G2 INTELLIGENCE

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CMS Sets July Date for Medicare Lab Test Pricing Forum

This is the first step in the annual process, required by law, to get public input on pricing for tests to be added to the Medicare lab fee schedule. Preliminary payment determinations will be posted in the fall for another round of comments. Final determinations will be published later this year in the lab fee schedule for 2012.

The Centers for Medicare and Medicaid Services (CMS) will hold a public meeting on July 18 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 2012.

It will also air requests to reconsider the agency's pricing of five codes currently on the Part B clinical lab fee schedule.

For 2012 there are two new CPT codes—one in immunology used to detect human bladder cancer, the other in microbiology used to detect HIV-1 antigen and HIV-1 and HIV-2 antibodies.

Payment levels 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.

Continued on p. 2

Alarm Sounded Over Potential Revival of Medicare Copay for Covered Lab Services

As Congress considers more Medicare spending cuts, one option getting serious attention is to shift some costs to beneficiaries by applying a uniform 20 percent copay for all covered services, including clinical laboratory testing that has been exempt from any cost sharing since the lab fee schedule was established in 1984.

In response, members of the Clinical Laboratory Coalition are mobilizing their constituencies to persuade lawmakers that imposing a lab copay is a bad idea, not only because it hikes out-of-pocket expenses for beneficiaries and may even cause many to shun advanced diagnostics for disease prevention and early detection, but also because in most cases the amount the lab must collect is far less than what it costs the lab to collect.

Of immediate concern are the bipartisan negotiations over raising the debt ceiling coupled most likely with Medicare spending cuts. Though the talks are secret, an across-the-board copay reportedly is on the table as part of elements of a deficit-reduction plan.

"It's time for the lab industry to be vocal in opposition to the lab copay idea," Mark Birenbaum, head of the American Association of Bioanalysts and the National Independent Laboratory Association, told *NIR*.

Continued on p. 7

INSIDE *NIR*

CMS to hold annual pricing forum for new, reconsidered codes on Medicare lab fee schedule 1

Lab coalition raises the alarm over potential return of Medicare lab copay 1

CMS schedules special discussion session on new molecular pathology codes ... 2

Pathology, lab organizations aim to carve out a stake in new Medicare shared savings program 4

Medicare touts numbers of beneficiaries getting preventive care at no out-of-pocket expense 6

G2 Conference Calendar 8

- Molecular Diagnostics—Fall 2011
- Lab Leaders Summit
- Lab Institute
- LabCompete: Sales & Marketing

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Medicare Lab Test Pricing Forum, *from p. 1*
The following is a list of the newly created CPT codes and the reconsideration requests on which recommendations are sought in order to be included in the Part B clinical laboratory fee schedule for 2012. (Note: numbering of the new codes has yet to be finalized.)

NEW CODES	
IMMUNOLOGY	
863XX	Nuclear Matrix Protein 22 (NMP22), qualitative
MICROBIOLOGY	
873XX	HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
RECONSIDERATION REQUESTS	
G0434	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter (current national fee cap, $20.47)
G0435	Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening (current national fee cap, $16.88)
83861	Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity (current national fee cap, $23.58)
86481	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension (current national fee cap, $87.22)
87906	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion) (current national fee cap, $181.14)
CPT codes © American Medical Association. *Any changes to the listing of the above will be updated as they occur, CMS notes. Check its Web site at* www.cms.gov/ClinicalLabFeeSched/. *Click on "Laboratory Public Meetings."*	

CMS to Hold Special Session on New Molecular Pathology Codes

On July 18 immediately after the public forum on lab test pricing (*related story, p. 1*), the Centers for Medicare and Medicaid Services (CMS) will convene a special session to discuss how the agency should handle new genetic test codes approved by the CPT Editorial Panel.

This has fueled industry speculation that the agency might not implement all the codes on Jan. 1, 2012 (when they take effect for CPT purposes) to allow time for public input.

There are 101 new molecular pathology codes classified in two tiers: 92 analyte-specific codes in Tier 1 for high-volume procedures and nine resource-level codes in Tier 2 for low-volume procedures.

The agency emphasized that while it is not accepting payment recommendations for these codes at this time, it wants input on how they should be addressed going forward:

- Their assignment to the clinical lab fee schedule or the physician fee schedule
- Current CPT codes used to reflect test steps

- How various genetic tests are similar to or different from existing lab tests

The codes for the CMS information session are posted at *www.cms.gov/ClinicalLabFeeSched/*. Click on "Laboratory Public Meetings."

Next Up for CPT: Coding for IVDMIAs

Continuing an initiative on molecular diagnostics coding, the American Medical Association and CPT staff are planning an all-day meeting on July 20 in Chicago with interested stakeholders to discuss the next steps in establishing a process for the coding of in vitro diagnostic multivariate index assays (IVDMIAs).

