Medicare Lab Test Pricing Forum Set for July 10

The Centers for Medicare and Medicaid Services (CMS) will hold a public meeting July 10 at its Baltimore headquarters to hear recommendations on setting Medicare payment rates for new or substantially revised clinical laboratory codes for the Part B lab fee schedule in 2014.

The agency announced the meeting in the May 24 Federal Register. Comments on the new or revised codes are due by June 28. CMS will determine pricing of the codes either through crosswalking (mapping to an existing code) or gap-filling (pricing determined by Medicare contractors based on charges, resources, and payment amount determined by other payers).

The agency plans to publish proposed determinations for new and reconsidered codes for 2014 by early September. Final fee decisions are expected in November.

For the 2014 clinical laboratory fee schedule, there are 16 new Current Procedural Terminology codes and 11 reconsideration requests. (Note: numbering of new codes will be finalized later.)

Lab Industry Files Petition Against FDA Regulation of Laboratory-Developed Tests

After several years of threats by the Food and Drug Administration (FDA) that it intends to regulate laboratory-developed tests (LDTs), the lab industry has taken the matter into its own hands.

The American Clinical Laboratory Association (ACLA) on June 4 filed a citizen petition under the Federal Food, Drug, and Cosmetic Act (FDCA) challenging FDA authority to regulate LDTs as “devices” under the FDCA.

The ACLA petition notes that LDTs differ from in vitro diagnostic test kits, which are packaged and commercially distributed and are regulated by FDA as medical “devices.” LDTs, argues ALCA, are laboratory services, not products, and are not distributed, delivered, nor placed into market. They are “proprietary procedures for performing a diagnostic test using reagents and laboratory equipment . . . essentially know-how, not articles,” says the petition.

According to the ACLA petition, FDA cannot and should not regulate LDTs as medical devices under the FDCA for several reasons:
### NEW AND RECONSIDERED CODES FOR THE 2014 MEDICARE LAB FEE SCHEDULE*

#### NEW TEST CODES

**THERAPEUTIC DRUG ASSAYS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>801XX1</td>
<td>Caffeine</td>
</tr>
<tr>
<td>801XX2</td>
<td>Clozapine</td>
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<tr>
<td>801XX3</td>
<td>Everolimus</td>
</tr>
<tr>
<td>801XX4</td>
<td>Gabapentin</td>
</tr>
<tr>
<td>801XX5</td>
<td>Lamotrigine</td>
</tr>
<tr>
<td>801XX6</td>
<td>Levetiracetam</td>
</tr>
<tr>
<td>801XX7</td>
<td>Mycophenolate (mycophenolic acid)</td>
</tr>
<tr>
<td>801XX8</td>
<td>Oxcabazepine</td>
</tr>
<tr>
<td>801XX9</td>
<td>Tiagabine</td>
</tr>
<tr>
<td>802XX</td>
<td>Zonisamide</td>
</tr>
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</table>

**TIER 1 MOLECULAR PATHOLOGY PROCEDURES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>81161</td>
<td>DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed</td>
</tr>
<tr>
<td>812XX</td>
<td>MGMT (O6-methylguanine DNA methyltransferase) (eg, Brain Cancer) allele specific identification of dense promoter methylation, analysis of the MGMT gene, prognostic/predictive for response for treatment which include alkylating agents such as temozolamide therapy in tumor tissue</td>
</tr>
</tbody>
</table>

**MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>815XX1</td>
<td>Oncology (tissue of origin), microarray gene expression profiling of &gt; 2000 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as tissue similarity scores</td>
</tr>
<tr>
<td>815XX2</td>
<td>Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy</td>
</tr>
<tr>
<td>81508</td>
<td>Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score</td>
</tr>
</tbody>
</table>

**MICROBIOLOGY**

<table>
<thead>
<tr>
<th>Code</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>876XX</td>
<td>Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique</td>
</tr>
</tbody>
</table>

**RECONSIDERATION REQUESTS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>0001M</td>
<td>Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver</td>
</tr>
<tr>
<td>0002M</td>
<td>Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ASH)</td>
</tr>
<tr>
<td>0003M</td>
<td>Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)</td>
</tr>
<tr>
<td>81500</td>
<td>Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score</td>
</tr>
<tr>
<td>81503</td>
<td>Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score</td>
</tr>
<tr>
<td>81506</td>
<td>Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbAlc, insulin, hs-CRP, adoponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score</td>
</tr>
</tbody>
</table>
### Part B Lab Spending Rose 9% in 2012

Medicare spending on Part B clinical laboratory spending totaled $9.741 billion in calendar year 2012, an increase of 9 percent over 2011, according to data from the 2013 Medicare Trustees Report, prepared by actuaries at the Centers for Medicare and Medicaid Services.

