LABORATORY

ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

NO BIG SURPRISES IN FINAL PHYSICIAN FEE SCHEDULE FOR 2015

A fter two years of bloodletting that saw drastic reimbursement reductions from Medicare to most major pathology codes (i.e., 88305, 88342, FISH testing, etc.), pathologists should see relatively calm waters in 2015. *Full details on pages 4-7*.

| Key Medicare Rate Changes for 2015* |
|---|
| CPT Code Change 88305-PC +1.8% 88305-TC +5.5% 88307-TC +8.2% 88342 (IHC) ~ Flat Prostate biopsies ~ Flat Multiplex FISH testing -8 to -20% Digital Pathology 88361-TC +10.8% Microdissection (88380 & 88381) -30% Clinical Lab Fee Schedule -0.3% *Assumes conversion factor of 35.8013 in 2015 Source: Laboratory Economics from CMS |

CMS FINALIZES PLANS TO PACKAGE PATHOLOGY SERVICES FOR OUTPATIENTS

CMS has finalized its proposal to package payment for the technical component of most pathology services provided to hospital outpatients, effective January 1, 2015. Reimbursement for these services will now be included within the payment for the associated primary procedure and hospitals will no longer be able to bill for them separately when delivered in the hospital outpatient setting. But physicians can continue to seek reimbursement under the Medicare Physician Fee Schedule for professional services provided to hospital outpatients. The change is likely to have the greatest effect on independent pathology labs that serve hospitals because it could result in lower utilization and changes to their laboratory service agreements with hospital clients. *Cont'd on page 3*.

LABCORP GOING DEEP INTO DEBT TO FUND ACQUISITION OF COVANCE

LabCorp has agreed to buy the contract research organization Covance Inc. (Princeton, NJ) for \$6 billion, in a largely debt-financed transaction. LabCorp CEO Dave King calls the deal, which is expected to close early next year, a "transformational transaction." Covance will be by far LabCorp's largest acquisition and represents a significant departure from the company's historic strategy of acquiring smaller regional clinical labs. Covance is a sprawling operation with annual revenue of \$2.5 billion and more than 12,500 employees spread over 60 countries. It conducts clinical trials or manages the logistics of central lab samples in more than 100 countries. *Continued on page 2.*

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LABORATORY CECONOMICS

LABCORP GOES DEEP INTO DEBT TO FUND ACQUISITION (*cont'd from page 1*)

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Approved by the boards of both companies, the deal will pay Covance shareholders \$75.76 in cash and 0.2686 LabCorp shares for each Covance share they currently own. That will give Covance's shareholders approximately 15.5% ownership of the combined company.

LabCorp will issue 15.6 million shares, currently valued at \$1.6 billion, to Covance shareholders. To fund the cash portion, LabCorp will spend \$400 million of its cash holdings and borrow another \$3.9 billion. The added debt will raise LabCorp's total debt outstanding to nearly \$7 billion after the close of the acquisition.

The ratings agencies S&P and Moody's have each viewed the deal negatively. "The higher leverage will leave LabCorp limited cushion to absorb any negative developments at the current rating level (Baa2), including the potential for reductions in reimbursement and ongoing weaknesses in lab volume trends," says Moody's. And Standard & Poor's Ratings Services has placed all of LabCorp's debt on "CreditWatch" with the likelihood of a one notch downgrade from its current BBB+ rating when the acquisition is completed.

The \$6 billion dollar price tag values Covance at 37 times its free cash flow of \$161 million for the 12 months ended September 30, 2014. In terms of revenue, the deal values Covance at 2.4 times its current annual revenue of \$2.5 billion.

LabCorp's investors have questioned whether the Covance acquisition represents the best choice for spending \$6 billion. Alternatively, LabCorp could have launched a massive \$3 billion share repurchase plan and then used the remaining \$3 billion to try to acquire nearly every independent lab in the nation.

In the 10 days after the Covance deal was announced on November 3, shares of LabCorp fell 9%, erasing nearly \$1 billion of shareholder wealth.

As mentioned earlier, LabCorp is calling Covance a "transformational transaction." Covance is a faster-growing business (approx. 5-6% per year) and will diversify LabCorp's revenue, as Covance's customer base consists almost exclusively of pharmaceutical and biotechnology companies. The diversification away from the clinical lab business could wind up being a masterstroke for LabCorp given that CMS is in the process of repricing the entire Clinical Lab Fee Schedule. The agency plans to collect private payer data from labs in 2016 and implement price cuts of up to 10% per test per year beginning with the 2017 CLFS.

After the deal, LabCorp will generate 32% of its revenue from managed care, 29% from pharmaceutical and biotech companies, 22% from commercial clients, 12% from Medicare/Medicaid and 5% from private patients.

The acquisition of Covance will also make LabCorp bigger than its rival Quest Diagnostics in nearly every category, including annual revenue, employees and stock market value.

