA, FACB,** Director, Clinical Toxicology, The Johns Hopkins Hospital
- **Judy Davis, MA, DLM (ASCP),** Director, Laboratory Quality Management at Vanderbilt University Medical Center and member of the Government Affairs Committee at ASCLS
- **Stanley R. Hamilton, MD,** Head of Pathology and Laboratory Medicine at The University of Texas M. D. Anderson Cancer Center and member of the CAP Economic Affairs Committee
- **Curt A. Hanson, MD,** Professor of Laboratory Medicine and Pathology at Mayo Clinic, Chief Medical Officer at Mayo Medical Labs and member of ACLA's Board of Directors
- **Kandice Kottke-Marchant, MD, PhD,** Chair of the Cleveland Clinic's Pathology and Laboratory Medicine Department
- **Raju Kucherlapati, PhD,** Paul C. Cabot Professor, Genetics, Harvard Medical School
- **Bryan A. Loy, MD, MBA,** Vice President Oncology, Laboratory and Personalized Medicine, Humana
- **Gail Marcus, MSE, MBA,** President and CEO, Calloway Labs
- **Carl Morrison, MD,** Clinical Chief of Roswell Park Cancer Institute's Dept. of Pathology and Laboratory Medicine and Executive Director of its Center for Personalized Medicine
- **Victoria M. Pratt, PhD, FACMG,** Director, Pharmacogenomics at Indiana University School of Medicine
- **Michele M. Schoonmaker, PhD,** Vice President, Government Affairs at Cepheid
- **Rebecca Sutphen, MD, FACMG,** President and Chief Medical Officer, InformedDNA

The first meeting of the panel is scheduled to take place at CMS's headquarters in Baltimore, on August 26. The panel will specifically recommend crosswalks for new laboratory codes, recommend an appropriate coding structure for drugs-of-abuse testing, and recommend crosswalks for such drugs-of-abuse testing. The meeting agenda includes no mention of discussion of a proposed rule for repricing the CLFS.

Labs Still Waiting for Proposed Rule on CLFS Repricing

Consequently, it now looks very likely that CMS will be forced to delay the Jan. 1, 2016 start date for clinical labs to begin reporting private-payer data that will be used to reprice tests on the CLFS. And such a delay might also roll back the Jan. 1, 2017 schedule for implementing lab test price changes to the CLFS based on private-payer rates.

CMS has already missed several deadlines related to the CLFS repricing exercise, which was mandated under the Protecting Access to Medicare Act of 2014 (PAMA). The agency missed its June 30, 2015 deadline for issuing a final rule explaining how it will collect private-payer data and set new CLFS rates. In fact, CMS has not even issued a proposed rule yet. "The longer we wait for the proposed rule, the more difficult the January 2017 implementation date looks," says Alan Mertz, President of the American Clinical Laboratory Assn.

CLFS Headed for 0% Update in 2016

Separately, *LE* notes that the CLFS is headed for no change in prices in 2016. An inflation adjustment of 0.1% is expected minus a "productivity adjustment" of 0.6%. However, the productivity adjustment cannot reduce the inflation adjustment below zero. As a result, no change is expected for lab test prices on the CLFS in 2016. (Note: The July issue of *Laboratory Economics* incorrectly reported an expected -0.5% change to the CLFS in 2016.)

CALIFORNIA LABS SEEING MEDI-CAL CUTS (*cont'd from page 1*)

There are three factors pushing Medi-Cal lab test reimbursement lower, notes Foy.

Firstly, there is a 10% cut that was approved by the California Legislature in 2011 (AB 97), but held up in the courts until this year. AB 97 applies to all Medi-Cal providers and is being implemented prospectively. Because it is a payment reduction, not a change to the actual rates, it will come off the final fee schedule rates, explains Foy.

Secondly, there is another 10% reduction effective from July 1, 2012 through June 30, 2015. This 10% across-the-board cut was mandated by AB 1494. It applies only to lab services and is being implemented retroactively for claims with date of service of July 1, 2012 through June 30, 2015. The state is collecting that money by taking back 5% of each "check write" made to each lab until the entire amount owed is collected.