Intermediary labs (hospital lab outpatient and outreach) accounted for $4.661 billion of Part B lab spending in 2012, up from $4.351 billion in 2011 and $4.110 billion in 2010.

Carrier labs (independent labs and physician office labs) accounted for $5.080 billion in 2012, up from $4.579 billion in 2011 and $4.808 billion in 2010.

The 9 percent increase is substantial when compared to growth between 2010 and 2011, which was essentially flat. Between 2006 and 2011 lab expenditures rose an average of 4.3 percent per year, compared with average growth of 6.1 percent per year for total Medicare spending over the same period.

Total Medicare spending in 2012 reached $574.2 billion while Part B spending totaled $236.2 billion. Part B lab services represented about 1.7 percent of overall Medicare expenditures in 2012 and 4.1 percent of Part B expenditures.

In 2012, the number of beneficiaries covered increased to 50.7 million people, compared to 48.7 million people in 2011.

Over the next 10 years, the annual growth rate in Medicare spending is estimated to average 5.5 percent per year, which is less than the 6.2 percent projected last year. The estimated depletion date for the Medicare trust fund is 2026, two years later than was projected in 2011.

A number of factors have contributed to the slowed growth in overall Medicare spending, including lower projected spending for most service categories and lower projected Medicare Advantage program costs tied to the Affordable Care Act.


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**NEW AND RECONSIDERED CODES FOR THE 2014 MEDICARE LAB FEE SCHEDULE**

<table>
<thead>
<tr>
<th>RECONSIDERATION REQUESTS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81509</td>
<td>Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score</td>
</tr>
<tr>
<td>81510</td>
<td>Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score</td>
</tr>
<tr>
<td>81511</td>
<td>Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)</td>
</tr>
<tr>
<td>81512</td>
<td>Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score</td>
</tr>
<tr>
<td>82777</td>
<td>Galectin-3</td>
</tr>
</tbody>
</table>

Source: www.cms.gov/ClinicalLabFeeSched/, Click on “Laboratory Public Meetings” to access the download.

*CMS: Any changes to the list will be updated as they occur. CPT codes copyright American Medical Association.*
New Workplace Wellness Regulations Released; Too Soon to Tell If Labs Will Benefit

The U.S. Department of Health and Human Services (HHS), Internal Revenue Service, and Employee Benefits Security Administration have released final rules regarding workplace wellness incentive programs under the Affordable Care Act (ACA). These programs could present an opportunity for laboratories whose management is challenged about how to derive new revenue streams from the health care reform law.

The ACA contained provisions to promote healthy habits in the workplace when the legislation was originally signed into law in 2010. HHS spent the next three years developing the rules. The major provisions of the ACA—including the health insurance exchanges for small employers to purchase coverage—will be implemented on Jan. 1, 2014.

Workplace wellness has been an issue for years even before the passage of the ACA, particularly with rising rates of obesity, diabetes, and their related health issues. That, along with mental health issues such as depression, cost U.S. businesses hundreds of billions of dollars a year. Smoking, although it has declined dramatically since the 1970s and been banned in most workplaces, still costs businesses as much as $96 billion a year, according to the Morbidity and Mortality Report, a publication of the Centers for Disease Control and Prevention. However, some recent studies suggest much of the loss is tied to smoking breaks taken during work rather than illness.

Many larger employers have been pushing programs to encourage employees to stop smoking or lose weight and to exercise more regularly. Workers often receive incentives such as gift cards or small cash bonuses in return for meeting specific benchmarks.

Under the ACA, wellness programs are divided into two areas: participatory wellness programs that encourage gym use and some diagnostic testing in order to establish a health care benchmark. Health-contingent programs rely more deeply on testing of special medical conditions such as high levels of blood sugar and cholesterol.

Possible Bump in Testing
The ACA’s myriad of rules have presented a challenge for some laboratories. Large providers such as hospitals receive incentives if they improve and better coordinate care, and clinical laboratories can play a key part in helping hospitals reach their goals.

