Jondavid Klipp, Editor, labreporter@aol.com

Volume 10, No. 7 July 2015

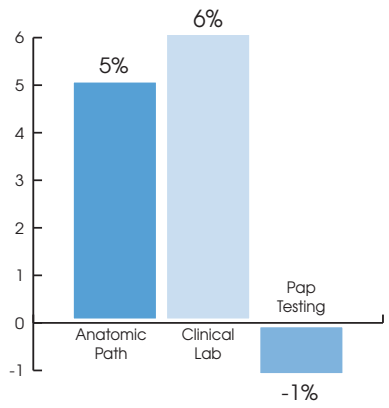
LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## GROWTH REBOUNDS IN ANATOMIC PATHOLOGY

After a few years of sluggish growth in the 2-3% range, anatomic pathology test volumes are expected to grow by 5% this year, according to an exclusive survey of 280 pathology groups and labs conducted by Laboratory Economics in early July. Expected clinical lab test volume growth is even stronger at 6%. Meanwhile, Pap testing is weakest and is expected to decline by 1% this year because of extended testing intervals due to HPV testing and new vaccines. For a full summary of *LE's Anatomic Pathology Market Trends Survey*, *see pages 4-6.*

**Test Volume Growth for 2015**



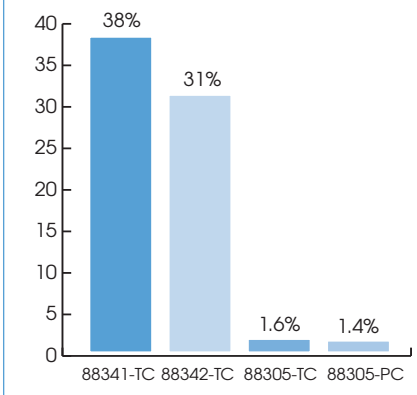

Source: *LE's Anatomic Pathology Market Trends Survey, July 2015; n=280*

## TECHNICAL RATES TO GET A BIG LIFT UNDER PROPOSED FEE SCHEDULE FOR 2016

Pathology labs will see substantial increases in Medicare rates for the technical component of several key immunohistochemistry codes next year, assuming the Proposed Physician Fee Schedule for 2016 is finalized.

Technical fees for the bread-and-butter IHC codes 88341 & 88342 are each set to rise more than 30%. Meanwhile, CPT 88305-TC will rise a more modest 1.6% next year, while CPT 88305-PC will rise 1.4%.

**Proposed Pathology Rate Changes for 2016**




Source: Proposed PFS Rule for 2016

Overall, CMS estimates that independent pathology labs and pathologists will see their Part B reimbursement increase by a healthy 8-9% in 2016. Of course, it should be recognized that these are only the proposed rates, and changes could be made when the Final Physician Fee Schedule Rule is released in November.
*More details on pages 2-3.*

## Contents

**CPT 88305**
Global reimbursement for CPT 88305 will increase by 1.5% to $74.39 next year, according to the Proposed Rule for 2016. CMS has proposed raising the professional component by 1.4% to $39.72; the technical component is set to rise by 1.6% to $34.67.

**Immunohistochemistry: CPT 88342 & 88341**
After IHC rates got whacked down by approximately 30% this year, CMS has proposed hiking rates for IHC by approximately 30% in 2016 (depending on the number of stains per specimen), with most of the gain coming on the technical side.

Global reimbursement for the first IHC stain on a specimen (CPT 88342) is set to increase by 20% to $108.69. The PC is being raised 2.5% to $37.55, while the TC is set to jump 31% to $71.14.

Global rates for each additional IHC stain on a specimen (CPT 88341) are proposed to increase by 35% to $91.72. The PC is set to increase by 28.5% to $28.17, while the TC is set to leap 38% to $63.55.

Increased rates for IHC come as Medicare Administrative Contractors (led by Palmetto GBA) are tightening utilization standards for IHC and special stains through local coverage determinations (LCDs—see page 10).

**Flow Cytometry: CPT 88184, 88185 & 88189**
On the negative side, CMS has proposed lowering rates for flow cytometry by more than 30% (depending on the number of markers) in 2016. For example, reimbursement for the highest-volume code—CPT 88185 (flow cytometry TC, each additional marker)—is set to decrease by 69% to $17.69 in 2016. In addition, CMS has identified CPT 88185 & 88189 as "potentially misvalued" and these codes will be reviewed in 2016 for possible further payment changes in 2017.

**Digital Pathology: CPT 88361**
Medicare rates for digital pathology (CPT 88361), used for quantitative immunohistochemistry for HER2 scoring, are set to decline next year. Global reimbursement will fall by 11% to $150.94. The PC is rising by 2% to $61.39, but the TC is falling 19% to $89.55. CMS has identified CPT 88361 as "potentially misvalued" and this code will be reviewed in 2016 with possible rate changes in 2017.