The IVDMIA work group will be asked to discuss:

- General construction of guidelines, descriptors, and codes
- Minimum elements for code descriptors
- Definition of minimum standards to establish a code (for example, evidence thresholds, literature thresholds, frequency thresholds, and Food and Drug Administration status)

In its draft guidance for industry, the FDA defines an IVDMIA as a device that combines the values of multiple variables using an interpretation function to yield a single, patient-specific result intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, and provides a result whose derivation is nontransparent and cannot be independently derived or verified by the end user.

IVDMIAs are sometimes referred to as "black box" assays. They use raw data obtained for a number of analytes and apply them to an algorithm to generate an index that organizes and prioritizes individual markers, producing a result in a simplified, readily usable format. The exact method to replicate the test is often not disclosed, therefore making the test proprietary.

Such tools make it possible to screen thousands of potential markers to find a subset or subsets of biomarkers that can predict a disease state, determine the likelihood of disease progression, or calculate the probability of responding to a therapy or other important medical information, the College of American Pathologists (CAP) has noted.

Examples of IVDMIAs as identified by the FDA include gene expression profiling assays for breast cancer prognosis or organ rejection; products and systems that predict disease risk by integrating results from multiple immunoassays; and tests that predict risk or diagnose disease by integrating age, sex, and genotype results from multiple genes.

Most available IVDMIAs (and those in development) address gaps in information needed for making patient-management decisions, according to CAP. "For example, some IVDMIAs attempt to subdivide diagnostic categories that show heterogeneity in clinical response (*e.g.*, dividing breast cancer patients into low and high risk recurrence groups)."

Carving Out a Stake in Medicare's Shared Savings Program

Pathology and clinical laboratory organizations are anxious to get in on the ground floor as the Centers for Medicare and Medicaid Services (CMS) develops the new Medicare shared savings program authorized by the health care reform law and due for launch on Jan. 1, 2012.

Laying out their case in comments to CMS this month on its proposed rule implementing the program, the American Society for Clinical Pathology (ASCP), the College of American Pathologists (CAP), and the American Clinical Laboratory Association (ACLA) stressed the key role of pathology and lab medicine in achieving the program's triple goals: controlling costs, measuring and improving quality, and promoting better outcomes for beneficiaries.

In that proposal, CMS said eligible physicians, hospitals, and other providers and suppliers may participate by forming or joining an accountable care organization (ACO) to provide coordinated quality care to fee-for-service beneficiaries across all care settings. Participants would continue to receive fee-for-service payments and also would share in the savings generated for Medicare by improved care outcomes and operational efficiencies *(NIR 11, 7/April 8, p. 1)*.

Close to 70 percent of attendees at G2 Intelligence's 10th annual Laboratory Outreach Conference, held June 15-17 in Las Vegas, believe that ACOs and other coordinated care models will fundamentally change the delivery of diagnostic services, especially clinical laboratory testing. Between 75 and 150 ACOs are expected to be created in the first three years of Medicare's shared savings program, and 1.5 million to 4 million beneficiaries are estimated to be enrolled. However, net savings to Medicare are expected to be a relatively modest $510 million, noted Richard Friedberg, M.D., Ph.D., chair of the pathology department at Baystate Health and medical director at Baystate Reference Laboratories, based in Springfield, Mass., in a keynote address at the conference.

ACOs and Diagnostic Capabilities

"While primary care is essential to ACO composition, a strong foundation of diagnostic capabilities is the core to an ACO's effectively assuming accountability for the full continuum of care for patients," CAP said, and should be reflected in governance of the ACO.

ASCP stressed the same point, noting that approximately 7 billion to 10 billion lab tests are performed annually and the results have an estimated impact on over 70 percent of medical diagnoses and treatment regimens. "Given the robust state of laboratory informatics and the fact that upwards of 50 percent of a patient's electronic health record is expected to be lab data, pathology and laboratory medicine is integral to ACO goals."

Laboratory testing already promotes these goals, ACLA observed. "For example, it provides health professionals with critical information about the patient's health status, which allows practitioners to select the most appropriate treatments and other interventions, as well as data analysis and tracking services that allow individual patients to be monitored over time. In addition, the growing availability of personalized testing can reduce the utilization of more costly interventions." ACLA further noted that ACOs would be required to meet a number of quality-performance measures dependent on lab testing and perform these tests consistently to be in compliance with their contractual obligations and thus qualify to receive shared savings.

Eligibility

In the proposed rule, CMS set forth definitions of who qualifies, including those specified in the law and other Medicare providers and suppliers as determined by the secretary of the Department of Health and Human Services.

