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# LABORATORY INDUSTRY REPORT®

Kimberly Scott, Managing Editor, [kscott@G2Intelligence.com](mailto:kscott@G2Intelligence.com)

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## Upcoming Conferences

### Lab Institute 2011

Oct. 19-21, 2011  
Crystal Gateway Marriott  
Arlington, Va.  
[www.labinstitute.com](http://www.labinstitute.com)

### LabCompete:

Laboratory Sales & Marketing  
Dec. 12-14, 2011  
Sheraton Wild Horse Pass Resort  
Chandler, Ariz.  
[www.labcompete.com](http://www.labcompete.com)

[www.G2Intelligence.com](http://www.G2Intelligence.com)

## Creating a Value-Driven Laboratory: Opportunities in the New Marketplace

In today's competitive marketplace, clinical laboratories must demonstrate that they provide more than just timely and accurate lab test results. Because labs are often viewed as cost centers, they are often popular targets for spending cuts. But if labs can demonstrate that they provide additional value for payers and for the health care system as a whole, they are more likely to be treated as valued members of a patient's health care team and may be more protected from cuts.

Molecular testing is one area where labs can provide added value both by helping payers understand this emerging field and by assisting them in managing molecular test utilization. If labs do not step up to meet these needs, others in the market will. For more on the forces shaping value-driven labs and why laboratorians need to take heed, see *Inside the Laboratory Industry* starting on p. 5. 

## MedPAC Recommends \$21 Billion in Cuts To Medicare Part B Lab Payments

Clinical laboratories are facing yet another threat to their Medicare reimbursement, and this time the threat is not coming from Congress.

The Medicare Payment Advisory Commission (MedPAC) is recommending a fix to the sustainable growth rate (SGR) formula used to update the physician fee schedule each year. To pay for the fix, MedPAC is proposing to cut payment to other Medicare providers, of which 9 percent, or \$21 billion, would come from Part B lab spending.

The proposal, which would require congressional approval, was unveiled at the commission's Sept. 15 meeting. The list of funding options was released Sept. 19 and is split into two sections: the first, totaling \$50 billion, is drawn from previous commission recommendations. The second, totaling \$180 billion, comes from other sources, such as the Congressional Budget Office and the Department of Health and Human Services.

In a Sept. 16 letter to MedPAC chairman Glenn M. Hackbarth, J.D., the American Clinical Laboratory Association (ACLA) said it was

*Continued on page 2*

### ■ MEDPAC RECOMMENDS \$21 BILLION IN CUTS, from page 1

"particularly concerned about the prospect of the commission making recommendations to Congress for fixing the SGR through cuts in providers' payments, including clinical lab fees and payments to pathologists."

While agreeing with MedPAC that the SGR payment system should be replaced with one that is stable and predictable, ACLA took issue with how to pay for the change by "sharing the cost of repealing the SGR across physicians, other health professionals, providers in other sectors, and beneficiaries."

Additional lab cuts are "unsustainable," said ACLA President Alan Mertz in the letter. "Clinical lab services inform 70 percent of health care providers' decisions, while accounting for only 1.6 percent of Medicare spending. Yet, payments for lab services have been reduced by about 40 percent in real (inflation-adjusted) terms over the past 20 years. They are scheduled to decline an additional 19 percent over the next 10 years under changes mandated by the health care reform law. And more cuts are reportedly on the table for the joint select committee."

The committee, a 12-member bipartisan panel composed of House and Senate members, is charged with recommending cuts of up to \$1.5 trillion in federal spending by Thanksgiving.

Pathology and other medical groups are looking to the joint select committee to repeal the SGR system. Under the SGR, physician fees are scheduled to be cut by 29.5 percent as of Jan. 1, 2012, and even deeper cuts are forecast for subsequent years. Even if the upcoming reduction is blocked, payments for primary care physicians would be frozen for 10 years and pathologists would see a reduction in payments for three years, followed by a seven-year freeze.

The American Medical Association wants the committee to block the impending cut and replace the SGR with stable fee increases over the next five years in the transition to a system based on payment and delivery alternatives to traditional fee-for-service. 

## HHS Proposes Allowing Patients Direct Access to Laboratory Test Results

In what it says is part of an effort to empower patients to be informed partners with their health care providers, the Department of Health and Human Services (HHS) has proposed a new rule that would allow patients or their representative direct access to their laboratory tests.

