G2 INTELLIGENCE

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Medicare Lab Test Pricing Forum Set for July 16-17

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.

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 (*related story below*).

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.

The new CPT lab codes and one reconsideration request are presented in the table on page 2. (*Note*: numbering of the new codes will be finalized later.)

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CMS to Price Molecular Pathology Codes Via Physician Fee Schedule Rulemaking

In announcing the mid-July forum on the Medicare Part B lab fee schedule, the Centers for Medicare and Medicaid Services (CMS) said it would solicit, in the proposed Medicare physician fee schedule rule for 2013, recommendations on the placement and pricing of new CPT molecular diagnostic codes introduced this year by the American Medical Association (AMA) but not yet recognized by Medicare.

The codes include 92 Tier 1 analyte-specific codes for high-volume procedures (CPT 81200-81383) and nine Tier 2 resource-level codes for low-volume procedures (81400-81408).

Also on the list are 10 molecular diagnostic codes for multianalyte assays with algorithmic analyses (MAAAs) for ovarian oncology, type 2 diabetes, fetal chromosomal abnormalities, and liver disease.

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Medicare Lab Test Pricing Forum, *from p. 1*

Next Steps

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.

NEW CPT CODES FOR THE 2013 MEDICARE LAB FEE SCHEDULE*	
CHEMISTRY	
827XX	Galectin-3
IMMUNOLOGY	
861XX	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);
867XX	JC (John Cunningham) virus
TISSUE TYPING	
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class I
868XX	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class II
MICROBIOLOGY	
876XX	*Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, direct probe technique*; respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets
876XX	*Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, direct probe technique*; respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 6-11 targets
876XX	*Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, direct probe technique*; respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets
879XX	Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus
879XX	Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus
RECONSIDERATION REQUEST	
86386	Nuclear Matrix Protein 22 (NMP22), qualitative

*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 © American Medical Association.*

House Committee Gets Earful on Physician Pay Reform

The GOP members of the House Ways and Means Committee recently invited a large number of physician organizations to submit ideas on replacing the current Medicare physician reimbursement system and its sustainable growth rate (SGR) update.

The call for ideas emerged from a flurry of activity in Congress to find a way forward on crafting an alternative to the SGR, which has triggered ever-steeper reductions in physician fees for more than a decade and is set to cut them by 30.9 percent in 2013. Lawmakers have repeatedly blocked SGR cuts with short-term fixes but sentiment is strong to move to a system that does not require annual congressional intervention (*NIR 12, 10/May 24, p. 1*).

In their May 25 responses to the House committee request, the American Medical Association (AMA) and the Medical Group Management Association (MGMA) called for more flexibility to innovate and less regulatory threat of sanctions.

AMA and MGMA said physician groups should be allowed to experiment with different payment and delivery models that increase coordinated care and quality outcomes without fear of running afoul of antitrust and other anti-fraud and abuse laws and regulations.

The AMA called for extending antitrust protections—currently allowed for participants in the Medicare Shared Savings Program—to other providers that are pursuing innovative contracting arrangements with payers.

Congress also should ensure that "physicians who are engaged in trying new models of care delivery are not precluded from having a meaningful market presence by hospitals and insurers who have achieved an anti-competitive, dominant market share," AMA said.

MGMA said the Centers for Medicare and Medicaid Services (CMS) should give physician groups more flexibility in experimenting with new payment options, including bundled payments, partial capitation, accountable care organizations, medical homes, "and other hybrid approaches that couple fee-for-service payments with a risk-based bonus opportunity."

MGMA also advised that:

- Medicare should offer timely data sharing and positive financial incentives to assist medical practices that want to experiment with alternative approaches to achieve savings.
- Medicare should break down the "silos" that separate different sectors of the program from one another. "The Medicare program must be flexible and give physicians credit under Part B for savings they achieve in Part A."

The groups also said CMS should stop "backdating" penalties under the electronic health record meaningful use requirements. For example, CMS is basing its 2012 e-prescribing penalties on a physician's e-prescribing activity in 2011. "This approach will subject a significant number of physicians to financial penalties," MGMA said, "and slow down the ability of physicians to undertake meaningful payment and delivery reforms while under the duress of cumbersome reporting requirements."

Legislative Solution in the Hopper

Meanwhile, a bipartisan bill (H.R. 5707), introduced in the House May 9 by Reps. Allyson Y. Schwartz (D-Pa.) and Joseph J. Heck (R-Nev.), would repeal the update formula and require CMS to test and evaluate possible new reimbursement systems (*NIR, 12, 10/May 24, p. 1).*

In 2013, the measure would keep physician fees at their 2012 levels; then beginning in 2014, all physician services would get annual updates of 0.5 percent for four years (2.5 percent for primary care). By 2016, CMS would have to offer a menu of no fewer than four delivery and payment model options. Beginning in 2018, physicians in CMS-approved models would receive stable reimbursements (according to their primary care/non-primary care payment system), with an opportunity to earn more for achieving quality, cost, and effectiveness.

But the bill would pay for SGR repeal (currently an estimated $300 billion over 10 years) by using unspent funds from the wars in Afghanistan and Iraq. This idea has been floated in Congress this year as a way to fix the SGR problem, but it has run into potent opposition from numerous lawmakers who say the savings offset is illusory.