ASCP recommended that CMS should specifically designate both pathologists and Ph.D. clinical scientists as eligible ACO participants. Under the current definition, the latter would be ineligible to participate fully.

ACLA asked CMS to clarify that independent clinical labs can participate in the program as providers or suppliers and as full participants. "In addition, the final rule should make clear that labs could be involved in the formation of an ACO. Although labs cannot themselves be ACOs without the collaboration of ACO professionals and hospitals, many independent labs may be well positioned to function as the necessary link to bring together physician group practices, hospitals, and other providers to establish a successful ACO."

Quality Metrics

To ascertain the quality of care furnished by ACOs, CMS proposed 65 quality measures in five areas: patient and caregiver experience, care coordination, patient safety, preventive health, and at-risk populations and the elderly. It also linked the measures to the meaningful-use standards for incentive payments for adoption of electronic medical records.

ASCP said it is "concerned that such measures may unfairly hurt medical specialties for which adequate quality metrics are not yet available." ASCP advises that the CMS approach to physician specialty-specific measures should avoid the one-size-fits-all approach in the meaningful-use requirements for electronic medical records.

Pathologists and radiologists, for example, are considered "eligible" for financial incentives for meaningful use, yet are generally unable, through no fault of their own, to meet the reporting requirements because meaningful-use measures have no relevance to their medical specialty or too few have been approved.

CMS should allow ACOs, particularly with regard to individual medical specialties, to provide alternative data to support or document improvements in health care quality and cost, ASCP recommended.

Numerous other lab testing practice guidelines could be incorporated into the performance measurement of ACOs, ACLA said, pointing to up-to-date consensus guidelines by the American Society of Clinical Oncology and the National Comprehensive Cancer Network.

Risk Models

To provide an entry point for organizations with varied experience with and willingness to assume risk, CMS proposed a choice of a one-sided risk model (share savings only for the first two years and share savings and losses in the third year) or a two-sided risk model (share savings and losses for all three years).

ASCP favored the two-sided risk model, saying it would minimize the incentive for volume-increasing behavior that may be brought about by such practices as self-referral. "Instead, it provides an incentive to the ACO to prune out unnecessary or inappropriate testing."

Withholding or Reducing Services to Maximize Cost Savings

To guard against this strategy, ACLA recommended that CMS:

- Put a percentage cap on the amount that any one physician can earn in shared savings, such as 10 percent of his or her allowed charges.
- Consider requiring that savings be distributed on a per capita basis rather than proportionally to the savings generated by a particular physician.

Medicare Touts Numbers Getting Free Preventive Care

Since the start of this year, nearly one in six of the more than 33 million Americans with traditional Medicare has used one or more of the preventive benefits now available with no cost sharing under terms of the health care reform law, the Centers for Medicare and Medicaid Services (CMS) announced June 20.

Figuring prominently in the utilization rates from Jan. 1 to June 10 are mammograms (number of claims, 2,326,088), bone density screenings (1,549,056), and screenings for prostate cancer (1,137,131).

Utilization Rates for Free Medicare Preventive Benefits*

PREVIOUSLY SUBJECT TO BOTH THE PART B DEDUCTIBLE AND COINSURANCE/COPAYMENT	
Bone mass measurement	1,549,056
Hepatitis B vaccine	193,383
Tobacco cessation counseling	20,730
Medical nutrition therapy	*data not available*
PREVIOUSLY EXEMPT FROM THE PART B DEDUCTIBLE BUT SUBJECT TO COINSURANCE/COPAYMENT	
Pap tests that require physician interpretation	508,238
Pelvic examination	535,098
Screening mammography	2,326,088
Most screening procedures for colorectal cancer	472,075**
Ultrasound screening for abdominal aortic aneurysm	*data not available*
PREVIOUSLY EXEMPT FROM BOTH THE PART B DEDUCTIBLE AND COINSURANCE/COPAYMENT	
Pap tests that do not require physician interpretation	582,870
Fecal occult blood test for colorectal cancer screening	466,657
Prostate-specific antigen (PSA) test	1,137,131
Diabetes screening test	*data not available*
Cardiovascular disease screening test	*data not available*
Seasonal influenza virus vaccine	*data not available*
Pneumococcal vaccine	*data not available*
HIV screening	*data not available*

**Cumulative 2011 count of fee-for-service claims for beneficiaries using preventive services received as of June 10, 2011.*

***The fecal occult blood test was always free, and the Part B coinsurance/copayment continues to apply to barium enemas as well as to a screening colonoscopy if an abnormality is found and treated during the procedure. Total utilization for colorectal cancer screening was 928,520 from Jan. 1 through June 10, 2011.*

Source: CMS

The breakdown for other clinical laboratory and pathology benefits includes Pap tests that require physician interpretation, 508,238; Pap tests that do not require physician interpretation, 582,870; and fecal occult blood test for colorectal cancer screening, 466,657.

