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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Local, Regional Labs Face Being Shut Out Of Managed-Care Networks

Managed care plans increasingly are reducing the size of provider networks, steering members to in-network providers, and hiring benefit management companies, all of which are making it more difficult for local and regional laboratories to compete with the large national labs.

To prevent being shut out of networks altogether, smaller labs need to band together to form alliances, giving them more clout and leverage in their discussions with third-party payers, believes Michael Snyder, vice president laboratory services, Medical Spend Management LLC (Flemington, N.J.)

For more on managed care pressures and how labs can respond, see *Inside the Lab Industry* starting on page 5.

New Lab Company to Invest in Outreach; Warburg Pincus Pledges $250 Million in Capital

A group of industry veterans announced May 1 that they are joining forces with Warburg Pincus to create a new platform of regionally focused clinical laboratories formed by acquiring or entering into partnerships with hospital-based labs.

Regional Diagnostic Laboratories Inc., which will be based in Brentwood, Tenn., will receive up to $250 million in equity capital from Warburg Pincus, a global private equity firm.

The new organization will be lead by industry veteran Brian Carr, who will serve as chairman and chief executive officer. Carr started his career with Allied Clinical Laboratories before forming InformDX, a privately owned anatomic pathology company, which later merged wtih AmeriPath. Carr subsequently served as both president and a member of the board of directors of AmeriPath before cofounding and becoming chairman and CEO of American Esoteric Laboratories, a clinical laboratory company focused primarily on acquiring and operating outreach laboratories.

Joining Carr are John Mazzei, who will serve as president and chief operating officer; J. Mark Farrington, chief information officer; and Sam Daniel, chief financial officer.

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■ **New Lab Company to Invest in Outreach**, *from page 1*

"I'm thrilled to be working again with each member of this team," said Carr. "Our team will seek out opportunities where we can deploy the strategies and capital to create a number of regionally dominant outreach laboratories throughout the U.S. that can assure superior service and quality to health systems and their clinicians."

Raymond James Healthcare Investment Banking Group served as the exclusive financial adviser to the transaction.

Bio-Reference Invests in InCellDx, Launches New HPV, Cervical Cancer Test

Bio-Reference Laboratories' recent multimillion-dollar investment in a private molecular diagnostics startup company, combined with the launch of a new test used to determine the risk of developing cervical cancer, is expected to help contribute to at least 15 percent growth over the next two to three years.

Officials of Bio-Reference (Elmwood Park, N.J.) said April 30 that it was making a $6 million equity investment in InCellDx (Menlo Park, Calif.), whose technology enables quantification of molecular biomarkers in intact cells and quantification of gene expression for use in diagnosis and disease localization. The agreement includes a $4 million cash investment and a $2 million promissory note—giving Bio-Reference 20 percent to 25 percent ownership depending on option dilution.

GenCerv leverages the proprietary mRNA quantifying technology from InCellDx and is designed to serve as a confirmatory test of whether a high-risk patient based on HPV status will develop cancer—thus avoiding unnecessary colposcopies and cervical biopsies.

InCellDx was founded in 2004 by Bruce Patterson, M.D., former medical director of diagnostic virology at Stanford University Hospitals and Clinics and associate professor at Stanford University. InCellDx began generating revenue in 2010 with $1.1 million of revenue in 2011 (one-third from Europe). The company has not reached profitability.

Concurrent with the investment, Bio-Reference launched GenCerv, a quantitative mRNA test used to determine the risk of developing cervical cancer by quantifying certain human papillomavirus (HPV)-related gene expression levels using real-time polymerase chain reaction technology. GenCerv leverages the proprietary mRNA quantifying technology from InCellDx and is designed to serve as a confirmatory test of whether a high-risk patient based on HPV status will develop cancer—thus avoiding unnecessary colposcopies and cervical biopsies.