Finally, AB 1494 also required the Department of Health Care Services (DHCS) to implement a new rate-setting methodology for certain lab test codes based on third-party payer information. For the 2014 data collection process, DHCS requested third-party payer rate and utilization data from labs and applied this data to codes that meet two thresholds: 1) Medi-Cal paid claims volume equal to or greater than 1,000 per year; and 2) Medi-Cal paid amount equal to or greater than $500,000 per year.

A total of 571 California labs were required to submit their private-payer data, including any lab with paid Medi-Cal lab test claims totaling $100,000 or greater in 2013, or a total paid claims volume of 5,000 or greater.

DHCS used the range of private-payer rates that fell between zero and 80% of California's specific Medicare rate. These rates were then weighted based on the units billed to create an average. These averages were then individually applied to each code meeting threshold requirements.

Medi-Cal's new method for collecting and analyzing private-payer data to set lab rates could be used as a model by Medicare as it makes adjustments to the national Part B Clinical Lab Fee Schedule.

In all, DHCS used the private-payer data to adjust the Medi-Cal rates for 351 different CPT codes. The new rates became effective July 1, 2015.

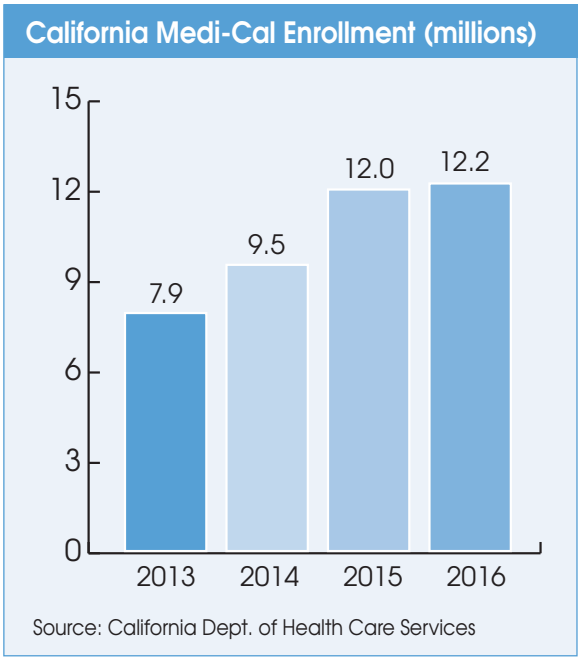
"The cuts are really code-specific, but overall it looks like they were cut by an average of about 15% to 20%," says Foy. Some test prices got hammered. For example, the Medi-Cal payment rate for a CBC (CPT 85027) is now at only 54% of the national Medicare rate. And the key pathology code CPT 88305 is set at a global rate of just $46.34, or 63% of the national Medicare rate.

An analysis by *Laboratory Economics* shows that the average lab test is now being reimbursed by Medi-Cal at approximately 64% of national Medicare rates (*see table next page*).

Obviously, labs that serve a greater percentage of Medi-Cal patients will be hit the hardest by the cuts, says Foy. However, she notes that the cuts apply only to fee-for-service payments, and roughly 75% of the Medi-Cal population is now under managed care. This should help minimize the impact on laboratories, she notes. However, with a total 12.2 million beneficiaries, the Medi-Cal program still pays fee-for-service for over 3 million individuals.

Rick Nicholson, chairman of West Pacific Medical Laboratories in Newport Beach, California, says that the cuts are expected to reduce his lab's net revenue by about 2%. Approximately 7-8% of West Pacific's revenue is from Medi-Cal, a figure that actually has decreased in recent years as more Medicaid patients move into HMOs. "There are a lot of labs out there that do a lot more Medi-Cal than us, and they are going to get hit much harder," says Nicholson.

Providing private-payer data to the state was "a very drawn out, time-consuming process," adds Nicholson. The state asked for payment information from labs' top five California third-party payers based on volume. West Pacific could not simply request the fee schedules from each payer;



instead, it had to calculate the payment amounts itself based on what it had been paid. "The government wanted to know what we were being paid, not what we were billing, or what the fee schedules showed. It took some time to calculate."

