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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

DOJ INVESTIGATING LAB PAYMENTS TO DOCTORS

The Department of Justice (DOJ) is conducting an investigation into the processing and handling fees that some labs pay to referring physicians. The P&H fees are meant to cover the costs that physicians incur for labeling and packaging patient samples, but DOJ believes the fees may constitute illegal remuneration designed to induce physician lab test orders.

In particular, DOJ is investigating several labs specializing in advanced lipid testing. These labs market test panels, which can include 20 or more tests, designed for early detection of heart attack, stroke and diabetes. A recent front-page article in the *Wall Street Journal* highlighted Health Diagnostic Laboratory Inc. (Richmond, VA), which, until late June, paid $20 per blood sample to most doctors ordering its tests. Formed in 2008, HDL has rapidly grown into one of the nation's largest lab companies with revenue of $383 million in 2013, including 41% from Medicare.

In response to the WSJ article, HDL said that it "vehemently disagrees with any insinuation that payments to doctors were an inducement, or that the payments were illegal or known to violate any law." *Cont'd on page 6.*

CMS DRIVING BLIND AS IT PUSHES MORE SERVICES INTO OUTPATIENT BUNDLES

This year CMS eliminated separate payment for approximately 1,000 clinical lab tests by packaging them under the outpatient prospective payment system (OPPS) rather than continuing separate payment for them under the CLFS. The agency asserted that this policy would "contain unnecessary growth" in spending in the outpatient setting. CMS's move towards greater levels of packaging is an effort by the agency to move the OPPS away from a fee-for-service type system and more towards a true prospective payment system where a single payment is made for a larger "bundle" of services. For 2015, CMS has proposed eliminating separate payment for 300+ more codes, including most pathology TC services and some professional services. *Cont'd on page 2.*

Proposed to be Bundled in 2015

- X-ray exams
- Blood typing tests
- Most Pathology TC services
- Some Pathology PC services

Source: CMS Proposed OPPS Rule 2015

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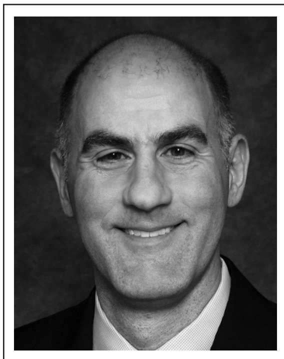
CMS PUSHES MORE SERVICES INTO OUTPATIENT BUNDLES (*cont'd from p. 1*)

This year's shift of clinical lab tests into outpatient bundled payments affected nearly $3 billion of Part B lab test spending, according to estimates from CMS's 2014 Medicare Trustees Report. CMS claimed that the shift in payment mechanism was budget-neutral, but the agency never provided any details to prove that the bundled payments were enough to cover the costs of all the services involved, including clinical lab tests. As a result, the 2014 bundling rule was uniformly opposed by all the major lab and pathology trade associations including AACC, ASCP, CAP as well as The American Hospital Association.

Although difficult to precisely quantify, the switch to bundled payment for outpatient lab tests has clearly resulted in reduced reimbursement for these tests, according to **Lale White**, President of the billing firm **XIFIN Inc.** (San Diego, CA).

Bundling is a capitated payment but with a less-threatening name, says White. She notes that capitation became a bad word when HMOs used it to contain healthcare costs in the 1990s, so CMS is using "bundled" or "packaged" payment terminology more consistent with the DRG concept.

White says that bundling has had a big impact on independent labs that perform outpatient reference tests. Independent labs have been forced to negotiate lower direct payment from hospitals. As a result, independent labs are now receiving roughly 20% to 30% less for outpatient lab tests versus the rates they had received when these services were paid off of the Clinical Lab Fee Schedule. She notes that this is somewhat offset by the lower bad-debt associated with non fee-for-service billing. Another positive is that molecular and genetic tests can still be billed separately through the CLFS and will not become part of the bundled payment for outpatient services any time soon, adds White.



Steven Kroft, MD, President of the **American Society for Clinical Pathology**, says ASCP opposed Medicare's bundling of outpatient clinical lab tests due to concern that this policy could result in inadequate payment rates and increased administrative burden on pathologists and labs. Kroft says that CMS provided scant information regarding the financial impact that bundling outpatient lab tests would have on hospitals and never responded to ASCP's concerns about a lack of detail in the rule.