**Prostate Biopsies: CPT G0416**
Reimbursement for pathology review of prostate biopsies (CPT G0416), which covers all methods regardless of the number of specimens, is proposed to be increased by 1% for a global rate of $656.83; PC up 1% to $184.88 and TC up 1% to $471.95. However, CMS requested to review payment for G0416 and a reduction to the TC rate is likely to be made when the Final Rule for 2016 is published later this year.

**Clinical Laboratory Fee Schedule**
The Consumer Price Index was up 0.1% for the 12 months ended June 30, 2015. This is the base figure that will be used to adjust the Clinical Laboratory Fee Schedule (CLFS) in 2016. A "multifactor productivity adjustment" of -0.6% is required by the Affordable Care Act. However, the productivity adjustment cannot reduce the CLFS update below zero. As a result, the CLFS is expected to be unchanged in 2016.

**No News on CLFS Repricing Rules**
The Proposed PFS for 2016 contained no information regarding plans to reprice the CLFS based on private payer rates as mandated by the Protecting Access to Medicare Act of 2014 (PAMA). A proposed rule outlining how clinical labs are to report private-payer data will be handled in a separate rule-making. Since CMS will have to provide a minimum of 60 days comment period after a proposed rule is published, it's looking increasingly unlikely that the agency will be able to get final guidance out by year's end. As a result, the January 1, 2017 start date for repricing the CLFS could be delayed. This would be welcome news for the lab industry.

## Proposed Physician Fee Schedule Rates for 2016

| CPT Code | Description | Proposed 2016* | Actual 2015** | Proposed % Change |
|---|---|---|---|---|
| 88112-Global | Cytopath cell enhance tech | 66.8 | 65.04 | 2.7% |
| 88112-26 | Cytopath cell enhance tech | 29.25 | 28.75 | 1.7% |
| 88112-TC | Cytopath cell enhance tech | 37.55 | 36.29 | 3.5% |
| 88120-Global | FISH-manual, 3-5 probes | 649.25 | 626.32 | 3.7% |
| 88120-26 | FISH-manual, 3-5 probes | 60.66 | 59.29 | 2.3% |
| 88120-TC | FISH-manual, 3-5 probes | 588.59 | 567.03 | 3.8% |
| 88121-Global | FISH-computer assisted, 3-5 probes | 566.92 | 556.97 | 1.8% |
| 88121-26 | FISH-computer assisted, 3-5 probes | 52.36 | 51.74 | 1.2% |
| 88121-TC | FISH-computer assisted, 3-5 probes | 514.56 | 505.23 | 1.8% |
| 88184-TC only | Flow cytometry/1st marker | 58.5 | 94.51 | -38.1% |
| 88185-TC only | Flow cytometry/each add'l marker | 17.69 | 57.49 | -69.2% |
| 88189-TC only | Flow cytometry, read 16+ | 115.19 | 113.91 | 1.1% |
| 88305-Global | Tissue exam by pathologist | 74.39 | 73.30 | 1.5% |
| 88305-26 | Tissue exam by pathologist | 39.72 | 39.17 | 1.4% |
| 88305-TC | Tissue exam by pathologist | 34.67 | 34.14 | 1.6% |
| 88307-Global | Level V, tissue exam by pathologist | 316.32 | 307.59 | 2.8% |
| 88307-26 | Level V, tissue exam by pathologist | 88.11 | 86.24 | 2.2% |
| 88307-TC | Level V, tissue exam by pathologist | 228.21 | 221.35 | 3.1% |
| 88312-Global | Special stains, group 1 | 100.38 | 98.10 | 2.3% |
| 88312-26 | Special stains, group 1 | 28.53 | 28.03 | 1.8% |
| 88312-TC | Special stains, group 1 | 71.86 | 70.07 | 2.6% |
| 88313-Global | Special stains; group 2 | 70.05 | 68.27 | 2.6% |
| 88313-26 | Special stains; group 2 | 12.64 | 12.58 | 0.5% |
| 88313-TC | Special stains; group 2 | 57.41 | 55.70 | 3.1% |
| 88341-Global | Immunohistochemistry (Add'l stain) | 91.72 | 67.91 | 35.1% |
| 88341-26 | Immunohistochemistry (Add'l stain) | 28.17 | 21.92 | 28.5% |
| 88341-TC | Immunohistochemistry (Add'l stain) | 63.55 | 45.99 | 38.2% |
| 88342-Global | Immunohistochemistry (1st stain) | 108.69 | 90.91 | 19.6% |
| 88342-26 | Immunohistochemistry (1st stain) | 37.55 | 36.65 | 2.5% |
| 88342-TC | Immunohistochemistry (1st stain) | 71.14 | 54.26 | 31.1% |
| 88360-Global | Tumor immunohistochem/manual | 122.77 | 136.55 | -10.1% |
| 88360-26 | Tumor immunohistochem/manual | 57.05 | 55.7 | 2.4% |
| 88360-TC | Tumor immunohistochem/manual | 65.72 | 80.85 | -18.7% |
| 88361-Global | Tumor immunohistochem/computer | 150.94 | 170.32 | -11.4% |
| 88361-26 | Tumor immunohistochem/computer | 61.39 | 60.37 | 1.7% |
| 88361-TC | Tumor immunohistochem/computer | 89.55 | 109.96 | -18.6% |
| 88367-Global | FISH Computer-assisted | 108.33 | 107.80 | 0.5% |
| 88367-26 | FISH Computer-assisted | 35.75 | 35.57 | 0.5% |
| 88367-TC | FISH Computer-assisted | 72.58 | 72.23 | 0.5% |
| 88368-Global | FISH Manual | 116.27 | 109.24 | 6.4% |
| 88368-26 | FISH Manual | 41.53 | 41.32 | 0.5% |
| 88368-TC | FISH Manual | 74.75 | 67.91 | 10.1% |