The proposed rule, published in the *Federal Register* on Sept. 14, would modify regulations under two statutes that impose restrictions on patient access to lab results: the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and the Health Insurance Portability and Accountability Act (HIPAA) of 1996. There will be a 60-day public comment period on the proposal.

In proposing the rule, HHS said it wanted to recognize current health reform concepts, such as individuals' involvement in their own health care, by allowing patients easier access to health information.

"When it comes to health care, information is power," HHS Secretary Kathleen Sebelius said in a statement. "When patients have their lab results, they are more likely to ask the right questions, make better decisions and receive better care."

The proposed rule was issued jointly by HHS, the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and the HHS Office for Civil Rights.

HHS said the move to relax current restrictions on patient access to laboratory results came about as a result of a review by the Health Information Technology Policy Committee. The federal advisory panel seeks to identify barriers to the adoption and use of health information technology. The committee concluded that current CLIA and HIPAA regulations prevent patients from taking a more active role in their personal health decisions, HHS said in an introduction to the proposed rule.

### **State Law Preemption**

Specifically, under a current CLIA regulation (42 C.F.R. § 493.1291(f)), patients in states that do not provide individual access to test results must request and receive the results through their health care provider, according to HHS.

Currently, 39 states—encompassing some 22,671 laboratories—prohibit a laboratory from releasing a test report directly to the patient or prohibit the release without the consent of the health care provider, HHS noted. HHS said it intends that the proposed rule would preempt the law in these states.

The proposed rule would also modify exceptions under HIPAA that impose restrictions on the release of certain laboratory results. A privacy rule (45 C.F.R. § 164.524) issued under HIPAA—which provides individuals with a general rights of access to health records—contains exceptions for laboratory results from CLIA-certified laboratories, HHS said.

"Because CMS is proposing to amend the CLIA regulations to allow CLIA-certified laboratories to provide patients with direct access to their test reports, there is no longer a need for the exceptions at §164.524 for CLIA and CLIA-exempt laboratories," HHS said. "Unless these exceptions are removed from the privacy rule, they would serve as a barrier to individuals' right of access to test reports."

After the notice and comment period, laboratories would be required to comply with the new rule within 180 days after the effective date of the final rule, which would be 60 days after the final rule is published in the *Federal Register*, HHS said.

### **Compliance Costs**

HHS said the proposed rule, if it becomes final, would not constitute an "economically significant rule," which Office of Management and Budget guidelines define as one imposing overall annual costs of more than \$100 million. HHS estimated that the rule, if implemented in 2011, would impose compliance costs of \$3 million to \$56 million.

The first-year costs would include initial costs of developing an internal process to handle patient requests for laboratory results, which HHS estimated would

range from \$2.2 million to \$10.2 million. Because the start-up costs would not be necessary in subsequent years, HHS said it expected that compliance costs would diminish over time.

In measuring benefits of the proposed rule, HHS noted it would have a positive but not quantifiable impact on patients, a majority of whom express a preference for being able to obtain test results directly from a laboratory.

States, Territories Affected by Direct Access Proposed Rule		
NO STATE LAW AUTHORIZING ACCESS		ALLOWS TEST REPORTS ONLY TO PROVIDER
Alabama	Nebraska	Arkansas
Alaska	New Mexico	Georgia
Arizona	North Carolina	Hawaii
Colorado	North Dakota	Illinois
Guam	N. Mariana Islands	Kansas
Idaho	Ohio	Maine
Indiana	Oklahoma	Missouri
Iowa	South Carolina	Pennsylvania
Kentucky	South Dakota	Rhode Island
Louisiana	Texas	Tennessee
Minnesota	Utah	Washington
Mississippi	Vermont	Wisconsin
Montana	Virgin Islands	Wyoming

Source: CMS

Other benefits include reduced workload for health care provider offices, which would be relieved from having to request test results, and fewer patients who fail to seek appropriate medical care, HHS said.

Surya Mohapatra, Ph.D., chairman and CEO of Quest Diagnostics (Madison, N.J.) praised the rule, noting that "patient engagement in health care decisionmaking is vital to promoting better health outcomes and reduced costs in our health care system."

Mark Birenbaum, Ph.D., administrator of the National Independent Laboratory Association and the American Association of Bioanalysts, says his groups favor allowing patients to have access to their own lab test results but are still evaluating the proposal to determine what the costs will be for smaller laboratories.

"If the logistics and costs are reasonable, then we support [the proposal]," he tells *Laboratory Industry Report*.

The American Clinical Laboratory Association, which represents larger labs, has not taken a position on the rule. 62

# Inside The Lab Industry

*This article is excerpted from G2 Intelligence's latest report, Creating a Value-Driven Laboratory: Opportunities in the New Marketplace, written by L. Eleanor J. Herriman, M.D., MBA, director of research and analysis. The full report will be available in October and can be purchased from [www.G2Intelligence.com](http://www.G2Intelligence.com). To preorder the report, please call customer service at 973-718-4700.*

## Transformation to a Value-Driven Laboratory Model

These are transformative times in the health care industry, with policy, purchaser, and scientific developments creating game-changing dynamics. Like other sectors, the clinical laboratory industry is beginning to be morphed by these forces. The principal factors driving these changes include:

- Health care crisis-driven market reforms:
  - Payment reform—fee for service is being phased out and replaced with value-based purchasing, at risk contracting
  - Delivery reform—provider-coordinated services, population management
- Increasingly significant reimbursement cuts:
  - Clinical laboratory fee schedules declining annually
  - Payers putting caps on new diagnostic test pricing
- Emerging era of precision (aka personalized) medicine:
  - Clinicians need help navigating and implementing laboratory testing, especially molecular
  - Payers need to manage molecular testing utilization

These dynamics all point to a new health care market driven by value, defined as patient health outcomes generated per unit of resources expended. Value is the new industry currency, metric, and business objective, and clinical laboratory practice is being drawn into this market.

### Major Disruptive Forces Driving Labs Toward Value-Driven Models

The challenge is that the current laboratory model is not centered on supporting this type of clinical value. Clinical laboratories are designed and optimized for efficient and accurate test analyses and results delivery. In a value-driven health care delivery system with new care delivery and payment systems, this approach may no longer be sufficient or optimal.

Paul Epner, principal, Paul Epner LLC, argues that labs currently find themselves in a sort of commodity orientation and must change to a patient-centric one to enter the value-driven marketplace. Epner explains that currently laboratorians focus on operational costs and efficiency—getting accurate answers, at the lowest cost, quickly. He refers to this as the “factory model,” and it inevitably designates the work a commodity. The value model instead centers operations on optimizing patient outcomes and patient care efficiency.

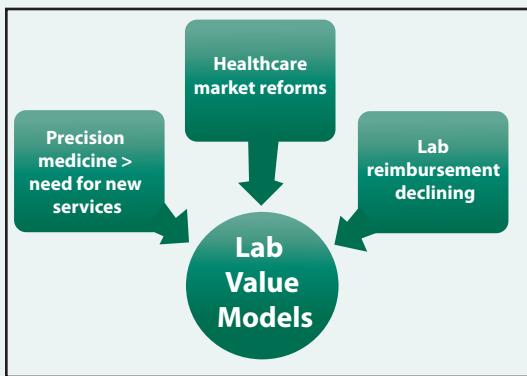
Brian Jackson, M.D., assistant professor of clinical pathology at the University of Utah and medical director of informatics at ARUP Laboratories in Salt Lake City, adds, “Providers’ and policymakers’ focus on quality and outcomes is reaching a climax at the same time that the reform law is rolling out trials of integrated care and bundled payments, creating a new environment

that will require rethinking cost and value." He predicts, "I think we're getting close to an inflection point where suddenly it will make more sense to focus on the actual medical value and the downstream costs associated with lab testing, and the fee-for service side will become a sideline rather than the main picture."<sup>1</sup>

Laboratories have begun exploring a number of new value-driven approaches that deviate from the traditional lab model. Generally, they can be categorized into three groups—strategies employing differentiated, value-driven lab offerings, marketing and distribution channels, and revenue generation approaches. All value-driven lab strategies start with understanding market needs, which, in turn, derive from the disruptive forces introduced above. For this reason, it is worth delving into them a bit deeper.

### **Disruptive Force 1—Value-Driven Health Care Market Reforms**

The long-term health care market reforms now being implemented are centered on measuring and rewarding the value of clinical services and interventions. This equates to a focus on outcomes, quality, and cost efficiencies. Thus, providers are being measured and increasingly compensated based on quality and efficiency—i.e., value. Interventions are reimbursed if they meet value hurdles.



Beginning around 2006, a "value-based purchasing" paradigm was introduced through the Value Driven Health Care Initiative by the Department of Health and Human Services (HHS). Value-based purchasing compensates providers based on the value of the services they provide, in addition to the volume of services.