What’s more, industry experts say that wellness programs under the ACA could create a bump upward in diagnostic testing.
“With a greater emphasis on workplace wellness we may see an increase in screening for some conditions such as cholesterol and lipid panels, tests for monitoring diabetes such as hemoglobin A1c,” said Francisco Velázquez, M.D., chief executive officer of PAML Laboratory in Spokane, Wash. Such tests are typically bread-and-butter tests with relatively low prices.

However, Velázquez stopped short of predicting volumes.

“Wellness as a discipline and clinical effort has been difficult to quantitate from a laboratory perspective,” he said.

According to Velázquez, the spending data that are available indicate the average U.S. household spends $148.50 a month on products with a “wellness halo” such as healthy foods and vitamins and related supplements. But of that, only about $10—around 7 percent of the total—is spent on clinically related or diagnostic items such as blood pressure tests.

However, the ACA provisions contain some fairly generous incentives to improve workplace health—employer groups can give their workers as much as 30 percent of the overall cost of an employer’s health care plan and as much as 50 percent if it involves smoking cessation.

The regulations also encourage employees to improve their glucose and cholesterol levels—both benchmarks that call for regular laboratory testing.

But a big question is how employer groups will structure their wellness efforts. According to the regulations, the less diagnostic-oriented participatory wellness programs have been the majority of such efforts, and that is expected to be unchanged under the ACA.

Moreover, the regulations require that employers provide alternatives to the outcome-based wellness programs so as to avoid any risk that such testing is a subterfuge for discrimination or insurance underwriting based on a health factor.

“There are a lot of different configurations for these kind of initiatives,” said Donald Crane, chief executive officer of the California Association of Physician Groups (CAPG).

One such successful program involved CAPG members and health plan enrollees associated with the California Public Employees Retirement System in Santa Cruz County, Calif., which was launched in 2011. But Crane noted that while that specific program showed a dramatic increase in employee health indicators, much of that was connected to improved diets and smoking cessation. “I don’t know if it really translated into a big medical spend” such as laboratory testing, Crane noted.

According to Velázquez, there are some wellness programs that use a laboratory test for cotinine, a metabolite associated with nicotine consumption and smoking, although it is unclear whether volumes for such a test might grow, even with the relatively generous incentives associated with the new ACA rules.

“It remains an episodic test as employers have been reluctant to use it, since non-smoking environments do not preclude smoking outside of work,” he said.
Concern About LDTs
Since 1988, laboratories performing LDTs have been regulated under CLIA. While the FDA has said for years that it has enforcement discretion to regulate LDTs, it made little attempt to exercise what it viewed as its authority. In 2010, however, the FDA said it planned to exercise its enforcement discretion over LDTs and would issue guidance detailing its oversight scheme. Since then, the lab industry has been awaiting the guidance.

While the agency is required to give Congress 60 days’ notice before issuing such guidance, FDA Commissioner Margaret Hamburg recently made some unexpected comments about LDTs that raised industry eyebrows. During remarks made June 2 during the American Society of Clinical Oncology’s annual meeting in Chicago, Hamburg said that LDTs are marketed without evaluation through FDA’s premarket approval process to determine whether they are accurate and clinically valid. “That can be a problem,” she noted.

Concern has been expressed about the potential effect increased regulatory oversight of LDTs would have on personalized medicine. At the 2013 Policy Meeting of the College of American Pathologists in Washington, D.C., Debra G.B. Leonard, M.D., Ph.D., professor and chair of pathology at the University of Vermont College of Medicine, noted that genetic testing by next-generation sequencing is an LDT. “We must promote rigorous laboratory interpretive standards for clinical genomic testing. And we must advocate that interpretation of genomic data is the practice of medicine and not under the regulatory purview of the FDA,” Leonard told a CAP meeting audience.

While Hamburg noted that advanced diagnostics are the cornerstone of personalized medicine, she argued that “not all complex diagnostics used in cancer diagnosis or treatment have been developed to perform at the same demonstrated standards.”

She recalled how in 2008, OvaSure, an early-stage ovarian cancer screening test, came onto the market. “For high-risk patients and their doctors, this simple blood test appeared to offer great promise for combating the disease and providing peace of mind. Although FDA did not consider OvaSure to be a laboratory-developed test, it was offered as an LDT and thus did not undergo adequate clinical validation.
before the test was used across the country. Thanks in large part to the involvement of the oncology community, together with FDA, this flawed test was eventually withdrawn from the market, some four months after it had been launched.”