DHCS plans to collect third-party payer rate and utilization data annually from labs. New Medi-Cal lab test rates will be calculated annually based on the prior year's data.

Additional information about the lab cuts, including a link to current lab payment rates under Medi-Cal, can be found at http://www.dhcs.ca.gov/provgovpart/Pages/CLLS.aspx.

2015 Medicare vs. Medi-Cal Lab Test Rates

CPT	Description	National Medicare	California Medi-Cal*	As Percent of Medicare
80048	Basic Metabolic Panel	$11.51	$7.41	64%
80061	Lipid Panel	18.22	11.63	64%
80299	Quantitative Assay Drug	18.64	12.66	68%
83970	Parathyroid Hormone	56.17	34.84	62%
84153	Total PSA	25.03	16.51	66%
84443	TSH	22.87	14.95	65%
85027	CBC	10.58	5.74	54%
85610	Prothrombin Time	5.35	3.53	66%
87536	HIV-1 RNA Quantitative	115.80	76.33	66%
86141	High-Sensitivity CRP	17.62	11.69	66%
88175	Liquid-based Pap test With Auto Screen	36.05	24.34	68%
88305	Global-Tissue Exam by Pathologist	73.03	46.34	63%
	Overall Average for 12 tests			64%

*Medi-Cal rates are as of July 1, 2015. These rates do not include the 10% cut mandated by AB 97.
Source: *Laboratory Economics* from CMS and Medi-Cal

NO IMMEDIATE PLANS TO EXPAND BeaconLBS, SAYS UNITED

Is the BeaconLBS lab benefit management program helping UnitedHealthcare to lower lab costs in Florida? "With only a couple months of data, it's too early to draw any conclusions regarding costs and utilization," UnitedHealthcare spokesman Daryl Richard tells *Laboratory Economics*. He says UHC is still only in the early stages of this pilot (full-scale implementation was just launched in mid-April) and is monitoring its progress closely.

We also asked if UHC had any plans to expand BeaconLBS to additional states. "We want to thoughtfully review how the program has worked in Florida and will continue to enhance it to ensure it is improving the quality of outpatient laboratory services, supporting evidence-based guidelines for patient care and lowering costs for the people we serve before considering other states," answered Richard.

BeaconLBS is owned by LabCorp. UHC is requiring that physicians in Florida use the system before ordering a list of 79 high-volume lab tests for approximately 430,000 of its fully-insured commercial members in Florida.

LabCorp says BeaconLBS helps physicians order appropriate tests. Florida physicians have complained that the system is a cumbersome extra step and is difficult to integrate with many EHRs.

LabCorp reports that BeaconLBS contributed 1.1% to the revenue growth for its lab testing division in the second quarter ended June 30. The 1.1% gain equates to roughly $16 million in added revenue for the quarter (or an estimated $64 million on an annualized basis). This is the lab test revenue that passed through the BeaconLBS system from other labs that have been designated as a "Laboratory of Choice." Labs of Choice have their UHC claims processed and paid through BeaconLBS.

So far, only a handful of non-LabCorp labs have joined the "Laboratory of Choice" program. These include Bako Pathology, Clarient Diagnostic Services, KWB Pathology and Millennium Laboratories. The main benefit of becoming a Laboratory of Choice is that they are featured when physicians use BeaconLBS.

"I congratulate the entire BeaconLBS team on achieving an outcome that was little more than a dream when they began work on this project some five years ago. The BeaconLBS team remains engaged in discussions with existing and prospective clients that are expanding BeaconLBS' utilization and we look forward to providing updates in the future," LabCorp's Chairman and CEO Dave King told investors on a July 28 conference call.