*Conversion Factor for CY2016=36.1096
**Conversion Factor for CY2015=35.9335
Source: Physician Fee Scheduled Proposed Rule for 2016

**DECLINING REIMBURSEMENT IS TOP CONCERN** (*cont'd from page 1*)

Declining reimbursement remains the biggest challenge that pathology groups and labs will face over the next five years, according to *LE's Anatomic Pathology Market Trends Survey*. Twenty-eight percent of survey respondents cited reimbursements as their biggest concern in *LE's* latest poll, down slightly from 31% in our previous poll in 2013.

*"Pathology is literally being squeezed to death by the government, insurance companies, and hospitals/healthcare systems. Reimbursements are low, workload volumes are now so intolerable or eroding quality so badly that our best pathologists are retiring as soon as possible,"* according to a pathologist from California.

*"The reduction in reimbursement for bread-and-butter procedures has had a significant negative impact on revenue. The insurance companies followed suit and that multiplied the effect. Many labs have sold out or literally gone out of business. The next few years are going to be very significant for independent AP lab survival,"* observed a pathologist from Texas.

The next most frequently cited challenge was "exclusion from managed care contracts," which was cited by 15%, up from 9% in our 2013 survey. And "competition from large commercial labs" was the third highest ranked challenge at 14%.

*"The big lab companies have made it a priority to coerce insurance companies to not allow competition. Insurance companies are excluding smaller labs from becoming in-network providers even at budget-neutral pricing,"* noted a pathology executive from Texas.

*"Insurance companies in the Southeast, including BCBS, Cigna, UHC and Aetna are developing models that mandate that tests are referred to low-cost national labs, LabCorp or Quest,"* said a pathology executive from Tennessee.

Medicare's "bundled payment for outpatient tests" was a new challenge that was cited by 11% of survey takers this year.

*"We have seen a decline in GI volume due to bundling packages for screening colonoscopy and the likely widespread adoption within 2 or 3 years of 'remove and discard' practice for colon polyps under 6mm,"* noted a pathologist from Massachusetts.

**What is the biggest challenge pathology groups will face over the next 5 years?**

| | 2015 | 2013 | 2011 | 2010 | 2009 | 2008 | 2007 |
|---|---|---|---|---|---|---|---|
| Declining reimbursement | 28% | 31% | 26% | 29% | 25% | 27% | 23% |
| Exclusion from managed care contracts | 15% | 9% | 9% | 8% | 10% | NA | NA |
| Competition from large commercial labs | 14% | 13% | 16% | 15% | 15% | 19% | 20% |
| Specialty physician groups insourcing pathology | 12% | 15% | 19% | 17% | 18% | 14% | 15% |
| Bundled payment for outpatient tests | 11% | NA | NA | NA | NA | NA | NA |
| Staffing shortages | 5% | 6% | 7% | 8% | 13% | 19% | 15% |
| Technical staff shortages | 4% | 5% | 5% | 7% | 12% | 13% | NA |
| Pathologist shortages | 1% | 1% | 2% | 1% | 1% | 6% | NA |
| Increased expenses for information technology | 6% | 6% | 8% | 9% | 10% | 6% | NA |
| Difficulty/expense of adding new molecular diagnostics | 5% | 6% | 5% | 5% | 7% | 9% | NA |
| Weak economy | 2% | 6% | 8% | 8% | NA | NA | NA |
| Increased utilization mgt. leading to lower test volume | 2% | 3% | NA | NA | NA | NA | NA |
| Other | 0% | 5% | 2% | 1% | 1% | 2% | 16% |