"Nine-five percent of women who test positive for high-risk HPV do not progress to cervical cancer. We believe the GenCerv test will help physicians identify the subset of HPV DNA-positive patients that progress to cervical cancer," said

Patterson. "Our technology is being used extensively in Europe, and we look forward to working with BRLI and GenPath Women's Health as we seek to reach our full potential."

InCellDx technology enables the quantification of molecular biomarkers inside intact cells using cell-based instruments and in-situ hybridization. This process allows protein and gene expression to be measured by distinct cell type, aiding in both diagnosis and disease localization. GenPath adapted this technology for the quantification of E6 and E7 mRNA in HPV.

"We believe that the science behind InCellDx is compelling. HPV is a surrogate for the disease process that results in cervical cancer. By allowing for the quanitification of E6 and E7 oncogene overexpression, our assay based on InCellDx technology seeks to track the neoplastic process; therefore, it is not about the infection, it's about the disease," said Marc Grodman, M.D., president and CEO of Bio-Reference. "We anticipate that this technology, which has been well reviewed in academic publications, should not only improve the specificity that accompanies HPV testing but also should be cost-effective in identifying those HPV cases that do not progress to cervical cancer."

Genomic Health Reports 17 Percent Increase in Revenue, Inks New Strategic Alliance for Biomarker Research

Genomic Health (Redwood City, Calif.) reported total revenues of $58.5 million in the first quarter of 2012, compared with $49.8 million in the same period in 2011, an increase of 17 percent.

Net income was $800,000 for the quarter ended March 31, 2012, an improvement of $1.1 million, compared with a net loss of $300,000 in the first quarter of 2011. Basic and diluted net income per share applicable to common stockholders was 3 cents and 2 cents, respectively, in the first quarter of 2012, compared with net loss of 1 cent per share the same period last year.

"We delivered strong product revenue growth in the first quarter of 2012 driven by a 15 percent year-over-year increase in test volume and strong cash revenue," said Kim Popovitz, chairman, chief executive officer, and president of Genomic Health. "During the quarter we invested to expand our global commercial reach in both breast and colon cancer, while continuing to invest in key pipeline programs including next-generation products and additional indications for our colon cancer test. Further, we continue to advance our prostate cancer program and look forward to reporting topline results from our clinical validation study in the second half of this year."

In the first quarter, 18,630 Oncotype DX test results were delivered, an increase of 15 percent, compared with more than 16,230 test results delivered in the same period in 2011.

In separate news, Genomic Health and OncoMed Pharmaceuticals Inc. announced a strategic alliance to use next-generation sequencing (NGS) to identify

biomarkers that can be applied to the clinical development of OncoMed's novel antibody cancer therapeutics.

Under terms of the agreement, OncoMed will provide Genomic Health with breast, prostate, colon, and lung tumor samples. A subset of these tumors will include OncoMed's extensive bank of proprietary xenograft models derived from freshly resected human cancers. Genomic Health will apply its NGS capabilities, including proprietary sample preparation, high-throughput sequencing, and bioinformatics, to discover biomarkers that can help identify subsets of patients that will more likely respond to cancer therapeutics targeting the Notch, Wnt, and other pathways critical to cancer stem cells.

Aetna Relaxes Accreditation Requirements For Some Surgical Pathology Services

Aetna is eliminating its dual certification requirement for dermatologists and dermapathologists, meaning payment of surgical pathology services will continue without additional certification.

The recent announcement from Aetna came about one month after the health plan notified physicians that, effective Aug. 1, 2012, dermatology practices performing in-office pathology testing will be required to be both certified under the Clinical Laboratory Improvement Amendments and accredited by the College of American Pathologists (CAP) to be paid.

According to the California Medical Association (CMA), dermatologists will be exempt from the new dual certification policy. However, it remains unclear whether the policy still applies to other specialists operating in-office pathology labs. CMA says it is awaiting clarification on the issue.

Following Aetna's initial announcement requiring dual certification, CMA and the American Academy of Dermatology had expressed concern about the ability of physicians to obtain the CAP accreditation prior to the deadline imposed by Aetna. According to CAP, the accreditation process can take up to a year (six to nine months from receipt of the complete application to initial inspection and another two to three months for accreditation to be issued if the lab meets all qualifications). Costs are estimated at $1,400-$1,600 per year, plus a $799 application fee.

Inside The Lab Industry

Managed Care Pressures Putting the Squeeze on Labs; New Models Needed in Competitive Environment

Increasing pressure from health plans is putting the squeeze on local and regional labs, which are finding it more and more difficult to compete with the low prices offered by the nation's two largest lab companies, Quest and LabCorp. To survive, labs will need to come up with new strategies that will give them greater leverage in their discussions with third-party payers, advises Michael Snyder, vice president laboratory services, Medical Spend Management LLC (Flemington, N.J.).

As employers demand lower cost of benefits, health plans continue to ratchet down provider payments. Because the national labs are able to accept highly discounted payments, many of the smaller and midsized labs are being cut out of the networks altogether. Snyder discussed managed care and the lab industry at the Executive War College in New Orleans and elaborated in an interview with *Laboratory Industry Report*.

Snyder tells *LIR* that labs need to keep an eye on four major threats that can affect their role in managed care:

1 Downsizing of Provider Networks. National labs are leveraging their contracts to gain new volume and squeeze competitors out. Several managed care health plans recently have issued termination notices to smaller labs that have been unable to match the discounted payment levels accepted by Quest and LabCorp. Labs that wish to stay with the network are often forced to accept those lower payments, which sometime barely cover their costs. In some cases, even labs that are willing to accept reduced payments are being excluded because of agreements between the health plans and the national labs.

2 Steerage to In-Network Providers. Managed care companies increasingly are sending letters to both physicians and members encouraging them to refer to and use in-network providers, which typically are the big national labs. Recently, for example, Aetna sent a letter to members reminding them their out-of-pocket costs would be lower with in-network providers. While this also keeps the cost lower for the health plan, it again shuts out local and regional labs that can't match Quest and LabCorp pricing. "The plans are using the patient's out-of-pocket costs as a driver [to in-network], and it's working," says Snyder.

New Blue Card Rule

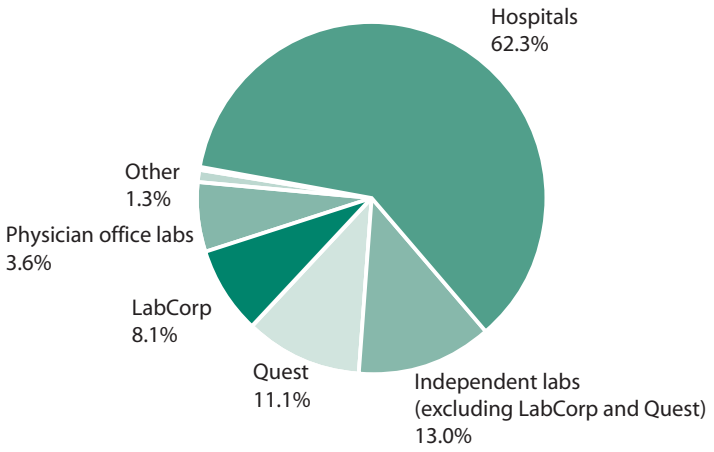
The following is from Blue Cross Blue Shield of Alabama's program provider manual, issued in December 2010.

"A remote ancillary provider is an independent clinical laboratory, durable/home medical equipment and specialty pharmaceutical provider located outside of Alabama. Claim filing rules for these remote providers have been clarified and result in a change. Claims for independent clinical laboratories should be filed to the Blue Plan where the specimen was drawn and not the local plan where the laboratory is located."

3 Benefit-Management Companies Leading to Disintermediation. Companies that handle benefit management for health plans, including Beacon LBS, which is owned by LabCorp, are leading to "disintermediation"—that is, they are coming between labs and health plans, making it more difficult for labs to negotiate directly with the payers, notes Snyder. While many labs have refused to participate in LabCorp's benefits-management program, some feel they will be completely shut out of provider networks if they don't.