LDTs are being used with a family history of cancer to decide whether to take preventive action, Hamburg said. “FDA does not know how many women may have received erroneous results from the OvaSure test, or how many may have used that flawed information to make critical medical decisions. But relying on advanced diagnostics to make critical, life-altering treatment decisions exposes patients to obvious risks if these tests do not perform as expected. False results put patients at risk of a missed diagnosis or a wrong diagnosis that could result in either inappropriate treatment or no treatment at all.”

The agency is working to make sure that the accuracy and clinical validity of high-risk tests are established before they come to market, Hamburg said, and the risk-based framework under development will ensure that diagnostics used in cancer treatment will provide medical professionals with a critical baseline for confidence in the tests they order for their patients.

The ACLA petition is available on the association’s Web site at www.acla.com.

OSHA Cites LabCorp for Safety Violations

The U.S. Department of Occupational Safety and Health Administration (OSHA) has cited LabCorp for alleged repeat and serious health violations following a November 2012 complaint inspection of its Schenectady, N.Y., location by the OSHA’s Albany, N.Y., area office.

OSHA found that phlebotomy technicians who drew blood did not receive required training until after working with the blood. In addition, workers were not trained on procedures in the event of an exposure incident. OSHA’s bloodborne pathogen standard requires employers to provide workers with regular training, which includes steps to take in the aftermath of an exposure, and to provide training before workers begin working with blood.

One repeat violation was issued with $38,500 in proposed fines. A repeat violation exists when an employer previously had been cited for the same or similar violation of a standard, regulation, rule, or order at any other facility in federal enforcement states within the last five years. Similar hazards were cited in 2011 at a Jersey City, N.J., facility.

“"The failure of Laboratory Corp. to provide adequate and timely training needlessly placed workers at risk,” said Kimberly Castillon, OSHA’s area director in Albany. “The health and wellness of Laboratory Corp. workers depends on this company promptly and effectively addressing these issues at all its locations.”

Three serious violations, with $19,500 in proposed fines, includes the failure to have specific procedures to inform workers on obtaining post-exposure care, update the exposure control program to reflect technological changes to eliminate or reduce bloodborne pathogen exposures, and train workers exposed to traysol, a chemical used in stabilizing and shipping blood samples, about its physical and health hazards. A serious violation occurs when there is substantial probability that death or serious physical harm could result from a hazard about which the employer knew or should have known. 
CMS Clarifies TC-Bundling Dilemma for ASCs

The Centers for Medicare and Medicaid Services (CMS) has clarified a long-standing dilemma faced by laboratories and pathologists that provide services to patients of freestanding ambulatory surgery centers (ASCs). In the past, most Part B Medicare administrative contractors would deny the technical component (TC) if the claim displayed place of service code 24, saying that the TC was subject to an institutional bundling rule (which, in fact, was not true).

Transmittal 2714, issued May 24, 2013, updates the Medicare Claims Processing Manual to memorialize the end of the hospital TC-bundling grandfather exception for pathology services effective July 1, 2012. However, as part of the transmittal, CMS also clarifies the ASC TC-bundling issue.

Specifically, CMS states, “Payment is made under the physician fee schedule for TC services furnished in institutional settings where the TC service is not bundled into the facility payment, e.g., an ambulatory surgery center (ASC). Payment may be made under the physician fee schedule for the TC of physician pathology services furnished by an independent laboratory, or a hospital if it is acting as an independent laboratory, to non-hospital patients.”

The implementation date of the transmittal is June 25, 2013.

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**Webinar** (2 p.m. - 3:30 p.m. Eastern)

June 19

Keeping Ahead of the Curve: CLIA Compliance 2013

www.G2Intelligence.com/CLIACompliance

**Conferences**

Oct. 16-18

It’s Make or Break Time: A Path Forward For Labs

Hyatt Regency Crystal City

Arlington, Va.

www.laboutside.com

Dec. 9

Lab Leaders’ Summit 2013

Union League Club of New York

New York City

Dec. 10

Laboratory and Diagnostic Investment Summit

Union League Club of New York

New York City

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