Source: *LE's Anatomic Pathology Market Trends Surveys, 2007-July 2015*

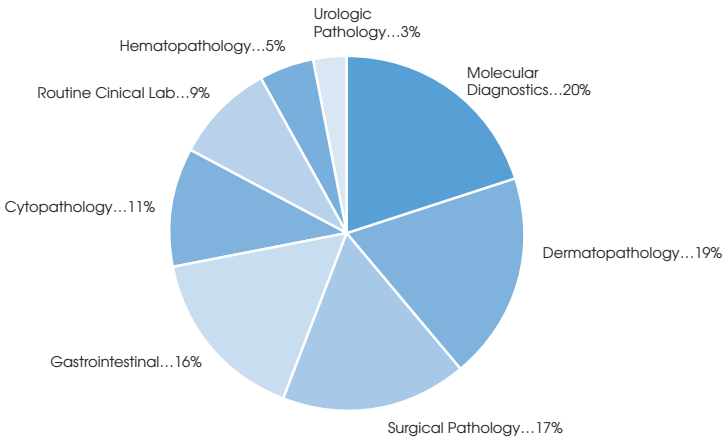
## Which Subspecialty is Growing Fastest?

Twenty percent of survey respondents said they were seeing their fastest growth in molecular test volumes. The second fastest area of growth was dermatopathology. The slowest area of growth was urologic pathology, which was cited by only 3% of survey takers.

*"We are seeing more outsourcing to commercial labs for the trendy new neoplastic marker studies, and genetic studies for all types of cancer,"* observed a pathologist from Mississippi.

*"Consolidation of insurance market and overutilization of 'molecular tests' are going to push business to the largest corporate labs,"* predicted a pathologist from Oklahoma.

### Where is your lab growing fastest?




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

## Dealing with Lower Medicare Reimbursement

Medicare rates for pathology services should improve next year. However, pathology labs are still stinging from the massive cuts to 88305-TC in 2013 and 88342 in 2014. In terms of adapting to lower reimbursement, the most popular response was "improve billing and collection efficiency" cited by 40% of survey takers. Thirty-eight percent said they would "put pressure on reagent suppliers and other vendors to lower costs." Only 2% of survey takers said they planned to sell their pathology lab.

| How will your pathology group/lab adapt to lower Medicare rates?* | 2015 | 2013 |
|---|---|---|
| Improve billing and collection efficiency | 40% | 8% |
| Put pressure on reagent suppliers and other vendors to lower costs | 38% | 47% |
| We will grow our way out of it | 35% | 42% |
| We will hold or reduce employee compensation | 35% | 33% |
| We will delay new instrument/equipment purchases | 26% | 23% |
| We will reduce staff | 23% | 27% |
| We will consolidate offices/labs | 0% | 1% |
| We will sell our technical lab | 2% | 1% |

*Survey respondents were allowed to select multiple answers

Source: *LE's Anatomic Pathology Market Trends Surveys, April 2013 & July 2015*

## Conclusion

Finally, a pathologist from Delaware summed up the outlook for independent pathology groups: *"Utilization will decrease in ACOs and reimbursements are going down, but expenses are going up because of technology, so we will need to become more and more efficient."*

***Survey Demographics:*** The survey was e-mailed to approximately 6,000 pathology groups, independent labs and hospitals in early July 2015. A total of 280 surveys were judged usable, yielding a response rate of 5%. Among the respondents, 85 were from hospital-based pathology groups, 118 from local or regional independent pathology groups and labs, 33 from academic medical center-based pathology groups, 30 from national pathology companies and 14 from in-office pathology labs.

**In-Office Pathology Labs Remain a Problem**

The percentage of pathology groups and labs that say they have lost significant business to specialty groups that have built in-office histology labs is down from the all-time high shown in *LE's* 2013 survey. However, while the insourcing trend may have slowed down, it has not gone away. Seventeen percent of respondents to our latest survey said they had lost "significant business" over the past year and 34% said they lost "some business."

**Has your pathology group/lab lost business in the past year because a physician group client created its own histology lab?**

| | 2015 | 2013 | 2011 | 2010 | 2009 | 2008 | 2007 |
|---|---|---|---|---|---|---|---|
| Yes, we've lost significant business | 17% | 27% | 11% | 17% | 15% | 8% | 5% |
| Yes, we've lost some business | 34% | 32% | 36% | 29% | 37% | 28% | 28% |
| No, we have not been affected | 49% | 32% | 53% | 54% | 48% | 64% | 67% |

