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Volume 7, No. 11 November 2012

LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

# MEDICARE SLASHES CPT 88305-TC BY 52%

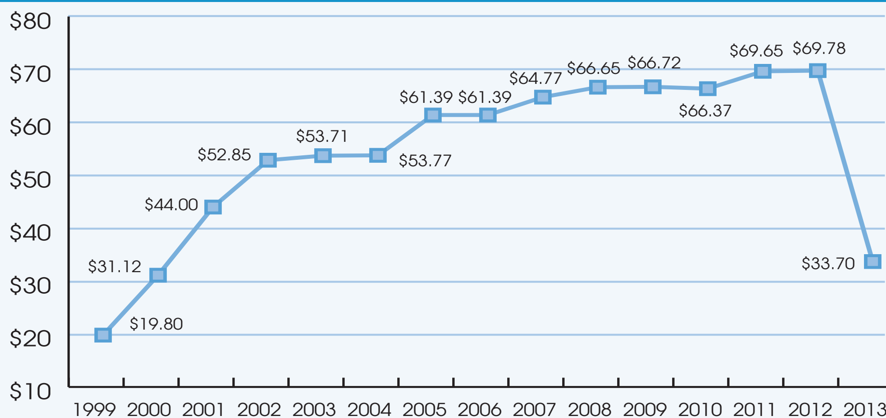
It's a nightmare scenario for pathology labs. Effective January 1st, Medicare reimbursement for the technical component of CPT 88305 will decrease by 52% to $33.70 (unadjusted for geography). The reduction could be even worse if a scheduled 26.5% cut to the physician fee schedule conversion factor based on the Sustainable Growth Rate methodology takes effect, although the Obama Administration has pledged to prevent the SGR cut.

CPT 88305-TC is by far the single most important code for pathology labs. It is used to reimburse labs for preparing the biopsy tissue slides that pathologists review by microscope. The drastic cut to 88305-TC will reduce Medicare payments to pathology labs by more than $400 million next year (*see table on page 5*). And pathology labs could lose hundreds of millions of dollars more if private health insurers make proportionate cuts.

Over the past decade, Medicare reimbursement for 88305-TC increased steadily (*see chart below*) leading to structural changes in the pathology market. The lucrative rates led to the formation of dozens of independent pathology labs by pathologists and entrepreneurs. For the same reason, Quest, LabCorp and private equity investors were willing to pay high prices to acquire pathology lab companies. And hundreds of large urology, gastroenterology and dermatology groups built in-office labs to capture slide prep revenue.

But Medicare's severe rate cut may force many small independent and in-office pathology labs to shut down. "Hospitals that were smart enough to keep their histology in-house and intact will be the beneficiaries as outpatient biopsies will flow back into those hospitals," notes Robert Babkowski, MD, Chair, Dept. of Pathology at The Stamford Hospital in Connecticut. *Continued on page 2.*

**Medicare Reimbursement for CPT 88305-TC***




*National payment unadjusted for geographic practice cost differences.

Source: Medicare Physician Fee Schedules, 1999 to 2013

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**MEDICARE SLASHES CPT 88305-TC BY 52%** (*cont'd from page 1*)

The College of American Pathologists (CAP) says the revaluation of the CPT 88305—as well as other codes in this surgical pathology family—is not surprising. As directed by the healthcare reform law, CMS has been focused on scrutinizing high-volume codes from all specialties as potentially overvalued services. CAP notes that 88305 is not only high volume, but its TC had not been reviewed since initially valued in 2000.

Nonetheless, the size of the cut to 88305-TC has stunned the pathology field. "I suppose it could have been worse, but a 52% cut is quite severe and will definitely impact labs….I think between the expiration of the TC grandfather clause, the 52% reduction in reimbursement for 88305 and the cap on prostate biopsies, the outcome is devastating to the bottom line of anatomic pathology labs who lack the margins to absorb this kind of cut," notes Lale White, president of the billing management firm Xifin (San Diego).

CMS was prompted to initiate a new review after an anonymous stakeholder argued that it costs labs only $18 to produce a routine biopsy tissue slide versus Medicare's national payment rate of $70. In late 2011, CMS asked the AMA's Specialty Society Relative Value Scale Update (RUC) Committee to review the direct costs associated with the technical component of 88305, as well as five other codes in surgical pathology (88300, 88302, 88304, 88307 and 88309). The RUC Committee reviewed cost data supplied by CAP and other sources. The committee submitted its recommendation to CMS, which published its rate determination in its Final 2013 Physician Fee Schedule Rule issued on November 1.