The objective of payment reform is to eventually phase out fee for service altogether, as rewarding volume results in perverse incentives that negatively impact quality and costs. National health policy

leader Paul Ginsburg, Ph.D., writes, "The shift from volume-driven to value-driven payment is inevitable, and getting limited shared savings while embarking on the needed investments to build the infrastructure and relationships for improving delivery is better than getting no rewards under the fee-for-service system. It may be better to spend now in order to save later and avoid the consequences of the inevitable ratcheting down of fee-for-service rates."<sup>2</sup>

### **Disruptive Force 2—Laboratory Reimbursement Deterioration**

Payers and providers alike are searching for ways to cut the bottom line. While this is not new per se, the magnitude and urgency of the effort are. Because laboratories are primarily viewed as cost centers without substantial political clout, they are popular targets for spending cuts.

For example, as Medicare is facing insolvency, its search for spending cuts

<sup>1</sup> Bill Malone, "Reimbursement and Reform in 2011," Clinical Laboratory News, January 2011.

<sup>2</sup> Paul Ginsburg, Ph.D., "Spending to Save — ACOs and the Medicare Shared Savings Program," New England Journal of Medicine, NEJM.org, May 25, 2011.

is expected to only intensify in the coming decade. Thus, laboratory fee schedules are likely to get repeatedly hit. The Patient Protection and Affordable Care Act of 2010 implements reductions to the Medicare Clinical Laboratory Fee Schedule (CLFS) for 2011-2015, including both a productivity adjustment cut to the consumer price index update ranging from 1.1 percent and 1.4 percent, and a 1.75 percent CLFS reduction.

For provider institutions, the value-based purchasing paradigm represents a shift from a top-line to a bottom-line financial model. Health care leaders facing value-based purchasing programs are therefore looking for ways to reduce costs across their institutions and service areas. Clinical laboratories are looked at by many hospital institutions as a cost center, and even a commodity. A survey of chief financial officers conducted in 1999 by the Medical Laboratory Observer offers some data in this regard.<sup>3</sup> Almost half, 45 percent, of CFOs of hospitals with over 201 beds considered their labs cost centers. This was despite the fact that 68 percent of these hospitals had outreach programs, and 46 percent conducted clinical trials.

Together, these trends point to a potentially bleak picture of a “race to the bottom” financially for clinical laboratory services unless laboratories can externally demonstrate their value propositions and find new commercial models.

#### **Disruptive Force 3—Demand for Precision Medicine Diagnostic Expertise**

The sequencing of the genome ushered in the start of a new era in medicine, delineated by more precise and earlier diagnosis, prescribing, prognosis, and disease management, all targeted to an individual’s genetic and phenotypic profile. Molecular diagnostic testing is at the core of precision medicine, so it places laboratory medicine and pathology in a central and critical position in health care. Precision medicine is well-aligned with value-driven health care models, as greater precision delivers improved outcomes and higher efficiencies.

As is typical of many new scientific fields, molecular diagnostic testing is experiencing an information explosion, both in terms of number of tests and volume of associated knowledge. G2 Intelligence estimates that the market for molecular diagnostics laboratory testing will reach \$7 billion in 2011 and that it is growing at 15 percent compound annual growth rate.

The Association for Molecular Pathology (AMP) reports that there are about 100 different analytes available as molecular tests, each of which can be the basis of multiple tests. Further, there are more than 1,500 distinct gene tests for detecting DNA and RNA abnormalities compiled at [www.genetests.org](http://www.genetests.org). There are well over a hundred Food and Drug Administration cleared molecular diagnostic assays, according to the AMP. And likely an order of magnitude more molecular laboratory-developed tests available.

In addition to high volumes of tests, many molecular tests carry high reimbursement charges, either because they are billed by code stacking that

<sup>3</sup> Marcia Ringel, "How financial executives view their hospital labs-An MLO Special Report-includes related article on surveying techniques-survey of hospital CFOs regarding their medical laboratories-Cover Story." *Medical Laboratory Observer*, May 2011

sums up to a high price, or because they have received multithousand-dollar negotiated prices with payers.

As a result of all of these issues, two needs have emerged from the marketplace:

- ❑ Providers are unable to keep up with the vast and rapidly growing knowledge base of molecular testing, and thus need help navigating this field—ordering the appropriate tests, understanding the results and how to use them, and counseling patients; and
- ❑ Payers need help managing molecular test utilization.