For these same reasons, ASCP is opposing CMS's proposed plans to add most pathology technical services (levels 1 and 2) into bundled payments for outpatients starting in 2015. "The impact of the first year of bundling hasn't been assessed, yet CMS wants to expand bundling to pathology services," notes Kroft.

Kroft notes that many of the services impacted by the Proposed Rule for 2015 may be medically necessary multiple times per day, depending on the primary service and the patient's specific condition. Failure to precisely craft packaged payment rates could lead to inaccurate, and likely insufficient, payment. ASCP is concerned that if CMS is unable to properly value and estimate the typical number of ancillary services accompanying each primary service, that this could result in the undervaluation of critical pathology and clinical lab services and eventually their underutilization at hospitals.

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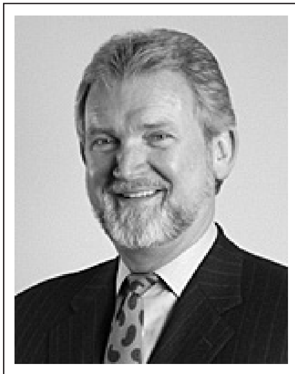
"We believe that the packaging proposal could adversely impact hospital laboratories' financial outlook, which could, in turn, affect the service menu offerings of hospital laboratories. The reduced reimbursement may force hospitals to outsource some of the pathology services they now provide in-house. Such a development could be problematic for patient care, as it could negatively affect turnaround times on critical pathology and clinical laboratory services," according to ASCP's comments to CMS on the Proposed Rule for 2015.

Kroft says another concern with bundling is that it shrinks the market share that hospital labs will have in the calculations that CMS will use when repricing the CLFS. Only those tests that are reimbursed on a fee-for-service basis (e.g. outreach tests) will be counted. The exclusion of hospital outpatient lab test volumes and prices will lower the weighted average lab test price, he notes.



CAP President **Gene N. Herbek, MD**, tells *LE* that "The CAP continues to have serious concerns with packaging policies in general and with the expanded packaging proposed by CMS for 2015. As in the proposed rule for 2014, we believe that CMS is proposing an unwarranted and untested expansion of bundling without first taking adequate steps to define the proposals in sufficient detail to engage with stakeholders, to understand the impact of the proposal on affected groups, or to anticipate possible consequences that could adversely affect quality of care and access to services. The CAP urges CMS to withdraw its proposal to package laboratory services under this proposed ruling."

"CMS contends that the OPPS is budget neutral, so in theory, all of the packaging is fine…but it's important that the packaged dollars go to the right place and not just wherever they land."
—Jugna Shah

Jugna Shah, President of **Nimitt Consulting** (Washington, DC), a consulting firm that specializes in hospital outpatient reimbursement issues, says that it's very difficult to determine whether lab and other ancillary service costs have been appropriately packaged into the payment of other services, which continue to be separately paid. For example, the 2015 proposed APC payment rate for an evaluation and management clinic visit (G0463) only rises by 6% over the current rate, yet this rate is supposed to cover the cost of treating any clinic visit patient on average; whether that is a level one or a level five and it's intended to cover the cost of clinical lab tests, pathology TC services, X-rays, EKG and many other ancillary services. Medicare's proposed rates for CY 2015 raise questions about the expanded packaging proposed and given that we don't even know the impact of all of the lab packaging that went into effect for this year it seems premature for the agency to make such an aggressive move forward to even more packaging. The question at hand is whether Medicare's packaging logic has appropriately accounted for the costs of the services such as lab tests that are no longer paid separately though the payment of other APC services.

In particular, Shah says, hospitals which see higher-acuity clinic visit patients are likely being hit the hardest and facing a double whammy of a singular clinic visit payment (G0463 currently set at $92.53) combined with the removal of separate payment for lab tests and many other ancillary services. "Of course CMS's intent is to create incentives for hospitals so they reduce 'waste and inefficiency'

but this must be balanced with continuing to provide fair and appropriate payment," says Shah. But she notes that analysts including herself are still trying to understand all of the details behind CMS's proposals to determine whether the move to a greater bundled payment system is being done appropriately. "The fact that CMS is marching forward with its plans to eliminate separate payment for even more services in 2015 is likely premature and hopefully the agency will listen to commenters and delay further packaging," says Shah.