Assuming the CF stays at 34.0376, the new rates for the six surgical pathology codes are as follows:

**Medicare Rates* for Surgical Pathology, Levels I through VI**

| Code | Modifier | Description | Total RVUs | Conversion Factor | 2013 Rate | 2012 Rate | % Chg |
|---|---|---|---|---|---|---|---|
| 88300 | Global | Level I-Surgical Pathology | 0.43 | 34.0376 | $14.64 | $28.25 | -48.2% |
| 88300 | Technical | | 0.30 | 34.0376 | 10.21 | 23.83 | -57.1% |
| 88300 | Professional | | 0.13 | 34.0376 | 4.42 | 4.42 | 0.1% |
| 88302 | Global | Level II-Surgical Pathology | 0.91 | 34.0376 | $30.97 | $55.82 | -44.5% |
| 88302 | Technical | | 0.71 | 34.0376 | 24.17 | 49.35 | -51.0% |
| 88302 | Professional | | 0.20 | 34.0376 | 6.81 | 6.47 | 5.2% |
| 88304 | Global | Level III-Surgical Pathology | 1.31 | 34.0376 | $44.59 | $61.95 | -28.0% |
| 88304 | Technical | | 0.98 | 34.0376 | 33.36 | 51.06 | -34.7% |
| 88304 | Professional | | 0.33 | 34.0376 | 11.23 | 10.89 | 3.1% |
| 88305 | Global | Level IV-Surgical Pathology | 2.07 | 34.0376 | $70.46 | $105.86 | -33.4% |
| 88305 | Technical | | 0.99 | 34.0376 | 33.70 | 69.78 | -51.7% |
| 88305 | Professional | | 1.08 | 34.0376 | 36.76 | 36.08 | 1.9% |
| 88307 | Global | Level V-Surgical Pathology | 8.74 | 34.0376 | $297.49 | $234.52 | 26.9% |
| 88307 | Technical | | 6.33 | 34.0376 | 215.46 | 155.55 | 38.5% |
| 88307 | Professional | | 2.41 | 34.0376 | 82.03 | 78.97 | 3.9% |
| 88309 | Global | Level VI-Surgical Pathology | 13.21 | 34.0376 | $449.64 | $355.35 | 26.5% |
| 88309 | Technical | | 8.95 | 34.0376 | 304.64 | 216.48 | 40.7% |
| 88309 | Professional | | 4.26 | 34.0376 | 145.00 | 138.87 | 4.4% |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.
Source: *Laboratory Economics* from CMS

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Professional component rates for the surgical pathology codes were not reviewed because they had already been scrutinized in April 2010. It's a small consolation that the professional component for 88305 will be increased by 1.9% to $36.76 in 2013. When combined with the 52% reduction to the technical component, the global rate for 88305 will be decreased by 33% to $70.46.

After CPT 88305, the second most important surgical pathology code (in terms of Medicare expenditures) that has been revalued is CPT 88307. In this case, technical component rates are being increased by 38.5% to $215.46 with professional rates raised by 3.9% to $82.03. Overall, the global rate for 88307 will increase by 26.9% to $297.49 in 2013.

In addition, the technical component for CPT 88309 is being increased by 41% to $304.64, while the professional rate is being raised 4.4% to $145. Overall, the global rate for 88309 will increase by 26.5% to $449.64 in 2013.

**Potential TC Rate Adjustments for 2014**

The Final Rule for 2013 indicated that CMS is evaluating two factors that could result in adjustments to reimbursement to 88305-TC and the other surgical pathology codes in 2014:

- CMS noted that the AMA RUC recommendations for technical component rates were developed based on assumptions regarding the typical number of blocks used for each of the six surgical pathology codes. The number of blocks assumed has a significant impact on the supply and the number of clinical labor and equipment minutes assigned as direct PE inputs to each code. CMS said that it was concerned that the number of blocks assumed for each code might be inaccurate. For CPT 88305, the AMA RUC assumed that the typical number of blocks used is 2. The agency stated: "We are requesting public comment regarding the appropriate number of blocks and urge the AMA RUC and interested medical specialty societies to provide corroborating, independent evidence that the number of blocks assumed in the current direct PE input recommendations is typical prior to finalizing the direct PE inputs for these services." Its request for independent evidence suggests that CMS is skeptical of the data given to them by the AMA RUC. Any downward revision to the number of blocks used to calculate PE inputs would put further pressure on technical component rates in 2014, notes *Laboratory Economics*.

- The AMA RUC recommended that CMS create new direct practice expense items to account for the cost of computer equipment and software used to import patient demographic information and export test results and billing information. CMS said it believes that computer system and associated software reflects an indirect practice expense for clerical and administrative services [i.e., not reimbursable]. However, CMS said it would consider additional information that showed the clinical functionality of the equipment so that it might be considered a direct cost as medical equipment [i.e., reimbursable] for CY 2014 rulemaking. Inclusion of computer equipment and software as a new direct practice expense item would raise technical component rates for the surgical pathology codes.

