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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LABS FLOOD CMS WITH COMMENTS ON PROPOSED LAB TEST REPRICING

More than 1,300 lab industry stakeholders submitted comments to CMS regarding its proposed rule for repricing clinical lab tests based on private-payer rates. The deadline for comments was November 24, and CMS must now review all comments prior to issuing a final rule.

As expected, most comments were focused on the proposed exclusion of hospital lab pricing data in the formulation of new lab test prices. The exclusion of hospitals will skew the data toward the lower test prices charged by a handful of the largest commercial lab companies (e.g., Quest Diagnostics, LabCorp, Sonic Healthcare, Bio-Reference, et al.), argued most stakeholders.

The huge volume of comments could sway CMS toward at least requiring hospitals with large outreach labs to submit their pricing data, according to Alan Mertz, President of the American Clinical Laboratory Assn. *Continued on page 2.*

QUEST TO MANAGE LABS FOR BARNABAS HEALTH

Quest Diagnostics has signed an agreement to manage the inpatient clinical labs for all seven Barnabas Health hospitals in northern New Jersey. The arrangement is expected to lower inpatient testing costs and provide expanded information connectivity at Barnabas. *More details on page 7.*

FDA PUSHES FOR NEW ROLE AS LDT WATCHDOG

The Food and Drug Administration (FDA), which has been threatening to begin regulating lab-developed tests for several years now, appears to be positioning itself to become the agency that will crack down on LDTs. The agency on Nov. 16 issued a new report discussing problems with LDTs and presenting case studies of 20 "problematic LDTs," including tests for Lyme disease, ovarian cancer, whooping cough and HPV. "As several lab organizations have now shown, there were some pretty big flaws in that report. However, in terms of timing, I think it shows that FDA is still serious about regulating LDTs, and will likely do something sometime during 2016, if Congress does not act," Peter Kazon, attorney with Alston & Bird, tells *Laboratory Economics*. *Continued on page 6.*

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LABS FLOOD CMS WITH COMMENTS (*cont'd from page 1*)

Mertz notes CMS is required to review all comments submitted and respond to them in its final rule. As a result, he says that CMS will be hard-pressed to issue a final rule before January 1—the date that labs are supposed to begin reporting their private-payer payment rates. The implementation of the newly calculated lab test prices—now scheduled to take effect January 1, 2017—is also likely to be delayed.

In its comments, ACLA recommended that CMS delay its schedule by one year, with the reporting period starting January 1, 2017 and the effective date for new pricing starting January 1, 2018.

Encouragingly, the American Hospital Assn. (AHA), which represents 5,000 hospitals and health systems, came down in favor of requiring hospitals to report their private-payer lab test pricing data. In its comments, AHA noted that while payments for most hospital lab tests provided to Medicare beneficiaries are packaged into their inpatient and outpatient prospective payment systems rates, reimbursement for lab outreach testing services is still made on a fee-for-service basis through the Clinical Laboratory Fee Schedule (CLFS). And for some hospital laboratories, outreach testing represents a significant portion of their overall Medicare services provided. The inclusion of data from hospital lab outreach programs will increase the median CLFS rates and make them more representative of overall market rates, according to AHA.

Some Key Questions and Concerns

- Will hospital labs and more POLs be required to report their private-payer pricing data?
- In what format will labs be required to submit their private-payer data?
- How will CPT codes that are methodology-based or generic in nature be evaluated? These codes are used for more than one procedure and are often paid at different rates.
- How will G codes be handled (i.e., the new drug screen G codes)?
- Will denials (zero payments) be excluded in the data set?
- Will the current timeline for reporting data and effective date for new rates be delayed?

But not all hospital organizations are in favor of reporting, given the complexity of gathering private-payer data and the substantial proposed penalty for failing to report correct data (up to $10,000 per day per test). The Federation of American Hospitals (FAH), which represents 1,000 investor-owned hospitals, has urged CMS to finalize its proposed rule and exclude hospitals from reporting. "Identifying and or reporting individual [lab test] payment values would likely be impossible for hospitals and if the "$0" value of bundled payments is reported, it would likely skew and distort the collected payment information," commented FAH.