Though Medicare's increased packaging towards greater bundles of services is intended to incentivize hospital outpatient departments to better coordinate care and discourage overutilization of imaging and lab tests, Shah worries that if the rates are inappropriately low, CMS's policies may backfire and could actually result in care fragmentation where hospitals end up scheduling a patient's services on different days so they are able to remain whole by receiving separate payment for the services provided.

In the long run, Shah says, there is danger that future bundled payment rates will not be adjusted to accurately reflect all services provided by hospitals' outpatient departments, given that CMS's packaging logic is not as sophisticated as it needs to be to account for increased bundling. Another concern is that as more items and services are bundled and hence not paid for separately, providers may have little to no incentive to take the time to report all of their services. "We've seen this in the past and though Medicare has been clear that everything provided should be reported, that simply isn't the reality. So future Medicare rate decisions for bundled payments won't fully reflect all outpatient costs," explains Shah.

The Bundling of Pathology Professional Services?

The million dollar question is "If and when will CMS bundle professional component payments?" Under this scenario, physicians would no longer bill Medicare separately for their professional services or receive reimbursement for them, but instead the hospital would bill for the services and receive a single payment from Medicare for both the technical and professional costs and would then pay out their physicians. Shah believes that payors would probably prefer this approach, but the odds of this happening are slim to none until the American Medical Assn. and other physician groups agree to have their money paid out by hospitals.

But the bundling of pathology professional services may already be starting. The OPPS Proposed Rule for 2015 targets several pathology codes for bundling, including CPT codes 88380 (Microdissection laser), 88381 (Microdissection manual), 88387 (Tissue exam molecular study) and 88388 (Tissue exam molecular study, add-on), that are reimbursed under the PFS.

Matthew Schulze, Director of Government Relations at **ASCP**, believes these codes may have been included in the proposal in error. Nonetheless, ASCP maintains that it is inappropriate to package any pathology professional service into OPPS payment rates. "It would be wrong to incorporate any professional services into the OPPS packaging policies without clearly stating in the NPRM the Agency's plans and rationale," says Schulze. Accordingly, ASCP has urged CMS to remove these codes from its bundling proposal.

Bundling's Impact on CLFS Repricing

Beginning Jan. 1, 2016, "applicable laboratories" must report to CMS the payment rates (after all discounts) that they receive from private payers for all clinical lab tests. The information will be used by CMS to reprice tests on the CLFS effective Jan. 1, 2017.

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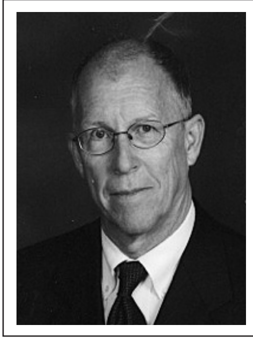

Charles Root, PhD, Chief Executive of **CodeMap LLC** (Schaumburg, IL), notes that the bundling of outpatient lab tests and pathology services will disqualify most hospitals from having to report their pricing data. This is because the term “applicable laboratory” is defined by CMS as a lab that receives the majority of its Medicare revenue from the CLFS or PFS. The switch to bundled payments for outpatient clinical lab tests and pathology services means that only hospitals with very large lab outreach programs will fall under the definition of an “applicable laboratory” and be required to report their private payer pricing data, explains Root.

Because hospitals tend to have higher lab test prices as compared with independent labs, the loss of hospital pricing data will lower the “weighted median” prices calculated by CMS when it reprices the CLFS. Root says that this could result in significant price cuts (up to 10% per year) for most tests on the CLFS beginning in 2017. As a result, the American Clinical Laboratory Assn. is actively lobbying to convince CMS to require hospital lab outreach test volumes to be reported and included in the repricing formula.

But hospitals are leery of the complexity involved with reporting private payer data and the penalties associated with reporting incorrect data. So the American Hospital Assn. is seeking to minimize the reporting burden on hospitals. In an August 27 Comment Letter to CMS, AHA stated that given the bundled payment policies, “It seems unlikely that there would be many hospital laboratories for which revenue for clinical diagnostic laboratory tests paid under the CLFS or the PFS would constitute the majority of their Medicare laboratory revenue, i.e., that would be considered to be “applicable laboratories” required to report under the PAMA.”

CMS is expected to release the exact parameters for data collection through rulemaking, possibly by the end of this year.