Source: *LE's Anatomic Pathology Market Trends Surveys, 2007-July 2015*

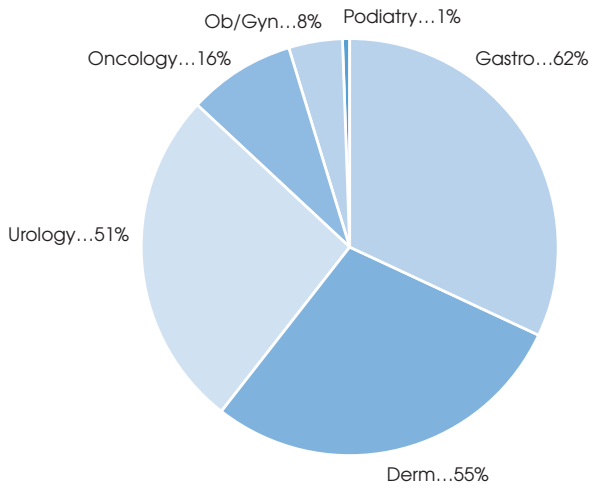
The insourcing trend has been strongest at urology, gastroenterology and dermatology groups. And it now looks like its spreading to oncology. Sixteen percent of survey respondents said that an oncology group had insourced pathology in their area. Among the states where pathologists reported insourcing by oncologists were California, Florida, Tennessee, Texas and Utah.

The insourcing trend also appears to have taken hold within ob/gyn practices. Eight percent of survey respondents reported that an ob/gyn group had insourced testing in their area. States where ob/gyn insourcing was reported included Connecticut, Florida and Illinois.

*"Continued insourcing by seemingly everyone continues to screw hospital-based groups like us. The only bright light is that the hospital-owned practices have to send specimens to the hospital/mothership,"* according to a pathologist from Connecticut.

*"Abusive clinician self-referral of anatomic pathology specimens and abusive pathologist self-referral of ancillary testing continue to plague the southeast. It's almost impossible for an honest pathologist to compete in the current business climate,"* said a pathologist from North Carolina.

**What types of groups have insourced pathology in your area?**




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

Several surveyed pathologists urged support for the Promoting Integrity in Medicare Act (H.R. 2914), which would eliminate the Stark exception for self-referral for advanced imaging, anatomic pathology, radiation therapy, and physical therapy. If passed into law, H.R. 2914 would require physician practices that currently provide these ancillary services to restructure or unwind these service models completely.

*"Internalization of dermatopathology (and anatomic pathology) services is a conflict of interest to the detriment of the payers and patients. It needs to be stopped. Get behind H.R. 2914 and get the rest of the industry behind it,"* urged a pathologist from Georgia.

## QUEST TO BUY CALIFORNIA LAB OUTREACH BUSINESS

MemorialCare Health System, a not-for-profit health system in Los Angeles and Orange counties, has agreed to sell its lab outreach business to Quest Diagnostics. MemorialCare's lab outreach does business as Memorial Healthtech Laboratories in southern California. Under the agreement, MemorialCare will transition its outreach lab testing to Quest's major laboratory in West Hills, California. MemorialCare's hospital-based labs are not a part of the transaction. Quest and MemorialCare expect to complete the acquisition in August. Financial terms were not disclosed.

## LABCORP BUYS PHYSICIANS REFERENCE LAB

LabCorp acquired Physicians Reference Laboratory LLC (PRL-Overland Park, KS) in May for an undisclosed amount. PRL had been one of the largest independent lab companies in the Midwest. The company has approximately 525 employees, including 17 pathologists, and estimated annual revenue of between $50 million and $75 million.

PRL was founded in 1976 by Pierre Keitges, MD. Its chief executive and lab director is Spencer Kerley, MD, and its president and CFO is Greg Keitges.

PRL provides clinical lab and anatomic pathology services throughout the Kansas City area. Its largest competitors include Quest Diagnostics' LabOne (Lenexa, KS) and Boyce & Bynum Pathology Laboratories (Columbia, MO).

Over time, PRL is likely to be consolidated into LabCorp's existing major laboratory in Kansas City, observes *Laboratory Economics*.

## THERANOS TO EXPAND INTO PENNSYLVANIA

Theranos (Palo Alto, CA) has signed a non-exclusive contract to provide lab testing services to Capital BlueCross (Harrisburg, PA), which covers approximately 725,000 members in central Pennsylvania. Theranos must now build a laboratory and a network of patient service centers (PSCs), and hire hundreds of lab employees, phlebotomists and couriers in Pennsylvania to service this contract. In the meantime, any patient samples it collects will need to be flown across the country to California for testing.

Theranos will also need to compete for business with Quest Diagnostics, Health Network Laboratories (HNL-Allentown, PA) and other labs that have existing contacts with Capital BlueCross. Quest Diagnostics operates more than 100 PSCs throughout Pennsylvania and southern New Jersey and operates major labs in Philadelphia and Teterboro, New Jersey.

*Theranos must now build an entire lab infrastructure in Pennsylvania starting from scratch.*

HNL has 900 employees, including 17 pathologists, with 45 PSCs throughout Pennsylvania and southern New Jersey. The lab company recently moved into a new 102,000 square foot lab and headquarters in Allentown where it performs more than 6.5 million clinical and anatomic pathology tests per year. HNL was founded in 1998 and is owned by Lehigh Valley Health Network, which includes four hospitals.