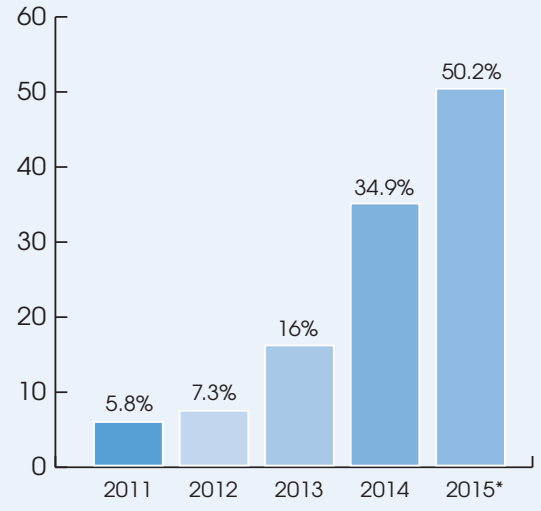
RESPONSE GENETICS FILES FOR BANKRUPTCY

Response Genetics Inc. (Los Angeles), which specializes in cancer therapy response testing, has declared Chapter 11 bankruptcy and plans to sell its assets to Cancer Genetics Inc. (Rutherford, NJ) for $14 million. The two companies expect that Response's day-to-day operations will continue uninterrupted during the process. Barring a competing bid, the two firms expect the sale to be completed within 60 days.

The bankruptcy of Response Genetics illustrates how much more stringent payers have become in paying for molecular diagnostic tests.

Response has 100 employees and operates a CLIA-certified and CAP-accredited 27,000-square-foot laboratory in Los Angeles. The company derives the majority of its revenue from its ResponseDx cancer tests and by providing clinical trial testing services to GlaxoSmithKline. For example, the company's ResponseDx lung cancer test panels, which can include more than a dozen tests (e.g., EGFR, KRAS, BRAF mutation analysis), is designed for patients with lung cancer who are being considered for treatment with crizotinib (Xalkori).

Bad-Debt Expense Ratio at Response Genetics



*For 3 months ended March 31, 2015
Source: Response Genetics' financial reports

Over the past two years, Response has struggled with declining reimbursement rates for molecular diagnostic tests, delays in payment and increased claims denials. For example, in the three months ended March 31, 2015, Response reported revenue of $3.79 million and bad debt of $1.9 million for a bad-debt expense ratio of 50.2%. Its average days sales outstanding was 145 days for the first quarter of 2015.

Cancer Genetics Inc. (CGI) expects the acquisition of Response to add $10 to $12 million of revenue to CGI over the next 12 months. CGI

operates a CLIA-certified and CAP-accredited laboratory in New Jersey that performs proprietary tests targeting hematological, urogenital and HPV-associated cancers. In the six months ended June 30, 2015, CGI reported a net loss of $9.3 million versus a net loss of $6.7 million in the same period in 2014; revenue increased to $8.6 million from $2.9 million. CGI's average days sales outstanding was 122 days for first half of 2015.

MEDICARE LAB SPENDING RISING SLOWLY

Medicare Part B carrier spending on lab tests paid through the Clinical Lab Fee Schedule (CLFS) to independent labs and physician offices labs (POLs) will total an estimated $5.789 billion in calendar year 2015, up 4.7% from $5.528 billion in 2014, according to CMS's 2015 Medicare Trustees Report.

Medicare Part B intermediary spending on lab tests provided by hospitals will increase by an estimated 3.7% to $2.838 billion this year. The increase follows a decline of 31% in 2014 due to the switch to bundled payment for lab tests provided to hospital outpatients which became effective January 1, 2014.

Contrary to popular opinion, Medicare spending on clinical lab tests is growing more slowly than overall program spending.

Total Medicare program spending in 2015 will be an estimated $649.1 billion, up 5.8% from $613.3 billion in 2014. The number of Medicare beneficiaries this year increased by 3.3% to 54 million.

Over the five-year period 2010-2015, total Medicare program spending increased by an average of 4.4% per year. During the same time frame, Part B spending on lab tests provided by independent labs and POLs was up 3.8% per year, while Part B spending on lab tests provided by hospitals fell 4.8% per year.

Part B lab services will represent only 1.3% of overall Medicare program expenditures this year.

