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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

LabCorp Acquisition of Medtox Largest Deal in Slow Year

In a big change from the first six months of last year, mergers and acquisitions (M&A) in the lab and anatomic pathology space has slowed significantly, with LabCorp's planned acquisition of Medtox (St. Paul, Minn.) the biggest deal so far this year.

LabCorp said in early June that it would buy Medtox for $241 million, or $27 per share. Medtox specializes in toxicology testing. The deal is expected to close later this year.

Terms for three much smaller acquisitions were not announced, but altogether the four deals are unlikely to top $300 million. In the first six months of 2011, lab and pathology M&A topped $1.5 billion. There are a number of factors contributing to the M&A slowdown, say experts, including a generalized sense of uncertainty.

For more on M&A in the lab and pathology segments and the outlook for the rest of the year, see *Inside the Lab Industry* starting on page 5.

Insurers to Maintain Preventive Screening Benefits, Regardless of Supreme Court Ruling

The decision by three major health insurers to continue providing preventive health care benefits without copayments regardless of what the Supreme Court decides on the reform law is a boon not only for patients, but also for the clinical laboratory industry.

UnitedHealthcare, the largest health insurer in the United States, and Humana Inc., say they will continue five health insurance reform provisions that are already in effect, regardless of the high court ruling, expected next week. Aetna Inc. pledged to keep at least three of the provisions in effect.

United made its announcement before Aetna and Humana.

The provisions being extended by UnitedHealthcare and Humana are:

- Preventive health care services without copayments. UnitedHealthcare said it "will continue to offer a spectrum of preventive health care services such as those tailored to preventive health care needs," including annual preventive medical visits, screening for high blood pressure and diabetes, and standard recommended immunizations.

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■ **Insurers to Maintain Preventive Screening Benefits**, *from page 1*

- ❑ Dependent coverage up to age 26, which UnitedHealthcare was the first to provide. The coverage will be offered on parents' plans, regardless of young adults' eligibility for other insurance coverage, whether they are in school, and whether they are married.
- ❑ Elimination of lifetime coverage limits.
- ❑ No recissions of health coverage, except for in cases of fraud or intentional misrepresentation of material facts.
- ❑ Provision of what Humana called "a clear and simple process for appeals claims decisions," as well as the option to have cases reviewed by independent review organizations.

Aetna said in its statement that it intends to "keep provisions such as coverage for dependents to age 26, 100 percent coverage for certain preventive care, and access to appeals through independent third parties in our benefit plans, regardless of how the Supreme Court rules." Company spokesman Matt Wiggin said more provisions may be kept, but the company will wait until the Supreme Court's ruling on the health reform law to make further announcements.

The health insurers' actions come as the health care industry awaits the Supreme Court's decision on the challenges by 26 states to the constitutionality of the Patient Protection and Affordable Care Act (PPACA), including its mandate to buy health insurance or pay a penalty.

AMA Weighs in on Reform

In anticipation of the high court's ruling on PPACA, the American Medical Association (AMA) June 19 supported a policy statement directing the group to reassess its positions on federal health care reform if some or all of the law is declared unconstitutional.

Aetna said in its statement that it intends to "keep provisions such as coverage for dependents to age 26, 100 percent coverage for certain preventive care, and access to appeals through independent third parties in our benefit plans, regardless of how the Supreme Court rules."

But the AMA declined to affirm a statement forwarded by PPACA opponents demanding full repeal or broad revision of the law.

In other action, the AMA adopted policies supporting financing reform to the Medicaid and Medicare programs. The Medicaid proposal envisions a system of tax credits permitting some participants to purchase private health insurance coverage. The Medicare proposal describes a defined contribution program, allowing seniors to purchase traditional Medicare coverage or private health insurance.

The various policy proposals came in the form of reports and resolutions supported during the 2012 Annual Meeting of the AMA's House of Delegates. The HOD, the association's primary governing body, met in Chicago June 16-20.