## HOSPITAL PATHOLOGISTS REACT TO THE RATE CUT

Many hospital-based pathology groups are celebrating Medicare's rate reduction for 88305-TC. They believe it will take the profit motive out of sketchy client billing arrangements, TC/PC splits and in-office pathology labs.

> *We are just -26 modifier billers which means we will have a slight pay increase for the professional component next year. At the hospital, we have a majority of payers who pay the hospital on a DRG. This includes Medicare, Medicaid, Blue Cross Blue Shield, United, etc. The DRGs are not affected by this change in the TC. So for the majority of our patients, there will be no change in revenue.*
>
> *Our cost to do an 88305-TC is between $12 and $13. We will see a decrease in revenue from our outpatients (a minority of our cases). However, at $34, reimbursement will still exceed our cost by a considerable amount. If we are able to add a couple thousand new cases, the new business will make the hospital whole.*
>
> *More importantly, CMS (the taxpayer) is not being ripped off and an unnatural incentive is greatly decreased.*
>
> —From an anonymous pathologist in Mississippi

Other pathologists believe the indirect fallout from the rate cut will hurt even those pathology groups that provide professional services only.

> *I hate insourcing too, but the rate cut is akin to cutting off your nose to spite your face. Even if you're a hospital-based group that receives zero money from TC, it will still hurt. Your hospital's histolab just became unprofitable. How much staff will be cut when they can't cover costs? And you can forget about new equipment.*
>
> —From an anonymous pathology resident
>
> *This change won't be good for anybody. It will hurt all pathology labs and groups. Some won't survive. In the long term, it may hurt some patients as slide quality and the quality of the techs making them degenerates.*
>
> —From a pathology lab executive in Georgia

## WILL IN-OFFICE PATHOLOGY LABS SURVIVE?

In-office pathology labs will survive, but will have smaller profit margins, according to Joe Plandowski, co-founder of IOP LLC (Lake Forest, IL). His consulting firm has helped build about 50 in-office pathology labs, primarily at gastroenterology groups, over the past 10 years. He says that large in-office pathology labs currently have a 50% profit margin and can withstand the rate cut.

"Assuming one-third of a specialty practice is covered by Medicare, the net effect on their lab will be about 10%. So the practice will initially survive on a 40% profit margin," according to Plandowski. He says that if third-party payers follow Medicare over the next year, the profit margin will drop to about 20% at in-office labs.

Plandowski says that to offset the technical rate cut, specialty groups will seek to reduce professional pay to contracted pathologists. He says they will now be paid $12 to $18 per read versus $20 to $25 previously. "We are going to aggressively bid out the in-office pathology professional work versus the prior collegial approach we have taken with local hospital-based pathologists."

And IOP's Bernie Ness adds, "If any groups decide to close their in-office labs and start referring Medicare work out again, it will not go to local pathology groups, as CAP members are dreaming about. It will go back to the commercial labs that the groups used before."

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## GAUGING THE REVENUE LOSS TO PATHOLOGY GROUPS AND LABS

The 33.4% cut to the Medicare global rate for 88305 will result in an estimated revenue loss of $460 million for pathology groups and labs next year. This estimate is based on $1.378 billion of allowed charges for 2011 multiplied by the 33.4% reimbursement reduction.

The reductions in technical reimbursement for surgical pathology will be partially offset by increased rates for immunohistochemistry, flow cytometry and UroVysion FISH testing. Overall, *Laboratory Economics* estimates that Medicare expenditures on pathology services will decline by $358 million, or 14%, next year as a result of the rate changes.

However, the Medicare rate changes will also influence rates paid by commercial third-party payers. Jane Pine Wood, attorney at McDonald Hopkins, notes that many payers base their rates on a percentage of the Medicare Physician Fee Schedule and others will adjust their rates not tied to MPFS to reflect the changes.

"It is going to be devastating," says Michael Snyder, president of laboratory services at Medical Spend Management Systems LLC (Cherry Hill, NJ). "Most will not get hit until the end of their current contract cycle; however, some plans have built-in contract language that allows them to change pricing with notice (usually 30-90 days)." Snyder says pathology groups may need to consider dropping contracts and going out-of-network with their lowest paying health plans.