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

Medicare Part B Spending on Lab Services, 2010-2015 ($ millions)*

	2015E	2014	2013	2012	2011	2010	5-Year CAGR**
Carrier Labs (independents & POLs)	$5,789	$5,528	$5,198	$5,126	$4,620	$4,800	3.8%
Intermediary Labs (hospitals)	2,838	2,737	3,954	4,028	3,834	3,628	-4.8%
Total Part B Lab Spending	8,627	8,265	9,152	9,154	8,454	8,428	0.5%
Total Medicare Spend (all services)	649,100	613,300	582,900	574,200	549,100	522,900	4.4%
Lab Spend as % Medicare	1.3%	1.3%	1.6%	1.6%	1.5%	1.6%	

*Part B expenditures on an incurred basis for the calendar year **CAGR=compound annual growth rate

Source: 2015 Medicare Trustees Report

FORMER MEDICARE CHIEF CASHING IN

The former head of the Centers for Medicare and Medicaid Services, Marilyn Tavenner, is now the top lobbyist for health insurance companies. America's Health Insurance Plans (AHIP), the trade group representing Aetna, Cigna, Humana, et al., has hired Tavenner as its new CEO. Tavenner replaces Karen Ignagni, who resigned from the position earlier this year. Tavenner's compensation package has not been disclosed, but it's probably safe to assume it will be similar to her predecessor Ignagni, who earned $2 million as CEO of AHIP in 2013.

PROPOSED RATE CHANGES FOR 2016 AND THE REVENUE IMPACT TO PATHOLOGY GROUPS AND LABS

Proposed Medicare rate changes for 12 key pathology codes will result in an estimated revenue gain of approximately $42 million in Part B payments to pathology groups and labs next year. This estimate is based on $1.9 billion of annual Medicare Part B expenditures for 12 top pathology codes multiplied by reimbursement changes that average 2.2% on a weighted basis.

Our 2.2% estimate is significantly less than the 8% to 9% gain that CMS initially estimated for independent pathology labs and pathologists next year (see *LE*, July 2015, pp. 1-3) because of a revision to the proposed rate for CPT 88185 (flow cytometry/each add'l marker). The initial Proposed Physician Fee Schedule for 2016 showed CPT 88185 declining by 18% to $46.94. However, CMS has revised the proposed rate for CPT 88185 to $17.69—a decrease of 69%.

The new proposed rate reduction for CPT 88185 will result in the loss of $69.2 million per year of Part B revenue for pathology labs. However, this loss will be more than offset by a proposed hike to immunohistochemistry rates (CPT 88341 & 88342) which will rise by an average of roughly 30% on a global basis depending on the number of stains tested.

MEDICARE REIMBURSEMENT ESTIMATES FOR KEY PATHOLOGY CODES*

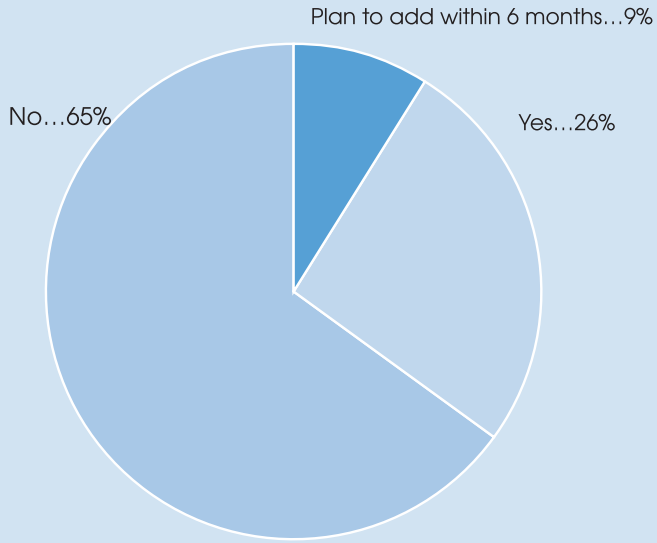
Code (Description)	*Annual Medicare Allowed Charges ($ millions)**	*Proposed 2016 Global Rate Change***	*Est'd 2016 Revenue Impact ($ millions)*
88305 (Level IV, tissue exam by pathologist)	$971.1	1.5%	$14.4
88341 & 88342 (Immunohistochemistry)	285.0	20% to 35%	$85.5
88185 (Flow cytometry, add on)	99.9	-69.2%	-$69.2
88312 (Special stains)	93.2	2.3%	$2.2
88112 (Cytopath cell enhance tech)	90.2	2.7%	$2.4
84153 (Total PSA)	86.7	0.0%	$0.0
88307 (Level V, tissue exam by pathologist)	81.7	2.8%	$2.3
88313 (Special stains)	63.8	2.6%	$1.7
88120 (FISH-manual for urine specimen)	53.1	3.7%	$1.9
88368 (FISH-manual)	46.2	6.4%	$3.0
88331 (Pathology consult during surgery)	38.4	-6.5%	-$2.5
88121 (FISH-computer assisted	32.4	1.8%	$0.6
	$1,941.7	2.2%	$42.3