4 Change in BCBS "Blue Card" Administration. A new rule issued by Blue Cross Blue Shield requires that lab services be billed to the Blue Plan in the state where the member had the specimen taken. Previously, labs could bill the plan where the lab was located. This change, says Snyder, has lead to increased claims denials. "The impetus behind this is to stop labs from getting a contract with one Blue plan and then, by proxy, affiliate with all the Blue plans across the country," he explains. "The problem is, this puts the patient in the middle, and the plans start playing hockey with the claims." This rule change could quite possibly backfire and result in Blue Cross actually losing business to its competitors, believes Snyder.

Lab Market Share by Revenue



Source: G2 Intelligence, 2011 Lab Industry Strategic Outlook

While some small and mid-sized labs believe they can't effectively compete on price with Quest and LabCorp, Snyder says those labs actually have more clout than they realize. According to 2010 data from G2 Intelligence, hospital labs represented 62.5 percent of the lab market share by revenue; independent labs excluding Quest and Labcorp, 13 percent; Quest, 11.10 percent; LabCorp, 8.30 percent; physician office labs, 3.60 percent; and other labs, 1.5 percent (*2011 Lab Industry Strategic Outlook*).

"Why do the nationals control the majority of plan contracts yet a lesser portion of revenue and utilization?" asks Snyder.

The solution, argued Snyder, is for labs to create new service models that focus on local employer needs and that relate testing with outcomes. "The plans are asking for more and more services from labs," he explains. "Labs need to move to service-based pricing, not just pricing based on tests."

Lab Association Provides Leverage

Snyder also recommends that labs form networks or associations that will give them the clout and leverage to effectively compete with the big national labs. He is currently leading development of one such association, which is expected to launch this summer. The not-for-profit association will be funded by membership fees based on lab size and will be run by Snyder, who will serve as the third-party administrator. The administrator will negotiate services for that association under a group purchasing organization model and will manage the requirements of the plans for network management on a plan-by-plan basis.

Benefits of an Association Model	
LABS	**INSURERS**
Creates standard requirements for participation in health plan contracts.	Offers a "managed" network of independent labs.
Emphasizes value of requirements beyond testing services.	Ensures the fulfillment of requirements necessary to manage the benefits of the plan membership.
Leverages the purchasing power of membership.	Allows the plans an alternative to increasing administrative cost; instead, addresses a positive impact to medical loss ratio calculation.
Ensures the ability of members to compete for lab contracts.	Reduces "lab leakage" by fielding a broad network of qualified labs.
Source: Mike Snyder, Medical Spend Management, LLC	

To ensure that it complies with antitrust laws, the association is being formed as a "messenger model." Under this model, a third party collects price and other offering terms from network members. The "messenger" conveys the information to purchasers who can then make contract offers to members through the messenger. Each member makes a unilateral decision to accept the contract conveyed by the messenger. As long as the members do not coordinate or collaborate on pricing, there are no antitrust violations; the messenger cannot act as agent for *collective* negotiation.

Snyder says he hopes to launch the association with 25 to 30 labs, enough to begin discussions with the major health plans. While it will be a national association, contracts will be set up in regions. In representing labs, the association will also provide other services, including credentialing and quality management, data integration, decision support and physician education, capitation management, genetic counseling, and consulting on contracts and policies. The association will not participate in any lobbying or political activities, says Snyder.

