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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PROPOSED RULE EXCLUDES DATA FROM MOST HOSPITAL LABS TO REPRICE LAB TESTS

On September 25, the Centers for Medicare & Medicaid Services (CMS) published its long-awaited proposed rule to reprice lab tests on Medicare's Clinical Lab Fee Schedule (CLFS) based on private-payer rates beginning January 1, 2017. Surprisingly, the proposed rule excludes most hospital labs from reporting their data—a move that would lower the average private-payer rates calculated by CMS. *Full details on pages 2-5.*

DID THERANOS MANIPULATE PROFICIENCY TESTING RESULTS?

An article in the *Wall Street Journal* suggests that media-darling Theranos (Palo Alto, CA) is using traditional analyzers from Siemens AG to run most of its tests rather than the revolutionary fingerstick testing system ("Edison") it claims to have invented. Furthermore, the *WSJ* says that Theranos may have misrepresented its proficiency-testing results reported to accrediting organizations.

Theranos' founder and CEO Elizabeth Holmes declined interview requests from the *WSJ* for more than five months prior to publication of the article on October 15. In a statement posted on its website, Theranos said the *WSJ* article was "factually and scientifically erroneous" and "relied only on the views of four anonymous disgruntled former employees, competitors and their allies."

The *WSJ* article marks the end of the "free ride" that the general media has given Theranos and Holmes over the past two years, and could severely limit the company's ability to raise cash from investors in the future, observes *Laboratory Economics*. *More details on pages 5-7.*

MEDICARE PROPOSES BIG CUTS TO DRUG TESTING RATES

Medicare payment for drug testing codes would drop significantly in 2016 under preliminary payment determinations for the Clinical Laboratory Fee Schedule (CLFS) released by the Centers for Medicare & Medicaid Services (CMS) in late September. If finalized, the new payment rates could put many drug testing labs out of business.
Continued on pages 9-10.

Contents

PROPOSED RULE EXCLUDES MOST HOSPITAL LABS (*cont'd from page 1*)

Which Labs Must Report Private-Payer Data?

The proposed rule would require "applicable laboratories" to report their private-payer rates and volume to CMS. An applicable lab is defined as one that receives: 1) $50,000 or more per year in Medicare revenue from the Clinical Lab Fee Schedule (CLFS); and 2) more than 50% of its Medicare revenue from the entire organization from services paid by Medicare under the CLFS and the Physician Fee Schedule (PFS). In addition, CMS is proposing to define applicable labs at the Taxpayer Identification Number (TIN) level rather than the National Provider Identifier (NPI) level.

As a result, nearly all hospital labs will not be required to report. The exception is the small number of hospital outreach lab businesses that operate independently with their own TIN. There are only a handful of health-system-owned labs that meet this criteria (e.g. ARUP Laboratories, Clinical Laboratory Partners, Mayo Medical Labs, TriCore Reference Labs, et al.).

In addition, CMS estimates that more than 50% of independent labs and more than 90% of physician office-based labs will be exempt from reporting their private-payer data because they do not earn more than $50,000 per year in Medicare revenue from the CLFS.

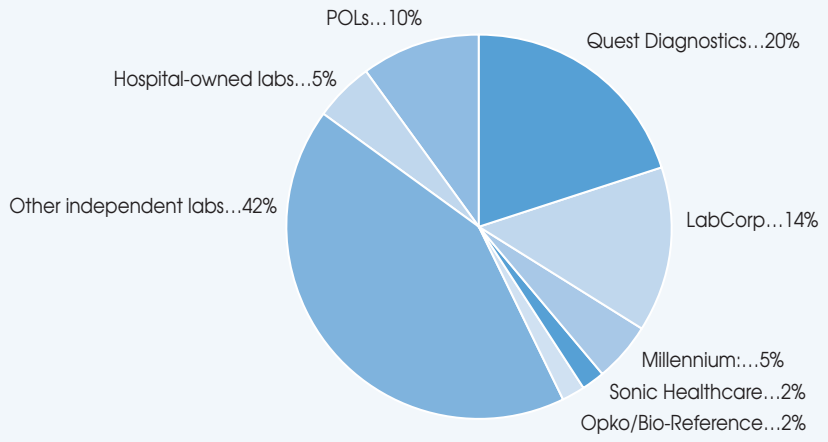
Consequently, if the proposed rule is finalized, private-payer data from the nation's largest commercial labs is expected to dominate the information used by CMS to calculate new lab test prices. In fact, *Laboratory Economics* estimates that information from just five lab companies (Quest Diagnostics, LabCorp, Millennium Health LLC, Opko/Bio-Reference Labs and Sonic Healthcare) will account for nearly half of all the reported pricing information.