*Medicare allowed charges are for 2013 (the latest available data)
**Assumes conversion factor of 36.1096 in 2016
Source: *Laboratory Economics*

FAILURE TO LAUNCH: U.S. DIGITAL PATHOLOGY MARKET

More than five years ago, digital pathology was being promoted as an inevitable technology that would transform the practice of anatomic pathology. And several major IVD manufacturers placed big bets on the technology. GE Healthcare launched a new digital pathology company named Omnyx LLC in 2008, Roche's Ventanna Medical Systems purchased BioImagene for $100 million in 2010 and Leica Biosystems acquired Aperio Technologies for roughly $175 million in 2012. But market adoption of digital pathology in the U.S., especially for clinical use, is crawling, not sprinting.

Does your pathology group/laboratory use digital imaging to analyze patient slides?



Source: *LE's Anatomic Pathology Market Trends Survey*, July 2015; n=280

Nationwide, there were an estimated 625 labs using digital pathology at the end of 2014. However, only a handful of labs are performing high volumes of digital pathology for clinical testing (*see table next page*).

Twenty-six percent of labs in the United States currently have a digital imaging system in place for analyzing patient specimens, and another 9% said they planned to add a system within 12 months, according to *LE's Anatomic Pathology Market Trends Survey* in July 2015. It should be noted that our survey was biased toward larger pathology groups/labs. There were 280 survey respondents with an average pathology group/lab size of 13.2 pathologists. And those pathology groups/labs that reported using digital pathology had an average size of 16.5 pathologists.

What do you use digital pathology for?*

HER2 scoring	80%
Education and/or training	66%
ER/PR scoring	63%
Second opinions and/or consultations	57%
Archiving specimens	20%
Contract research for clinical trials	14%
Photography of autopsies	11%
Primary clinical diagnosis	9%

*Survey respondents were able to select multiple answers
Note: Survey participants included 85 hospital labs, 33 academic medical centers, 118 independent labs, 30 national labs and 14 physician office labs.
Source: *LE's Anatomic Pathology Market Trends Survey,* July 2015; n=280

Among surveyed pathologists and labs using digital pathology, 80% are using it for quantitative immunohistochemistry for HER2 scoring. Sixty-six percent use it for education and/or training, while 63% use it for ER/PR scoring, and 57% use it for second opinions and/or consultations. Other uses include archiving specimens (20%), contract research for clinical trials (14%) and photography for autopsies (11%). Only 9% of survey respondents said they use digital pathology for primary clinical diagnosis.

TOP 25 LABS IN DIGITAL PATHOLOGY

Oral Cancer Prevention International (Airmont, NY), which specializes in oral, esophageal, and laryngeal cancer testing, is the biggest digital pathology lab as measured by volume of Part B claims for CPT 88361. OCPI was paid for 9,309 claims for CPT 88361 (including global, TC-only and PC-only claims) in 2013, according to provider utilization and payment data from CMS.

LabCorp's Accupath Diagnostic Labs (Tustin, CA) was paid for 1,130 units of service for CPT 88361 in 2013. In total, LabCorp had five different lab locations performing CPT 88361 with combined volume of 2,372 claims in 2013.

Quest Diagnostics and its subsidiary Ameripath had a total of seven lab locations that performed CPT 88361 with a combined volume of 6,101 claims in 2013.