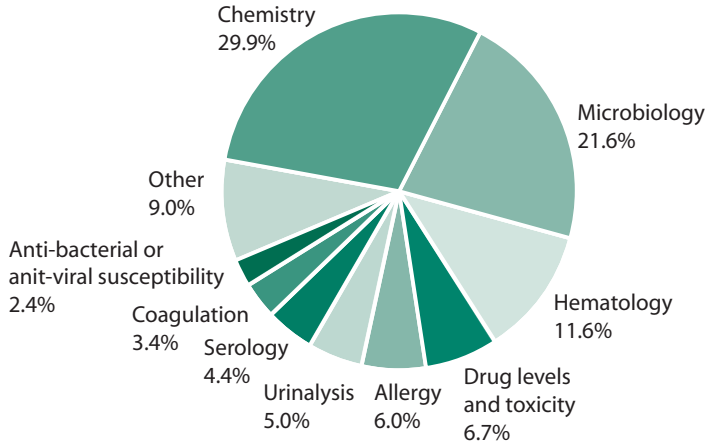
"It's a different way of doing business, but local and regional labs are going to have to change the way they do things if they expect to survive," he explains. "It's a different world out there."

Frost Estimates of Lab Market Growth Consistent With G2; Market Expected to Grow 5.7 Percent Annually

In findings consistent with G2 Intelligence estimates, market research firm Frost & Sullivan is projecting that the U.S. clinical laboratory testing market is growing at a compound annual growth rate (CAGR) of 5.7 percent with revenue expected to reach $89.31 billion by 2017.

In G2's *Lab Industry Strategic Outlook 2011*, we estimated that the lab market would grow by about 6.1 percent in 2011, slightly less than the projected CAGR of 6.2 percent for total national health service expenditures. The economic recession of the past several years, however, has taken a toll on physician office visits, thus reducing test referrals and volume even further.

Percent of Laboratory Test Volume by Specialty
U.S. Clinical Laboratory Market 2011



Source: LOINC Common Lab Orders Value Set Version 1.2, Frost & Sullivan analysis

According to Winny Tan, Ph.D., industry analyst with Frost & Sullivan, the U.S. clinical laboratory market is now worth about $63.92 billion, with chemistry and microbiology tests representing over half of the total laboratory test volume (see pie chart). Molecular diagnostic tests are represented in the "other" category, which comprises just 9 percent of the total test volume.

"While molecular diagnostic testing is the fastest-growing segment in the industry, it's currently only a tiny sliver of the total diagnostic pie," explained Tan.

Responding to Change

To survive in today's highly competitive and budget-driven market, labs are having to evolve to become more collaborative and to operate more as profit centers, notes Tan. In an outdated practice model, pathologists interpreted laboratory results but did not interface with patients. However, in an evolved practice, pathologists have a great role in treatment decisions and patient care. Similarly, in an outdated practice model for hospital laboratories, the lab was a cost center for the hospital while in an evolved model, the lab is a profit center for the hospital.

Labs are also evolving from part of disjointed health care delivery to be a part of collaborative medicine, which is critical to improving patient outcomes and reducing overspending, said Tan. Labs that in the past perhaps lacked customer marketing programs are now becoming more aggressive in competing for market share, she added.

Key market drivers for the lab industry include the regular need for infectious testing and the increased testing that comes with an aging demographic. Not

surprisingly, the most significant market restraint is falling reimbursement levels. Despite the challenges they face, laboratories have unique market opportunities that leverage their strengths and are learning to use new strategies in response to industry shifts, said Tan.

The report, *New Strategies for the U.S. Clinical Laboratory Market*, is available for purchase from *www.frost.com*.

Myriad Reports Sixth Quarter of Strong Results

After a difficult 2010, Myriad Genetics (Salt Lake City) in May reported its sixth quarter of better-than-expected results. Revenues for the third quarter of fiscal 2012, ended March 31, 2012, were $129.8 million, an increase of 27 percent over the $102.4 million reported in the third fiscal quarter of 2011. Earnings per diluted share were 34 cents, an increase of 10 percent over the same period of the prior year.

Revenue from the BRACAnalysis test, which represented 81 percent of total revenue in third quarter, was $105.9 million, a 17 percent increase over the same period last year. Revenue from the COLARIS AND COLARIS AP tests, which represented 9 percent of total revenue during the quarter, was $11.2 million, an increase of 51 percent. Myriad's other molecular diagnostic tests contributed $6.2 million to third-quarter revenue, or 5 percent of total revenue, an increase of 34 percent over the prior year.