It took HNL 17 years to grow to its current size. *Laboratory Economics* has to wonder how long it will take Theranos to achieve similar market share in the backyard of Quest Diagnostics.

# PROPOSED OPPS SEEKS TO EXPAND PACKAGING FOR PATHOLOGY

Medicare's Hospital Outpatient Prospective Payment System (OPPS) proposed rule for 2016 is seeking to expand packaged payment for more complex pathology services. If finalized, outpatient pathology lab technical services for higher-cost codes, including CPT 88309, 88333 and 88348, will be added to the list of packaged services no longer eligible for separate billing on the OPPS fee schedule.

Packaging refers to a decision not to pay for certain additional services for hospital outpatients if associated with a primary service such as a biopsy surgery. The proposal seeks to make the OPPS system more similar to the inpatient hospital DRG, in which a single payment is made for a patient's stay at the hospital, and less like the Physician Fee Schedule or the Clinical Lab Fee Schedule, in which each individual unit of service is paid.

In 2014, CMS packaged nearly all clinical lab tests and last year most pathology technical services were packaged, including the all-important CPT 88305.

Separate payment from the OPPS or clinical lab fee schedules is available for lab and pathology tests only if: (1) they are the only services furnished to an outpatient and are the only services on a claim; or (2) they are unrelated to a primary service. Also excluded from packaging are molecular diagnostic tests in the CPT code ranges of 81200-81383, 81400-81408 and 81479.

Packaged or "bundled" payment for outpatient lab tests was cited by pathologists as one of the biggest challenges facing pathology groups and labs, according to *LE's Anatomic Pathology Market Trends Survey for 2015* (see page 4).

## Status and Proposed OPPS Payment Rates for Key Pathology Codes

| HCPCS Code | 2016 APC | Short Descriptor | 2016 Status | Proposed Payment Rate 2016* | Payment Rate 2015 | Percent Change |
|---|---|---|---|---|---|---|
| 88112 | 5671 | Cytopath cell enhance tech | Packaged | $48.63 | $54.28 | -10.4% |
| 88120 | 5673 | Cytp urne 3-5 probes each spec. | Packaged | 209.49 | 183.69 | 14.0% |
| 88121 | 5672 | Cytp urine 3-5 probes computer | Packaged | 96.56 | 183.69 | -47.4% |
| 88173 | 5671 | Cytopath eval fna report | Packaged | 48.63 | 54.28 | -10.4% |
| 88185 | NA | Flow cytometry/tc add-on | Packaged | NA | NA | NA |
| 88304 | 5671 | Tissue exam by pathologist | Packaged | 48.63 | 54.28 | -10.4% |
| 88305 | 5671 | Tissue exam by pathologist | Packaged | 48.63 | 54.28 | -10.4% |
| 88307 | 5673 | Tissue exam by pathologist | Packaged | 209.49 | 183.69 | 14.0% |
| 88309 | 5674 | Tissue exam by pathologist | Packaged | 439.94 | 294.25 | 49.5% |
| 88312 | 5672 | Special stains group 1 | Packaged | 96.56 | 54.28 | 77.9% |
| 88313 | 5671 | Special stains group 2 | Packaged | 48.63 | 54.28 | -10.4% |
| 88331 | 5672 | Path consult intraop 1 block | Packaged | 96.56 | 183.69 | -47.4% |
| 88333 | 5674 | Intraop cyto path consult | Packaged | 439.94 | 294.25 | 49.5% |
| 88342 | 5673 | Immunohistochem antibody stain | Packaged | 209.49 | NA | NA |
| 88348 | 5674 | Electron microscopy, diagnostic | Packaged | 439.94 | 294.25 | 49.5% |
| 88367 | 5673 | Insitu hybridization auto | Packaged | 209.49 | 183.69 | 14.0% |
| 88368 | 5673 | Insitu hybridization manual | Packaged | 209.49 | 183.69 | 14.0% |

*Separate payment rates are available only when a test is unrelated to a primary service.

Note: The packaging rules affect pathology technical services, but pathologists are still able to bill separately for professional services provided to hospital outpatients.

Source: *Laboratory Economics* from CMS

# OIG RAMPS UP FOCUS ON COMPENSATION ARRANGEMENTS

The Health and Human Services Office of Inspector General (OIG) appears to be ramping up its focus on physicians who enter into questionable compensation arrangements with laboratories, hospitals, dialysis clinics and other institutional providers.

In a special fraud alert issued June 9, the OIG warned that physicians who enter compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, an arrangement may violate the anti-kickback statute (AKS) if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of federal health care program business, says the OIG, which encourages physicians to carefully consider the terms and conditions or medical directorships and other compensation arrangements before entering into them.