Alan Mertz

The proposed rule's definition of applicable labs does not match the legislative intent of PAMA, according to Alan Mertz, President of the American Clinical Laboratory Association. "Without data from hospital labs, an enormous part of the lab market will be missing. It's confounding," says Mertz.

"Clearly, the largest players in the laboratory market—the two national publicly-traded laboratories—will drive the test volumes and their rates will dominate CMS' evaluation," says Mark Birenbaum, PhD, Administrator of the National Independent Laboratory Assn.

Proportion of Pricing Data That Will Be Used To Set Medicare Lab Test Prices



Source: *Laboratory Economics* based on each company's Medicare lab test revenue in 2013

Which Data Must Labs Report?

CMS has proposed that applicable information to be reported would include: 1) the payment rate paid by each private payer for each CLFS test (by CPT code) during the data collection period; and 2) the volume of each test for each payer.

CMS is defining "private payer" as a health insurance company or group health plan, a Medicare Advantage plan, or a Medicaid managed care organization. Pricing information for Medicaid fee-for-service and other government payers would be excluded.

The payment rate reported by a laboratory must reflect all discounts, rebates, coupons and other price concessions, and it would be inclusive of all patient cost sharing amounts. Lab tests paid on a capitated basis will be excluded.

Lale White, Executive Chairman and CEO at the billing management firm XIFIN Inc. (San Diego, CA), says collecting and organizing the data could be time-consuming and costly for labs without sophisticated billing systems. "The biggest problem for labs is to make sure they are being paid their contracted prices for the reporting period, and that can take months of effort to correct with the payer if they do not have a system that flags missed payments for prompt correction. If labs are not going to see these types of trends until they generate the PAMA report, they will not be able to correct payer errors and will have to report what was paid for the reporting period whether it was paid correctly or not," explains White.

Lale White

She notes that if a lab does not have easy access to this data, it can take months to dump the data into spreadsheets, sort the data for paid claims and then by CPT code and allowable amounts. In some cases where payments are received on paper EOBs and either processed manually or converted to electronic format, the manual entry or converted information must be reviewed for accuracy and it can take substantially longer to generate an accurate report. "When labs in California had to do similar type of reporting for the Medi-Cal contractor, some labs spent up to four or five months cleansing their data," according to White.

Reporting Compliance

A lab's President, CEO, CFO or a delegated individual must sign a certification statement assuring that the data provided to CMS is accurate, complete and truthful. If CMS determines that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, a civil monetary penalty of up to $10,000 per day per violation may apply, according to the proposed rule.

Jane Pine Wood

The proposed rule "has teeth" and is similar to the reporting compliance and penalties that the drug companies face when reporting their pricing information, according to Jane Pine Wood, attorney at McDonald Hopkins. She adds, "Given some of the uncertainty and vagueness in the proposed regulations regarding the definition of an 'applicable laboratory' and 'private-payer rate,' the penalties for failure to report accurately are troubling."

Laboratory Economics notes that regulators have punished several drug companies for misreporting data. For example, AstraZeneca and Cephalon Inc. recently agreed to pay $46.5 million and $7.5 million, respectively, to resolve allegations that they underreported prices for a

number of their drugs, thereby reducing the rebates they paid to state Medicaid programs.

Importantly, the proposed rule says that the pricing information collected by CMS must be kept confidential. However, CMS can disclose information to the Office of Inspector General or Department of Justice for oversight and enforcement activities.

Comparison of Medicare Payment Systems for Clinical Lab Tests

Year Implemented	*Current 1984*	*Future 2017*
Basis of Payment Rates	Lab Charges in 1984-1985, adjusted across-the-board each year for inflation and other factors	Private-payer rate data, updated every 3 years using then-current data
Number of Fee Schedules	57 regional fee schedules	Single national fee schedule

Source: CMS

How Will New CLFS Rates Be Calculated?

There will be no more inflation adjustments or across-the-board productivity adjustments to the CLFS starting in 2017. Instead, CMS will organize the data it collects from all applicable labs for each test on the CLFS by rate, from low to high. Each rate will be weighted by the volume of tests performed at that rate. CMS will choose the middle rate in this array as the new national rate for each test effective January 1, 2017. There will be no adjustments for geography. Any potential rate cuts will be limited to 10% per year per test for the first three years of the policy (2017-2019). Potential rate cuts will be held to a maximum of 15% per year for the subsequent three years (2020-2022).