The American Medical Assn. (AMA) supported the proposed rule's requirement that only those labs with more than $50,000 in annual Medicare CLFS revenue be required to report. This cutoff would eliminate 94% of physician office labs (POLs) from reporting. AMA had originally advocated for the exclusion of all POLs due to the costs associated with collecting and reporting private-payer data. Similarly, the American College of Physicians, which represents 143,000 internal medicine physicians, supports the proposed rule's plans to exclude nearly all POLs.

The Clinical Laboratory Management Assn. (CLMA) suggested that CMS obtain payment data directly from payers rather than labs. This would remove the issue of defining an applicable

reporting lab by TIN versus NPI or CLIA number. And this would remove the bias of who the applicable reporting labs are and get a fair representation of private-payer rates from the total lab market, commented CLMA.

It's hard to handicap how CMS will respond to these comments in its final rule, says ACLA's Mertz. "We're hoping they find middle ground between requiring no hospitals to report and having all hospitals report."

2016 PRICING FOR DRUG TESTING CODES BETTER THAN ANTICIPATED

As anticipated, the Centers for Medicare and Medicaid Services (CMS) will delete all current drug testing G codes (G6030-G6058, G0432 and G0434) and continue not to recognize the new AMA CPT codes (80300-80377) for drug testing in 2016.

New Drug Testing G Codes and Medicare Rates for 2016

CPT Code	*Description*	*CMS Preliminary Determination*	*Drug Testing Coalition Recommendation*	*2016 Final Rate*
Presumptive				
G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures (e.g., immunoassay) capable of being read by direct optical observation only, per date of service	$9.90	$14.84	$14.86
G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures (e.g., immunoassay), read by instrument-assisted direct optical observation, per date of service.	$19.79	$19.79	$19.81
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers, per date of service.	$59.37	$79.25	$79.25
Definitive				
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolites if performed.	$61.45	1-7 billed individually at $24.58 per drug class	$79.94
G0481	Same as above, 8-14 drug classes.	$78.66	$196.64	$122.99
G0482	Same as above, 15-21 drug classes.	$127.82	$245.80	$166.03
G0483	Same as above, 22 or more drug classes.	$167.14	$294.96	$215.23

Source: https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/clinlab.html

Instead, the agency has created three new G codes for presumptive testing and four new G codes for definitive testing. Only one of the presumptive and one of the definitive G codes may be billed per day. For definitive testing, the unit used to determine the approved definitive G code to bill is "drug class." Each drug class may only be used once per day in determining the appropriate definitive G code to bill.

In terms of pricing these codes, the final payments are not as low as initially proposed; however, they still will result in lower reimbursement for almost all providers of toxicology and drug testing.

Paul Radensky, MD, JD, a principal with McDermott+ Consulting (Washington, D.C.) tells *Laboratory Economics* that stakeholders generally are pleased with the cross-walked rates for the presumptive drug testing codes, but unhappy about the definitive drug test codes and cross-walked amounts. Radensky represents the Drug Testing Coalition, a group consisting of test manufacturers and supported by several lab industry groups (*Laboratory Economics*, Sept. 2015, p. 5).

"The concerns with the definitive drug testing codes are that the descriptors do not provide the granularity that some payers have indicated is important so they can know what specifically is being tested," he says. "The cross-walked amounts result in rates that are substantially lower than current payments."

For definitive testing Tier I through IV, labs are looking at reimbursement cuts of 50% or more compared to current Medicare payment. Tier I is a mixed bag, depending on how many tests a lab performs.

MILLENNIUM LOWERS DEBT THROUGH BANKRUPTCY

Millennium Health (San Diego, CA) has won court approval to proceed with its bankruptcy reorganization plan that will reduce its debt to $600 million from $1.75 billion. In conjunction with the bankruptcy plan, Millennium's founder James Slattery and its biggest investor, TA Associates Inc., have agreed to contribute $325 million to the reorganization.

The lowered debt and $325 million cash infusion will allow Millennium to remain in business and pay a $256 million settlement with the federal government for allegedly billing Medicare and Medicaid for unnecessary tests.