As of Jan. 1, 2011, the Patient Protection and Affordable Care Act eliminated Part B coinsurance and deductibles for the majority of recommended screenings and services and added a new annual wellness visit at no cost to beneficiaries. As part of that visit, beneficiaries and their physicians can review the patient's health and develop a personalized wellness plan, including lab and pathology services. Over 780,000 beneficiaries received an annual wellness visit between Jan. 1 and June 10.

Also, more seniors have used the baseline Welcome to Medicare exam this year, CMS reported. By the end of May, 66,302 had availed themselves of the benefit, compared to 52,654 at the same point in 2010, or a 26 percent increase.

In announcing the preventive services tally on June 20, CMS also launched a nationwide public outreach campaign, including a letter to doctors and a new public service announcement to raise awareness of the benefits now covered at no out-of-pocket expense to patients.

Alarm Sounded Over Lab Copay, *from p. 1*

Even if the idea does not survive final budget talks, there is always a real possibility it may appear in other legislation down the road, he said. One vehicle could be legislation to block a 29.5 percent cut in Medicare physician fees scheduled for 2012 and pay for canceling the reduction.

Lost in the debate thus far, Birenbaum said, are important distinctions between labs and other providers and the differing impact the copay requirement would have on them. For example, while a 20 percent copay for a test that costs $500 would amount to $100, the cost of collecting it would likely be much less, $5 to $10; however, for most commonly ordered lab tests ranging from $5 to $6, the cost of collecting the copay is a money-losing proposition, and failure to collect it for even small amounts would expose a lab to fraud-and-abuse scrutiny.

What's Different This Time?

Beneficiary cost sharing for Medicare-covered lab services was eliminated in 1984 as part of a deal that dropped balance billing and established a fee schedule under which providers were assured of 100 percent payment by the program.

Clinical Lab Coalition

American Association of Bioanalysts
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Medical Technologists
American Society for Microbiology
American Society for Clinical Pathology
American Society for Clinical Laboratory Science
Clinical Laboratory Management Association
College of American Pathologists
National Independent Laboratory Association

The lab industry has twice beaten back previous proposals over the last 10 years to institute a copay specifically targeted to clinical labs, a notion last floated during the health care reform debate but dropped from the legislation.

It might be more difficult to fend it off this time, caution industry sources. The previous attempts were aimed squarely at labs, while the current threat is embedded in a larger principle, summed up as "everything in Medicare should have a copay."

So far the debate has seemed focused on the ideological bent, not practicality, said Birenbaum.

Would the copay make a beneficiary more cost-conscious and affect utilization, as proponents contend? He thinks not. While this behavior may be a key influence in direct-to-consumer testing where the cost is all out of pocket, in Medicare the driving force in utilization is the treating physician who orders lab tests related to the patient's condition. The physician or the insurer then decides which lab will perform the testing. Patients rely on the physician to know which tests are needed and which lab will perform the work.

Negative Consequences

A uniform cost-sharing structure for Medicare would have a significantly adverse impact on labs and patients alike, the American Clinical Laboratory Association notes in an action alert and related talking points on the issue.

- Many lab test copay amounts would be well under $5. In most cases the cost of collecting the copay would exceed the amount of the copay itself. For almost one-third of the 30 most commonly ordered laboratory tests—such as glucose, complete blood count, cholesterol, and other critical tests for diabetes, heart, kidney, and other diseases—the coinsurance would be less than $2.
- Laboratories would have to generate over 100 million new bills each year to seniors and attempt to collect from them. Medicare would require *Continued on p. 8*

Alarm Sounded Over Lab Copay, *from p. 7*

that beneficiaries be billed for the copay, no matter how small the amount. Labs would bear the cost of billing, collection, and, of course, bad debt.

- A lab copay would hit the sickest and poorest seniors the hardest, according to an Institute of Medicine study.
- The lab copay conflicts with congressional intent to encourage more prevention and early detection of chronic diseases such as diabetes, heart disease, kidney disease, and cancer. Medicare has already implemented key changes required under the health care reform law that eliminate cost sharing for most covered preventive benefits, plus the new annual wellness visit.
- The lab copay could have a perverse effect by creating a disincentive to take advantage of more expensive advanced diagnostics used for early detection and treatment of cancer and other serious diseases and conditions, saving countless lives and billion of dollars on hospitalizations and other complications. The co-pay could run into hundreds of dollars or more for beneficiaries, discouraging them from seeking care that could avoid hospitalization and other conditions that would end up costing Medicare more in the long run.

G2 Conference Calendar

Sept. 22
Molecular Diagnostics—Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

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NIR 6/11B

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