Projected Savings

Medicare currently pays approximately $7 billion to $8 billion per year for lab tests reimbursed through the CLFS. As a baseline, CMS has estimated a difference between private payer rates and Medicare CLFS payment rates of approximately 6.4% in 2017. The initial estimated difference between Medicare CLFS payment rates and private payer rates (-6.4%) will result in approximate savings to the Medicare program of $360 million in 2017, according to CMS.

Over the course of 10 years, CMS has estimated that the new rate-setting mechanism will save Medicare a total of $5.1 billion compared with what it would have otherwise spent on today's current method of across-the-board cuts based on inflation and productivity adjustments.

In a nutshell, CMS seems to be pointing to an average cut of 6.4% for lab tests in 2017, followed by another cut of approximately 5% in 2018 and then a cut of roughly 1% in 2019. After that, CMS' projections indicate that Medicare reimbursement for lab tests will stabilize from 2020 to 2026.

CMS based its estimates for cuts on a study from the Office of Inspector General (*Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings*, OEI-07-11-00010, June 2013). The OIG study showed that Medicare paid between 18% and 30% more than state Medicaid programs for 20 high-volume lab tests in 2011. The study did not evaluate private insurance rates. So in reality, CMS has no firm ground for estimating what impact its new rate-setting mechanism will have on Medicare lab test prices, observes *Laboratory Economics*.

Implementation Schedule Not Reasonable

Comments on the proposed rule are due by November 24. That gives CMS only about one month to review the comments and publish a final rule. In addition, CMS is supposed to release a separate guidance before the end of the year that details how labs should format the pricing data they submit to the agency.

Meanwhile, applicable labs are scheduled to begin submitting their pricing data from 2015 to CMS starting on January 1, 2016 and ending on March 31, 2016. CMS says it will publish the new rates it formulates from this information in November 2016. The new rates would become effective January 1, 2017.

But ACLA's Mertz says this schedule is "completely unworkable." He notes that it will take CMS at least two or three months to review comments and write a final rule after the comment period ends on November 24. It's unlikely that a final rule will be issued before February 2016, according to Mertz. "Labs will then need time to set up systems and compile pricing data. The timetable as it stands right now looks implausible, including the January 1, 2017 effective date for new rates."

Timeline for CMS and Laboratories

Sept. 25, 2015	Proposed Rule is issued
Sept. 25, 2015 to Nov. 24, 2015	Proposed Rule Comment Period
Unknown	CMS issues Final Rule
Unknown	CMS releases reporting guidance
January 1, 2016 to March 31, 2016	Applicable labs report pricing data to CMS
November 2016	CMS publishes new rates
January 1, 2017	New CLFS rates become effective

Source: *Laboratory Economics* and CMS

DID THERANOS MANIPULATE PT RESULTS? (*cont'd from page 1*)

The most serious allegation in the *WSJ* article concerns the manipulation of proficiency-testing results. The *WSJ* article says that in early 2014, Theranos' President Sunny Balwani ordered lab personnel to stop using the company's Edison analyzers on any proficiency-testing samples and report only the results obtained by traditional instruments, which were providing more accurate test results. This is alleged to have been done even though Theranos routinely used its Edison machines to test patient samples for vitamin D, thyroid hormones and prostate cancer.

Proficiency testing relies on the integrity and honesty of the laboratory in reporting its own test results.

Manipulating the Proficiency-Testing Process is a Serious Violation

"PT samples must be tested in the same manner you test patient specimens. This means testing the PT samples the same number of times as patient specimens, at the same time as patient specimens, by the same personnel that routinely test the patient specimens, and using the same test system that is routinely used for the patient specimens," according to CMS regulations.

Knowingly cheating on the PT process would be a serious violation that could result in revocation of a lab's CLIA certificate, according to Hope Foster, attorney at Mintz Levin.

Where are the Regulators?
In early 2014, a Theranos employee using the alias Colin Ramirez alleged to New York State's public-health lab that the company might have manipulated the proficiency-testing process, according to the *WSJ*. The New York State Department of Health (NYSDoH) has confirmed that it got a formal complaint in April 2014 "in regard to testing practices at Theranos" and forwarded it to CMS.