Under the company's reorganization plan, its $1.75 billion senior secured term loan due in 2021 will be lowered to $600 million. Those creditors, including Oppenheimer Funds, Fidelity Investments and Eaton Vance Funds, will also receive equity ownership of Millennium. The reorganized Millennium will worth an estimated $900 million, so lenders are getting a recovery of about 50 cents on the dollar.

Despite its problems, Millennium is still the biggest drug-testing lab in the U.S. and the biggest recipient of Medicare drug-testing payments. The company has approximately 1,200 employees, including 516 sales and marketing employees. Millennium's bankruptcy reorganization plan projects that the company will generate operating cash flow of $98 million on revenue of $434 million in 2016.

But these projections might prove to be too optimistic, notes *Laboratory Economics*. Medicare payments for drug testing are being capped next year (see article above). In addition, Millennium and other drug testing labs face increased scrutiny of test utilization, lower reimbursement and potential settlement payments with commercial health insurance companies.

2016 MEDICARE PAYMENT DECISIONS FOR MOLECULAR TEST CODES

Final 2016 Medicare payment decisions for new molecular test codes is mostly consistent with recommendations from leading industry groups, although at least one code (81246) will be priced at about half of what the College of American Pathologists (CAP) had recommended.

For genomic sequencing procedures, CMS chose to use the gapfilling process, which was supported by the American Clinical Laboratory Association, says Paul Sheives, vice president, reimbursement and regulatory policy for ACLA.

"It is important that CMS work with the local contractors through the gapfill process to ensure adequate data is collected to accurately set the rates for these codes," Sheives tells *Laboratory Economics*. Medicare payment decisions for these codes is expected in late 2016 and effective Jan. 1, 2017.

Final Medicare Payment Decisions for Molecular Tests for 2016

CPT Code	Description	CAP Recommends	2016 Final Payment	% Difference
81162	BRCA1, BRCA2	$2,759.30	$2,485.86	-9.9
81170	ABL1 (ABL proto-oncogene 1)	329.18	329.51	0.1
81218	CEBPA mutation analysis	329.18	329.51	0.1
81219	CALR gene analy., common variants in exon 9	165.51	165.68	0.1
81272	KIT gene, targeted seq. analysis	329.18	329.51	0.1
81273	KIT gene analysis, D816 variant(s)	178.80	124.87	-30.2
81276	KRAS gene analysis; add'l variant(s)	196.99	197.19	0.1
81311	NRAS gene analysis, variants in exon 2	393.98	295.79	-24.9
81314	PDGFRA targeted sequence analysis	329.18	329.51	0.1
81246	FLT3, gene analysis	165.51	83.04	-49.8
81288	MLH1 gene, promoter methylation analysis	190.20	159.64	-16.1
81313	PCA3/KLK3	282.12	260.26	-7.7
Genomic Sequencing (selected)				
81412	Ashkenazi Jewish disorders sequence analysis panel (at least 9 genes)	$2,188.12	Gapfill	NA
81432	Hereditary breast cancer (14+ genes)	$2,586.92	Gapfill	NA
81433	Hereditary breast cancer disorders; duplication/deletion analysis panel	$1,591.95	Gapfill	NA

Source: *Laboratory Economics* from CAP and CMS

Meanwhile, CMS has chosen to price new multi-analyte algorithmic assays (MAAAs) using the gapfill process rather than crosswalking as proposed in its preliminary determinations. If CMS's preliminary determinations had been finalized, the cross-walks would have resulted in payment cuts of 30% to 90% from existing reimbursement.

For example, CMS's initially proposed cross-walk for CareDx's AlloMap test, a MAAA for heart transplant recipients, would have reduced reimbursement from the current rate of $2,821 to $645, a cut of 77%.

The decision to gapfill new MAAAs is in line with recommendations from The Advisory Panel on Clinical Diagnostic Laboratory Tests (the expert panel required by PAMA). Under the gapfill process, local Medicare Administrative Contractors (e.g., Palmetto) will price these tests and rates are expected to be retained close to current rates.

FDA Pushes for New Role as LDT Watchdog (*cont'd from p. 1*)

The report was released on the eve of a congressional hearing held by the House Energy and Commerce subcommittee, which is considering legislation that could limit the agency's regulatory powers. The FDA has long maintained that it has exercised "enforcement discretion" toward LDTs, but the agency issued draft guidance on regulation of these tests last year and reportedly is working on finalizing this guidance. Lab stakeholders argue that such regulation will stifle innovation.

"We examined events involving 20 LDTs that illustrate, in the absence of compliance with FDA requirements, that these products may have caused or have caused actual harm to patients," writes the FDA in the report. "In some cases, due to false-positive tests, patients were told they have conditions they do not really have, causing unnecessary distress and resulting in unneeded treatment. As a result, patients failed to receive effective treatments."

During the Nov. 17 hearing, officials from the Centers for Medicaid Services (CMS) supported an increased oversight role by the FDA, but a number of lawmakers appeared unconvinced that the FDA needs to take over LDT oversight from CMS.

Rep. Joe Barton (R-Texas) said he didn't believe that the current system of oversight under CLIA was insufficient. "I'm not being a horse's rear on this, but if it's not broke, don't fix it," he said. "It just looks to me like we're looking for ways to give FDA and CMS more authority."

The draft guidance released by the FDA in 2014 would base oversight on levels of risk and would phase in requirements for tests over nine years. About half of the estimated 11,000 LDTs (FDA's number) would fall into the low-risk category and would not require pre-market approval, while 2% of the high-risk and 48% of the moderate-risk tests would have varying levels of approval required.

In contrast, the House has been considering an alternative proposal from the Diagnostic Test Working Group, which consists of representatives from Becton Dickinson, Roche, Mayo Clinic, LabCorp, Abbott and ARUP Labs. This plan would spread LDT oversight over FDA, CMS and the states and would create a new category of tests, in vitro clinical tests (IVCTs), which could describe LDTs or kits. CMS would remain in charge of traditional lab activities necessary to perform the tests while FDA would have authority over test development and validation.

FDA Questions Seven Genetic Testing Companies

Meanwhile, the FDA continues to assert its authority to regulate genetic tests marketed directly to consumers. Since September, the agency has sent letters to seven genetic testing companies asking each to explain why their tests do not need regulatory clearance. The seven companies are:

1. **DNA4Life** (Mandeville, LA): Markets a pharmacogenetic test to predict patient response to 120 commonly prescribed drugs.
2. **DNA-CardioChek Inc.** (Lisle, IL): Offers a test for genetic markers associated with cardiovascular disease, stroke, deep-vein thrombosis, and thrombophilia.
3. **Genomic Express** (Westlake Village, CA): Markets drug metabolism tests for Plavix, Coumadin and Tamoxofin.
4. **Harmonyx** (Cordova, TN): Markets genetic tests to consumers at pharmacies (see page 8).
5. **Healthspek LLC** (Brentwood, TN): Markets drug metabolism tests.
6. **Interleukin Genetics** (Waltham, MA): Markets tests to identify individuals with a genetic predisposition for periodontal disease, osteoarthritis-related conditions, and obesity.
7. **Pathway Genomics** (San Diego, CA): Markets a test for the early detection of up to 10 different cancer types in high-risk populations.

QUEST TO MANAGE LABS FOR BARNABAS HEALTH (*cont'd from page 1*)
The deal does not include outpatient/outreach testing or anatomic pathology services, which will remain under the management of Barnabas Health and its pathology department. Barnabas Health will also retain medical directorship at all its laboratories.

Under the agreement, Quest Diagnostics will manage the inpatient lab operations for:

- Clara Maass Medical Center (Belleville).....429 beds
- Community Medical Center (Toms River) .....533 beds
- Jersey City Medical Center (Jersey City) .....316 beds
- Monmouth Medical Center Southern Campus (Lakewood) .....350 beds
- Monmouth Medical Center (Long Branch) .....329 beds
- Newark Beth Israel Medical Center (Newark).....408 beds
- Saint Barnabas Medical Center (Livingston) .....577 beds

Some hospital lab management positions will be transferred to Quest Diagnostics, but the majority of 700+ lab workers will remain employees of Barnabas Health. In addition, over the next six months, some clinical lab testing volumes will be transitioned to Quest's regional lab in Teterboro, NJ.

On an October 22 conference call with investors, prior to the announcement of the Barnabas agreement, Quest's Chief Financial Officer Mark Guinan described Quest's search to provide management services to hospital inpatient labs:

> The way these deals work is, given our economies of scale and our efficiencies, we can save them [hospital inpatient labs] significantly enough money to get them to sign a multiyear contract with us to perform that service for them and we basically split that savings with them as part of the negotiation, but we don't have a large capital outlay. It's a source of organic growth that largely was unaddressable previously.

In addition, Quest says it will continue to pursue the acquisition of hospital lab outreach businesses. Last month, Quest announced a deal to buy Clinical Laboratory Partners (Newington, CT), an outreach lab owned by Hartford Healthcare (see *LE*, November 2015, p. 8).

LABCORP TO BUY PATHOLOGY INC. IN CALIFORNIA

LabCorp has agreed to buy the operating assets of Pathology Inc. (Torrance, CA). The purchase price was not disclosed. The deal is expected to close in early 2016.

Pathology Inc. is a full-service histology and Pap testing lab that receives professional services from Affiliated Pathologists Medical Group (Rancho Dominguez, CA), an independent pathology group with approximately 35 pathologists.

Upon closing of the transaction, Pathology Inc. will cease operations. Its volumes are expected to be transitioned to nearby LabCorp facilities.

Pathology Inc. was founded by pathologists, including its Chairman Alfred Lui, MD, in 1979.

Pathology Inc. was acquired by ABS Capital Partners in 2009. ABS then hired Vicki DiFrancesco as CEO and Steve Pierce as CFO to run the company. Pathology Inc. went on to acquire two clinical labs in 2011: Central Coast Clinical Labs (Templeton, CA) and West Coast Clinical Labs (Van Nuys, CA).

ABS Capital has backed other lab companies, such as Inform DX (sold to AmeriPath for $55 million), US Pathology Labs (sold to LabCorp for $155 million) and American Esoteric Labs (sold to Sonic Healthcare for $180 million).

SONORA QUEST OFFERING DTC TESTS AT SAFEWAY STORES

Sonora Quest Laboratories (Tempe, AZ) has opened patient service centers at one Safeway Store in Scottsdale, Arizona (opened Nov. 16) and a second at a Safeway Store in Phoenix (opened Nov. 30). The PCSs will provide consumers access to lab testing with or without a physician order inside Safeway stores, directly next to the pharmacy. Earlier this year, Sonora Quest began offering a limited menu of direct-to-consumer (DTC) tests through its existing 70 PSCs throughout Arizona (see *LE*, Sept. 2015, p. 1).

Christina Noble, Vice President of Business Development at Sonora Quest, says the two new PSCs at Safeway will serve both out-of-pocket consumers buying lab tests on their own, as well as patients with a doctor's order covered by Medicaid, Medicare or private insurance. Marketing is limited to the Sonora Quest website and in-store advertising at the two Safeway stores. If the first two sites are successful, Noble says there is the potential to expand into more Safeway stores.

Noble says Sonora Quest is offering approximately 30 tests and test panels direct to consumers, but it doesn't market esoteric tests that may confuse consumers if results are interpreted out of context. She describes the company's pricing as fair. "We don't want to be the low-price leader." For example, Sonora Quest has priced a lipid panel at $21, Vitamin D test at $36 and STD screen (GC/chlamydia, herpes, syphilis and HIV) at $210.

Safeway had previously had a more ambitious deal with Theranos to open PSCs at 800 Safeway supermarkets nationwide. However, Safeway reportedly backed out after Theranos missed several deadlines, and due to concern that its technology might still be "a work in progress." [*WSJ*, Nov. 10, 2015]

Meanwhile, the Sonora Quest-Safeway deal represents Quest's second attempt to crack the elusive DTC testing market. Quest tried in 2002-2004 by opening PSCs at CVS Stores, Giant Food Supermarkets and Stop & Shop Supermarkets. But these partnerships were shut down in 2005 due to lack of demand.