### Mediare Reimbursement Estimates For Key Pathology Codes

| Code (Description) | Allowed Charges 2011 ($ Millions) | 2013 Global Rate Change* | 2013 Revenue Impact ($ Millions) |
|---|---|---|---|
| 88305 (Level IV, tissue exam by pathologist) | $1,377.9 | -33.4% | -$460.2 |
| 88342 (Immunohistochemistry) | $278.5 | 9.7% | $27.0 |
| 88185 (Flow cytometry, add on) | $142.5 | 8.2% | $11.7 |
| 88312 (Special stains) | $96.8 | 4.7% | $4.6 |
| 88112 (Cytopath cell enhance tech) | $87.0 | 7.0% | $6.1 |
| 88307 (Level V, tissue exam by pathologist) | $84.9 | 26.9% | $22.8 |
| 88313 (Special stains) | $68.5 | 3.1% | $2.1 |
| 88368 (FISH-manual) | $58.6 | 4.9% | $2.9 |
| 88331 (Pathology consult during surgery) | $37.9 | 7.4% | $2.8 |
| 88120 (FISH-manual for UroVysion) | $36.0 | 31.3% | $11.3 |
| 88367 (FISH-computer assisted) | $30.9 | -2.1% | -$0.6 |
| 88304 (Level III, tissue exam by pathologist) | $30.3 | -28.0% | -$8.5 |
| 88173 (Cytopath eval FNA) | $29.6 | 7.8% | $2.3 |
| 88121 (FISH-computer assisted for UroVysion) | $28.8 | 37.1% | $10.7 |
| 88309 (Level VI, tissue exam by pathologist) | $25.9 | 26.5% | $6.9 |
| 88346 (Immunofluorescent study) | $22.3 | 5.6% | $1.3 |
| 88189 (Flow cytometry, read 16+) | $18.1 | 4.0% | $0.7 |
| 88321 (Microslide consultation) | $17.2 | 3.8% | $0.7 |
| 88108 (Cytopath, concentrate tech) | $14.0 | -11.7% | -$1.6 |
| 88237 (Cytogenetic bone marrow analysis) | $11.0 | -5.0% | -$0.6 |
| Total | $2,496.8 | -14.3% | -$357.8 |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.
Source: *Laboratory Economics* from CMS

## UROVYSION REIMBURSEMENT INCREASED BY +30%

CMS created two new codes (88120 and 88121) that cut reimbursement by about 50% for UroVysion bladder cancer testing in 2011. Now CMS is swinging rates for UroVysion back up. Furthermore, CMS says the rates for 2013 are interim and will be reviewed for another potential adjustment for 2014.

UroVysion is a FISH probe that detects genetic changes in bladder cells from urine specimens. The FDA-cleared test can spot cancer up to six months earlier than other methods. The UroVysion test is made by Abbott Diagnostics.

Effective January 1, 2013, the global rate for 88120 (FISH manual with UroVysion) is being raised by 31% to $621.87. The technical component will increase by 34% to $565.36, while the professional component is going up 9.2% to $56.50.

The global rate for 88121 is being raised by 37% to $559.58. The technical component will go up 41% to $510.22 and the professional component will go up 7.4% to $49.35.

In 2011, Medicare spent $65 million on codes 88120 and 88121 (*see table on page 5*).

**Medicare Rates* for UroVysion Bladder Cancer Testing**

| Code | Modifier | Description | Total RVUs | Conversion Factor | 2013 Rate | 2012 Rate | % Chg |
|---|---|---|---|---|---|---|---|
| 88120 | Global | FISH manual with UroVysion | 18.27 | 34.0376 | $621.87 | $473.46 | 31.3% |
| 88120 | Technical | | 16.61 | 34.0376 | 565.36 | 421.73 | 34.1% |
| 88120 | Professional | | 1.66 | 34.0376 | 56.50 | 51.74 | 9.2% |
| 88121 | Global | FISH computer with UroVysion | 16.44 | 34.0376 | $559.58 | $408.11 | 37.1% |
| 88121 | Technical | | 14.99 | 34.0376 | 510.22 | 362.16 | 40.9% |
| 88121 | Professional | | 1.45 | 34.0376 | 49.35 | 45.95 | 7.4% |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.

Source: *Laboratory Economics* from CMS

## IMMUNOHISTOCHEMISTRY RATES HIKED BY 10%

Global reimbursement for CPT 88342 is set to increase by 9.7% to $115.73 in 2013. The technical rate will increase by 13.7% to $73.52 and the professional rate will rise by 3.3% to $42.21.

CPT 88342 is used to bill for immunohistochemistry. Immunohistochemical (IHC) staining is used in the diagnosis of abnormal cells such as those found in cancerous tumors. In 2011, Medicare spent $278.5 million on 88342, which ranked it second among pathology codes (*see table page 5*).

CMS has targeted the technical and professional components of 88342 for review as potentially overvalued. The AMA RUC will review 88342 in 2013 with any potential rate changes effective in 2014.