The HOD adopted a resolution calling for the association to formulate contingency plans if the Supreme Court declares the individual mandate component of PPACA unconstitutional. The resolution does not suggest a specific course of action. Instead, the HOD directed AMA to evaluate possible policy revisions and recommend necessary changes to the body during its interim meeting in November.

Alternate Reform Options

In addition, the resolution calls for AMA to "begin preparation for advocacy of alternate federal health care reform options'' in the event the court voids all or a portion of PPACA. It further specifies that such action should include the development of materials or a report for review by the HOD during the interim meeting.

Delegates declined to support a group of resolutions pointing to flaws in the reform law and calling for either repeal or a massive revision. A Reference Committee report noted that the association continues to see PPACA, while imperfect, as an important tool for improving the health care delivery system.

"Your Reference Committee heard that some continue to be angered about our AMA's position on the ACA,'' the report stated. "Your Reference Committee agrees with those who testified in favor of modifying the ACA rather than repealing it, but extends our assurance to all physicians that their voices are being heard, and that our AMA is aggressively seeking to achieve changes in the ACA as directed by policy adopted through the collective will of our House of Delegates, including Policies H-165.833 and H-165.835, which direct our AMA to advocate for needed reforms of the defects of the ACA.''

OIG Details Coverage of Genetic Tests; Report Designed to Assist CMS in Pricing

Nearly every state Medicaid and Federal Employees Health Benefits (FEHB) plan covers laboratory genetic testing in a similar manner to Medicare, according to a report from the Department of Health and Human Services Office of Inspector General (OIG).

The memorandum report, *Coverage and Payment for Genetic Laboratory Tests* (OEI-07-11-00011), presented the results of surveys of state Medicaid and FEHB plans about their coverage policy and establishment of payment rates for selected genetic tests. The report, which did not give any recommendations, was released June 13.

OIG in the report noted that officials from the Centers for Medicare and Medicaid Services (CMS) told them that a collection of pricing data for genetic tests from other health care insurers would assist CMS in establishing payment rates for genetic tests.

OIG said it surveyed state Medicaid and FEHB plan staff to determine payment rates for each state and FEHB plan, and obtained 2011 payment rates for selected genetic tests by name and by Common Procedural Terminology (CPT) code from each of the health care insurers surveyed.

Medicare does not pay for preventive screening tests except for those specifically authorized by statute (e.g., prostate-specific antigen test), OIG said. In addition, since CMS considers predictive tests to be screening tests, genetic tests for this purpose are not covered by Medicare, the report said.

However, genetic tests used to diagnose or determine treatment in the presence of signs and symptoms of disease can be covered by Medicare. The OIG report noted that a common use of genetic tests in the Medicare population is "to assist in determining cancer treatment." Genetic tests "can be used to predict optimal chemotherapy regimens and avoid exposing patients to ineffective or overly toxic regimens," the report added.

Payment Techniques

According to OIG, the AMA in 1992 added a new section of CPT codes for genetic tests. These codes focused on the laboratory procedures used for a test rather than the substance or chemical analyzed. This coding system was developed to accommodate rapidly developing technologies.

Until 2012, OIG noted, Medicare did not use single CPT codes for genetic tests as it does for other lab tests. For nearly a decade, Medicare contractors, as well as other health care insurers, have used a reimbursement method referred to as "stacking." Stacking is the use of multiple generic molecular diagnostic CPT codes to form the basis of reimbursement for a single genetic test.

Medicare rules do not address the quantity or configuration of stacking codes for genetic tests, OIG stated in the report. The lack of standardization results in wide variation in payment amounts for the same genetic test.

For example, among state Medicaid programs, the payment rate for a BRCA1 gene analysis ranged from $1,000 in Pennsylvania to nearly $4,500 in Iowa. Among FEHB plans, the AlloMap test ranged from $2 to $3,658. Other tests had less variation, such as the Pathwork Tissue of Origin test, which ranged from $5 to $38. One plan official said the variation in payment rates is likely due to low test volume and services provided by nonpreferred provider organizations.

Another shortcoming of this reimbursement method is that it does not provide specificity to the payer as to what was tested because the same set of codes is used in a variety of genetic test types. "Different laboratories may use differing procedures to perform the same lab test; therefore, they use differing quantities of CPT codes to file claims for the tests. For example, a cystic fibrosis profile at one lab might be coded with a total of 29 units of five different CPT codes, while the same test from another lab might be coded with a total of 89 units of six different CPT codes."

Effective Jan. 1, CMS instructed Medicare Administrative Contractors (MACs) to include in claims for genetic tests one of the 101 new single CPT codes representing a genetic test as well as the underlying stacked codes. According to OIG, the new claim payment procedure may provide more information to CMS on the quantities of stacked codes underlying a single genetic test and the quantities and types of genetic tests provided to Medicare beneficiaries. However, OIG said, it does not resolve the issue of variation in payment amounts.

Survey Results

According to the survey results, OIG found all but one of the state Medicaid programs described some level of coverage for genetic tests. Officials from each of the three national FEHB plans also described some level of coverage for genetic tests, OIG said.

Thirty-nine state Medicaid programs reported that they paid for genetic tests using only the stacking method, OIG found, and eight states reported using a combination of stacking and paying for genetic tests only by test name. Of the 47 state Medicaid programs that reported paying for genetic tests using the stacking method, only Iowa determined a maximum quantity and combination of stacked codes that it would reimburse for a given test.

The report is available at *http://go.usa.gov/dJF.*

Inside The Lab Industry

Lab M&A Slows in 2012; Outlook Unclear for Rest of Year

Following a record-setting year in 2011, mergers and acquisitions (M&A) in the clinical laboratory and anatomic pathology (AP) markets got off to a slow start in 2012, with four acquisitions totaling less than $300 million in the first half of the year. In comparison, M&A in the first six month of 2011 topped $1.5 billion.

LabCorp's acquisition of Medtox for $241 million, announced in early June, is by far the largest thus far in 2012. The deal is expected to close later this year. Acquisition terms were not announced for three smaller deals—the acquisition of Millennium Laboratories by LabCorp, Atlanta Dermatology by PathGroup, and Sterling Reference Labs by Waud Capital.

Experts believe that M&A in 2012 is unlikely to top the $3 billion in activity in 2011. This is due, in part, to the fact that there aren't that many large lab and pathology companies left to be acquired. In fact, there are only a handful of publicly traded lab and AP companies remaining, other than Quest Diagnostics and LabCorp. These include Bio-Reference Laboratories, Enzo Biochem, Genomic Health, Neogenomics, Psychemedics, and Myriad Genetics.

The slowdown "is not for lack of acquisition candidates," says Christopher Jahnle, managing director of Haverford Healthcare Advisors (Paoli, Pa.). "There are a lot of companies available for acquisition. And it's not a lack of capital. I think there's a continued sense of uncertainty out there, which I think causes both buyers and sellers to proceed at a more measured pace."

2012 Lab and Pathology Acquisitions *(through June 22)*

Date	Buyer	Target	Purchase Price ($MM)
April 12	LabCorp	Millennium Laboratories	NA
April 12	PathGroup	Atlanta Dermatology	NA
April 12	Waud Capital	Sterling Reference Labs	NA
June 12	LabCorp	Medtox*	241

**Expected to close in third quarter*

Contributing to the uncertainty is the imminent Supreme Court ruling on the health care reform law and the presidential election. "It's not just a slowdown in the lab space," he notes. "There generally has been a decline in the number of completed middle-to-lower-middle-market-sized deals in health care so far in 2012 compared to last year."

The total dollar amount of lab and AP acquisitions also is likely to be less than in 2011. While there are many smaller privately held lab and pathology companies that could be acquired, the total value of potential acquisitions is unlikely to surpass $3 billion. Valuation multiples—which have been trending upward in the past few years—are also unlikely to remain as high. The

average purchase price to revenue multiples paid in 2011 was 3.4x revenues, almost double what they were earlier in the decade.

According to Jahnle, a number of factors contributed to the record deal activity in 2011:

- **Aging of the Population**. In 2010 there were more than 40 million people over the age 65, representing 15 percent of the U.S. population and one-third of health care consumption. By 2030, those over 65 years old will increase to 72 million. Longer life spans and the desire to maintain more active lifestyles will further increase the demand for health care.
- **Economic Recovery**. Transactions that had been delayed by the recession created a pent-up demand for lab acquisitions by buyers and an oversupply of willing sellers.
- **Health Care Reform.** At least for now, the ranks of the insured are expected to rise dramatically. Despite expected lower reimbursement and tighter control over lab utilization, the lab industry is hot.
- **New and Returning Entrants to the Lab Market**. Big pharma and other large health care companies are entering or re-entering the lab industry by paying top dollar for lab acquisitions.
- **New Technologies Creating New Markets.** Technological advances in molecular diagnostics, pharmacogenomics, and companion diagnostics are driving demand for specialty labs.

What's the Outlook for 2012?

Experts believe there could be an uptick in M&A activity in the lab and pathology sectors over the second half of 2012 given that the lab industry fundamentals remain very strong and the lab industry remains highly fragmented. According to Jahnle, there are more established acquisition-oriented lab industry players than have existed for many years. In addition, sellers will be motivated to sell prior to tax rate increases; capital gains tax rates are scheduled to revert from 15 percent back to 20 percent on Jan. 1, 2013.

Some of the most active acquirers in 2011 have been quiet the first six months of this year, leading some to predict they have been working on deals that might be announced later in the year. Solstas Lab Partners, for example, completed six deals in 2011, while Aurora Diagnostics completed four transactions, LabCorp completed three, and Quest completed two.

"It's been very slow so far this year," says Dennis Weissman, a senior adviser to England and Co., an investment bank based in Washington, D.C., and executive editor of G2 Intelligence. "The general feeling is that it's going to increase the second half of the year, but it's really going to have to pick up a lot of steam to make up for the first six months."

Weissman attributes some of the slowdown in 2012 to the tremendous amount of activity in 2011. Negotiations that began early this year may not be finalized yet. "It does take time to consummate these deals," he adds.

Jahnle agrees. "Because there's adequate supply and substantial capital pursuing these transactions, I can only expect that the second half of the year is going to be much more active than the first half."

Private Equity Interest

There is no shortage of private equity interest in the lab space, notes Jahnle, who is a consultant to a new lab company that has received a $250 million equity capital commitment from Warburg Pincus, a global private equity firm. Regional Diagnostic Laboratories of Brentwood, Tenn., plans to acquire hospital-based outreach labs. The new organization is led by Brian Carr, a longtime industry veteran.

Private equity's appetite for investing in anatomic pathology laboratories appears to be insatiable, Jahnle says. Despite in-office pathology lab headwinds, more than one-third of the 35 transactions that were completed in 2011 and the first quarter of 2012 were acquisitions of pathology laboratory companies by private equity firms or private equity-backed firms.

"Despite all these years of consolidation, there are still segments of the overall lab space that remain very fragmented; this is a positive factor from private equity's perspective," he explains. "It's an industry that exhibits clear economies of scale, so by aggregating through acquisition, you can create value." G2

LabCorp Acquires Medtox for $241 Million; Could Enzo Biochem Be Next?

The biggest deal so far in 2012 is LabCorp's acquisition of Medtox (St. Paul, Minn.) for $241 million. LabCorp announced the transaction in early June, saying it would pay $27 per share for the lab testing company, which specializes in toxicology testing.

On a trailing 12-month basis, the purchase price equates to 2.2x sales, 47x earnings per share, and 27x free cash flow. "At first blush, this looks like a pretty expensive acquisition," writes Paul Nouri, a hedge fund manager and blogger at seekingalpha.com, an online investment forum. "However, when looked at more critically, investors can see why LabCorp was willing to pay up for this asset." While Medtox's net income of about $5 million over the last year is off its peak of $6.7 million in 2007, the company has managed to grow sales significantly. Organically, the company grew sales in the Minnesota market from $0 in 2008 to $36 million heading into 2012.

"While these investments in growth helped to hold back margins in 2008 and 2009, management's strategy of leveraging its capacity has clearly worked out for the company," writes Nouri. "Our guess is that LabCorp saw a growing competitor in a major market and wanted to purchase the book of business while it could still justify the acquisition price."

Nouri predicts that Enzo Biochem could be the next acquisition target. Enzo is similar to Medtox in that it has both a product and service business, notes Nouri. The primary difference is that about 55 percent of Enzo's sales come from lab services, while 78 percent of Medtox's sales are from lab services.

While Enzo is not profitable currently, it should be cash flow breakeven in 2013, says Nouri, who notes that it's entirely possible that LabCorp and Quest could find Enzo to be an attractive acquisition target.

Bio-Reference Reports Record Revenues for Quarter

Bio-Reference Laboratories (Elmwood Park, N.J.) on June 7 reported revenues of $163.4 million for the second quarter, the highest in corporate history and 19 percent more than the same quarter last year.

Operating income for the quarter ended April 30 was $16.8 million, an increase of 26 percent over the second quarter in 2011. Revenue per patient for the quarter was $83.21, an increase of 2 percent compared to the same period the previous year. The number of patients served increased 16 percent to 1,952. Esoteric business for the company was 59 percent of revenues for the quarter.

The biggest surprise in the quarter, according to equity research firm William Blair & Co., was continued strength in cash flow generation. Days sales outstanding were 81, a meaningful sequential reduction from the 91 days the company reported in the first quarter and the lowest the company has ever reported. Bio-Reference generated $24 million in operating cash flow in the first six months of fiscal 2012, up 132 percent over fiscal 2011 and meaningfully above net income.

"Bio-Reference has been able to demonstrate the value of its business strategy," said Marc Grodman, M.D., CEO. "During the first six months of this fiscal year, we introduced several initiatives based on innovative technologies and innovative reporting techniques that we believe will enable us to continue our growth. OnkoMatch, Inherigen, and GenCerv are now being introduced to physicians around the country by our national sales force. . . . As we move these new initiatives out of the development cycle and into the production cycle, we look forward to a continuation of our strong financial metrics."

Enzo Biochem Revenues Relatively Flat

Enzo Biochem reported relatively flat revenues for the third quarter ended April 30, with total revenue of $25.9 million, only slightly better than the $25.8 million in the same quarter last year. Revenues from Enzo's clinical laboratory services increased about 10 percent, from $13.8 million in the third quarter of 2011 to $15.2 million in the third quarter of 2012.

The higher clinical labs volume resulted in increased testing expenses, offset by lower cost of goods at Enzo Life Sciences. As a result, gross margins improved to $12.1 million, from $11.6 million in the immediately preceding quarter. However, margins declined from $12.4 million in the same quarter last year.

Enzo's launch of ColonSentry in March was too late in the quarter to materially impact third-quarter results but is expected to make a more meaningful contribution throughout the year.

Also in March, Enzo filed an application with the New York State Department of Health for the first assay based on its proprietary AmpliProbe nucleic acid

detection platform. Upon approval, the company plans to market its HCV RNA quantification assay for viral load determination through its clinical laboratory. The company also has moved to obtain CE-IVD designation for this assay in order to make it available as a diagnostic product in the European Union. Both applications are still pending.

For the first nine months of fiscal 2012, total revenues at Enzo were $76.7 million, an increase of 2 percent over the same period in 2011. Revenues at Enzo Clinical Labs increased 13 percent, from $38.5 million to $43.6 million. Operating loss for the nine months was $11.8 million, compared to $8.6 million for the same period last year.

Personalized Medicine Hampered by Regulatory Maze

The growth of personalized medicine depends on industry navigating a maze of Food and Drug Administration (FDA) centers and offices that have differing approaches to approval of a drug or biologic and its companion diagnostic, according to a biopharma executive.

Christine Gathers, senior director of regulatory affairs–diagnostics at Eli Lilly and Co., said FDA admits it is having problems with personalized medicine—defined as using biomarkers to determine the right dose of the right drug for the right indication in individual patients. A clear regulatory process currently is lacking to navigate the varying FDA office requirements for simultaneous approval of drugs and companion diagnostics, she said.

Gathers spoke June 6 during a webinar, Conquering Today's Regulatory Challenges to Realize Personalized Medicine, sponsored by the Regulatory Affairs Professionals Society.

Gathers noted that personalized medicine is no longer a futuristic concept but is a reality. "Drug companies are moving from a 'one-size-fits-all' mentality to more targeted therapies, which is due in part to the faster and cheaper availability of genome sequencing."

The biopharma industry is adapting from what has been its norm, where typical therapeutics effectively treat only 50 percent of the patient population with a disease. "Diagnostics enable identifying the right drug for each patient, with biomarker development at the heart of realizing personalized medicine," Gathers said.

According to Gathers, great progress has been made in personalized medicine. "The pace has accelerated, with nearly 10 percent of all U.S. drug labels now having pharmacogenomics information, with similar progress in Europe, where over 100 approved drugs have genomic biomarkers in their labels."

A companion diagnostic provides essential information for the safe and effective use of a corresponding therapeutic product. Gathers described how in vitro diagnostics (IVDs) involve basically running a test in a test tube, while labora-

tory developed tests (LDTs) generally are defined as IVDs that are developed, validated, and used for in-house pathology and diagnostic purposes by the lab entity where they are developed. They are not distributed through interstate commerce in that they are not marketed or sold as devices.

"The lab's position is that these are self-services and not products, which is why labs have escaped having LDTs approved by the Food and Drug Administration, although FDA has historically exercised enforcement discretion for LDTs," Gathers said.

"The regulatory landscape is quickly evolving," Gathers said, noting that the following FDA guidances are anticipated within the next year or so:

- ❑ Final guidance on in vitro companion diagnostic devices, originally expected to be issued in June, although it may take longer, Gathers said, since industry's reaction to the draft guidance was that it created more questions than answers;
- ❑ Final research use-only (RUO) guidance;
- ❑ Draft guidance for LDTs, which will create a framework for developing such tests for the marketplace with classes based on risk, a test registry, and quality system requirements;
- ❑ Draft codevelopment guidance;
- ❑ Draft enrichment guidance; and
- ❑ Draft pre-investigational device exception meeting guidance.

Differences Between FDA Centers

Regulatory challenges are likely to remain, Gathers said. "There is no clear regulatory process to navigate the agency, and FDA is a maze of multiple centers and divisions. There is a lack of clear guidance for codevelopment globally, and it is too early to have valid precedents," she said. "We have indicated a need for greater guidance on clinical utility, but FDA has been clear that it requests submission of a companion diagnostic application at the same time as the drug application for simultaneous review."

To achieve simultaneous submission of the drug and companion diagnostic, the diagnostic must be developed early in the clinical trial, Gathers said. "That's the idealized codevelopment process, where the biomarker is identified in Phase I. When that happens, there are many regulatory strategies available, risk mitigation is optimal, there is time flexibility to facilitate collaboration with the regulatory bodies, and it's possible for the biopharma to partner with its diagnostic manufacturer early to enable the commercialization at the first registration dose."

As development moves into later-phase clinical testing, the codevelopment process becomes more difficult, and there is likely to be a delay in the drug launch, Gathers said.

She noted that early interaction with the appropriate regulatory bodies for drug and diagnostics codevelopment—the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) for the drug or biologic, respectively, and the Center for Devices and Radiological Health (CDRH) for the IVD or LDT—is essential. "It's preferable to have all the right players at the same meeting," Gathers said.

"The problem is the centers differ in approaches. CDRH is less formal, its recommendations nonbinding, and its pre-investigational device exemption [IDE] meetings unlimited," she said. In contrast, CDER and CBER are more formal, their recommendations are binding, and the interactions between the applicant and the centers are limited and dependent on the division, Gathers said.

For approval of the commercialization of companion diagnostics, regulatory agencies want analytical validation—reliable measurement of the analyte in vitro; clinical validation—the ability of the test to detect the analyte in the associated disorder, with the clinical cutoff points independently validated; and a demonstration of clinical utility—benefit/risk in diagnosing or predicting risk for an event, Gathers said.

Who Owns the Challenges?

Gathers listed future challenges as personalized medicine advances:

- ❑ With a limited tissue sample from a patient, how can multiple markers be evaluated when markers may be on different lab platform systems?
- ❑ How will physicians track drugs and their appropriate companion diagnostics such that the right test is ordered when there is more than one drug and companion diagnostic in the marketplace?
- ❑ How much longer will it be before a decision is made about which test to run while LDT and companion diagnostic kits both exist for the same analyte?
- ❑ Who makes the decision—the lab or the physician—on which to use?
- ❑ Will reimbursement drive the decision?
- ❑ Should physicians be permitted to prescribe a drug without its companion test?
- ❑ Most important, who owns all of these challenges?

Gathers concluded by stating FDA has indicated it is having difficulty providing guidance related to personalized medicine. To assist FDA and, ultimately, to benefit patients, biopharmas need to ensure accurate test results to appropriately guide therapy decisions; create partnerships with diagnostic companies, reference laboratories, and the appropriate regulatory bodies; and, through collaborations, build awareness of development complexities and create flexibility, she said. G2

INDUSTRY BUZZ

Medicare Lab Test Pricing Forum Set for July 16-17

The Centers for Medicare and Medicaid Services (CMS) will hold a public meeting July 16 and 17 at its Baltimore headquarters to hear recommendations on setting Medicare payment rates for new clinical laboratory codes to be added to the Part B lab fee schedule in 2013.

The agency announced the meeting in the May 29 *Federal Register* but also noted that the forum will not discuss new molecular diagnostic codes. They will be handled in a separate formal rulemaking.

This is the first step in the annual process, required by law, to get public input on payment rates for new tests to be added to the Medicare lab fee schedule, effective Jan. 1, 2013. Final fee decisions are expected this November.

For the 2013 lab fee schedule there are 16 new Current Procedural Terminology (CPT) codes in chemistry, immunology, tissue typing, and microbiology.

Payment levels for these codes are to be determined using one of two approved methods:

- ❑ Crosswalk to an existing code on the lab fee schedule and reimburse the test at that code's rate and national fee cap; or
- ❑ Set a gap-fill amount for the code, based on local pricing patterns.

Following the forum in July and consideration of public comments, CMS said it will post its preliminary payment determinations in early September for another round of comments. Final fee decisions will be published in November when the 2013 lab fee schedule is released.

References

Aetna 888-632-3862

Bio-Reference 201-791-3600

American Medical Association 800-621-8335

England & Co. 202-386-6500

Enzo Biochem 800-522-5052

Haverford Healthcare Advisors 610-407-4024

HHS Office of Inspector General 202-619-0088

Humana 502-580-8880

LabCorp 336-436-5274

Medtox 800-832-3244

UnitedHealthcare 866-204-0911

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