It's been more than 18 months since CMS received the formal complaint from NYSDoH. During this time period, Theranos claims to have tested millions of patients.

Laboratory Economics notes that this can only mean one of two things:

1) CMS investigated the complaint and found that Theranos did not manipulate the PT process; or
2) CMS is allowing a laboratory that has cheated the PT process to continue to test patients.

LE contacted CMS to get an update on where its review of the complaint stood. Karen Dyer, Director, Division of Laboratory Services, Survey and Certification Group, at CMS, said the agency cannot comment on the status of any investigations.

Who is Laboratory Director at Theranos?
Meanwhile, *LE* notes that any confusion concerning Theranos' PT process could be quickly cleared up if the company's laboratory director stepped forward to answer questions. But who is the company's lab director?

In late 2014 Theranos' Laboratory Director, Adam Rosendorff, MD, resigned and took a job at the DNA testing lab company Invitae (San Francisco, CA). Since then Theranos has been and continues to advertise that it is seeking a Laboratory Director. This leads *Laboratory Economics* to believe that the position may have been vacant for almost 1 year now. *LE* called and e-mailed Theranos to get clarification on who is acting as the company's lab director, but Theranos did not respond.

The Fallout
After the *WSJ* article was published, Theranos' Holmes was interviewed on CNBC, where she said, "This is what happens when you work to change things, at first they think you're crazy, then they fight you and then all of a sudden you change the world."

The *Wall Street Journal* says it "fully stands by [author] John Carreyrou's article about Theranos.

Not the First Time Theranos Exaggerated Its Technology
Back in May 2005, Holmes had a Podcast interview with Dr. Moira Gunn from *Tech Nation* that has been transcribed and posted on the website www.rationalconspiracy.com. In the interview, Holmes told Dr. Gunn, who has a PhD in mechanical engineering, that she had developed a handheld testing device called the RDX Metabolic Analyzer. Holmes said the device could test small samples of blood from a fingerprick.

In the interview, Holmes described the RDX Metabolic Analyzer: "It's a little tiny needle that pulls a little tiny drop of blood, and when it gets the drop of blood, basically it runs it through, what we call, a biochip which separates out all the cells and other types of analytes in your blood which

could traditionally clog a biosensor. And then, in real time it runs many different chemistries. Looking for different, in this case, targeted markers."

Holmes said the device could provide results in minutes and would initially test patients for adverse drug reactions. "Our first applications are actually in monitoring acute pain killers. And that device is going into the production phase. We hope to release it, actually, to a pharmaceutical partner around mid to late this year [2005]," she told Dr. Gunn.

But the RDX Metabolic Analyzer never made it to market and all history of it seems to have been erased from the Internet, except for the 2005 interview with Dr. Gunn.

Will Investors Continue to Fund Theranos?

Theranos has raised some $400 million from venture capital investors since being formed in 2003. Its investors include Draper Fisher Jurvetson, ATA Ventures, Tako Ventures and Continental Properties, Inc. But Theranos is likely to be burning through its cash at a fast rate. The company does not seem to be generating meaningful patient volume at its Walgreens patient service centers in Arizona and has had difficulty winning and keeping physician office clients, according to field reports from several competing labs in Arizona.

Meanwhile, *Laboratory Economics* notes that Theranos has created an enormous cost structure for itself. The company's biggest expenses include its 700-employee workforce and rent. The company's office/lab space includes a 220,000-square-foot facility in Newark, CA; 86,000 sq. ft. in Palo Alto, CA; and 23,000 sq. ft. in Arizona. In fact, Nichols Management Group (York Harbor, ME), which has done extensive research on Theranos over the past two years, has estimated that the company's cash burn rate could be as high as $50 million per year.

It's just a matter of time before Theranos will need to raise more cash. Investors will be hard to find unless Theranos can prove its technology and business model are for real, observes *Laboratory Economics*.

STRATA TO PAY $559K TO SETTLE KICKBACK ALLEGATIONS

Strata Pathology Laboratory Inc. (Lexington, MA), known as StrataDx, has agreed to pay $559,000 to resolve allegations that it violated the False Claims Act by paying kickback fees to doctors in return for Medicare and Medicaid patient referrals.

The case was initiated by a former Strata employee, Henry O'Dell, who sued Strata under the False Claims Act. As whistleblower, O'Dell will receive $103,000 of the settlement. O'Dell is a pathologists' assistant who was formerly Laboratory Safety and Compliance Officer at Strata.