### Medicare Rates* for Immunohistochemistry

| Code | Modifier | Description | Total RVUs | Conversion Factor | 2013 Rate | 2012 Rate | % Chg |
|---|---|---|---|---|---|---|---|
| 88342 | Global | Immunohistochemistry | 3.40 | 34.0376 | $115.73 | 105.52 | 9.7% |
| 88342 | Technical | | 2.16 | 34.0376 | $73.52 | 64.67 | 13.7% |
| 88342 | Professional | | 1.24 | 34.0376 | $42.21 | 40.85 | 3.3% |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.
Source: *Laboratory Economics* from CMS

## FLOW CYTOMETRY TC RATES UP BY 7-8%

Technical reimbursement for flow cytometry (CPT 88184 & 88185) will increase by 7-8% in 2013. Interpretations for flow cytometry (CPT 88187, 88188 & 88189) will increase by 3-4.5%. Flow cytometry is used to diagnose leukemias and lymphomas. Medicare spends approximately $200 million per year on flow cytometry services.

### Medicare Rates* for Flow Cytometry

| Code | Modifier | Description | Total RVUs | Conversion Factor | 2013 Rate | 2012 Rate | % Chg |
|---|---|---|---|---|---|---|---|
| 88184 | NA | Flow cytometry/ tc 1 marker | 2.61 | 34.0376 | $88.84 | $82.71 | 7.4% |
| 88185 | NA | Flow cytometry/tc add-on | 1.59 | 34.0376 | $54.12 | $50.04 | 8.2% |
| 88187 | NA | Flow cytometry/read 2-8 | 2.02 | 34.0376 | $68.76 | $66.71 | 3.1% |
| 88188 | NA | Flow cytometry/read 9-15 | 2.57 | 34.0376 | $87.48 | $83.73 | 4.5% |
| 88189 | NA | Flow cytometry/read 16 > | 3.13 | 34.0376 | $106.54 | $102.45 | 4.0% |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.
Source: *Laboratory Economics* from CMS

## SPECIAL STAINS REIMBURSEMENT UP 3-5%

Medicare reimbursement for special stains (CPT 88312 & 88313) will increase by 3-5% in 2013. The global rate for 88312 will increase by 4.7% to $98.03, while the global rate for 88313 will increase by 3.1% to $67.73. Special stains are ordered when routine H&E staining does not provide the pathologist with all the information they need. Medicare spends approximately $165 million per year on special stains.

### Medicare Rates* for Flow Cytometry

| Code | Modifier | Description | Total RVUs | Conversion Factor | 2013 Rate | 2012 Rate | % Chg |
|---|---|---|---|---|---|---|---|
| 88312 | Global | Special stains group 1 | 2.88 | 34.0376 | $98.03 | $93.60 | 4.7% |
| 88312 | Technical | | 2.1 | 34.0376 | $71.48 | $67.73 | 5.5% |
| 88312 | Professional | | 0.78 | 34.0376 | $26.55 | $25.87 | 2.6% |
| 88313 | Global | Special stains group 2 | 1.99 | 34.0376 | $67.73 | $65.69 | 3.1% |
| 88313 | Technical | | 1.64 | 34.0376 | $55.82 | $54.12 | 3.1% |
| 88313 | Professional | | 0.35 | 34.0376 | $11.91 | $11.57 | 3.0% |

*National payment unadjusted for geographic practice cost differences. Assumes CF remains at 34.0376.
Source: *Laboratory Economics* from CMS

## Q&A WITH TWO PATHOLOGY PRACTICE CONSULTANTS

*Laboratory Economics* asked two pathology consulting experts for their opinions on what Medicare's 88305-TC reduction means for pathology groups. Mick Raich is president of the pathology practice management firm Vachette Pathology (Blissfield, MI). Robert Tessier is senior reimbursement consultant at HBP Financial Services Group (Woodbridge, CT), which provides consulting and practice management services to hospital-based physician groups. Here's what they had to say:

***How much does it really cost to make a slide?***

**Robert Tessier:** The new Medicare level seems outrageously low. A small community hospital has a significantly higher cost to provide an 88305-TC than a large commercial lab. I estimate that small hospitals with histology labs (e.g., 10,000 slides per year) have direct costs of $30 to $35 per slide plus indirect costs of $15 to $20, so reimbursement really should be about $50 per slide. It's a mystery how CMS determined its new rate, but I have a feeling that a lot of costs were not included, such as pathology assistant salaries (total salary and benefits of $125-$150K per FTE), the allocation of Part A medical director fees, and billing costs and bad-debt expense.

***What does 88305-TC rate cut mean for pathology groups that buy slide-prep services from their hospital?***

**Mick Raich:** If a group buys the slide prep work from the hospital and bills this globally then the group's revenue for this work will decrease. Therefore they will have to approach the hospital about paying less for this service since the revenue per unit is decreasing. On a larger scale, this means that over time all the profit margin out of the technical side is eroded. This means only those histology labs that are most efficient and cost effective will survive.