Total revenue for the first nine months of fiscal 2012 was $363 million, an increase of 23 percent over the first nine months of fiscal 2011. Net income for the first nine months of 2012 was $133 million, an increase of 15 percent year over year. For the first three quarters, diluted earnings per share increased 19 percent to 96 cents from 80 cents for the same period the previous year.

The company has increased its expectations for fiscal year 2012 financial performance. Total revenue is now expected to be $492 million to $496 million, an increase from the original guidance of $445 million to $465 million. This revenue is expected to result in fully diluted earnings per share of $1.29 to $1.31, up from the original guidance of $1.20 to $1.25.

Oral Arguments Scheduled

In separate news, oral arguments for the renewed review of the *Myriad* case on patent eligibility of isolated DNA will be held July 20 (*Association for Molecular Pathology v. United States Patent and Trademark Office*, Fed. Cir., No. 2010-1406, appeal reinstated 4/30/12).

The U.S. Supreme Court remanded the case March 26 for reconsideration by the appeals court in light of the high court's decision on statutory subject matter, under 35 U.S.C. §101, in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012). At issue are nine composition of matter and six method claims on the patents of the BRCA1 and BRCA2 genes.

Pathologists Have Key Role to Play in Shared Savings Models

Pathologists have a key role to play in accountable care organizations (ACOs), according to a new white paper from the College of American Pathologists (CAP) that examines three ACOs and the ways in which pathologists are helping manage chronic illness among beneficiaries.

"This CAP white paper is a blueprint for ACOs, as well as institutions looking to form an ACO," said Kavita Patel, M.D., managing director for clinical transformation and delivery at the Brookings Engelberg Center for Health Care Reform. "The analysis makes clear the potential impact that pathology can have on how ACOs achieve their savings goals."

ACOs represent the most recent trend in trying to restrain the growth in U.S. health care spending, notes the paper. With an explicit goal of improving quality of care and health care outcomes, as well as restraining spending, ACOs are coordinated care systems in which providers are incentivized on the basis of outcomes rather than the number of services. The Patient Protection and Affordable Care Act allowed for the establishment of ACOs within Medicare, and ACOs and other coordinated care delivery systems already exist in the private sector.

To better understand how some pathology practices have been able to take leading roles in ACOs, CAP visited three health care organizations representing diverse models of health care delivery: Geisinger Health System in Danville, Pa.; Accountable Care Alliance in Omaha, Neb.; and Catholic Medical Partners-IPA (CMP) in Buffalo, N.Y. For each of these organizations, the evolution to a coordinated care delivery model was more a function of natural outgrowth of existing business models than a reaction to health care reform or the Medicare Shared Savings Program in particular, notes the white paper.

In studying the three different organizations, CAP identified four examples of how pathologists and laboratory medicine have added value:

- **Development of protocols for laboratory ordering**. One important way that pathologists in these institutions contribute to ACO goals is by setting up test ordering protocols for high-cost or high-volume tests. Officials and pathologists at the institutions CAP visited said that clinicians don't always know or understand which tests are appropriate for different conditions. "There is evidence that, in settings in which care is not coordinated, ordering protocols for the same condition are not always standardized—protocols can vary between sites or between physicians at the same site, and that the continuum of evidence behind those protocols can vary from being well investigated to being developed on an ad hoc basis," notes the paper. "Other studies point to the substantial effort needed to ensure that protocols are consistently updated to reflect medical advances and new information on clinical effectiveness."
- **Population health management**. Pathologists are applying their expertise to help ACOs develop standards for identifying and managing chronic illness

among the population enrolled in the system. Geisinger, for example, has implemented standards under its ProvenCare programs, which establish clinical guidelines and offer guarantees to patients and third-party payers that they would not have to pay for readmissions due to care that should not have been needed. As a result of laboratory standards for this program, Geisinger has reduced the median days it takes for renal patients on erythropoietin to reach a target hemoglobin level from 62.5 days to 35 days, at a savings of about $2,200 per patient per year.

- **Improving physician access to actionable data from the laboratory**. Access to electronic patient data is a foundation of an ACO's ability to effectively coordinate care. As electronic health records (EHRs) and Health Information Exchanges (HIEs) become more common, a key role for pathologists is to design the format for lab results in the EHR and HIE, making the format as "actionable" as possible. Pathologists at CMP are working on how they can use data to improve care management. For example, they are looking at how to use the EHR to identify diabetic patients who had not been getting the HgA1cb tests that are needed to determine whether their disease is under control. The medical director of Univera Health plan, which covers many of the ACO members with which CMP has a contract, has expressed a desire for pathologists and the laboratory community to give extra help to primary care physicians and other ordering physicians on when follow-ups are needed.

Despite their successes, pathologists in these organizations, as well as the organizational leadership, continue to face challenges related to achieving the greatest possible value from improving laboratory medicine, including payment, improving the capabilities of health information technology systems, and the difficulty of culture change.

- **Greater collaboration with other clinicians**. Both pathologists and non-pathologists agreed that pathologist leadership and collaboration with other physicians and with ACO leaders are major contributors to their success. The opportunities for pathologists to collaborate are varied. Pathologists at the three institutions visited by CAP achieved their leadership roles by proactively asserting their ability to help the ACO meet its goals. In each organization, there is an established culture of pathologists working in a coordinated and integrated manner with other clinicians.

Despite their successes, pathologists in these organizations, as well as the organizational leadership, continue to face challenges related to achieving the greatest possible value from improving laboratory medicine, including payment, improving the capabilities of health information technology systems, and the difficulty of culture change. The white paper suggests some potential areas where public policy changes can establish an environment that would enhance opportunities for ACOs to be more effective. It also recommends ways in which pathologists can best avail themselves of the opportunity to be part of this new world.

The white paper, "Contributions of Pathologists in Accountable Care Organizations," is available online at *www.cap.org/apps/docs/membership/transformation/new/initiatives_index.html.*

INDUSTRY BUZZ

Palmetto Delays MolDx Edits Until June 1

Palmetto GBA has delayed the activation date for the Molecular Diagnostic Services Program (MolDx) edits to June 1, 2012. After the June 1 deadline, all clinical laboratories performing molecular diagnostic testing and billing in the Medicare J1 Region must enter an assigned unique identifier for each assay in order to be paid.

The MolDx program applies to all claims for molecular tests in Medicare's J1 Part B region, which covers California, Nevada, Hawaii, and the U.S. Pacific territories of Guam, American Samoa, and the Northern Mariana Islands. Under the program, Palmetto is requiring that all labs that perform molecular diagnostic testing and bill Medicare in the J1 region obtain either a McKesson Z-Code or a Palmetto Test Identifier (PTI) to identify each molecular diagnostic test for which it is seeking coverage and reimbursement. Applications are required for CPT codes 83890-83914, 88384-88386, and the "pathology/laboratory not otherwise classified" codes. Certain tests are exempt.

Labs are required to submit test information and supporting evidence for each test, which then will go through a technical assessment process in which subject matter experts from academia and industry will assess the scientific literature and determine coverage.

The Z-Code identifier issued by McKesson may be used to identify tests outside the Palmetto GBA MolDx program, and public information about the test and associated performing labs will be available through the McKesson Diagnostics Exchange public registry. The PTI, however, will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDx program.

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Aetna 888-632-3862

Bio-Reference 201-791-3600

College of American Pathologists 800-392-9994

Frost & Sullivan 877-463-7678

Genomic Health 650-556-9300

InCellDx 650-777-7630

Medical Spend Management 856-797-1555

Myriad Genetics 801-584-3600

Palmetto GBA 866-931-3903

Regional Diagnostic Laboratories 615-577-5888

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