If clinical laboratories do not provide services to fulfill these needs, new entrants will do so. In fact, that has already begun to happen. New entities called genetic benefit managers, such as DNA Direct and Generation Health, now part of pharmacy benefit managers Medco and CVS Caremark, respectively, are offering payers complete services regarding molecular testing—utilization management, patient counseling, physician education, and contracts with clinical laboratories.

### Creative Destruction and Innovation

A well-known tenet of corporate strategy holds that in times of industry tumult, when business models are morphing, players' roles changing, and market shares shifting, innovators frequently emerge, seizing opportunities and market power.

The clinical laboratory industry is primed for such innovation—the market, regulatory, and technologic forces that are changing the rules open doors to new business models. Some aspects of laboratory medicine will undoubtedly be negatively impacted or no longer be viable. But fundamentally laboratorians have a number of opportunities to remake their business and delivery models for greater professional prominence and market success.

In response to these new stakeholder needs, laboratories are beginning to develop a variety of innovative solutions to generate value and capture financial returns. These strategies are still in nascent stages, given that (1) the financial requirements and reimbursements for laboratory tests are dependent on regulatory and policy issues which have yet to be settled, and (2) the ripple effects of value-based purchasing and reform programs are just beginning to disseminate. These disruptive market forces create new market needs and opportunities along different parts of the laboratory business chain (i.e., offerings, market channel, and lab revenues).

There is no doubt that laboratories have substantial value to contribute to clinical care. The challenge is adapting to a new marketplace with new laboratory offerings and business models. Changing business strategies and offerings, and perhaps models, is, needless to say, quite difficult.

This is amplified in the case of laboratory medicine by regulatory and reimbursement uncertainties and a reimbursement system that serves as a deterrent to change. Laboratories will need new capabilities, tools, and resources to pursue these models. 

### LabCorp Extends Pact With UnitedHealthcare, Strengthens Test Portfolio

Laboratory Corporation of America (LabCorp, Burlington, N.C.) has extended its agreement with UnitedHealthcare Company for an additional two years, with their pact now lasting until 2018.

Under terms of the agreement, LabCorp will continue to be the national laboratory for UnitedHealthcare and Oxford Health Plans, as well as the exclusive laboratory provider for the health maintenance organization benefit plans of PacifiCare of Colorado, PacifiCare of Arizona, Neighborhood Health Partnership in Florida, and Mid-Atlantic Medical Services LLC in Maryland and Virginia.

In 2006 LabCorp entered into a 10-year agreement with UnitedHealthcare to become its exclusive national laboratory. Last year, LabCorp extended its contracts with Wellpoint Inc. and Cigna Corporation through 2013. The contract extensions emphasize the company's ability to attract and retain managed care clients. In addition, effective August 2010, LabCorp became a member of Empire BlueCross BlueShield of New York's lab network.

In separate news, LabCorp said Sept. 12 that it will offer a new companion diagnostic test for melanoma patients. The test (cobas 4800 BRAF V600) is a companion diagnostic with the drug Zelboraf, both of which received approval from the Food and Drug Administration (FDA) in August. Both the test and drug were developed by Roche.

The companion diagnostic will be available through LabCorp under the name BRAF Gene Mutation Assay, Melanoma. The test detects the BRAF gene mutation within a tumor sample and is the only diagnostic that has been clinically validated and approved to identify patients eligible for treatment with Zelboraf. An estimated 9,000 individuals will develop advanced melanoma in the United States in 2011, and of those, 50 percent are projected to have the BRAF mutation. 

### Myriad Provides Capital to Crescendo With Option to Buy

Diagnostic testing company Myriad Genetics Inc. (Salt Lake City) has lent \$25 million to Crescendo Biosciences Inc. as part of a deal that includes an exclusive three-year option for Myriad to buy Crescendo.

The potential acquisition of Crescendo would expand Myriad's portfolio of transformative molecular diagnostic products to include products for autoimmune disorders, such as rheumatoid arthritis. Additionally, if the option to buy is exercised, the acquisition of Crescendo Bioscience would add a sixth disease specialty, rheumatology, to Myriad's current strategic focus, which includes oncology, preventive care, urology, dermatology, and neuroscience.

Crescendo Bioscience is a leader in the development of molecular diagnostic tests for patients suffering from autoimmune disorders. Crescendo's first product, Vectra DA, is the only blood-based molecular diagnostic test available that can determine the level of disease activity in patients with rheumatoid arthritis. Based on 12 key biomarkers, the product offers a baseline assessment of disease post-diagnosis so that a patient's disease progression can be tracked by a physician and appropriate intervention can be made at the optimal time. 



## Medical Groups Sound Off on Proposed Imaging Cuts

**A**n array of health care organizations, including the American Medical Association (AMA), the Medical Group Management Association, and the Medical Imaging Technology Alliance, have come out in opposition to a proposal by the Centers for Medicare and Medicaid Services (CMS) to further reduce payment for certain imaging procedures administered to the same patient, on the same day, in the same setting.

Currently, when multiple surgical, nuclear medicine, or specified imaging procedures are performed together, Medicare pays the full price for the most expensive procedure but pays 50 percent less for the other procedures. For imaging services, the cut applies only to the technical component (TC).

***The American Hospital Association said the agency failed to provide any data or statistical analysis supporting the expansion of the MPPR policy to the professional component of imaging services. AHA urged CMS to "withdraw its unjustified application of [an] MPPR."***

In its quest to find other imaging efficiencies, CMS has proposed expanding the 50 percent payment reduction to the professional component (PC) of the second and subsequent advanced imaging services furnished in the same session. Full payment would be made for the PC and TC of the highest-paid procedure, and payment would be reduced by 50 percent for the PC and TC for each additional procedure furnished to the same patient in the same session. The

suggested change was contained in the proposed Medicare physician fee schedule for 2012, published July 19.

The American Medical Association and Federation of American Hospitals (FAH) in respective letters said CMS used flawed reasoning to justify the expansion. The FAH said it "does not support establishment of any multiple procedure payment reduction (MPPR) without appropriate analysis of the specific efficiencies involved when performing multiple procedures."

AMA called on CMS to "withdraw its proposal to apply a 50 percent multiple procedure payment reduction to the professional component of some 119 imaging procedures and drop consideration of other even broader versions of this proposal."

CMS estimated its proposal would redistribute approximately \$100 million in payments through a small increase in the conversion factor and a small adjustment to all practice expense (PE) relative value units (RVU) and that the change would primarily reduce payments to the specialties of radiology and interventional radiology.

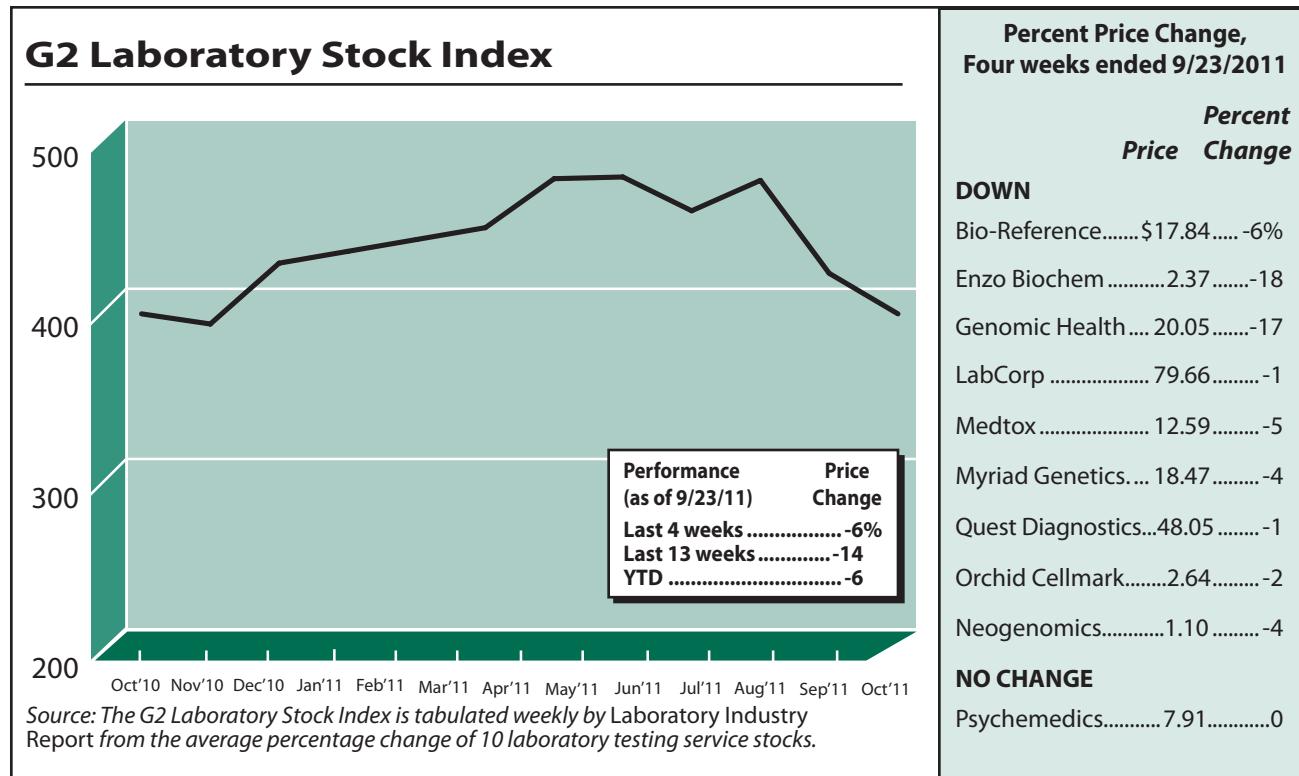
The American Hospital Association said the agency failed to provide any data or statistical analysis supporting the expansion of the MPPR policy to the professional component of imaging services. AHA urged CMS to "withdraw its unjustified application of [an] MPPR." 