Combined Company Analysis vs. Quest Diagnostics (for 12 months ended Sept. 30, 2014)

| | LabCorp | Covance | Combined | Quest Diagnostics |
|----------------|---------|---------|----------|-------------------|
| Revenue | \$5,936 | \$2,510 | \$8,446 | \$7,308 |
| Free cash flow | 557 | 161 | 718 | 550 |
| Net income | 518 | 180 | 698 | 509 |
| Employees | 34,500 | 12,500 | 47,000 | 41,000 |

Source: Laboratory Economics from LabCorp, S&P Capital IQ and Zacks

CMS FINALIZES PLANS TO PACKAGE PATHOLOGY SERVICES (cont'd from page 1) More than 30 pathology services will be impacted by the new packaged payment system including: Surgical Pathology (CPT 88304/88305/88307); Cytopathology (88173); Special Stains (88312/88313); FISH (88365/88120/88121); IHC (88342/88360/88361); Flow Cytometry (88184); and Frozen Section 1st Block (88331).

In addition, all Level I Transfusion Laboratory Services (APC 0345) will be moved to packaged payment as well as Phlebotomy Services (APC 0624) effective January 1, 2015.

The expanded packaging program follows in the footsteps of bundled payment for nearly all clinical lab tests for outpatients (with the exception of molecular tests) which started January 1, 2014.

The packaged payment scheme was strongly opposed by both the American Society for Clinical Pathology (ASCP) and CAP. The primary concern is that CMS has not increased the payment of outpatient primary procedures enough to compensate for the packaged pathology tests and other ancillary services.

It is difficult to predict the exact impact until we know whether or not CMS is able to adequately estimate the typical volume of each ancillary service provided in conjunction with the designated primary service, notes ASCP. Accordingly, absent CMS's ability to do so, inadequate valuation of the subsequent payment bundles may threaten reimbursement and patient access. In addition to threats to reimbursement, ASCP is also concerned with the administrative challenges that arise from the bifurcated billing system underlying the complex payment bundles unique to Medicare reimbursement.

From Laboratory Economics' perspective we find it difficult to reconcile two claims from CMS. On the one hand, CMS says that its switch to packaged payments from fee for service is budget neutral and will not lead to decreased payments to hospitals. But on the other hand, CMS says

that packaged pay-Key Pathology Services Being Bundled For Hospital Outpatients ments are expected to CPT Description APC **Outpatient Volume** reduce utilization and promote efficiency. Based on volume figures from CMS, Laboratory Economi estimates that more

| promote efficiency. | 342 | 88305 | Tissue exam by pathologist | 3,129,463 |
|--|--------|----------|-----------------------------|-----------|
| Based on volume | 433 | 88342 | Immunohisto antibody stain | 636,779 |
| figures from CMS, | 342 | 88304 | Tissue exam by pathologist | 342,923 |
| Laboratory Economics | 342 | 88313 | Special stains group 2 | 327,873 |
| estimates that more | 342 | 88312 | Special stains group 1 | 321,272 |
| than \$100 million | 433 | 88307 | Tissue exam by pathologist | 281,122 |
| of Medicare fee-for- | 342 | 88112 | Cytopath cell enhance tech | 242,654 |
| service payments for pathology TC services | 342 | 88173 | Cytopath eval FNA report | 164,224 |
| will be shifted into | 433 | 88184 | Flowcytometry/TC 1 marker | 133,191 |
| the packaged payment | 433 | 88331 | Path consult intraop 1 bloc | 125,132 |
| system in 2015. | Source | Laborato | ory Economics from CMS | |

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NO BIG SURPRISES IN FINAL PFS FOR 2015 (cont'd from page 1)

CPT 88305

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Global reimbursement for CPT 88305 is scheduled to increase by 3.5% to \$73 in 2015. The technical component of 88305 is being raised by 5.5% to \$34, while the professional component is being raised by 1.8% to \$39.

PROSTATE BIOPSIES

Effective January 1, CMS is moving to a single code (G0416) for billing tissue preparation and exam for prostate biopsies. All prostate biopsies, regardless of the number of cores examined, will be reimbursed by Medicare at a global rate of \$649—the equivalent reimbursement of about nine 88305s at \$73.

The Medicare rate for G0416 in 2015 includes a professional component of \$183 and technical reimbursement of \$466.

The use of CPT 88305 with respect to prostate biopsies is being eliminated next year. So, for example, a prostate biopsy with six cores will be billed under G0416 and reimbursed at a global rate of \$649. Likewise, a prostate biopsy with 12 cores will be billed using G0416 at a rate of \$649. And a prostate biopsy with 20 cores will also use G0416 at \$649.

"We believe that using G0416 to report all prostate biopsy pathology services, regardless of the number of specimens, would simplify the coding and mitigate overutilization," according to CMS.

Medicare provider utilization data show that the average number of 88305s billed per prostate biopsy is approximately nine units, so the switch to a single code G0416 at \$649 will result in little change for the average pathology lab. Of course, those pathology labs that were billing in excess of nine cores per prostate biopsy will see a rate reduction and vice versa.

Furthermore, CMS has identified G0461 as a potentially misvalued code that will be reviewed in 2015 for a possible revaluation that would be effective in 2016.