Quest CEO Steve Rusckowski has said that the company will expand its DTC programs to other states if successful in Arizona.

THERANOS MEDICAL CONSULTANT QUESTIONS TECHNOLOGY

Theranos recently hired Waldo Concepcion, MD, the chief of clinical transplantation surgery at Stanford University Medical Center, who is working as a "senior medical staff member" at Theranos' laboratory in California, according to the company. However, in a recent interview with *Bloomberg Businessweek*, Dr. Concepcion seemed to cast doubt on the accuracy of Theranos' testing technology.

> Of all the advisers *Bloomberg Businessweek* interviewed, Concepcion was the most candid in saying the tests' accuracy isn't yet guaranteed. Based on the data he's seen, though, he says he's "encouraged" that the technology is feasible. The first step is, "Does it work?" he says. "And if it does not work, can we tweak it until it does work?"
>
> —from *Bloomberg Businessweek*, December 10, 2015

Keep in mind that Theranos had been testing some patient samples using its own technology for at least part of this year and in 2014. Then in the late summer, the FDA told Theranos its Nano-

tainer blood collection tube needed regulatory approval as a medical device. Theranos says that it has "temporarily paused" use of its Nanotainer tubes for all tests except its cleared HSV-1 test. The company is currently taking samples using venous blood draws and using traditional lab analyzers.

But can you imagine Roche Diagnostics or Beckman Coulter introducing a new lab analyzer to the market when its "accuracy isn't yet guaranteed?" We asked Theranos to respond to Dr. Concepcion's comments, but the company did not return our phone calls or e-mails.

Law Firm Investigating Theranos for Potential Action

Meanwhile, the law firm Kessler Topaz Meltzer & Check, LLP (Philadelphia and San Francisco) says its investigating a potential action concerning investors in Theranos. Kessler Topaz has 100 lawyers and specializes in contingent class-action lawsuits for victims of fraud.

RITE AID OFFERING HARMONYX GENETIC TESTS

The drug store chain Rite Aid Corp. (Camp Hill, PA) has begun offering select genetic tests at all its stores nationwide (except those in New York) to walk-in customers. The tests will be performed by Harmonyx Diagnostics, an independent lab company with a CAP-accredited laboratory in Memphis, TN.

The initial test menu includes three genotyping tests designed to predict a patient's response to three classes of medication, including those used to manage cardiac conditions, cholesterol and attention-deficit hyperactivity disorder.

Customers can purchase sample collection kits for the three tests at approximately 4,000 Rite Aid locations. (Harmonyx also markets its testing service at 1,000 independent pharmacies.) Prices are $49 for the SLC01B1 gene test for statin drugs, $59 for the CYP2C19 gene test for Plavix, and $89 for the gene panel test for ADHD drugs (Adderall, Dexedrine, Ritalin, Wellbutrin, et al.). The test prices include all costs to the patient, including collection kit, postage and test result.

The kits include two oral swabs that customers use to self-collect saliva samples from their left and right cheeks. The swabs are then placed in a sample collection envelope and sent to Harmonyx's lab in Memphis. Each test request is reviewed by a contracted clinician (MD or NP), who will, when appropriate, order the test in question.

Todd Poley, marketing director for Harmonyx, says the program has been rolled out at Rite Aid stores over the past 12 months. He says the greatest demand has been for Harmonyx's ADHD test. The test helps patients and their physician determine whether they can safely continue taking their medicine, or if they should seek a new course of treatment.

FDA Questions Harmonyx Tests

Meanwhile, on November 16, just days after Harmonyx issued a press release announcing its testing service at Rite Aid stores, the FDA sent a letter to Harmonyx stating that its tests may require regulatory clearance. "If you do not believe that you are required to obtain FDA clearance for the Harmonyx tests, please provide us with the basis for that determination," stated the FDA.

Poley says Harmonyx is responding to the FDA's inquiry and is confident that the agency will find that the company's testing process is in compliance with FDA guidance and regulations. In the meantime, he says that Harmonyx is continuing to offer its tests at Rite Aid stores and other pharmacies.