Some Problems with Bundled Payment:

- ❏ The switch to bundled payment turns outpatient lab testing into a cost center as opposed to a revenue generator in the eyes of hospital administration.
- ❏ Bundling makes it more difficult for hospitals to determine actual revenue attributable to outpatient lab tests, which will have a significant downstream effect on hospital lab budgeting and decisions regarding capital expenses.
- ❏ Academic medical centers and cancer hospitals have been hit the hardest through a combination of lowered average outpatient clinic visit rates plus the bundling of lab tests.
- ❏ Independent labs serving outpatients have been forced to seek payment directly from hospitals and are now receiving roughly 20% to 30% less for outpatient lab tests versus the rates they had received when these services were paid from the Clinical Lab Fee Schedule.
- ❏ Historically, when CMS no longer pays separately for an item, hospitals collectively respond by stopping reporting that item and this loss of claims data has a downward spiral effect on future payment rates.
- ❏ The shift of nearly $3 billion of outpatient lab tests from fee-for-service to bundled payment can only have a negative effect on CMS’s plans to reprice the CLFS. That’s because it limits the number of hospitals that will be categorized as an “applicable laboratory” required to report private payer lab test rates.

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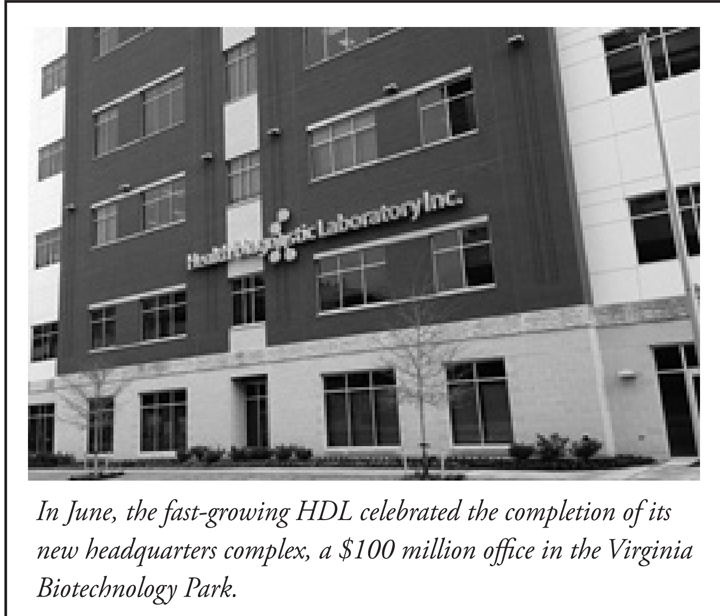
DOJ INVESTIGATING LAB PAYMENTS TO DOCTORS (*cont'd from page 1*)

In a Sept. 8 press release, HDL said:

> *"As we confirmed to The Journal, the Department of Justice (DOJ) is conducting what we understand to be an industry-wide review of certain clinical laboratory practices, many of which have been longstanding within the industry. HDL, Inc. has been cooperating fully with the government investigation and has consistently complied with all applicable legal and regulatory requirements. In the event that the DOJ investigation results in legal action against HDL, Inc., we are prepared to defend our business practices vigorously."*

Other labs under investigation include Quest's Berkeley HeartLab, Singulex Inc., Boston Heart Diagnostics and Atherotech Diagnostics Lab. Quest says Berkeley ended payments of $7.50 to $11.50 in 2011 when Quest acquired Berkeley. HDL, Singulex, Boston Heart and Atherotech say they stopped payment after the Office of Inspector General issued a Special Fraud Alert on June 25.

According to the OIG alert, the characteristics of a specimen processing arrangement that may violate the anti-kickback statute include: 1) Payment exceeds fair market value for services actually rendered by the party receiving the payment; 2) Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals; and 3) Payment is offered on the condition that the physician orders either a specified volume or type of test or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.



In June, the fast-growing HDL celebrated the completion of its new headquarters complex, a $100 million office in the Virginia Biotechnology Park.

While HDL and the other labs have stopped paying doctors packaging and handling fees, they are now offering to place in-office phlebotomists to draw specimens.

Laboratory Economics believes that the OIG may also be looking into the test panels offered by HDL and the other cardiovascular disease testing labs to see if they included medically unnecessary tests.