The OIG recently reached settlements with 12 individual physicians who entered into questionable medical directorship and office staff arrangements. The OIG alleged that the compensation paid to these physicians under the arrangements constituted improper remuneration under the anti-kickback statute for a number of reasons, including: 1) that the payments took into account the physicians' volume or value of referrals; 2) the payments did not reflect fair market value for the services to be performed; and 3) because the physicians did not actually provide the services called for under the agreements.

The OIG also alleged that some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff. Because these arrangements relieved the physicians of a financial burden they otherwise would have incurred, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians. The OIG determined that these physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

*Hope Foster*

The significance of the OIG's June 9 fraud alert stems from its focus on physicians' payments that have the potential for being perceived by the government (and possibly qui tam relators) to be disguised kickbacks to induce referrals, notes Hope Foster, a member with the law firm of Mintz Levin (Washington, DC).

"Much of the past enforcement of the kickback ban has been directed to those who allegedly pay kickbacks to physicians to induce referrals," says Foster. "Recently, however, the government has also been bringing such cases against physicians as alleged kickback recipients."

**Proactive Compliance**

While the OIG's fraud alert focuses on physicians, the AKS applies with equal force to institutional providers that enter into compensation arrangements with physicians, advises the law firm of Alston & Bird. Institutional providers, including laboratories, "should take the fraud alert as notice that their physician compensation practices may also come under increased scrutiny," says the firm in an advisory.

*Peter Kazon*

The best defense against an enforcement action is proactive compliance, notes Peter Kazon, senior counsel with Alston (Washington, DC). Providers, for example,

can avoid civil money penalties by entering into physician compensation arrangements with physicians that fit within the "personal services and management contracts" regulatory safe harbor.

Both Foster and Kazon advise that laboratories:

- Only engage and pay test-ordering physicians for bona fide and needed services that are actually performed and that are not the physician's obligation to provide;
- Require that the physician document the services that he/she provides pursuant to the agreement and in accordance with its terms;
- Pay documented fair market value rates;
- Guard against payments that vary with the volume or value of the referrals; and
- Seek, if possible, to safe-harbor the transaction.

Laboratories or other providers that engage physicians to provide services should also maintain and review time logs or similar documentation of services performed, only engage the number and type of physicians reasonably needed for the facility's legitimate purposes, and incorporate compensation arrangements with physicians into the organization's compliance program.

The June 9 fraud alert is available at http://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf.

## FIRST COAST PROPOSES TO LIMIT COVERAGE ON SPECIAL STAINS

Yet another Medicare administrative contractor has proposed to adopt a local coverage determination (LCD) policy to limit coverage on special histochemical stains and immunohistochemical (IHC) stains. First Coast Service Options Inc., which oversees Medicare administration in Florida, is proposing an LCD that is similar to the coverage policy on special stains adopted by Palmetto GBA (LE, Feb. 2015). Palmetto implemented that LCD with little revision despite objections by the College of American Pathologists (CAP). The CAP opposed the policy, arguing that the supporting evidence behind Palmetto's LCD lacked credibility and was unsubstantiated and that the LCD encroached on the pathologist's medical judgment.

The LCD implemented by Palmetto and subsequently proposed by three other Medicare administrative contractors limits Medicare coverage for reflex templates or pre-orders for special stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologists, as well as special stains and/or IHC stains without clinical evidence the stain is actionable. The LCD proposed by First Coast (DL36234) does differ slightly from the Palmetto LCD in that First Coast proposes to add further restrictions to the gastrointestinal section. Comments on the proposal are due July 27.

In addition to Palmetto and First Coast, Noridian and CGS Administrators have also proposed LCDs on special stains. Assuming that these LCDs are finalized, the policy on special stains will be in effect in 20 states.

## AURORA DIAGNOSTICS BUYS TEXAS PATHOLOGY GROUP

Aurora Diagnostics (Palm Beach Gardens, FL) has acquired two hospital-based practices of Brazos Valley Pathology, PLLC. (Bryan, TX). The practices, Brazos Valley Pathology (Bryan/College Station) and Trinity Pathology Associates (Tyler), include five pathologists who provide professional pathology services to St. Joseph Health System, College Station Medical Center and Trinity Mother Frances Health. The newly acquired practices will operate independently as part of Austin Pathology Associates, which Aurora acquired in 2011. Financial terms of the transaction, which closed July 15, were not disclosed.

Separately, Aurora reported a net loss of $9.4 million in the first quarter ended March 31, 2015, versus a net loss of $6.6 million for the same period last year; revenue increased 4% to $59.5 million. As of March 31, Aurora reported total long-term debt of $371 million.

As of July 16, Aurora's senior debt (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at approximately 82 cents on the dollar with a yield to maturity of 20%.