MEDICARE SPENDING ON DIGITAL IHC REBOUNDS

Medicare Part B carrier spending on CPT 88361 (digital pathology for quantitative IHC) increased by 22% to $14.3 million in 2014. This rebound follows two years of shrinkage of the digital pathology market in 2012 and 2013. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor.

The increase in 2014 was driven by two factors: 1) the number of Part B allowed claims for CPT 88361 rose by 9% to 155,806 claims; and 2) the average allowed payment per claim (including TC, PC and global claims) increased by 11% to $91.51.

Nonetheless, the digital pathology market is evolving much more slowly than experts had predicted a few years ago. Barriers to greater adoption include: cost, speed and limited FDA clearance.

FDA officials have repeatedly stated that "Whole Slide Imaging (digital pathology) raises new questions of safety that must be answered by premarket approval (Class III)."

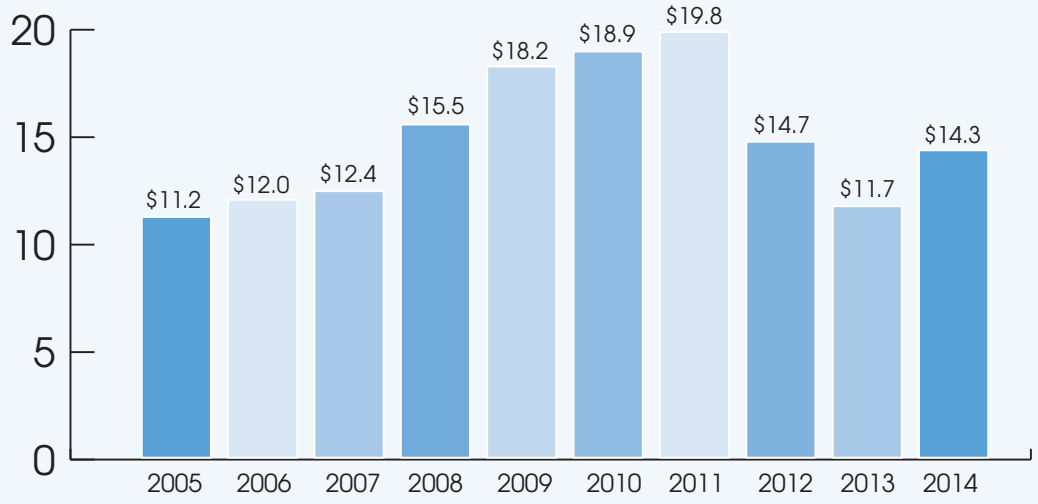
FDA Behind the Curve?

Several digital pathology vendors, including Leica Biosystems, Roche's Ventana, Royal Philips, and Omnyx LLC (a GE-UPMC joint venture), have received FDA clearance for HER2 scoring and a handful of other breast cancer tests.

But no vendor has received the Holy Grail: FDA clearance to use digital pathology for primary diagnosis of cancer (i.e. signing out cases based solely on the review of the digital slide). In fact, vendors are still waiting for the agency to issue final guidance providing details on the design of pivotal clinical studies supporting safety and effectiveness that will be required to obtain FDA clearance.

Meanwhile, digital pathology vendors are making much more progress abroad. Aperio (now owned by Leica Biosystems) had its digital pathology system CE Marked (Conformité Européene) in the European Union for primary diagnosis in June 2012. Systems made by Omnyx LLC, Royal Philips, and Ventana were CE marked in 2013-2014. Similarly, several digital pathology systems have received Health Canada approval as Class II medical devices.

Medicare Part B Allowed Charges for CPT 88361 ($ millions)



Source: CMS National Summary Data Files, 2005-2014

FORMER AP MANAGER GETS 5 YEARS FOR STEALING FROM AURORA

Jessica L. Hess has been sentenced to five years in prison for embezzling $371,496 from Aurora Diagnostics over five years (see *LE*, April 2015, p. 7). As an accounts payable manager at Aurora's corporate headquarters in Palm Beach Gardens, Florida, Hess manipulated documents and diverted funds 138 times between March 2011 until she was fired in July 2014. The theft was only uncovered after an Aurora executive received an anonymous phone call tipping her off that Hess was stealing from company accounts. The theft by Hess devastated Aurora, which was already reeling under Medicare rate cuts and competition, company officials told Palm Beach County Circuit Judge Charles Burton.