**Robert Tessier:** Hospitals will be reluctant to lower their slide-prep charges to pathology groups. Hospital charges are based on their cost to produce a slide rather than what their pathology group is getting reimbursed. In fact, many hospitals resent the large profits that pathology groups made from their technical service work over the past ten years.

Some hospitals charge their pathology groups as little as $20 per slide and these groups will still earn a profit from Medicare rates. Other hospitals include indirect costs and charge as much as $50 per slide and their pathology groups will no longer be able to profit from the purchase of 88305-TC.

***How should independent pathology groups with histology labs approach their private payers (Aetna, United, Cigna, BCBS, etc.)?***

**Robert Tessier:** The average independent pathology group receives about 20% to 25% of their revenue from Medicare. The key is what happens to reimbursement for the other 75% to 80% of their business. As quickly as possible, pathology groups should structure 3-5 year arrangements with modest annual increases in the range of 2.5-3%. Avoid any reference to "Medicare" rates or base future adjustments on current fees. You have to break the link to the Medicare Physician Fee Schedule.

**Mick Raich:** Some independent pathology labs will work hard and renegotiate their contacts and survive and some labs won't. Many commercial payers may use this as a fulcrum to force labs out of their network or force pricing to the lowest possible point. However, it can easily be argued that the Medicare cut is based on taxes and the national revenue stream. The commercial payers are not driven by the same variables. This means that if these payers follow the Medicare cuts, then the lower pricing will fall directly to their bottom line.

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## MDx TESTS KEPT ON CLFS; CARRIERS TO GAP-FILL RATES FOR 2013

CMS has made a final decision to keep 115 new CPT codes for molecular diagnostic tests on Medicare's Part B Clinical Laboratory Fee Schedule (CLFS). These new codes will replace the molecular diagnostic "stacking" codes effective January 1, 2013.

CMS did not publish payment rates for the new molecular test codes. Payment rates will be determined by Medicare carriers using the gap-fill method effective January 1, 2013.

Gap filling is used when no comparable test exists on the CLFS. For 2013, carriers will determine rates for the new MDx test codes using the following sources of information: charges for the test after discounts; costs to perform the test; and payment amounts from other payers. CMS will then calculate the median of the carrier-specific rates to establish a national limit amount (NLA) for each code for 2014.

Preliminary reimbursement amounts will be made public in April 2013 and will be followed by a public comment period. CMS should announce final rates in September 2013. There had been significant debate between clinical labs and pathologists regarding whether the new MDx test codes should be paid under the Medicare Physician Fee Schedule (MPFS) or the CLFS.

The College of American Pathologists (CAP) had argued for placing all the new MDx test codes on the MPFS. CAP said that physician interpretation is required for the majority of these tests and the MPFS allows for more frequent updating, which is necessary for this rapidly changing test area. Placing the tests on the MPFS would also have secured a professional component fee for interpretive services provided by pathologists.

"After reviewing the comments, we believe that the molecular pathology CPT codes describe clinical diagnostic laboratory tests that should be paid under the CLFS because these services do not ordinarily require interpretation by a physician to produce a meaningful result," stated CMS in its Physician Fee Schedule Final Rule for 2013. "While we recognize that these tests may be furnished by a physician, after reviewing the public comments and listening to numerous presentations by stakeholders throughout the comment period, we are not convinced that all these tests ordinarily require interpretation by a physician."

For those cases that will require physician interpretation, CMS has created a temporary code (G0452-molecular pathology procedure; physician interpretation and report) which pathologists can use to bill Medicare for professional services they've performed as part of a molecular test "above and beyond the report of laboratory results." G0452 will be paid under the MPFS at a physician work RVU of 0.37, which suggests a reimbursement rate of approximately $20.

CMS will monitor utilization and billing of G0452 to ensure the code is only being used when interpretation and report by a pathologist is needed and is not duplicative of laboratory reporting paid under the CLFS. In the near future, CMS plans to reassess whether this interim code is necessary, and if so, in conjunction with which MDx tests. Clinical labs performing MDx tests with Ph.D. geneticists will not be allowed to bill using G0452.

In addition, CMS said it was not instituting new codes or payment for multi-analyte assays with algorithmic analyses (MAAAs). MAAAs are combinations of assays whose test results are put into proprietary mathematical formulas to derive a single numeric score or index that can predict a patient's risk of cancer or other disease. CMS instructed labs to continue using existing codes and that the agency would study the issue further next year.