Earlier this year, on the Science-Based Medicine Blog, Harriet Hall, MD, wrote about a particularly egregious example of ordering unnecessary tests. The name of the ordering physician was not mentioned, but the lab conducting the tests was HDL.

> *"A friend's 21-year-old son went to a board-certified family physician for a routine physical. This young man is healthy, has no complaints, has no past history of any significant health*

problems and no family history of any disease. The patient just asked for a routine physical and did not request any tests; the doctor ordered labwork without saying what tests he was ordering, and the patient assumed that it was a routine part of the physical exam. The patient's insurance paid only $13.09 and informed him that he was responsible for the remaining $3,682.98 (no, that's not a typo)."

More than 25 tests were performed, including genetic tests for CYP2C19*2*3, CYP2C19*17, Factor V Leiden, Prothrombin Mutation, MTHFR (C677T) and MTHFR (A1298C). The blog went on to report that the young man called his doctor's office to complain about the lab test charges. They referred him to the billing department. The billing department said there was nothing they could do and he should call the lab that did the tests. He called HDL and they told him to just forward the check for $13.09 that his insurance company had sent to him and he would not be billed for the rest of the charges.

HDL collected total payments of $139.1 million from Medicare in 2012, according to the latest available Medicare utilization and payment data. The company provided 6.8 million lab test services for 147,691 Medicare beneficiaries. That works out to an average of 46 test services and $942 in collected revenue per Medicare patient served in 2012.

In comparison, Quest's Berkeley HeartLab performed an average of only 21 test services and $469 in collected revenue per Medicare beneficiary in 2012.

Meanwhile, since the start of year, HDL has seen the departure of two of its top executives. CFO Steve Carroll retired on March 1, while Mark Herzog, Senior VP of Corporate and Government Affairs, left HDL in mid-March. New hires at HDL include Kathy Johnson, Chief Compliance Officer.

Lab Companies Offering Specialized Cardiovascular Disease Testing

Laboratory Company	*Location*	*Total Beneficiaries*	*Total Services*	*Total Medicare Payment*	*Avg. Payment Per Beneficiary*	*Avg. Services Per Beneficiary*
Health Diagnostic Laboratory	Richmond, VA	147,691	6,848,884	$139,071,673	942	46
Berkeley Heartlab Inc	Alameda, CA	36,963	776,909	$17,329,319	469	21
Atherotech	Birmingham, AL	73,244	963,782	$16,075,987	219	13
Boston Heart Diagnostics	Framingham, MA	23,751	1,004,986	$13,066,202	550	42
Singulex, Inc	Alameda, CA	40,440	370,572	$8,063,505	199	9
Hunter Laboratories Inc	Campbell, CA	31,839	384,343	$5,661,945	178	12
Cleveland Heartlab Inc	Cleveland, OH	24,716	179,521	$4,324,449	175	7
Liposcience Inc	Raleigh, NC	26,181	65,430	$2,121,637	81	2
Spectracell Laboratories	Houston, TX	9,089	104,484	$2,020,866	222	11
Aviir, Inc.	Irvine, CA	1,625	14,707	$202,730	125	9
AVERAGES					316	17

Source: *Laboratory Economics* from Medicare Provider Utilization and Payment Data CY2012

NEW PRACTICE REVENUE SOURCES: HEALTH DIAGNOSTIC LABORATORIES

This was the title of an article posted on the website physicianpractice.com on August 16, 2012. The article noted that HDL's Advanced Lipid Test can be performed four times a year per patient with proper indications and can be performed with an annual physical. "To compensate offices for the time it takes their staff to pack the samples, HDL pays the physician's office $20 per patient, providing a new revenue stream." In addition, the article noted that:

> *"When a patient's results are received by the office, the physician is recommended to see that patient back for a follow-up visit to review the results. HDL's Advanced Lipid Testing allows physicians to bill one level to two levels higher for the office visit. Typically a doctor would bill a follow-up visit at a level 2 or level 3. The level of information reported in this instance justifies a level 4 or 5, generating an additional $60 to $85 per patient."*

See the complete article at: http://www.physicianspractice.com/blog/new-practice-revenue-sources-health-diagnostic-laboratories#sthash.cKGqQ7tG.dpuf

BESTCARE LAB OWNERS MUST PAY $10.6 MILLION FOR OVERBILLING

The husband-and-wife owners of BestCare Laboratory Services (Houston, TX) must pay back $10.6 million for filing false claims with Medicare for mileage-based travel allowance fees for lab technicians, a federal judge ruled on August 21. Karim Maghareh and his wife, Farzaneh Rajabi, are sole owners of BestCare, which provides lab test services to nursing homes.