## CMS WEIGHING PRICING REVISIONS FOR DRUG TESTING CODES

CMS is reviewing pricing recommendations for more than 30 new CPT codes, as well as more than two dozen reconsideration requests (including 21 tier 2 molecular pathology codes), for 2016. The agency will release preliminary determinations in September, along with final code numbers. Final determinations will be released in November.

**Big Changes Likely for Drug Testing Reimbursement**

For 2015, CMS delayed pricing of new CPT codes for drugs-of-abuse testing due to concerns about the potential for overpayment when billing for each individual drug test rather than billing for a single code that pays the same amount regardless of the number of tests performed. For 2015 the agency maintained the 2014 status quo by creating alphanumeric G codes to replace the 2014 CPT codes that were deleted for 2015.

For 2016, CMS is proposing major changes as follows:

- Delete the following G codes: G0431, G0434, G6030 through G6058 (28 codes);
- Continue not to recognize the following CPT codes: 80300 through 80377 (64 codes);
- Create two new G codes that will be priced: GXXX1 (Drug screen, any number of drugs or drug classes, any procedure(s)/methodology(ies), any source(s), per day), and GXXX2 (Drug test(s) (confirmatory and/or definitive, qualitative and quantitative), any number of drugs or drug classes, any procedure(s)/methodology(ies), any source(s), includes sample validation, per day).

The consolidation of dozens of drug test codes into just two codes with capped reimbursement has the potential to cause financial devastation to toxicology labs, observes *Laboratory Economics*.

**Other New Codes, Reconsideration Requests**

Among other new codes for 2016 is 800XA (Obstetric panel), G0472 (Hepatitis C antibody screening), and 16 new molecular pathology codes, including 812XX (BRCA1, BRCA2), 814XB (Ashkenazi Jewish associated disorders), and 814XL and 814XM (hereditary breast cancer-related disorders).

CMS also seeks to price 12 CPT codes for multianalyte assays with algorithmic analyses (MAAAs). In previous years, CMS has chosen to use the gap-fill method to price MAAAs and is likely to do so again. Under the gap-fill methodology, Medicare contractors set reimbursement levels based on a number of factors, such as local pricing patterns, the resources needed to perform the test, and how other payers price them. After one year, CMS uses the median rate from contractor-specific amounts to issue a national reimbursement rate for each code.

## LAB STOCKS UP 14% YTD

Fourteen lab stocks have increased by an unweighted average of 14% year to date through July 15. In comparison, the S&P 500 Index is up 2% and Nasdaq is up 7%. The top-performing lab stocks so far this year are Cancer Genetics Inc., up 86%; NeoGenomics, up 56%; and Foundation Medicine, up 47%. Meanwhile, Quest Diagnostics is up by 9% and LabCorp is up 14%.

| Company (ticker) | Stock Price 7/15/15 | Stock Price 12/31/14 | 2015 Price Change | Market Capitalization ($ millions) | P/E Ratio | Price/ Sales | Price/ Book |
|---|---|---|---|---|---|---|---|
| Bio-Reference (BRLI) | $44.79 | $32.13 | 39% | $1,250 | 24.6 | 1.4 | 3.7 |
| Cancer Genetics Inc. (CGIX) | 12.44 | 6.68 | 86% | 122 | NA | 9.2 | 3.9 |
| CombiMatrix (CBMX) | 1.63 | 1.29 | 26% | 21 | NA | 2.5 | 2.1 |
| Enzo Biochem (ENZ) | 3.16 | 4.44 | -29% | 146 | NA | 1.6 | 4.4 |
| Foundation Medicine (FMI) | 32.74 | 22.22 | 47% | 1,120 | NA | 16.3 | 12.8 |
| Genomic Health (GHDX) | 27.74 | 31.97 | -13% | 895 | NA | 3.2 | 5.7 |
| LabCorp (LH) | 122.76 | 107.90 | 14% | 12,330 | 27.2 | 1.9 | 2.7 |
| Myriad Genetics (MYGN) | 34.83 | 34.06 | 2% | 2,420 | 27.8 | 3.4 | 3.7 |
| NeoGenomics (NEO) | 6.50 | 4.17 | 56% | 392 | NA | 4.3 | 6.5 |
| Psychemedics (PMD) | 12.61 | 15.15 | -17% | 68 | 24.8 | 2.3 | 5.4 |
| Quest Diagnostics (DGX) | 73.24 | 67.06 | 9% | 10,520 | 20.8 | 1.4 | 2.5 |
| Response Genetics (RGDX) | 0.11 | 0.32 | -65% | 4 | NA | 0.3 | NA |
| Sonic Healthcare (SHL.AX) | 22.46 | 18.50 | 21% | 9,029 | 23.6 | 2.3 | 3.0 |
| Veracyte (VCYT) | 11.11 | 9.66 | 15% | 305 | NA | 7.3 | 7.1 |
| Unweighted Averages | | | 14% | | 24.8 | 4.1 | 4.9 |

Source: Capital IQ



Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor