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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

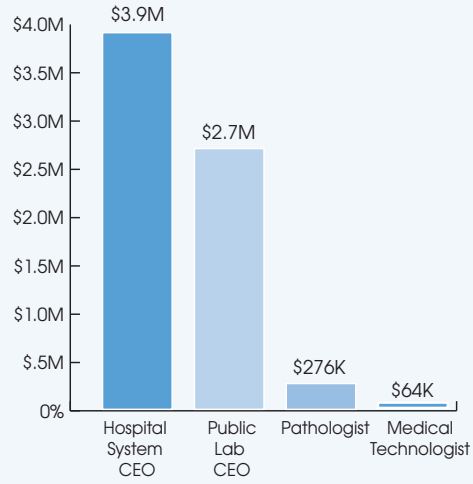
NON-PROFIT HOSPITAL CEOs EARN MULTI-MILLION $ PAY PACKAGES

The compensation packages for chief executives at large non-profit hospital systems exceed that of their counterparts at many publicly-traded healthcare companies. The chief executives at 20 of the largest non-profit hospital systems in the nation earned combined total compensation of $78.5 million in 2013, or an average of $3.9 million per executive, according to an exclusive analysis of IRS Form 990s performed by *Laboratory Economics*.

In comparison, the chief executives at 16 publicly-traded lab companies were paid an average of $2.7 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*.

Meanwhile, pathologists earn an average of $267,000 per year, while medical technologists make an average of $64,000, according to the latest surveys by Medscape and Salary.com. *Full details on pages 5-8.*

Compensation Comparison



Source: *Laboratory Economics* and surveys by Medscape and Salary.com

CMS ALMOST CERTAIN TO MISS JUNE 30 DEADLINE FOR PRIVATE-PAYER REPORTING PROPOSAL

The clock is winding down and it now looks like the Centers for Medicare and Medicaid Services (CMS) will indeed miss its June 30 deadline for publishing a proposed rule outlining how clinical labs are to report private-payer test rates to the agency beginning in 2016.

Speaking at the annual meeting of the American Clinical Laboratory Association (ACLA) on May 5, a CMS official said the proposed rule would be out soon but did not promise it would be out by June 30. "We are doing our best to meet the June 30 date but it's very complicated," said Marc Hartstein, director of the Hospital and Ambulatory Policy Group at CMS. "I am concerned about the lateness of the rule." *Continued on page 2.*

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CMS ALMOST CERTAIN TO MISS JUNE 30 DEADLINE (*cont'd from page 1*)
Once the rule is published, there will be a 60 day comment period. CMS staff must then analyze all comments submitted before publishing a final rule. Such an analysis typically takes months, so even if a proposed rule came out over the summer, the agency would be hard pressed to get a final rule out by the end of the year.

When asked whether CMS might delay the Jan. 1, 2016, start date for labs to begin reporting payer data if the proposed rule is delayed, Hartstein declined to answer but did acknowledge concerns raised by the lab industry about needing enough time to establish reporting systems. Hartstein also said that CMS is developing its own system for receiving and analyzing the data, which is a major undertaking.

Given the complexity of the task at hand, *Laboratory Economics* predicts that CMS will not only miss the June 30 deadline for publishing a proposed rule, but may very well delay or modify the January start date for reporting of private-payer data.

PAMA Mandate

The requirement for CMS to collect private payer prices from labs beginning in 2016 was included in the Protecting Access to Medicare Act (PAMA), enacted April 1, 2014. CMS is to use this data to develop a new payment system for paying for tests under the Clinical Laboratory Fee Schedule (CLFS). The law mandates that beginning Jan. 1, 2016, and every three years thereafter, "applicable laboratories" report private payer data, including volume and what labs are paid for tests. An applicable laboratory is one that receives the majority of its revenues under the CLFS or the Physician Fee Schedule.

Under PAMA, payment for a clinical diagnostic laboratory test furnished on or after Jan. 1, 2017, will be equal to the weighted median of private payer rates for that test. Payment reductions will be limited to 10% for 2017 through 2019 and 15% from 2020 through 2022.

The law also establishes a new category for advanced diagnostic laboratory tests, with initial payment (for the first nine months), based on the actual list charge, which the law defines as "the publicly available rate on the first day at which the test is available for purchase by a private payer." Labs offering these tests will have to report private payer rates beginning the second quarter the test is on the market and annually thereafter. After the initial period, the data will be used to establish the payment amount using the same method described for other tests.

Concerns to be Addressed

Among the issues that must be addressed in the proposed rule are whether some labs might be exempt from reporting private payer data. The law does allow the Secretary of Health and Human Services (HHS) to establish a low-volume or low-expenditure threshold for excluding a laboratory from the definition of applicable laboratory. While this potentially could exempt physician office labs, the question remains whether other small labs might also be exempted.

Hartstein notes that in addressing this issue, CMS is faced with conflicting goals: to reduce the reporting burden on small laboratories while collecting as much data as possible.

Another challenge the agency faces is adequately defining an advanced diagnostic laboratory test (ADLT). The law defines an ADLT as a test furnished by a single laboratory that meets one of the following criteria: 1) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins

combined with a unique algorithm to yield a single patient-specific result; 2) the test is cleared or approved by the Food and Drug Administration; 3) the test meets other similar criteria established by HHS.

"The challenge will be in defining the first criteria, particularly 'unique algorithm,'" said Hartstein. "We're doing our best to make sure we get this right."

WHERE WILL BEACONLBS STRIKE NEXT?

UnitedHealthcare says it is assessing the progress of its lab benefit management program pilot in Florida and will decide within the next few months whether to expand the program to other states. "We're hopeful we can," UHC chief medical officer Sam Ho, MD, told *Modern Healthcare* (May 2, 2015).

UHC's lab benefit management program is being managed by BeaconLBS, which is a subsidiary of LabCorp. UHC is requiring that physicians use the system prior to ordering a list of 79 high-volume lab tests for approximately 430,000 of its full-insured commercial members in Florida.

"It's our goal to expand BeaconLBS both to additional markets and to additional payers and we've had a number of discussions with additional payers. Obviously we've been live for a relatively short period of time. We got to get some experience under our belt and we'll look forward to updating you on progress and when those expansions will occur over time," LabCorp CEO Dave King said on an April 27 teleconference with investors.

However, Florida doctors are complaining that the BeaconLBS system is a cumbersome extra step that takes away from their time to see patients. Jeff Scott, the Florida Medical Association's director of legal and governmental affairs, told *Modern Healthcare* that there remains "absolute, complete dissatisfaction with this program." He said the Florida Medical Association has drafted legislation to block other insurers from instituting similar programs.

"Soon we won't be able to see patients, we'll just spend all our time documenting everything," according to Tampa orthopedist Dr. Michael Wasylik, chairman of the medical association's medical services committee. "It makes me want to puke just talking about it."

Finally, *Laboratory Economics* asked UnitedHealthcare if there were any areas in the BeaconLBS pilot program that it was trying to improve or correct. Elizabeth Calzadilla-Fiallo, director of Public Relations for UHC in Florida, said that UHC is receptive to feedback from doctors and specialty societies and to date has held more than 100 in-person meetings with physician and pathologist groups.

Calzadilla-Fiallo said that UHC has made several important changes to the program as a result of feedback from the physician and lab community:

1) Two tests were removed from the list of lab tests requiring pre-notification: prenatal profile and gestational diabetes;
2) For dermatopathology, cytopathology and hematopathology, UHC will accept either a single review from a sub-specialist or a secondary review from an anatomic pathologist;
3) The program's Physician Decision Support tool has been integrated with four additional ordering applications (eClinical Works, Allscripts, Hello Health, and Medics DocAssistant), bringing the total to 13.

THERANOS HIRES FILM MAKER FOR YOUTUBE COMMERCIALS

Theranos has hired acclaimed documentary film director Errol Morris to direct a series of short infomercial-type films that the company is posting on its website and YouTube channel. Morris, who has directed a number of highly regarded documentary films including *The Thin Blue Line* (1998) and *The Fog of War* (2003), has lately been branching out into fictional movies. His latest film—*Holland, Michigan*—is a dark comedy starring Bryan Cranston and Naomi Watts.

Theranos posted six short films (about 60 seconds each) directed by Morris on its YouTube Channel on May 2. Three of the films tout a benefit of using Theranos, e.g., convenience, low prices and small blood sample. Two films feature Theranos' founder and CEO Elizabeth Holmes, while another features an employee talking about why he likes working at Theranos.

David Nichols, president of the lab consulting firm Nichols Management Group (York, ME), notes that while he has many questions about Theranos' technology and the sustainability of its business model, the company has proven to be a master in generating positive media coverage.

Nichols believes that one big key to Theranos' public relations campaign success has been the recruitment of a seasoned PR executive as its chief creative officer (CCO). Theranos named former TBWA Creative Executive Patrick O'Neill as its CCO in July 2014. TBWA Worldwide is an international advertising agency headquartered in New York City and is a subunit of Omnicom Group, which is the world's largest advertising holding company. TBWA is known for its philosophy of "the disruption and Media Arts" and its long client list includes giants such as Visa, Gatorade, The Grammy's, Haagen-Dazs, Absolut, Taco Bell, Pfizer, GSK and Apple.

Nichols says that lab companies have traditionally directed their marketing at physicians because they are the people who order lab tests. Theranos, on the other hand, is promoting its CEO Elizabeth Holmes as the face of the company through numerous interviews, presentations and magazine articles aimed at the general public. Nichols says that Holmes presents in a rehearsed manner with a focus on empathetic story-telling, such as her fear of needles and anecdotal stories of sick relatives.

Nichols, who has written an extensive research report on Theranos, notes that the company's PR efforts have been extremely successful at getting flattering articles in the mainstream press (e.g., *Glamour, The New Yorker, Fortune, Forbes, USA Today, Wired*). However, he questions whether this has translated into meaningful patient traffic at Theranos' draw sites at Walgreens stores in Phoenix.

LabCorp to Sell Lab Tests to Consumers through Internet

In related news, LabCorp says it will soon let customers go online to pay for tests, visit a service center to get blood drawn, then view the results on the Web. For several years, LabCorp has provided lab testing services to a number of Internet sites that let consumers order tests online (see table). "It's a growth opportunity for us. It's something consumers increasingly want to have access to, and it's something we're doing already and our capabilities are being utilized without us getting the benefit from a branding perspective," LabCorp CEO Dave King said in a recent interview with Bloomberg Businessweek.

In addition, King said that LabCorp is exploring a partnership with an unnamed drugstore chain as well. This is an idea that the company tried and failed with Duane Reade drugstores in New York City back in 2006-2007. Duane Reade was acquired by the Walgreen Company in 2010.

Internet Firms Marketing Lab Tests

DAT Company	Lab Partner	Sample Prices Lipid Panel
Any Lab Test Now	Quest and LabCorp	$49
DirectLabs	LabCorp	$29
eStatLabs	Quest Diagnostics	$60
HealthCheckUSA	LabCorp	$35
Health-Tests-Direct	Quest and LabCorp	$20
MyLabsForLife	Quest Diagnostics	$32
WellnessFX	Quest and LabCorp	$78

Source: *Laboratory Economics* from companies

PUBLIC-LAB CEOs PAID AVERAGE $2.7 MILLION (*cont'd from page 1*)
LabCorp's Dave King, $10.5 million, Quest Diagnostics' Steve Rusckowski, $9.3 million, and Myriad Genetics' Peter Meldrum, $8.1 million, were the highest lab company CEOs in 2014.

LabCorp's King, 58, received five different categories of compensation last year that totaled $10.5 million. These included: 1) salary of $1 million; 2) stock awards of $7.5 million; 3) incentive plan cash bonus of $1.6 million; 4) increased pension value of $295,236; and other compensation of $25,723, which included financial planning services, 401K matching contributions, long-term disability insurance and personal liability insurance. Net income at LabCorp decreased by 11% to $511.2 million in 2014, while revenue increased 3.5% to $6 billion. LabCorp's stock price was up 18% last year.

Quest Diagnostics' Rusckowski, 57, received total compensation of $9.3 million last year, including a salary of $1.05 million, cash incentives of $1.3 million, and stock and option awards of $6.7 million. He also received $225,338 in perks, including $72,122 for personal use of a company car and driver plus $93,999 for personal use of company aircraft. Net income at Quest fell by 35% to $556 million in 2014, while revenue rose 4% to $7.4 billion. The total return, including dividends, for Quest stock last year was 28%.

Peter Meldrum, 67, president and CEO of **Myriad Genetics**, earned $8.1 million, including a salary of $996,157, a bonus and cash incentives of $1.3 million, stock option awards valued at $5.8 million, plus other compensation of $10,231. In the fiscal year ended June 30, 2014, Myriad reported net income of $176.2 million, up 20% from $147.1 million in 2013; revenue increased by 27% to $748.2 million; its stock price was up 62% in calendar-year 2014.

Kim Popovits, 56, chairman and CEO of **Genomic Health**, received $3 million, including a salary of $660,000, incentive plan compensation of $462,800 and stock and option awards worth $1.9 million. Genomic Health reported a net loss of $24.6 million on revenue of $275.7 million in 2014; its stock price was up 9% last year.

Panna Sharma, 44, president and CEO of **Cancer Genetics Inc.**, received $2.8 million, including a salary of $400,000, bonus of $200,000, stock and options worth $2.1 million, plus company-paid life insurance premiums of $4,248. Cancer Genetics incurred a net loss of $12.4 million on revenue of $4.3 million in 2014; its stock price was down 52% last year.

At the low end, **Randall Scott, PhD**, 57, chairman and CEO at **Invitae Corp.**, earned a salary of $203,703 and nothing more. Invitae recorded a net loss of $47.5 million in 2014 on revenue of $1.6 million. The company raised net proceeds of $106 million from an IPO priced at $16 per share on February 12, 2015.

Meanwhile, IRS Form 990s for 2013 reveal the total compensation for the top executives at the nation's laboratory and pathology trade organizations. **Charles Roussel**, chief executive at the **College of American Pathologists**, earned total compensation of $1.26 million in 2013; **Alan Mertz**, president of the **American Clinical Laboratory Association**, earned $858,145; **Blair Holladay, PhD**, chief executive at the **American Society for Clinical Pathology**, earned $507,640; and **Birenbaum & Associates**, the management company for the **American Association of Bioanalysts** (aka, National Independent Lab Association) received $668,015 in 2013.

2014 Laboratory Executive Total Compensation

Company/Executive	Salary	Bonus and Incentives	Value of Stock & Option Awards	Other Comp*	2014 Total Comp	2014 Revenue Growth	2014 Stock Price Total Return
Bio-Reference Labs Marc Grodman, MD, 63, Chmn. & CEO	$1,157,161	$70,000	$0	$243,274	$1,470,435	16%	26%
Cancer Genetics Inc. Panna Sharma, 44, Pres. and CEO	400,000	200,000	2,139,842	4,248	2,744,090	54%	-52%
CombiMatrix Mark McDonough, 45, Pres. & CEO	301,000	0	387,452	0	688,452	26%	-44%
Enzo BioChem Elazar Rabbani, PhD, 71, Chmn. & CEO	555,478	375,000	43,549	156,000	1,130,027	5%	52%
Foundation Medicine Michael Pellini, MD, 49, Pres. & CEO	415,957	167,622	0	36,093	619,672	11%	-7%
Genomic Health Kim Popovits, 56, Chairman & CEO	660,000	462,800	1,908,662	0	3,031,462	5%	9%
Invitae Randal Scott, PhD., 57, Chmn. & CEO	203,703	0	0	0	203,703	984%	NA
LabCorp David King, 58, Chairman & CEO	1,013,000	1,600,450	7,538,153	320,959	10,472,562	4%	18%
Myriad Genetics Peter Meldrum, 67, President & CEO	996,157	1,294,319	5,841,360	10,231	8,142,067	27%	62%
NeoGenomics Douglas VanOort, 59, Chairman & CEO	441,346	305,157	182,483	0	928,986	31%	15%
Psychemedics Raymond Kubacki, Jr., 70, Chmn. & CEO	429,510	107,377	194,610	6,750	738,247	9%	6%
Quest Diagnostics Stephen Rusckowski, 57, Pres. and CEO	1,050,000	1,291,290	6,700,207	225,338	9,266,835	4%	28%
Response Genetics Thomas Bologna, 66, Chairman & CEO	593,909	174,000	141,880	144,057	1,053,846	-16%	-72%
Sequenom William Welch, 53, Pres. & CEO	432,954	0	744,862	825	1,178,641	27%	58%
Transgenomic Inc. Paul Kinnon, 52, Pres. & CEO	350,000	0	79,920	10,875	440,795	-2%	-64%
Veracyte Inc. Bonnie Anderson, 57, Pres. & CEO	425,000	127,500	1,193,094	0	1,745,594	75%	-33%
Totals, 16 companies	9,425,175	6,175,515	27,096,074	1,158,650	43,855,414		
Averages, 16 companies	$589,073	$385,970	$1,693,505	$72,416	$2,740,963	79%	0%

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks.

Source: *Laboratory Economics* from company proxy statements

THE AVERAGE PATHOLOGIST EARNS $267K

Compensation earned by pathologists, at an average $267,000 per year, came in slightly below the middle when compared with all physicians, according to the Medscape Physician Compensation Report 2015. The Medscape Report was based on survey responses from a total of more than 19,500 physicians, including 590 pathologists, received between December 30, 2014 and March 11, 2015.

The lowest earners, starting from last place, were pediatricians ($189,000), followed by family physicians ($195,000), and endocrinologists and internists (both at $196,000). The top earners this year were orthopedists ($421,000), cardiologists ($376,000), and gastroenterologists ($370,000).

Pathologists in multispecialty groups ($356,000) and single-specialty groups ($327,000) earn the most. Those who earn the least money are in academic or government centers ($185,000) and office-based solo practices ($260,000).

Self-employed pathologists earn an average of $344,000 versus $237,000 for employed pathologists, according to the Medscape Report.

Pathologist Compensation by Practice Setting

Office-based multispecialty group practice	356,000
Office-based single-specialty group practice	327,000
Healthcare Organization	$270,000
Hospital	$265,000
Office-based solo practice	260,000
Academic/non-hospital/research/military/government	$185,000

Source: Medscape Physician Compensation Report 2015

NON-PROFIT HOSPITAL CEOs EARN MULTI-MILLION $ PAY (*cont'd from p. 1*)

Hospital system CEO compensation information was obtained by *Laboratory Economics* from IRS Form 990s, which are annual tax returns that tax-exempt organizations must file with the IRS. They provide information on the filing organization's mission, programs and finances.

At the top of the list of non-profit hospital system CEOs was **Anthony Tersigni** from **Ascension Health** (St. Louis, MO), which operates 73 acute-care hospitals in the Midwest with $16.5 billion in annual revenue. Tersigni earned total compensation of $8.5 million in 2013, including a salary of $1.6 million, bonus and incentives of $5.5 million and other compensation and perks of $1.4 million.

Second highest was **Charles Sorenson, Jr., MD**, president and CEO at **Intermountain Health Care** (Salt Lake City, UT). Sorenson earned total compensation of $7.4 million in 2013, including salary of $941,185, bonus of $703,566, retirement plan benefits of $930,113 plus supplemental retirement plan benefits of $4.8 million and other compensation of $39,791. Intermountain Health Care operates 17 acute-care hospitals and has annual revenue of more than $5 billion.

Next was **Jeffrey Romoff**, president and CEO of **University of Pittsburgh Medical Center** (UPMC-Pittsburgh, PA), who received total compensation of $6.6 million in 2013. UPMC operates 20 acute-care hospitals and generates more than $10 billion in annual revenue.

Non-Profit Hospital CEO Compensation for 2013

Hospital System & CEO	2013 Total Compensation	2013 Total Revenue	Number of Hospitals*
Ascension Health Alliance (St. Louis, MO) Anthony Tersigni, President & CEO	$8,497,310	$16,536,898,000	73
Intermountain Health Care (Salt Lake City, UT) Charles W. Sorenson, Jr., MD, President & CEO	7,398,723	5,041,500,000	17
UPMC (Pittsburgh, PA) Jeffrey Romoff, President & CEO	6,551,075	10,188,439,000	20
Sutter Health (Sacramento, CA) Patrick Fry, President & CEO	6,010,188	9,649,000,000	26
Banner Health (Phoenix, AZ) Peter Fine, President & CEO	5,487,071	5,085,004,000	16
Carolinas Healthcare System (Charlotte, NC) Michael Tarwater, Chief Executive	4,884,000	8,358,335,000	14
North Shore-LIJ Health Care (Westbury, NY) Michael J. Dowling, President & CEO	4,340,617	7,001,800,000	13
New York-Presbyterian Healthcare (NYC) Steven Corwin, MD, Chief Executive	4,006,812	4,264,510,000	17
Dignity Health (San Francisco, CA) Lloyd H. Dean, President & CEO	3,921,633	10,400,000,000	34
Sentara Healthcare (Norfolk, VA) David Bernd, Chief Executive	3,817,166	4,298,726,000	12
Cedars-Sinai Medical Center (Los Angeles, CA) Thomas M. Priselac, President & CEO	3,554,240	2,793,533,540	1
Cleveland Clinic Foundation (Cleveland, OH) Delos M. Cosgrove, President & CEO	3,264,716	6,450,159,000	10
Aurora Health Care (Milwaukee, WI) Nick Tukal, MD, President & CEO	3,184,302	4,248,975,000	13
Catholic Health Initiatives (Denver, CO) Kevin Lofton. President & CEO	3,131,203	9,892,990,000	32
Baptist Memorial Health Care (Memphis, TN) Stephen C. Reynolds, President & CEO	2,543,578	1,884,425,000	14
Mercy Health (Cincinnati, OH) Michael Connelly, President & CEO	2,131,633	3,955,601,000	17
Christus Health (Irving, TX) Ernie Sadau, President & CEO	1,958,735	3,701,272,000	22
Providence Health and Services (Seattle, WA) Rod F. Hochman, MD, President & CEO	1,918,810	11,136,680,000	26
Mayo Clinic Health System (Rochester, MN) John Noseworthy, MD, President & CEO	1,900,297	9,420,800,000	12
Adventist Health System (Winter Springs, FL) Don Jernigan, PhD, President & CEO	1,721,964	7,597,799,000	36
Grand Total for 20 CEOs	***$78,502,109***		
Average per CEO	***$3,925,105***		

*Number of hospitals is for acute-care hospitals only.

Source: *Laboratory Economics* from IRS Form 990 and audited financial statements.

FDA OVERSIGHT OF LDTS MAY BE A WAYS OFF

Final Food and Drug Administration (FDA) guidance on lab-developed tests (LDTs) probably won't be out this year, a senior FDA official said May 5 during the annual meeting of the American Clinical Laboratory Association (ACLA).

Elizabeth Mansfield, PhD, director of personalized medicine at the FDA's Center for Devices and Radiological Health, said she can't predict when the final guidance will be out, but given the number of high-level reviews it must go through, "this year might not be enough time."

Elizabeth Mansfield

The draft guidance, issued Oct. 3, 2014, has been largely opposed by the clinical laboratory industry, which argues that LDTs are already regulated under the Clinical Laboratory Improvement Amendments (CLIA). The FDA is proposing a nine-year phase-in of LDT oversight, beginning with premarket review of what the agency deems high-risk LDTs (Class III) and moving on to moderate-risk (Class II) LDTs. The FDA proposed to continue enforcement discretion for rare tests, tests for unmet needs, "traditional" LDTs, forensic LDTs, and LDTs used in CLIA-certified, high-complexity histocompatibility laboratories for transplantation.

Mansfield said that the FDA will consider "grandfathering" some existing LDTs into the new oversight framework, noting that this was a common theme in comments submitted on the draft proposal. Comments on the proposal were due Feb. 2.

In response to concerns that there would be too much overlap between the FDA and the Centers for Medicare and Medicaid Services (CMS), the agencies said in April that they have formed a task force to coordinate LDT oversight. The newly formed FDA/CMS Task Force on LDT Quality Requirements will identify commonality between FDA's quality system regulation and CLIA requirements; clarify responsibility for labs that have to meet requirements from both FDA and CMS; and manage resources so labs are not subject to duplicative regulations.

Alternative Proposal

Separately, a small group of labs and test manufacturers in April released an alternate proposal for regulating "in vitro clinical tests" or IVCTs. The group, known as the Diagnostic Test Working Group (DTWG), reportedly includes Becton Dickinson, Roche, Mayo Clinic, LabCorp, and ARUP Labs.

According to Allyson Mullen and Jeff Gibbs, attorneys with Hyman, Phelps and McNamara PC, the DTWG proposal offers a compromise for those on both sides of the LDT debate. For laboratories, it would mean greater regulation of LDTs while not trying to fit LDTs into the traditional medical device regulatory framework, and for IVD manufacturers, it would result in significant changes to the current regulatory model.

The proposal would apply to all in vitro diagnostic tests, both kits and LDTs and calls for establishment of a new center within FDA.

According to the work group, a regulatory framework for IVCTs should be based on the various types of activities involved in creating and conducting an IVCT, with oversight jurisdiction divided among FDA, CMS, and the states. The group identifies 10 steps in the life cycle of an IVCT (see chart on p. 10). Under the proposal, FDA would have jurisdiction over test development activities, including design, development, validation, the production of reagents or tests kits for distribution, and certain post-market activities.

CMS would retain jurisdiction over laboratory operations, which would include the preparation of reagents for a single laboratory facility and the process of actually performing an IVCT. The states would have oversight of the practice of medicine—primarily in the medical judgment used for determining what tests are appropriate for a specific patient and the interpretation of test results and related consultations.

"This activity-based approach facilitates application of the same regulatory requirements to the same activity while also drawing clear lines of exclusive jurisdiction between FDA, CMS, and the states," says the group in its draft document. "Because jurisdiction is tied to specific activities, not a specific entity type, a single entity can come under the jurisdiction of more than one regulatory authority for different activities. A single entity can engage in test development activities under FDA jurisdiction for one IVCT and engage in laboratory operations under CMS jurisdiction for a different IVCT. Similarly, with regard to a single IVCT, a single entity can engage in both test development activities under FDA jurisdiction and laboratory operations under CMS jurisdiction."

10 Steps in IVCT Life Cycle

- Design
- Development
- Validation
- Production for Another Facility or Third Party
- Production for a Single Facility
- Verifying Laboratory Performance
- Pre-Analytical Processes
- Performing the IVCT
- Reporting the IVCT Output
- Interpretation and Consultation

Source: Diagnostic Test Working Group, "A Proposed Regulatory Framework for In Vitro Clinical Tests"

This alternative proposal also calls for tests to be classified as high risk, moderate risk, and low risk. Developers of a new IVCT would propose a classification to FDA, and FDA would have 60 days to object. The proposal includes special pathways for IVCTs for rare disease, emergency use, and those for unmet needs. There is a proposed three or four year transition period for LDTs currently on the market and those that would enter the market after the proposal goes into effect.

"In our view, this proposal is an intriguing start toward a potential LDT compromise," write Mullen and Gibbs on the FDA Law Blog (www.fdalawblog.net). "There are certainly many areas of clarification and development that are still required and many key details will still need to be worked out. We expect that many laboratories will prefer the DTWG's proposal as it would mean less onerous regulation compared to FDA's proposed LDT framework. Manufacturers may also find the change to IVD regulation to be attractive. This proposal could form the basis of legislation that may be released in the near future."

Definition of an IVCT

An in vitro clinical test is any finished product or laboratory test protocol intended by the developer to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body, solely or principally for the purpose of identifying, measuring, predicting, monitoring, or assisting in selecting treatment for a disease or other condition; provided, however, that blood screening tests regulated under Section 351 of the Public Health Service Act are not in vitro clinical tests.

IVCTs are not drugs or devices as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act or biological products subject to Section 351 of the Public Health Service Act.

Source: Diagnostic Test Working Group, "A Proposed Regulatory Framework for In Vitro Clinical Tests"

MEDICARE TAKES ANOTHER STEP AWAY FROM FEE-FOR-SERVICE PAY

H.R. 2, the Medicare Access and CHIP Reauthorization Act (MACRA), was signed into law by President Obama on April 16, 2015. The new law has put an end to the Sustainable Growth Rate Formula (SGR) for determining annual changes to the Medicare Physician Fee Schedule (MPFS) and averted a 21% cut that had been set to take effect in April 1, 2015.

This recent legislation together with the Affordable Care Act are designed to push providers away from traditional fee-for-service and toward alternative payment models, such as ACOs and episodic bundled payment programs, that put physician payment at risk for bonuses or reductions.

The First Five Years – 0.5% Annual Increases
MACRA replaces the current SGR reimbursement formula with annual 0.5% payment increases to Medicare physician rates between July 1, 2015 and 2019. These increases are well below historic CPI averages for increases in physician fees, which have averaged about 2.4% per year since 2009. It is likely that these limitations will also impact increases paid by other third-party payers for physician services.

Physician Rate Freeze Between 2020-2025
Reimbursement rates under the Medicare Physician Fee Schedule will then be frozen from 2020 to 2025.

Two Payment Pathways
Under MACRA, physicians will need to choose one of two payment systems: a Merit-Based Incentive Payment System (MIPS), or an Alternative Payment Model. Both are complex and put physician payment levels at risk for either bonuses or penalties. The specific factors that CMS will use to determine whether a particular physician gets a Medicare bonus or reduction have yet to be determined. However, the net effect is that there will be less fee-for-service reimbursement from Medicare with these new options in place.

Medicare Physician Payment Changes by Pathway

	Fee-for-Service: MIPS Pathway	*Alternative Payment Model Pathway*
January to June 2015	0% MPFS change.	0% MPFS change.
July 1 to Dec. 31, 2015	0.5% MPFS increase.	0.5% MPFS increase.
2016 to 2019	Annual MPFS increase of 0.5%.	Annual MPFS increase of 0.5%.
2020 to 2025	*No annual MPFS change. *Providers receive incentive payments or penalties amounting plus or minus 4% based on composite performance score of various quality measures. *Incentive payment and penalties will rise each year to plus or minus 9% in eighth year.	*No annual MPFS change. *Opportunity for 5% bonus. *Shared savings or losses depending on ACO contract.
2026 and beyond	Annual MPFS increase of 0.25%.	*Annual MPFS increase of 0.75%. *Shared savings or losses depending on ACO contract.

Source: *Laboratory Economics* from H.R. 2 – Medicare Access and CHIP Reauthorization Act of 2015

LAB STOCKS UP 10% YTD

Fourteen lab stocks have increased by an unweighted average of 10% year to date through May 13. In comparison, the S&P 500 Index is up 2.7% and Nasdaq is up 5%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 76% on news that Roche is buying a majority stake in the company. Meanwhile, Quest Diagnostics is up by 6% and LabCorp is up 8%.

Company (ticker)	Stock Price 5/13/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$32.95	$32.13	3%	$915	18.2	1.1	2.8
Cancer Genetics Inc. (CGIX)	10.60	6.68	59%	104	NA	9.5	2.8
CombiMatrix (CBMX)	1.71	1.29	33%	22	NA	2.7	2.6
Enzo Biochem (ENZ)	2.52	4.44	-43%	114	NA	1.2	3.3
Foundation Medicine (FMI)	39.17	22.22	76%	1,340	NA	18.9	13.0
Genomic Health (GHDX)	27.87	31.97	-13%	1,800	NA	3.3	5.8
LabCorp (LH)	116.56	107.90	8%	11,700	18.7	1.6	2.6
Myriad Genetics (MYGN)	34.07	34.06	0%	2,370	27.2	3.3	2.6
NeoGenomics (NEO)	4.85	4.17	16%	293	NA	3.0	4.9
Psychemedics (PMD)	15.07	15.15	-1%	81	29.7	2.8	6.5
Quest Diagnostics (DGX)	70.88	67.06	6%	10,180	20.1	1.3	2.4
Response Genetics (RGDX)	0.32	0.32	1%	12	NA	0.7	NA
Sonic Healthcare (SHL.AX)	19.32	18.50	4%	7,766	20.3	1.9	2.4
Veracyte (VCYT)	8.65	9.66	-10%	198	NA	5.2	4.8
Unweighted Averages			10%		22.4	4.0	4.3

Source: Bloomberg

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