Richard Drummond, PhD, brought a False Claims Act case against Maghareh and BestCare in 2008, and the U.S. government intervened in the case three years later. Drummond is President of Access Clinical Laboratory LLC., a competing nursing home lab in Houston, Texas. Whistleblowers are entitled to receive 15-25% of any recovery if the United States intervenes in the suit, as it did here.

Under the Social Security Act, labs can bill the United States $1 per mile that its workers travel to collect specimens. But U.S. District Judge Lynn Hughes found that BestCare had violated the law by billing for each specimen's trip when its workers did not accompany the specimens. Hughes also determined that BestCare had illegally padded the mileage by adding the maximum number of miles each worker could have driven to retrieve each specimen, i.e. to Dallas and back to the lab in Houston, when the workers collected several specimens in one trip.

BestCare argued that it could not be held liable if it interpreted the Act reasonably. When asked whether it was reasonable to bill Medicare for $1,500 in travel expenses for a $43 blood test, Magahareh said, "I would assume it is reasonable because Medicare thought so too, and they paid us." But Judge Hughes disagreed and said that BestCare's argument "would embarrass a middle-school debater."

SPECIMEN COLLECTION FEE RAISED FOR NURSING HOME PATIENTS

Independent Labs collecting specimens from patients in skilled nursing facilities or on behalf of a home health agency will get a $2.00 raise from Medicare effective April 1, 2014, as directed by section 216(a) of the Protecting Access to Medicare Act. Labs should use the new code, G0471, which has been set at $5.00.

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PUBLICLY-TRADED LABS REPORT SMALL DECLINE IN REVENUE

On a combined basis, 18 publicly-traded labs saw their revenue shrink by 0.5% to $8.2 billion during the first six months of 2014 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 16 publicly-traded labs grew by 7.1% last year (after adjusting for acquisitions).

Revenue growth was fastest at three cancer-testing lab companies—Foundation Medicine, up 133%; Sequenom, up 43%; and NeoGenomics, up 24%.

Acquisition-adjusted revenue for Quest Diagnostics was down 4% in first-half 2014, while LabCorp's revenue was flat. The third largest U.S. lab company, Bio-Reference Labs, had estimated revenue growth of 11% (after adjusting for the acquisition of Hunter Laboratories in August 2013).

Revenue Growth at 18 Publicly-Traded Lab Companies ($000)

Company	First-Half 2014	First-Half 2013	Reported Change	Pro Forma Change*
Quest Diagnostics	$3,648,000	$3,602,387	1.3%	-4.0%
LabCorp	2,947,000	2,909,100	1.3%	0.0%
Bio-Reference (1)	382,635	337,709	13.3%	11.0%
Myriad Genetics	371,689	330,588	12.4%	8.0%
Sonic Healthcare USA	353,821	357,565	-1.0%	-1.0%
Genomic Health	137,479	126,785	8.4%	8.4%
Aurora Diagnostics	117,829	123,941	-4.9%	-4.9%
Sequenom	76,843	53,609	43.3%	43.3%
NeoGenomics	38,852	31,260	24.3%	24.3%
Enzo Clinical Labs (4)	28,390	26,704	6.3%	6.3%
Foundation Medicine	25,951	11,120	133.4%	133.4%
LipoScience	21,053	26,927	-21.8%	-21.8%
Psychemedics	14,739	13,331	10.6%	10.6%
Transgenomic	13,015	14,680	-11.3%	-11.3%
CareDx	12,700	10,438	21.7%	21.7%
Response Genetics	8,176	10,938	-25.2%	-25.2%
Combimatrix	3,763	3,111	21.0%	21.0%
Cancer Genetics Inc.	2,942	3,050	-3.6%	-3.6%
Total, 18 companies	$8,204,877	$7,993,243	2.6%	-0.5%
Total, 16 companies (excluding Quest and LabCorp)	$1,609,877	$1,481,756	8.6%	7.1%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.
[1]Bio-Reference's revenue is for the six months ended April 30, 2014; [2]Myriad Genetics' revenue is for six months ended June 30, 2014; [3]Sonic Healthcare USA's revenue is for six months ended June 30, 2014; [4]Enzo's revenue is for lab services only for six months ended April 30, 2014.
Source: *Laboratory Economics* from company reports

AVERAGE PRICE PER REQUISITION DOWN 2.2%

The unweighted average price per requisition for six publicly traded lab companies fell by 2.2% in the six months ended June 30, 2014 versus the same period a year ago. NeoGenomics reported the largest decline, down 4.6% to $719 per req. Bio-Reference reported the smallest decline, down 0.4% to $82.73 per req.

Average Price Per Requisition

Lab Company	First-Half 2014	First-Half 2013	% Chg
Aurora Diagnostics	$114	$116	-1.7%
Bio-Reference Labs	82.73	83.07	-0.4%
LabCorp	43.65	44.81	-2.6%
Liposcience	24.36	24.71	-1.4%
NeoGenomics	719	754	-4.6%
Quest Diagnostics	44.04	45.17	-2.5%
Unweighted			-2.2%

Source: *Laboratory Economics* from company 10Q reports

QUEST WINS DISMISSAL OF MEDICAID PRICING LAWSUIT IN MICHIGAN

Circuit Court Judge Clinton Canady entered an order last week dismissing all claims in the complaints filed by Hunter Laboratories and the State of Michigan against Quest Diagnostics. The case has been dismissed with prejudice.

In a statement, Quest Diagnostics said:

> *"We are pleased that Judge Canady, ruling on the merits, found in favor of Quest Diagnostics. As this ruling confirms, our testing services are priced appropriately. We comply with the laws and regulations governing our business, including Medicaid pricing requirements. As always, Quest Diagnostics remains firmly focused on putting patients first and serving their needs."*

The suit was originally filed in 2008 under the Michigan Medicaid False Claims Act by Hunter Laboratories and its owner Chris Riedel, who alleged that Quest overbilled Michigan's Medicaid program for routine lab tests. Michigan's Attorney General's Office joined the case in 2012.

Earlier this year, Quest settled Medicaid pricing lawsuits filed against it by Hunter Labs in Massachusetts, Nevada and Georgia and reached an agreement in principle to settle a similar case in Virginia. Quest still faces a Medicaid pricing lawsuit in Florida, where the State Attorney General's Office has intervened as a plaintiff.

VERACYTE TO BUY ALLEGRO DIAGNOSTICS FOR $21 MILLION

Veracyte (South San Francisco, CA) has agreed to acquire Allegro Diagnostics Corp. (Maynard, MA) for $21 million ($7.8 million in cash and $13.2 million in Veracyte common stock).

Allegro is developing a gene expression diagnostic test to improve the preoperative diagnosis of lung cancer. The test is designed to help physicians determine which patients with lung nodules who have had a non-diagnostic bronchoscopy are at low risk for cancer and can thus safely be monitored with CT scans rather than undergoing invasive procedures. Veracyte intends to launch the test in the second half of 2015, but meaningful revenue won't come in until 2017.

Allegro was founded in 2006 as a spin out of research conducted at Boston University by pulmonology specialists Avrum Spira, MD, and Jerome Brody, MD. The company is owned by two venture capital firms, Kodiak Ventures and Catalyst Health Ventures, and Boston University.

Veracyte is a publicly traded company that markets a thyroid cancer test, the Affirma Thyroid FNA Analysis, at a list price of $3,500. In the six months ended June 30, 2014, Veracyte reported a net loss of $13.3 million compared with a net loss of $13.4 million in the same period a year earlier; revenue increased 71% to $16.2 million.

TOP VITAMIN D TESTING LAB COMPANIES

The number of Vitamin D test orders (CPT 82306) submitted to the Medicare Part B program grew by 46% per year during the five year period from 2007-2012 to reach a total of 6.885 million tests, according to data from CMS.

Together, Quest Diagnostics (1.417 million tests) and LabCorp (1.384 million tests) accounted for 2.801 million Vitamin D tests, representing 41% of all Part B test orders in 2012. Sonic Healthcare USA was a distant third with 208,846 Vitamin D test orders for Part B in 2012. Solstas Lab Partners, which was acquired by Quest earlier this year, had 176,929 Vitamin D test orders.

In total, the top 25 lab companies accounted for 3.725 million Vitamin D tests, or more than 50% of all Part B test orders for CPT 82306 in 2012.

TOP VITAMIN D TESTING LABS BY MEDICARE TEST VOLUME FOR 2012

LABORATORY NAME	*TEST VOLUME*	*PATIENT VOLUME*	*AVG. FEE*	*AVG. # TESTS PER PATIENT*
QUEST DIAGNOSTICS	1,417,117	1,145,028	$41.40	1.2
LABCORP	1,384,219	1,063,673	41.20	1.3
SONIC HEALTHCARE USA	208,846	158,421	40.26	1.3
SOLSTAS LAB PARTNERS	176,929	132,901	41.94	1.3
BIO-REFERENCE LABORATORIES	91,551	68,592	41.94	1.3
SHIEL MEDICAL LABORATORY	62,278	42,728	41.94	1.5
VPA PC	55,764	28,178	41.94	2.0
ENZO CLINICAL LABS, INC.	30,927	22,830	41.94	1.4
ACL	30,803	24,058	41.94	1.3
ATHEROTECH	27,675	22,271	41.93	1.2
PAML	26,254	20,416	41.94	1.3
ACCURATE DIAGNOSTICS LABS	22,711	18,302	41.94	1.2
BIOTECH CLINICAL LABORATORIES	18,229	14,280	41.94	1.3
AMERICAN HEALTH ASSOCIATES INC.	16,990	11,081	41.94	1.5
SCRIPPS HEALTH	16,391	12,245	41.79	1.3
METWEST INC.	16,214	14,533	41.94	1.1
SMA MEDICAL, INC.	15,080	10,403	41.94	1.4
HUNTER LABORATORIES INC.	14,632	11,490	41.87	1.3
TOTAL RENAL LABORATORIES INC.	14,542	7,645	41.94	1.9
GAMMA HEALTHCARE INC.	14,236	9,206	41.94	1.5
ACCU REFERENCE MEDICAL LAB, LLC	13,395	10,299	41.94	1.3
CLINICAL LABORATORY PARTNERS	13,315	10,669	41.94	1.2
NORTH SHORE LIJ LABORATORIES	12,857	10,242	41.94	1.3
TEXAS HEALTH PHYSICIANS GROUP	12,654	9,251	38.49	1.4
UNIV. HOSPITALS LAB SERVICES	11,475	8,536	41.94	1.3

Source: 2012 Medicare Provider Utilization & Payment Data, Public Use File

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LAB STOCKS UP 10% YEAR TO DATE

Fourteen lab stocks increased an unweighted average of 10% year to date through September 12. In comparison, the S&P 500 Index is up 9.9%. The top-performing lab stock so far this year is Enzo Biochem, up 99%, followed by Myriad Genetics, up 74%, and NeoGenomics, up 65%. LabCorp is up 16% and Quest Diagnostics is up by 17%.

Company (ticker)	Stock Price 9/12/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$28.84	$25.54	13%	$800	20.2	1.0	2.7
Cancer Genetics Inc. (CGIX)	8.78	13.78	-36%	85	NA	10.0	2.1
CombiMatrix	1.51	2.30	-34%	17	NA	1.1	1.5
Enzo	5.81	2.92	99%	255	NA	2.6	6.7
Foundation Medicine (FMI)	22.29	23.82	-6%	630	NA	6.2	5.8
Genomic Health (GHDX)	28.99	29.27	-1%	914	NA	3.3	6.4
LabCorp (LH)	106.35	91.37	16%	9,029	17.2	1.6	3.4
LipoScience	3.13	4.25	-26%	48	NA	1.0	1.1
Myriad Genetics (MYGN)	36.53	20.98	74%	2,659	15.9	3.6	3.7
NeoGenomics	5.99	3.62	65%	341	115.0	4.0	12.9
Psychemedics	13.91	14.69	-5%	75	21.1	2.6	5.7
Quest Diagnostics (DGX)	62.62	53.54	17%	9,043	15.8	1.3	2.2
Response Genetics (RGDX)	0.77	1.16	-34%	30	NA	1.6	5.9
Sonic Healthcare (SHL.AX)	16.74	16.58	1%	6,715	17.4	1.7	2.2
Unweighted			10%		31.8	3.0	4.4

Source: Bloomberg and Zacks

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