### Lab Index Down Another 6% on Market Woes

The G2 Intelligence Laboratory Stock Index fell an unweighted average of 6 percent in the four weeks ended Sept. 23, 2011, with 9 stocks losing value and one staying virtually unchanged. Since the beginning of the year, the index is down 6 percent. In comparison, the Nasdaq is down about 6 percent and the S&P 500 is down almost 10 percent.

Shares of **Bio-Reference Laboratories** (Elmwood Park, N.J.) declined 6 percent to \$17.84 despite posting yet another quarter of impressive sales and earnings in the third quarter. For the full year, analysts project sales growth in excess of 21 percent and total sales of more than \$555 million. They expect earnings of \$1.14 per share for year-over-year growth of approximately 21 percent. Such growth is nothing new to Bio-Reference. Over the past three- and five-year time frames, it has managed to grow both sales and earnings around 23 percent annually. Annual profit growth over the past decade has been even stronger, growing nearly 70 percent on average. The company is experiencing double-digit revenue growth across all of its business lines, including routine testing (40 percent of revenue), GenPath oncology (32 percent to 36 percent of revenue), GenPath women's health (17 percent to 20 percent of revenue), and GeneDx (7 percent to 8 percent of revenue).

**LabCorp** (Burlington, N.C.) shares declined 1 percent to \$79.66. The company is still trying to satisfy Federal Trade Commission (FTC) requests for additional information about its proposed merger with DNA testing firm **Orchid Cellmark** (Princeton, N.J.), which fell 2 percent to \$2.64. As a result, LabCorp has once again extended the tender offer it has for all shares of Orchid. That offer already has been extended four times. The offer to buy shares now extends through Oct. 7. 



## GE to Invest \$1 Billion in New Oncology Solutions

**G**E Healthcare will dedicate \$1 billion of its total research and development budget over the next five years to expanding its advanced cancer diagnostic and molecular imaging capabilities. The investment will focus on developing new oncology solutions and build on advanced technologies and research already in progress. Among the areas of focus:

- **New Biomarkers.** With GE's recent purchase of Clariant for \$587 million, the company is able to focus on development of new biomarkers for cancer. Clariant currently is investigating a new biomarker, TLE3, to identify patients who will not respond to taxanes. The goal of this test is to help clinicians exclude those patients from this therapy who are least likely to benefit, thus saving them needless exposure to serious side effects. TLE3 is being developed for breast cancer, lung cancer, and ovarian cancer. GE Clariant expects to have the test ready for market launch in 2013.
- **Molecular Pathology.** GE Global Research scientists are working on an exclusive cancer diagnostic technology that may give a clearer picture of pathways driving specific tumors. This multiplexing technology could allow pathologists to conduct more than 50 different stains on a single tissue section and may lead to more effective, personalized treatment recommendations. **G2**

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- DNA Direct 877-646-0222
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- Generation Health 781-861-5500
- LabCorp 336-436-5274
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- Myriad Genetics 801-584-3600
- National Independent Laboratory Association 314-241-1445
- Quest Diagnostics 800-222-0446
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- UnitedHealthcare 800-339-5380

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