TOP 25 LABS IN DIGITAL PATHOLOGY BY VOLUME OF CPT 88361

PROVIDER NAME/AFFILIATION	CITY	STATE	2013 VOLUME	AVG. MEDICARE ALLOWED AMOUNT	TOTAL PART B PAYMENT
ORAL CANCER PREVENTION INTERNATIONAL	AIRMONT	NY	9,309	$173.02	$1,610,643
CLARIENT DIAGNOSTIC SERVICES	ALISO VIEJO	CA	6,739	$110.16	$742,379
AMERIPATH FLORIDA	ORLANDO	FL	2,449	$83.89	$205,453
GENOPTIX, INC.	CARLSBAD	CA	1,552	$146.28	$227,030
OSSAMA TAWFIK, MD, PHD/KANSAS UNIVERSITY MEDICAL CENTER	KANSAS CITY	KS	1,547	$54.86	$84,867
AMERIPATH TEXAS	DALLAS	TX	1,401	$78.34	$109,749
CYTOMETRY SPECIALISTS	ALPHARETTA	GA	1,302	$85.07	$110,760
BIO-REFERENCE LABORATORIES	ELMWOOD PARK	NJ	1,262	$88.61	$111,822
TERENCE CUDAHY, MD/AMERIPATH	INDIANAPOLIS	IN	1,145	$56.32	$64,485
LABCORP/ACCUPATH DIAGNOSTICS LABS	TUSTIN	CA	1,130	$101.65	$114,868
LABCORP/ACCUPATH DIAGNOSTICS LABS	BRENTWOOD	TN	1,014	$79.51	$80,619
SONIC/CLINICAL PATHOLOGY LABS	AUSTIN	TX	788	$136.94	$107,911
AMERIPATH FLORIDA	FORT MYERS	FL	785	$133.36	$104,685
AMERIPATH INDIANAPOLIS PC	INDIANAPOLIS	IN	775	$90.85	$70,410
STEPHEN DAVIDSON MD/MONGOMERY CANCER CENTER	MONTGOMERY	AL	725	$141.62	$102,674
LABORATORY MEDICINE CONSULTANTS LTD	LAS VEGAS	NV	652	$91.31	$59,537
NINGXING CHEN DO/SOUTHEASTERN PATHOLOGY ASSOCIATES	BRUNSWICK	GA	649	$55.45	$35,984
PROFESSIONAL PATHOLOGY SERVICES PC	COLUMBIA	SC	639	$53.17	$33,979
HARRY BARNES MD/MONTGOMERY CANCER CENTER	MONTGOMERY	AL	580	$141.62	$82,140
HEARTLAND PATHOLOGY CONSULTANTS	EDMOND	OK	553	$139.54	$77,166
THE DELTA PATHOLOGY GROUP LLC	SHREVEPORT	LA	553	$84.24	$46,587
WILLIAM BALANCE MD/GREENVILLE PATHOLOGY	GREENVILLE	NC	520	$135.23	$70,321
MINEOLA MEDICAL LABORATORY LLC	MINEOLA	NY	484	$65.53	$31,716
JOHN REARDON MD/MONTGOMERY CANCER CENTER	MONTGOMERY	AL	475	$141.62	$67,270
CYNTHIA COHEN MD/EMORY UNIVERSITY	ATLANTA	GA	469	$57.40	$26,921
TOTAL TOP 25 LABS			37,497		$4,379,975

Source: 2013 Medicare Fee-for-Service Provider Utilization & Payment Data

LAB STOCKS DOWN 4% YTD

Fifteen lab stocks have declined by an unweighted average of 4% year to date through August 14. In comparison, the S&P 500 Index is up 3.4% and Nasdaq is up 6.6%. The top-performing lab stocks so far this year are Cancer Genetics Inc., up 66%; NeoGenomics, up 52%; and LabCorp, up 15%. Meanwhile, Quest Diagnostics is up by 8%. The worst performing lab stock is Response Genetics, down 91%, which recently filed for bankruptcy (*see story this issue*).