Details on Recent Acquisitions by Aurora

Separately, Aurora reports that it paid $8.8 million in cash for its July 15 acquisition of Brazos Valley Pathology (Bryan, TX). In addition, Aurora issued contingent notes payable over six years. Payments up to a maximum total of $9.3 million will be made to the former owners subject to the acquired pathology group's retention of certain key hospital contracts and the cash received from specified client contracts. Brazos Valley Pathology includes two hospital-based groups with five pathologists serving three hospitals in central Texas (see *LE*, July 2015, p. 11).

Aurora also reported that it paid $6.6 million in cash for its Oct. 29 acquisition of Consultants in Laboratory Medicine of Greater Toledo Inc.(CLM). In addition, Aurora agreed to pay a maximum $2.65 million contingent upon the retention of certain hospital contracts and financial performance of the acquired pathology group. CLM is a hospital-based practice with 16 pathologists providing professional services to 11 hospitals of ProMedica Health System (see *LE*, Nov. 2015, p. 8).

PIEDMONT PATHOLOGY SETTLES FALSE CLAIMS CHARGE FOR $500K

Piedmont Pathology, an anatomic pathology group and lab located in Hickory, North Carolina, has agreed to pay the United States $500,000 to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring physicians.

The government's investigation was prompted by a former contract salesperson who alleged that the group was providing Electronic Medical Record (EMR) software licenses to various physicians' practices in exchange for referrals.

The salesperson filed a lawsuit under the qui tam provision of the False Claims Act. Subsequently, the Office of the Inspector General found that Piedmont Pathology provided EMR software licenses at little to no cost to nine physicians' practices and that those practices then entered into contracts to refer specimens to Piedmont Pathology's lab.

The whistleblower will receive 15% of the funds of the settlement, or $75,000, and is also entitled to reimbursement of her costs and attorney fees.

LAB STOCKS DOWN 14% YTD

Fifteen lab stocks have declined by an unweighted average of 14% year to date through December 14. In comparison, the S&P 500 Index is up 3%. The top-performing lab stocks so far this year are NeoGenomics, up 76%, and Myriad Genetics, up 25%. Meanwhile, LabCorp is up 11% and Quest Diagnostics is up 1%.

Company (ticker)	Stock Price 12/14/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.87	$6.68	-57%	$39	NA	1.8	1.3
CombiMatrix (CBMX)	0.71	1.29	-45%	9	NA	0.9	1.2
Enzo Biochem (ENZ)	4.78	4.44	8%	220	37.1	2.3	4.8
Exact Sciences (EXAS)	8.00	27.44	-71%	771	NA	29.1	2.1
Foundation Medicine (FMI)	16.68	22.22	-25%	575	NA	7.0	2.2
Genomic Health (GHDX)	28.80	31.97	-10%	937	NA	3.3	7.0
Invitae (NVTA)	7.33	16.00	-54%	234	NA	38.8	1.5
LabCorp (LH)	119.68	107.90	11%	12,110	26.1	1.6	2.5
Myriad Genetics (MYGN)	42.65	34.06	25%	2,980	34.4	4.0	4.3
NeoGenomics (NEO)	7.36	4.17	76%	446	NA	4.5	7.1
Opko Health (OPK)	9.60	9.99	-4%	5,230	NA	23.5	2.9
Psychemedics (PMD)	10.86	15.15	-28%	59	29.3	2.1	4.8
Quest Diagnostics (DGX)	67.46	67.06	1%	9,380	13.8	1.3	2.1
Sonic Healthcare (SHL.AX)	18.50	18.50	0%	7,645	21.5	1.8	2.3
Veracyte (VCYT)	6.82	9.66	-29%	189	NA	4.0	3.3
Unweighted Averages			-14%		27.0	8.4	3.3

Source: Capital IQ

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