IMMUNOHISTOCHEMISTRY

In an effort to discourage overutilization, CMS eliminated CPT 88342 (immunohistochemistry-IHC) for 2014 and replaced it with codes G0461 (1st IHC stain per site) and G0462 (additional IHC stain per site) for 2014. In connection, CMS lowered global reimbursement for G0461 by 23% and cut G0462 by 41% relative to the IHC rates in 2013.

However, CMS has reversed itself and is bringing back 88342 effective January 1, 2015. G0461 and G0462 are being eliminated and two new IHC codes (88341 & 88344) are being added. The descriptors for the three new IHC codes are:

- **88341:** Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)
- **88342:** Immunohistochem or immunocytochem, per specimen; initial single antibody stain procedure
- **88344:** Immunohistochem or immunocytochem, per specimen; each multiplex antibody stain procedure

For example, a cancer case that receives four separate IHC stains is currently reimbursed by Medicare under G0461 + (3x) G0462 for a total global payment of \$294. Next year, this same case will be reimbursed under 88342 + (3x) 88341 for a total global payment of \$293. Not much of a change.

In addition, multiplex antibody staining procedures, such as prostate triple stains, will be reimbursed under a single code, CPT 88344, next year at a global rate of \$117, including \$77 for the technical component and \$40 for the professional interpretation.

FISH TESTING

CMS revised codes 88365, 88367 and 88368 to specify "each separately identifiable probe per block." It also created six new codes, three (88364, 88373 and 88369) which apply to add-on FISH services and another three (88366, 88374 and 88377) which apply to multiplex probes.

From a reimbursement perspective, CMS established Relative Value Units (RVUs) that were lower than what was recommended by the American Medical Association/Specialty Society Relative (Value) Update Committee (RUC) for five of the nine FISH codes.

The coding changes will result in reimbursement changes that vary depending on the procedure. For example, a pathology lab that is billing manual FISH testing using an average of three separate probes per sample is currently reimbursed under CPT 88368 at a global rate of \$232. Next year, this same procedure will be billed using CPT 88368 (reimbursement of \$109) for the first probe and CPT 88369 (reimbursement of \$74) for the next two probes for a total global payment of \$257. This indicates an 11% increase in reimbursement.

The same three-probe example for computer-assisted FISH testing is currently reimbursed under CPT 88367 at a global rate of \$256. Next year, this same procedure will be billed using CPT 88367 (reimbursement of \$107) for the first probe and CPT 88373 (reimbursement of \$60) for the next two probes for a total global payment of \$227. This indicates an 11% decrease in reimbursement.

Next year, manual multiplex FISH testing procedures will be billed using a single new code, CPT 88377, per specimen at a global rate of \$214. This represents an 8% decline from current reimbursement of \$232.

Computer-assisted multiplex FISH testing will be billed using CPT 88374 at \$205 per specimen. This represents a 20% decline from current reimbursement of \$256.

MICRODISSECTION

Medicare rates for microdissection (88380 and 88381) were reviewed and cut by approximately 30% for 2015. Although payment for the service decreased, there was significant concern that Medicare would stop paying for the pathologists' interpretation as well as the technical costs. So maintaining reimbursement, albeit lower, was seen as a victory.

DIGITAL PATHOLOGY

Global reimbursement for digital pathology (88361) is scheduled to increase by 7% to \$169 in 2015. The technical component is being raised by 11% to \$109; the professional interpretation is going up 1% to \$60.

FLOW CYTOMETRY

The key flow cytometry add-on code CPT 88185 had been scheduled for rate review, but no decisions were finalized for 2015. Review is now scheduled for 2015 with rate changes likely in 2016.

CLINICAL LAB FEE SCHEDULE

The CLFS is scheduled to be reduced by 0.3% in 2015. This adjustment is based on three factors: 1) an inflation update of 2.1%; 2) a multi-factor productivity adjustment of -0.6%; and 3) the fifth and final year of an annual fixed cut of 1.75% as mandated by the Affordable Care Act.

LABORATORY CECONOMICS

Medicare Rate Comparison for Key Pathology Codes: 2015* vs. 2014

| | | | 2015 | 2014 | _ | | |
|--|----------|-------------------------------|---------|---------|-------|--|--|
| Code | Modifier | Description | Rate* | Rate | % | | |
| 88108 | Global | Cytopath concentrate tech | \$84.85 | \$78.81 | 7.7% | | |
| 88108 | TC | Cytopath concentrate tech | 61.22 | 55.88 | 9.6% | | |
| 88108 | 26 | Cytopath concentrate tech | 23.63 | 22.93 | 3.0% | | |
| 88112 | Global | Cytopath cell enhance tech | 64.80 | 63.05 | 2.8% | | |
| 88112 | TC | Cytopath cell enhance tech | 36.16 | 34.75 | 4.1% | | |
| 88112 | 26 | Cytopath cell enhance tech | 28.64 | 28.30 | 1.2% | | |
| 88120 | Global | Cytp urine 3-5 probes ea spec | 625.09 | 618.66 | 1.0% | | |
| 88120 | TC | Cytp urine 3-5 probes ea spec | 566.02 | 559.55 | 1.2% | | |
| 88120 | 26 | Cytp urine 3-5 probes ea spec | 59.07 | 59.11 | -0.1% | | |
| 88121 | Global | Cytp urine 3-5 probes cmptr | 555.64 | 535.19 | 3.8% | | |
| 88121 | TC | Cytp urine 3-5 probes cmptr | 504.08 | 484.32 | 4.1% | | |
| 88121 | 26 | Cytp urine 3-5 probes cmptr | 51.55 | 50.87 | 1.3% | | |
| 88173 | Global | Cytopath eval fna report | 151.80 | 146.87 | 3.4% | | |
| 88173 | TC | Cytopath eval fna report | 79.48 | 74.87 | 6.2% | | |
| 88173 | 26 | Cytopath eval fna report | 72.32 | 72.00 | 0.4% | | |
| 88184 | TC | Flowcytometry/ tc 1 marker | 93.80 | 87.77 | 6.9% | | |
| 88185 | TC | Flowcytometry/tc add-on | 56.92 | 53.73 | 5.9% | | |
| 88187 | 26 | Flowcytometry/read 2-8 | 72.32 | 71.65 | 0.9% | | |
| 88188 | 26 | Flowcytometry/read 9-15 | 91.65 | 90.27 | 1.5% | | |
| 88189 | 26 | Flowcytometry/read 16 & > | 113.13 | 110.69 | 2.2% | | |
| 88304 | Global | Tissue exam by pathologist | 45.83 | 43.35 | 5.7% | | |
| 88304 | TC | Tissue exam by pathologist | 34.01 | 31.88 | 6.7% | | |
| 88304 | 26 | Tissue exam by pathologist | 11.81 | 11.46 | 3.1% | | |
| 88305 | Global | Tissue exam by pathologist | 73.03 | 70.57 | 3.5% | | |
| 88305 | TC | Tissue exam by pathologist | 34.01 | 32.24 | 5.5% | | |
| 88305 | 26 | Tissue exam by pathologist | 39.02 | 38.33 | 1.8% | | |
| 88307 | Global | Tissue exam by pathologist | 307.18 | 288.37 | 6.5% | | |
| 88307 | TC | Tissue exam by pathologist | 220.89 | 204.19 | 8.2% | | |
| 88307 | 26 | Tissue exam by pathologist | 86.28 | 84.18 | 2.5% | | |
| 88309 | Global | Tissue exam by pathologist | 465.06 | 438.83 | 6.0% | | |
| 88309 | TC | Tissue exam by pathologist | 313.26 | 289.81 | 8.1% | | |
| 88309 | 26 | Tissue exam by pathologist | 151.80 | 149.02 | 1.9% | | |
| 88312 | Global | Special stains group 1 | 97.74 | 94.57 | 3.3% | | |
| 88312 | TC | Special stains group 1 | 69.81 | 66.99 | 4.2% | | |
| 88312 | 26 | Special stains group 1 | 27.93 | 27.58 | 1.3% | | |
| 88313 | Global | Special stains group 2 | 68.02 | 65.91 | 3.2% | | |
| 88313 | TC | Special stains group 2 | 55.49 | 53.73 | 3.3% | | |
| 88313 | 26 | Special stains group 2 | 12.53 | 12.18 | 2.9% | | |
| 88321 | 26 | Microslide consultation | 96.66 | 95.29 | 1.4% | | |
| Physician Fee Schedule rates assume conversion factor of 35.8013 | | | | | | | |