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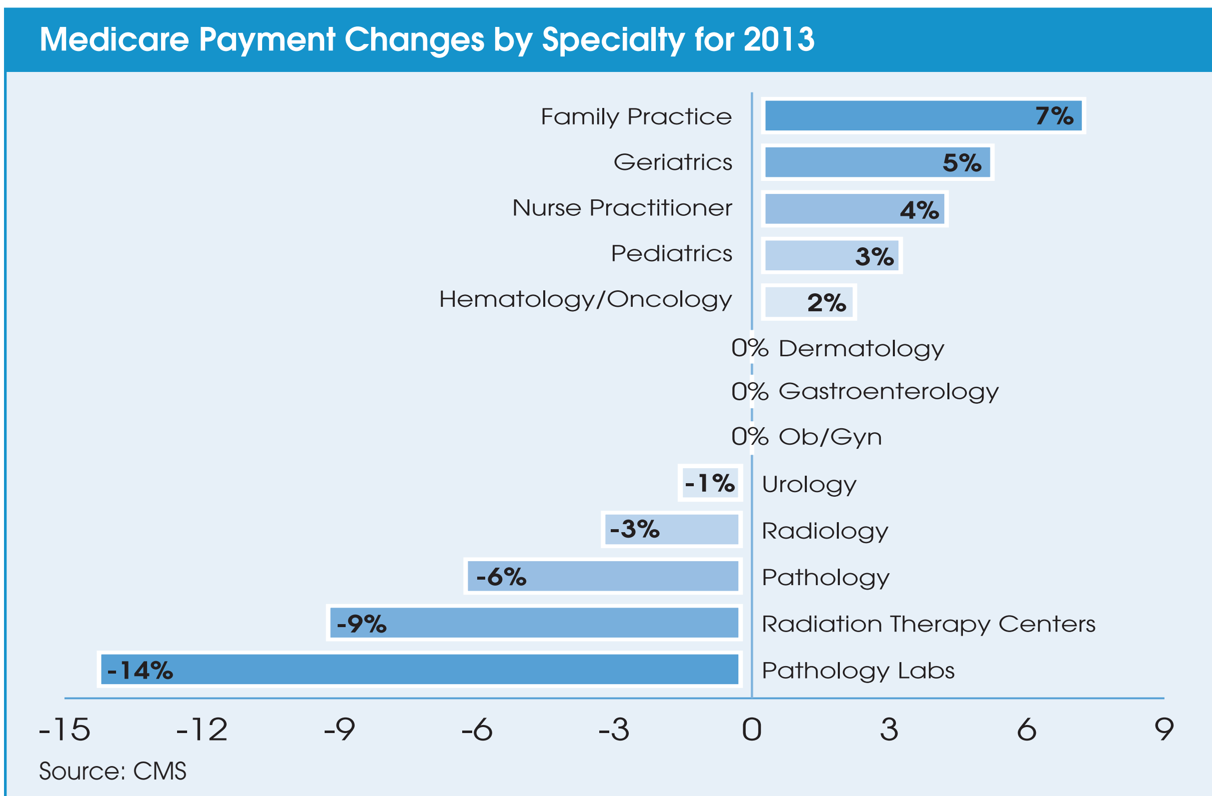
## NEW POLICIES BENEFIT PRIMARY CARE DOCS

Primary care physicians will see increased Medicare payments next year, assuming there is an SGR fix, under the Final 2013 Physician Fee Schedule Rule. Family practice physicians will see the largest Medicare payment increases at 7%, followed by geriatrics at 5% and nurse practitioners at 4%.

The pay raise for primary care physicians mostly takes the form of a separate fee for coordinating a patient's care for the first 30 days after leaving a hospital, skilled nursing facility, or certain outpatient services. Physicians can bill this service using two new billing codes, 99495 and 99496.

CMS has funded this raise for primary care by reducing reimbursement for many specialists. Independent pathology labs have been hardest hit. The 52% cut to the technical component of CPT 88305 means that independent pathology labs will see their overall Medicare payments decline by 14% in 2013 and pathologists will see a 6% cut.

Radiology was also hit hard. Radiation therapy centers will see payments decline by 9% and radiologists will see a 3% cut.




## PART B CLINICAL LAB FEE SCHEDULE SET TO DROP 5%

The Final 2013 Physician Fee Schedule Rule issued on November 1 states that the Medicare Part B clinical lab fee schedule will be cut by 5% next year, which is slightly worse than labs were expecting. Part B lab reimbursement changes for 2013 were based on a CPI adjustment of +1.7%, minus a productivity adjustment of 0.9% and a fixed cut of 1.75%. As part of the Sustainable Growth Rate fix, the Part B lab fee schedule will be re-baselined an additional 2% lower effective January 1, 2013. Furthermore, absent any congressional activity, mandatory sequestration will impose an additional 2% reduction effective February 2013. Together, these adjustments add up to a 5% cut to the Part B lab fee schedule for 2013.