Strata acknowledged paying consulting fees to two physician practices that did not actually provide consulting services, according to the U.S. Attorney's Office for the District of Massachusetts. In addition, Strata entered into client billing arrangements with seven referring physician practices that allowed the practices to bill patients' private insurers directly for pathology services that Strata performed. Strata then charged the physician practices for its services at deeply discounted rates, allowing the physician practices to collect the private insurers' full reimbursement. The U.S. says that Strata offered the discounts in exchange for Medicare and Medicaid referrals.

As part of the settlement agreement, Strata and its former executives Pat Noland, James Agnello and Robin Feeney have been released from any monetary claims from the U.S. Attorney's Office from the alleged misconduct in the lawsuit.

Strata Sold to Two Pathologists

On October 2, the day after the above settlement was announced, Strata was sold by its owner Linden Capital Partners (Chicago, IL) to two of Strata's pathologist employees, Lisa Cohen, MD, and Terence Harrist, MD. Linden is a private investment firm that acquired Strata in 2011.

Dr. Cohen is a dermatopathologist who joined Strata's pathology staff in 2013. She is the founder and former President of Cohen Dermatopathology (Newton, MA), which was sold to Caris Diagnostics (now Miraca Life Sciences) for $80 million cash in May 2007. Dr. Cohen is now President and CEO of the new Strata.

Dr. Harrist is also a dermatopathologist and entrepreneur. He is the former Medical Director of Pathology Services Inc. (Boston, MA), which he founded in 1980. Dr. Harrist is now Co-Director of Dermatopathology at Strata.

Strata is a full-service anatomic pathology lab with 115 employees, including 15 pathologists. The company has estimated annual revenue of $30 million.

In addition to having Dr. Cohen as President and CEO, the new Strata has named Beatriz Tapia-Centola, MD, as Medical Director; Ana-Maria Jojatu as Laboratory Director; and Robin Feeney as Chief Financial Officer.

FROEDTERT ENDS JOINT VENTURE WITH LABCORP

Froedtert Health Inc. (Milwaukee, WI) has ended its joint venture with LabCorp and assumed full ownership of United/Dynacare Laboratories LLC, in which it previously had a 50% interest. As of July 1, the business operates under the name Wisconsin Diagnostic Laboratories LLC as a wholly-owned but independent laboratory.

The 50-50 joint venture was originally formed in 1997 between Froedtert and Dynacare Inc. to serve Froedtert Hospital and Medical College of Wisconsin and market outreach testing services to other physicians and hospitals. LabCorp acquired Dynacare for $685 million in 2002, which then continued as 50% partner in the joint venture until recently.

In its financial report for the fiscal year ended June 30, 2015, Froedtert Health recorded a loss of $3.0 million related to the disposition of its equity ownership interest in United/Dynacare Laboratories LLC. In addition, Froedtert Health included $37.1 million of assets, $18.4 million of liabilities and $18.7 million of equity on its balance sheet related to Wisconsin Diagnostic Laboratories LLC.

Wisconsin Diagnostic Laboratories has 486 employees and performs about five million tests per year. Annual revenue is estimated at roughly $50 million, including approximately $6 million per year from Medicare.

Ceil Duclon, Executive Laboratory Director at Froedtert Health, is acting as interim CEO at Wisconsin Diagnostic Laboratories.

It is not entirely clear why the joint venture was dissolved. LabCorp may have chosen to exit because it was an unprofitable venture, or Froedtert Health and its affiliated pathologists at the Medical College of Wisconsin may have been seeking greater control and decision-making for the laboratory, notes *Laboratory Economics*.

Wisconsin Diagnostic Laboratories says it will continue to use the Medical College of Wisconsin Department of Pathology for professional services.

"Froedtert and LabCorp have different missions. The new arrangement gives both organizations more flexibility and control to fulfill their individual missions. LabCorp cooperated with Froedtert Health throughout the transaction," according to a statement from Froedtert.

MEDICARE PROPOSES TO CUT RATES (*cont'd from page 1*)

If the preliminary payment determinations are finalized, clinical laboratories could see their Medicare payment for drug testing cut substantially next year. CMS has long been concerned about overbilling for drug testing and has been trying to find ways to reduce overutilization. A November 2014 *Wall Street Journal* article reported that Medicare spent $445 million on 22 high-tech tests for drug of abuse in 2012, an increase of 1,423% in five years.

In a departure from a proposal released over the summer, CMS is now proposing to delete the following G codes: G0431, G0434 and G6030 through G6058 and replace them with new G codes. The agency will continue to not recognize AMA CPT codes 80300-80377.

For presumptive testing, CMS proposes to create three new G codes:

- GXXX1 Drug tests capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges). Crosswalk to 0.5 times existing code G0434.
- GXXX2 Drug tests read by instrument-assisted direct optical observation (eg, dipsticks, cups, cartridges). Crosswalk to G0434.
- GXXX3 Drug tests performed by instrumented chemistry analyzers. Crosswalk to 3 times G0434.

For definitive drug testing, CMS is proposing four new HCPCS codes crosswalked to CPT 82542 for the first two drugs tested, plus 10% of that amount for each additional drug tested:

- GYYY1 (Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessary stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all source(s), including specimen validity testing, per day, 1-7 drug class(es), including metabolite(s), if performed). Crosswalked to 2 times 82542 plus 5 times 82542 times 10%.
- GYYY2 Same as above, 8-14 drug classes. Crosswalk to 82542 times 2 plus 82542 times 12 times 10%.
- GYYY3 Same as above, 15-34 drug classes. Crosswalk to 82542 times 2 plus 82542 times 32 times 10%.
- GYYY4 Same as above, 35 or more drug classes. Crosswalk to 82542 times 2 plus 82542 times 48 times 10%.

The preliminary payment determinations are substantially less than the payment recommended by the Drug Testing Coalition, a group consisting of test manufacturers and supported by several lab industry groups (*Laboratory Economics*, Sept. 2015, p. 5). Paul Radensky, MD, JD, a principal

with McDermott+ Consulting (Washington, D.C.), who represents the coalition, says the group is generally pleased with CMS's determinations on presumptive testing but has great concerns about the preliminary determinations on definitive testing. The coalition has submitted revised recommendations to CMS, which is expected to announce final determinations in November or December. Comments on the preliminary determinations are being accepted through Oct. 26, and the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests will meet Oct. 19 to continue discussing CLFS rates for 2016.

"If CMS does not modify its preliminary determinations, labs performing medically necessary drug testing will be hurt because these rates are below what the labs have indicated it costs them to perform the tests," explains Radensky.

Finally, an executive at an independent drug testing lab, who wishes to remain anonymous, tells *Laboratory Economics*, "Currently our average reimbursement is approximately $216 per sample. The rate proposal by CMS would put the reimbursement at $123-161, depending on the definition of 'drug classes.' At $123 we could potentially be out of business. At $161 we would make just enough of a margin to survive."

"The proposed rate cuts will be devastating for those labs that are unbundling CPT codes and being paid $400-$1,000 per sample. But, quite frankly, they deserve what they get for doing billing wrong and illegally," he adds.

Drug Test Reimbursement Comparison

Code	Drug Testing Coalition Recommendations	CMS Preliminary Determination for 2016
PRESUMPTIVE		
GXXX1	$14.84	$9.90
GXXX2	$19.79	$19.79
GXXX3	Pending	$59.37
DEFINITIVE		
GYYY1	1-7 billed individually at $24.58 per drug class	$61.45
GYYY2	(8-14) $196.64	(8-14) $78.66
GYYY3	(15-21) $245.80	(15-34) $127.82
GYYY4	(22 or more) $294.96	(35 or more) $167.14

Source: CMS and Drug Testing Coalition

CALLOWAY LABS SHUTS DOWN

Citing "unforeseen circumstances beyond the company's control" but not specifying further, the drug-testing lab Calloway Labs (Woburn, MA) abruptly ceased operations on Friday, October 16. A short statement from Calloway said that its approximately 240 employees around the country have been paid through their last day of work and are in full control of their retirement funds.

In 2012, Calloway agreed to pay Massachusetts $20 million to resolve allegations that it funneled money to halfway houses in exchange for drug test referrals for residents that were billed to Medicaid. Then in May 2014, Calloway agreed to pay West Virginia more than $4.6 million to settle allegations it filed false claims with the state's Medicaid program between March 2009 and April 2013.

Calloway's President Gail Marcus is a member of the newly-formed Medicare Advisory Panel, which advises CMS on lab test payment issues. Calloway had been owned by the private investment firm Ampersand Capital Partners.

IOM STUDY RECOMMENDS GREATER PATHOLOGIST INTEGRATION

The Institute of Medicine (IOM) has issued a special report calling wrong or delayed diagnoses a vast "blind-spot" in U.S. healthcare system. The 369-page report, "Improving Diagnosis in Health Care," released September 22, found that 5% of U.S. adults who seek outpatient care each year experience a diagnostic error, which includes a wrong, inaccurate or delayed diagnosis; these errors contribute to about 10% of patient deaths, and up to 17% of hospital adverse events.

The IOM defined "diagnostic error" as the failure to 1) Establish an accurate and timely explanation of the patient's health problem(s) or 2) Communicate that explanation to the patient.

The report found that many diagnostic errors were the result of poor coordination of care and recommended greater collaboration between pathologists, radiologists and treating physicians. IOM also recommended the creation of new CPT codes to provide reimbursement for additional evaluation and management activities, such as time spent by pathologists and radiologists in advising treating physicians on testing for specific patients. "Realigning relative value fees to better compensate clinicians for cognitive work in the diagnostic process has the potential to improve diagnosis while reducing incentives that drive inappropriate diagnostic testing utilization," said the report.

Gene Herbeck, MD

The report's findings validate efforts by the College of American Pathologists (CAP) to gain reimbursement for consultations initiated by pathologists, according to CAP's immediate former President Gene Herbeck, MD.

Currently, consultation services provided by a pathologist to other physicians are reimbursable only if they are first requested by the attending physician. There are two existing CPT codes used for clinical pathology consultation under the Medicare fee schedule: CPT code 80500 (national rate=$23.27) is for a limited clinical pathology consultation without review of a patient's history and medical records; CPT code 80502 ($73.39) is for the comprehensive clinical consultation of a complex diagnostic problem with review of a patient's history and medical records.

Herbek says that CAP has been lobbying CMS for several years to change the descriptions of CPT 80500 and 80502 so that these consultations can be initiated by a pathologist. Reimbursement would incentivize pathologists to interact more proactively with physicians, Herbek tells *Laboratory Economics*. He is hopeful that the descriptions for these codes will be amended within the next year or two.

Among the organizations that helped fund the IOM study were CAP, American College of Radiology, and American Society for Clinical Pathology.

LAB STOCKS DOWN 15% YTD

Sixteen lab stocks have declined by an unweighted average of 15% year to date through October 16. In comparison, the S&P 500 Index is down 1.3%. The top-performing lab stocks so far this year are NeoGenomics, up 41%; Cancer Genetics Inc., up 19%; and Myriad Genetics, up 15%. Meanwhile, LabCorp is up 9% and Quest Diagnostics is down 3%.

Company (ticker)	Stock Price 10/16/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$7.98	$6.68	19%	$79	NA	5.0	3.0
CombiMatrix (CBMX)	1.17	1.29	-9%	15	NA	1.5	1.6
Enzo Biochem (ENZ)	4.01	4.44	-10%	185	NA	1.9	5.3
Exact Sciences (EXAS)	7.99	27.44	-71%	768	NA	51.4	2.9
Foundation Medicine (FMI)	21.55	22.22	-3%	741	NA	9.8	2.6
Genomic Health (GHDX)	21.65	31.97	-32%	703	NA	2.6	4.8
Invitae (NVTA)	9.58	16.00	-40%	305	NA	69.9	1.6
LabCorp (LH)	117.41	107.90	9%	11,870	25.4	1.7	2.4
Myriad Genetics (MYGN)	39.31	34.06	15%	2,730	36.4	3.7	4.1
NeoGenomics (NEO)	5.88	4.17	41%	356	NA	3.7	5.9
Opko Health	9.39	9.99	-6%	5,072	NA	35.5	5.2
Psychemedics (PMD)	11.30	15.15	-25%	61	28.7	2.2	5.0
Quest Diagnostics (DGX)	65.36	67.06	-3%	9,380	19.1	1.2	2.1
Response Genetics (RGDX)*	0.01	0.32	-97%	0.3	NA	0.0	NA
Sonic Healthcare (SHL.AX)	18.55	18.50	0%	7,533	21.4	1.8	2.3
Veracyte (VCYT)	6.52	9.66	-33%	180	NA	3.9	2.7
Unweighted Averages			-15%		26.2	12.2	3.4

*Response Genetics filed for Chapter 11 in early August 2015 and has an agreement to sell its assets to Cancer Genetics Inc.
Source: Capital IQ

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