*Physician Fee Schedule rates assume conversion factor of 35.8013

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| | | | 2015 | 2014 | |
|-------------|----------|------------------------------|--------|--------|-------------|
| Code | Modifier | Description | Rate* | Rate | % |
| 88323 | Global | Microslide consultation | 152.51 | 147.59 | 3.3% |
| 88323 | TC | Microslide consultation | 63.01 | 59.47 | 6.0% |
| 88323 | 26 | Microslide consultation | 89.50 | 88.12 | 1.6% |
| 88341/G0462 | Global | Immunohisto antibody slide | 67.31 | 68.42 | -1.6% |
| 88341/G0462 | TC | Immunohisto antibody slide | 45.47 | 55.88 | -18.6% |
| 88341/G0462 | 26 | Immunohisto antibody slide | 21.84 | 12.54 | 74.2% |
| 88342/G0461 | Global | Immunohisto antibody stain | 90.58 | 88.48 | 2.4% |
| 88342/G0461 | TC | Immunohisto antibody stain | 54.06 | 57.67 | -6.3% |
| 88342/G0461 | 26 | Immunohisto antibody stain | 36.52 | 30.81 | 18.5% |
| 88344 | Global | Immunohisto antibody slide | 117.07 | NA | NA |
| 88344 | TC | Immunohisto antibody slide | 76.97 | NA | NA |
| 88344 | 26 | Immunohisto antibody slide | 40.10 | NA | NA |
| 88360 | Global | Tumor immunohistochem/manua | 136.04 | 130.04 | 4.6% |
| 88360 | TC | Tumor immunohistochem/manua | 80.55 | 75.23 | 7.1% |
| 88360 | 26 | Tumor immunohistochem/manua | 55.49 | 54.81 | 1.2% |
| 88361 | Global | Tumor immunohistochem/comput | 169.34 | 157.98 | 7.2% |
| 88361 | TC | Tumor immunohistochem/comput | 109.19 | 98.51 | 10.8% |
| 88361 | 26 | Tumor immunohistochem/comput | 60.15 | 59.47 | 1.1% |
| 88367 | Global | Insitu hybridization auto | 107.40 | 255.77 | -58.0% |
| 88367 | TC | Insitu hybridization auto | 71.96 | 193.08 | -62.7% |
| 88367 | 26 | Insitu hybridization auto | 35.44 | 62.69 | -43.5% |
| 88368 | Global | Insitu hybridization manual | 108.84 | 232.49 | -53.2% |
| 88368 | TC | Insitu hybridization manual | 67.66 | 167.65 | -59.6% |
| 88368 | 26 | Insitu hybridization manual | 41.17 | 64.84 | -36.5% |
| 88369 | Global | M/phmtrc alysishquant/semiq | 73.75 | NA | NA |
| 88369 | TC | M/phmtrc alysishquant/semiq | 48.69 | NA | NA |
| 88369 | 26 | M/phmtrc alysishquant/semiq | 25.06 | NA | NA |
| 88373 | Global | M/phmtrc alysishquant/semiq | 60.15 | NA | NA |
| 88373 | TC | M/phmtrc alysishquant/semiq | 39.02 | NA | NA |
| 88373 | 26 | M/phmtrc alysishquant/semiq | 21.12 | NA | NA |
| 88377 | Global | M/phmtrc alysishquant/semiq | 214.45 | 232.49 | -7.8 |
| 88377 | TC | M/phmtrc alys ishquant/semiq | 148.93 | 167.65 | -11.1 |
| 88377 | 26 | M/phmtrc alys ishquant/semiq | 65.52 | 64.84 | 1.0 |
| 88380 | Global | Microdissection laser | 132.82 | 190.58 | -30.3% |
| 88380 | TC | Microdissection laser | 76.26 | 110.33 | -30.9% |
| 88380 | 26 | Microdissection laser | 56.57 | 80.24 | -29.5% |
| 88381 | Global | Microdissection manual | 124.59 | 160.84 | -22.5% |
| 88381 | TC | Microdissection manual | 98.45 | 105.68 | -6.8% |
| 88381 | 26 | Microdissection manual | 26.13 | 55.17 | -52.6% |
| G0416 | Global | Prostate biopsy, any method | 649.08 | 651.26 | -0.3 |
| G0416 | TC | Prostate biopsy, any method | 466.49 | 466.77 | -0.1% |
| G0416 | 26 | Prostate biopsy, any method | 182. | 184.49 | -1.0 |
| | | | | | cs from CMS |

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LABORATORY CECONOMICS

PDI BUYS REDPATH FOR MORE THAN \$23 MILLION

PDI Inc. (Parsippany, NJ) has acquired RedPath Integrated Pathology (Pittsburgh, PA) for more than \$23 million in cash and stock. PDI provides outsourced sales and marketing support services to pharmaceutical and medical device companies.

RedPath markets a proprietary laboratory-developed test named PathFinder TG Pancreas that helps gastroenterologists determine cancer risk in pancreatic cysts. The test is performed at Red-Path's CLIA-certified lab in Pittsburgh and generates annual revenue of approximately \$10 million. The PathFinder TG test uses clinical algorithms to stratify patients according to cancer risk by looking at DNA abnormalities in patients who have cysts or solid masses with the potential for cancer. Medicare reimbursement for the test is set at \$3,100 using CPT 84999 (unlisted chemistry procedure). RedPath is also developing tests for assessing risk for Barrett's esophagus and in the biliary tract.

RedPath was owned by a group of private equity investors (Inflexion Fund, CID Capital, Seneca Health Partners and NewSpring Health Capital) that had invested a total of roughly \$19 million in the company since it was founded in 2004.

PDI acquired all of the outstanding shares of RedPath. Terms of the deal include a \$12 million upfront cash payment, an \$11 million subordinated note to the shareholders of RedPath, and up to one million PDI shares (currently worth approx. \$1.8 million) payable upon the successful introduction of RedPath's Barrett's esophagus test. To pay for the acquisition of RedPath, PDI borrowed \$20 million from SWK Holdings Corporation (Dallas, TX).

In the nine months ended September 30, 2014, PDI reported a net loss of \$8.6 million versus a loss of \$899,000 in the same period a year earlier; revenue was \$93.6 million, down 18% from \$114.4 million.

AURORA DIAGNOSTICS BUYS WEST GEORGIA PATHOLOGY

A urora Diagnostics (Palm Beach Gardens, FL) has acquired West Georgia Pathology LLC., a hospital-based practice in Carrollton, Georgia. West Georgia Pathology has four pathologists led by Lawrence M. Alligood, MD, age 75, and provides service to three hospitals in the Tanner Health System.