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## OPKO TO BUY OURLAB FOR $40 MILLION

OPKO Health Inc. (Miami, FL) has agreed to acquire Prost-Data Inc., doing business as OURLab, for $40 million, including $9.4 million in cash and $30.6 million in stock. OURLab founder and CEO Jonathan Oppenheimer, MD, will become the CEO of OPKO's diagnostic division (which will include OURLab). Oppenheimer founded OURLab in 1996 and he is the sole shareholder.

The deal is expected to close by year's end. However, Medicare's newly announced 52% cut to the technical component of CPT 88305 might lead OPKO to review the terms of the purchase agreement, observes *Laboratory Economics*.

OURLab has its headquarters and main lab in Nashville. It also operates a smaller CLIA-certified lab in San Francisco and another in New York City. The company specializes in providing TC/PC services to urology groups. OURLab's "Dash-26" service model involves processing biopsies and preparing slides for urology groups. The urology group hires a pathologist for interpretations. OURLab bills for the technical service and the urology group bills for the professional component. In addition, the company has recently expanded into gastroenterology, dermatology and women's health (Pap tests and breast cancer).

OURLab provides OPKO with a platform to support the launch of its novel panel of biomarkers and associated algorithm (4Kscore) for the detection of prostate cancer. This laboratory-developed test is intended to predict the probability of a cancer-positive biopsy. OPKO claims it can reduce the number of unnecessary prostate biopsies now performed by up to 60%. An estimated 1.2 million prostate biopsies are performed per year in the United States and 750,000 of these are unnecessary.

OPKO is a publicly traded pharmaceutical and diagnostic development company. The company reported a net loss of $20 million in the six months ended June 30, 2012, versus a net loss of $12.7 million in the same period a year earlier; revenue increased 23% to $19 million.

## DERM ENTREPRENEUR TO OPEN INDEPENDENT PATH LAB

Florida dermatologist, Jon Ward, MD, has announced plans to open an independent pathology lab in Panama City. Ward has already been operating an in-office pathology lab at his practice, Gulf Coast Dermatology, since 2010.

The new independent lab is called GPD Pathology and has received a Qualified Target Industry tax refund in the amount of $415,000 through Florida's Department of Economic Opportunity. Ward expects to invest $4.6 million to build the lab and hire an 83-person workforce.

GPD Pathology will process slides for dermatologists, gastroenterologists, urologists and ob-gyns from across the Southeast. The new company plans to use digital pathology and contract with outside pathologists for professional interpretations.

The formation of GPD Pathology was announced in mid-October. The new Medicare reimbursement rate for CPT 88305-TC may put a damper on this venture, notes *Laboratory Economics*.

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## LAB STOCKS UP 30% YEAR TO DATE

Ten lab stocks have risen by an unweighted average of 30% so far this year. The combined market capitalization for the group is unchanged at $22 billion. In comparison, the S&P 500 Index is up 13% year to date through November 7. Shares of NeoGenomics have performed best (up 96%). In terms of valuation, Quest Diagnostics is currently trading at 1.2x its annual revenue with a price-to-earnings ratio of 12.5x. LabCorp trades at 1.5x its annual revenue and 13.6x trailing earnings.

| Company (ticker) | Stock Price 11/7/12 | Stock Price 12/30/11 | 2012 Price Change | Market Capitalization ($ millions) | P/E Ratio | Price/ Sales |
|---|---|---|---|---|---|---|
| Bio-Reference (BRLI) | $28.00 | $16.27 | 72% | $776 | 18.6 | 1.2 |
| CombiMatrix (CBMX) | 0.44 | 2.00 | -78% | 5 | NA | 0.9 |
| Enzo Biochem (ENZ) | 2.74 | 2.24 | 22% | 108 | NA | 1.0 |
| Genomic Health (GHDX) | 31.88 | 25.39 | 26% | 970 | 118.1 | 4.2 |
| LabCorp (LH) | 84.91 | 85.97 | -1% | 8,032 | 13.6 | 1.5 |
| Medtox Scientific (MTOX)* | 27.00 | 14.05 | 92% | 242 | 16.6 | 2.1 |
| Myriad Genetics (MYGN) | 30.05 | 20.94 | 44% | 2,448 | 21.9 | 4.8 |
| NeoGenomics (NGNM) | 2.75 | 1.40 | 96% | 124 | NA | 2.1 |
| Psychemedics (PMD) | 11.44 | 9.10 | 26% | 60 | 19.1 | 2.4 |
| Quest Diagnostics (DGX) | 58.06 | 58.06 | 0% | 9,230 | 12.5 | 1.2 |
| Unweighted Averages | | | 30% | $21,995 | 31.5 | 2.1 |

*Medtox was acquired by LabCorp on July 31 for $27 per share
Source: Bloomberg


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