Company (ticker)	Stock Price 8/14/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$35.45	$32.13	10%	$987	19.5	1.1	3.0
Cancer Genetics Inc. (CGIX)	11.09	6.68	66%	109	NA	6.9	4.0
CombiMatrix (CBMX)	1.30	1.29	1%	17	NA	1.8	1.9
Enzo Biochem (ENZ)	3.11	4.44	-30%	143	NA	1.5	4.2
Foundation Medicine (FMI)	20.13	22.22	-9%	692	NA	9.1	2.4
Genomic Health (GHDX)	24.85	31.97	-22%	807	NA	2.9	5.3
Invitae (NVTA)	8.70	16.00	-46%	277	NA	66.7	1.5
LabCorp (LH)	124.06	107.90	15%	12,480	26.9	1.8	2.6
Myriad Genetics (MYGN)	32.96	34.06	-3%	2,260	30.5	3.2	3.5
NeoGenomics (NEO)	6.34	4.17	52%	384	NA	4.0	6.3
Psychemedics (PMD)	12.46	15.15	-18%	68	31.6	2.3	5.4
Quest Diagnostics (DGX)	72.72	67.06	8%	10,440	21.3	1.4	2.4
Response Genetics (RGDX)	0.03	0.32	-91%	1	NA	0.1	NA
Sonic Healthcare (SHL.AX)	20.14	18.50	9%	8,096	21.3	2.0	2.6
Veracyte (VCYT)	9.18	9.66	-5%	254	NA	6.0	4.0
Unweighted Averages			-4%		25.2	7.4	3.5

Source: Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor

special teleconference

Save the DATE!
Sept. 22, 2015
1 p.m. Eastern

LABORATORY ECONOMICS

PRESENTS...

PRACTICAL TIPS FOR TRANSITIONING TO ICD-10: CODING STRATEGIES FOR LABS

In a few short weeks, all healthcare providers—including laboratories—must begin using ICD-10 codes when submitting claims for payment to Medicare. Effective Oct. 1, 2015, Medicare claims with a date of service on or after Oct. 1, will only be accepted if they contain a valid ICD-10 code. The Medicare claims processing system will not have the capability to accept ICD-9 codes as of that date.

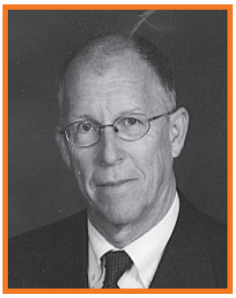
While for 12 months after ICD-10 implementation Medicare will not deny claims based solely on the specificity of the ICD-10 diagnosis code, providers must still use a code from the right code family to receive payment. Given that providers will have to transition from 14,000 codes under ICD-9 to 69,000 codes under ICD-10, this could be a challenge and potentially could affect cash flow if not done properly.

Please join *Laboratory Economics* for a 75-minute conference call on *Tuesday, Sept. 22, 2015, at 1 p.m. Eastern Time* with coding expert **Charles Root, PhD, Chief Executive of CodeMap**, who will discuss practical coding tips for transitioning to ICD-10.

- Learn how to convert ICD-9 codes to ICD-10 codes
- Find out what to do when referring physicians fail to use proper codes
- Get insight into how to determine specificity of a code
- Ease your labs transition to ICD-10
- Pose your specific questions to our expert
- Get 1 CEU credit ★ *Continuing Education Credit Available!* ★

Guest Speakers:

Kimberly Scott is a seasoned healthcare analyst with extensive experience covering medical diagnostics. From 2001 to 2014, Ms. Scott worked for G2 Intelligence (formerly Washington G-2 Reports) in various capacities, most recently as managing editor overseeing four monthly publications.



Dr. Charles Root is Chief Executive Officer of CodeMap, LLC. He has provided laboratory coding and reimbursement information to healthcare providers and manufacturers for over 22 years. His experience includes market research, product development, and studies on the economic impact of government regulations on healthcare delivery costs.

3 Ways to Register:

1. Call: 845-463-0080
2. Fax: 845-463-0470
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Order Form

- ❑ Please reserve your phone line for this Special Teleconference: *Practical Tips for Transitioning to ICD-10: Coding Strategies for Labs* for $225.00.
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