This marks Aurora's fourth acquisition so far this year. Others have included Arizona Dermatopathology, Mid-Atlantic Pathology Services in Virginia and Hallmark Pathology in Massachusetts.

Separately, Aurora reported a net loss of \$7.3 million in the three months ended September 30, 2014 versus a net loss of \$3.5 million in the same period last year; revenue increased by 1% to \$63 million (including \$1.5 million added from acquisitions). Aurora's average revenue per accession for the quarter increased by approximately 1% to \$116, from approximately \$115 last year.

As of September 30, 2014, Aurora had total debt outstanding of \$371 million and a shareholders' deficit of \$68.9 million.

Meanwhile, junk bond investors are showing more confidence in Aurora's ability to repay its debt than they did earlier this year. As of November 17, Aurora's senior debt (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at approximately 88 cents on the dollar with a yield to maturity of 15.5%.

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ARE UROLOGISTS BILLING FOR TOO MANY FISH TESTS?

In late October, *The Wall Street Journal* published an article detailing the government's investiga-Ltion of the in-office pathology lab at 21st Century Oncology (Fort Myers, FL). In particular, the Office of Inspector General has requested information regarding the utilization of fluorescence in situ hybridization (FISH) bladder cancer tests ordered by some of 21st Century Oncology's employed physicians and performed by the company's pathology lab in Fort Myers, Florida, as part of a civil False Claims Act investigation.

21st Century Oncology says it is cooperating fully with the subpoena requests, but does not believe that it or its physicians knowingly submitted false claims in violation of Medicare regulations. 21st Century Oncology is the nation's largest oncology group. The company employs more than 450 physicians, including 164 urologists, and has annual revenue of approximately \$1 billion.

The WSJ article noted a steep rise in FISH testing after 21st Century Oncology opened its pathology lab in 2007. The two pathologists who head the company's lab, George Kalemeris, MD, and Brian Babbin, MD, billed Medicare for \$4.1 million of computerized FISH testing/CPT 88121 in 2012, representing 21% of what Medicare paid to all 379 pathologists billing for the test nationwide that year. 21st Century Oncology says that Kalemeris's and Babbin's Medicare billings were collected by the company, not by the doctors themselves, and that its urologists refer tests to the in-office lab for valid medical reasons, not financial ones.

But what about the urologist that orders pathology tests from his or her own pathology lab and then bills Medicare using their individual provider ID number (see table)? *LE* thinks these physicians are putting themselves at risk for medical liability for work they did not perform as well as a government investigation...sparked, perhaps, by an infuriated pathologist.

| NAME | UROLOGY GROUP | LOCATION | 2012 VOLUME | AVERAGE PAYMENT | 2012 TOTAL |
|--------------------|-------------------------------------|------------------------------|----------------|--------------------|---------------|
| M. OHEBSHALOM | PROGRESSIVE UROLOGY | MANHASSET, NY | 729 | \$385 | \$280,772 |
| D. KESSARIS | PROGRESSIVE UROLOGY | MANHASSET, NY | 612 | \$384 | \$235,098 |
| S. LUKE | SPECIALISTS IN UROLOGY | NAPLES, FL | 330 | \$339 | \$111,849 |
| J. JAY | SPECIALISTS IN UROLOGY | BONITA SPRINGS, FL | 293 | \$339 | \$99,285 |
| M. D'ANGELO | 21st CENTURY ONCOLOGY | NAPLES, FL | 276 | \$337 | \$92,915 |
| K. VORA | MICHIGAN INSTITUTE OF UROLOGY | STERLING HEIGHTS, MI | 265 | \$329 | \$87,115 |
| E. GUREVITCH | SPECIALISTS IN UROLOGY | NAPLES, FL | 257 | \$339 | \$87,031 |
| B. GUZ | MICHIGAN INSTITUTE OF UROLOGY | ST CLAIR SHORES, MI | 235 | \$332 | \$78,020 |
| S. SACKS | TOWER UROLOGY | LOS ANGELES, CA | 214 | \$330 | \$70,711 |
| D. WILKINSON | 21st CENTURY ONCOLOGY | BONITA SPRINGS, FL | 195 | \$340 | \$66,264 |
| E. SCHERVISH | MICHIGAN INSTITUTE OF UROLOGY | ST CLAIR SHORES, MI | 185 | \$334 | \$61,813 |
| R. RIVERA | 21st CENTURY ONCOLOGY | BONITA SPRINGS, FL | 158 | \$339 | \$53,556 |
| E. GRIECO | SPECIALISTS IN UROLOGY | NAPLES, FL | 155 | \$339 | \$52,489 |
| M. LIBIN | PREMIER MEDICAL GROUP | POUGHKEEPSIE, NY | 162 | \$309 | \$50,098 |
| M. HOLLANDER | MICHIGAN INSTITUTE OF UROLOGY | WEST BLOOMFIELD, MI | 152 | \$329 | \$49,956 |
| V. GEORGE | MICHIGAN INSTITUTE OF UROLOGY | ST CLAIR SHORES, MI | 146 | \$333 | \$48,678 |
| S. CHAN | PROGRESSIVE UROLOGY | MANHASSET, NY | 126 | \$383 | \$48,216 |
| J. HARDING | MICHIGAN INSTITUTE OF UROLOGY | UTICA, MI | 144 | \$332 | \$47,847 |
| B. SEIFMAN | MICHIGAN INSTITUTE OF UROLOGY | SOUTHFIELD, MI | 147 | \$322 | \$47,321 |
| J. FRONTERA | MICHIGAN INSTITUTE OF UROLOGY | ST CLAIR SHORES, MI | 141 | \$331 | \$46,683 |
| Source: Laboratory | Economics and Medicare Part B carri | er utilization data for 2012 | 2 from CMS | | |

UROLOGISTS BILLING MEDICARE FOR FISH TESTING/CPT 88212

DRUGS-OF-ABUSE TESTING LEADS IN GROWTH

The fastest-growing clinical lab tests over the three-year period 2010-2013 were concentrated in drugs-of-abuse testing related to pain management medication, according to a *Laboratory Economics* analysis of Medicare Part B carrier expenditures for the top 50 CPT codes.

The single-fastest-growing CPT code was 82542 (cannabinoids quantitation by GC/MS), a confirmation test for marihuana/THC. Part B carrier spending on CPT 82542 increased by an average of 59% per year between 2010 and 2013.

In addition, Part B carrier spending on four other test codes for drugs of abuse grew by 30% per year or more during the three-year period. Part B carrier spending on CPT 83925 (opiates) was up an average of 56% per year, while CPT 82145 (amphetamine or methamphetamine) increased 49%, CPT 80154 (benzodiazepines), up 51%, and CPT 83840 (methadone), up 39%.

Other fast-growing tests include CPT 84999 (unlisted chemistry test), commonly used for new molecular and genetic tests, which grew by 32% per year, and Part B carrier expenditures on 84403 (testosterone, total) increased by 15.6% per year during the three-year period.

Overall, Medicare Part B carrier spending on the top 50 clinical lab tests increased by 1% per year between 2010 and 2013.

| СРТ | 2013 | 2010 | 3-Year CAGR* |
|---------------------------------|---------------|---------------|--------------|
| 84443 (TSH) | \$354,797,315 | \$352,458,946 | 0.2% |
| 85025 (CBC) | 327,589,766 | 349,653,828 | -2.1% |
| 80053 (metabolic panel) | 321,183,628 | 318,770,152 | 0.3% |
| 80061 (lipid panel) | 294,955,369 | 309,441,479 | -1.6% |
| 82306 (vitamin D) | 234,140,814 | 222,848,003 | 1.7% |
| 83036 (A1C) | 176,726,748 | 174,384,990 | 0.4% |
| 83925 (opiates) | 172,979,424 | 45,790,112 | 55.7% |
| 82542 (cannabinoids | 106,547,369 | 26,467,993 | 59.1% |
| quantitation by GC/MS) | | | |
| 85610 (prothrombin time) | 100,262,683 | 122,737,331 | -6.5% |
| 84999 (unlisted chemistry test) | 98,215,928 | 43,023,141 | 31.7% |
| 84153 (PSA) | 86,730,810 | 95,558,653 | -3.2% |
| 80048 (metabolic panel) | 84,236,657 | 93,958,136 | -3.6% |
| 82607 (vitamin B12) | 77,937,653 | 71,712,705 | 2.8% |
| 83970 (parathormone) | 72,561,623 | 211,295,265 | -30.0% |
| 84439 (thyroxine, free) | 57,379,897 | 51,552,723 | 3.6% |
| 87086 (urine culture) | 56,327,994 | 53,005,095 | 2.0% |
| 80154 (benzodiazepines) | 52,813,848 | 15,226,247 | 51.4% |
| 82728 (ferritin) | 46,301,329 | 84,786,054 | -18.3% |
| 84403 (testosterone, total) | 45,401,621 | 29,417,647 | 15.6% |
| Continued on next page | | | |

MEDICARE PART B CARRIER SPENDING ON TOP 50 CLINICAL LAB TESTS

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| СРТ | 2013 | 2010 | 3-Year CAGR* |
|---|---------------|---------------|-----------------|
| 83880 (BNP) | 44,184,497 | 54,296,251 | -6.6% |
| 82746 (folate) | 43,687,137 | 43,045,372 | 0.5% |
| 83840 (methadone) | 40,852,607 | 15,296,526 | 38.7% |
| 82570 (creatinine) | 40,397,971 | 31,772,791 | 8.3% |
| 82145 (amphetamine or methamphetamine) | 34,269,232 | 10,279,521 | 49.4% |
| 87186 (MIC) | 33,370,956 | 30,908,064 | 2.6% |
| 85027 (CBC) | 31,626,849 | 27,259,409 | 5.1% |
| 81001 (urinalysis) | 31,415,716 | 30,233,015 | 1.3% |
| 87088 (urine culture) | 26,768,715 | 27,161,428 | -0.5% |
| 83704 (quantitation of lipoprotein) | 25,703,023 | 13,488,835 | 24.0% |
| 86235 (nuclear antigen antibody) | 25,576,726 | 25,478,637 | 0.1% |
| 83550 (TIBC) | 24,553,735 | 52,555,725 | -22.4% |
| 83735 (magnesium) | 24,383,624 | 23,252,214 | 1.6% |
| 83540 (iron) | 23,216,140 | 49,875,219 | -22.5% |
| 84481 (triiodothyronine T3; free) | 23,199,677 | 17,119,467 | 10.7% |
| 82043 (albumin) | 22,544,586 | 18,267,070 | 7.3% |
| 87077 (culture, bacterial) | 21,649,376 | 20,469,249 | 1.9% |
| 81003 (urinalysis) | 19,583,649 | 15,371,321 | 8.4% |
| 80076 (hepatic function panel) | 18,809,939 | 24,576,795 | -8.5% |
| 84480 (triiodothyronine T3; total) | 18,122,115 | 18,449,146 | -0.6% |
| 86003 (allergen specific IgE) | 17,762,243 | 20,589,454 | -4.8% |
| 82784 (immunoglobulin; IgA, IgD, IgG, IgM, each) | 17,719,740 | 16,282,676 | 2.9% |
| 84436 (thyroxine; total) | 17,106,123 | 20,170,877 | -5.3% |
| 84165 (protein; electrophoretic fractionation) | 17,078,685 | 15,428,981 | 3.4% |
| 82378 (CEA) | 16,961,525 | 19,566,410 | -4.7% |
| 83721 (lipoprotein, direct measurement) | 16,216,263 | 19,504,214 | -6.0% |
| 87536 (HIV-1 detection by nucleic acid) | 15,702,171 | 16,171,604 | -1.0% |
| 81002 (urinalysis) | 15,444,325 | 15,922,589 | -1.0% |
| 86038 (Antinuclear antibodies-ANA) | 13,707,103 | 14,016,519 | -0.7% |
| 81000 (urinalysis) | 12,652,596 | 18,244,350 | -11.5% |
| 80102 (drug confirmation) | 12,429,508 | 14,812,300 | -5.7% |
| TOTAL | 3,513,787,028 | 3,411,954,527 | 1.0% |

*CAGR=compound annual growth rate Source: *Laboratory Economics* from CMS's Part B Extract and Summary System (BESS), 2010-2013

LABORATORY ECONOMICS

LAB STOCKS UP 4% YTD

Fifteen lab stocks increased an unweighted average of 4% year to date through November 13. In comparison, the S&P 500 Index is up 11%. The top-performing lab stock so far this year is Enzo Biochem, up 68%, followed by Myriad Genetics, up 59%, and NeoGenomics, up 33%. Quest Diagnostics is up by 19% and LabCorp is up 9%.

| Company (ticker) | Srock Price 11/13/14 | Stock Price 12/31/13 | 2014 Price Change | Market Capitalization (\$ millions) | P/E Ratio | Price/ Sales | Price/ Book |
|-----------------------------|----------------------------|----------------------------|-------------------------|---|--------------|-----------------|----------------|
| Bio-Reference (BRLI) | \$28.98 | \$25.54 | 13% | \$804 | 17.6 | 1.0 | 2.7 |
| Cancer Genetics Inc. (CGIX) | 6.58 | 13.78 | -52% | 64 | NA | 7.5 | 1.7 |
| CombiMatrix (CBMX) | 1.37 | 2.30 | -40% | 15 | NA | 1.1 | 1.8 |
| Enzo Biochem (ENZ) | 4.90 | 2.92 | 68% | 218 | NA | 2.2 | 5.9 |
| Foundation Medicine (FMI) | 24.95 | 23.82 | 5% | 706 | NA | 13.3 | 7.3 |
| Genomic Health (GHDX) | 32.77 | 29.27 | 12% | 1,040 | NA | 3.7 | 7.2 |
| LabCorp (LH) | 99.56 | 91.37 | 9% | 8,413 | 16.1 | 1.4 | 3.1 |
| LipoScience (LPDX) | 5.23 | 4.25 | 23% | 80 | NA | 1.9 | 1.9 |
| Myriad Genetics (MYGN) | 33.35 | 20.98 | 59% | 2,434 | 18.3 | 3.3 | 3.4 |
| NeoGenomics (NEO) | 4.81 | 3.62 | 33% | 288 | NA | 3.0 | 4.9 |
| Psychemedics (PMD) | 15.14 | 14.69 | 3% | 81 | 24.0 | 2.8 | 6.3 |
| Quest Diagnostics (DGX) | 63.77 | 53.54 | 19% | 9,217 | 15.8 | 1.3 | 2.2 |
| Response Genetics (RGDX) | 0.55 | 1.16 | -53% | 21 | NA | 1.2 | 4.2 |
| Sonic Healthcare (SHL.AX) | 18.77 | 16.58 | 13% | 7,530 | 19.5 | 1.9 | 2.4 |
| Veracyte (VCYT) | 7.46 | 14.50 | -49% | 168 | NA | 4.4 | 3.6 |
| Unweighted | | | 4% | | 18.5 | 3.3 | 3.9 |
| Source: Bloomberg | | | | | | | |

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