Giving CMS Leeway on CLIA PT Referral Enforcement

Changing one word in the Clinical Laboratory Improvement Amendments (CLIA) that prohibits a clinical lab from referring proficiency testing (PT) samples to another lab would give the government leeway in enforcing this requirement and give labs more protection against losing their CLIA license.

That change is envisioned in legislation being worked up in the House and the Senate. Under a draft Senate version, the wording in the statute would go from requiring that a lab's certification "*shall* be suspended" to "*may* be suspended."

The draft also calls for a study on improper referrals and would require that the Centers for Medicare and Medicaid Services (CMS) issue guidance on how it defines "improper and intentional referrals."

PT Requirements

All CLIA-certified labs (except those performing only CLIA-waived tests) must participate in PT for analytes that are regulated. Most sets of PT samples are sent to participating labs three times per year. After testing the samples in the same manner as its patient specimens and by the same personnel who routinely test patients' samples, the laboratory reports its PT results to its PT provider. The lab director or designee and testing personnel must sign an attestation sheet, and each step in testing must be documented, with records retained for two years.

Severe PT Sanctions

Labs may not send PT samples to another laboratory with a different CLIA number for testing even if they typically send patients' specimens out for confirmation or identification testing. Doing so may be considered a PT referral and result in the lab losing its CLIA certificate for at least one year. In addition, the lab's director cannot direct a lab for two years, and the lab's owner may not own or operate a lab for two years.

Even though CMS has cautioned labs not to send out PT samples, not even for a reflex or confirmatory test, there are a certain number of referrals that occur each year. Under the current law, CMS does not have discretion in enforcement. A lab will lose its CLIA certificate, even if it can prove that the referral was inadvertent or in cases where it sends a PT sample to a sister lab with a different CLIA certificate number.

According to an article published in 2009 in the *Archives of Pathology and Laboratory Medicine*, between 1993 and 2006, only 78 of about 45,000 labs subject to PT testing received a principal sanction for a PT violation involving sample referral or communication of results.

Judy Yost, director of the division of laboratory services at CMS, says she recognizes that there are instances when referrals are made by accident and supports legislation that would give her division more enforcement discretion.

While CMS has been upheld in almost all administrative appeals involving PT referrals, a lab in September 2011 actually won its appeal, but it took two years to prevail. The case revolved around PT samples involved in three testing events in 2008 and one testing event in 2009.

In *J.B. and Greeta B. Arthur Comprehensive Cancer Center v. CMS*, an administrative law judge (ALJ) for the Health and Human Services Departmental Appeals Board said that CMS could not revoke a cancer center's laboratory based on its having sent unused portions of the PT samples to a lab operated by Audrain Medical Center of Mexico, Mo., with which the cancer center is affiliated, for storage and disposal. The medical center's lab tested the samples before the cancer center lab had reported its PT results.

The ALJ found that "what happened during the time period at issue was not an intentional referral and not for purposes of analysis." The cancer center laboratory did not direct the medical center to test its PT samples, the ALJ noted, and did not require or suggest that the medical center advise it of its own test results. The medical center ran the tests to check its own equipment, not to verify the cancer center's results. To the ALJ it was clear that "the prohibition is against the sending of the proficiency samples to another laboratory for analysis. The intent requirement is not met by the simple act of sending PT samples to another laboratory" (*NIR, 12, 1/Jan. 12, p. 3*).

CMS to Price Molecular Pathology Codes, *from p. 1*

At last year's lab test pricing forum, CMS deferred action on the Tier 1 and Tier 2 molecular diagnostic codes, saying it needed public comment on their appropriate placement and pricing (*NIR 11, 12/June 23, p. 2*).

This year, CMS wants still more comment. In a notice in the May 29 *Federal Register*, the agency said there is still debate "in the molecular pathology community whether Medicare should pay for [these codes] under the clinical lab fee schedule or the physician fee schedule (PFS). We will benefit from additional public comment on this issue in the 2013 PFS proposed rule and will make final decisions in the 2013 PFS final rule with comment period."

Which Fee Schedule Is the Right Fit?

The placement of the codes is significant because it determines the pricing and whether beneficiaries are subject to cost sharing (deductible and coinsurance).

- ❑ On the clinical laboratory fee schedule, payment rates are set using the crosswalk or gap-fill method and there is no beneficiary cost sharing for tests.
- ❑ On the physician fee schedule, covered services typically require physician work. Payment rates are set using relative value units (work, practice expense, and malpractice expense) that are subject to adjustments under the sustainable growth rate formula and periodic CMS review of the relative values. Beneficiary cost sharing of 20 percent generally is required.

CMS noted that if, based on comments received in response to proposals set forth in the 2013 PFS proposed rule, it decides that some of the molecular diagnostic codes should be payable under the lab fee schedule, it will post final payment determinations for these codes in November when the final 2013 PFS is published.

The new CPT Tiers 1 and 2 codes are designed to replace billing for molecular pathology procedures using "stacking codes" (CPT 83890–83914) that focus on methodology rather than analyte.

The Tier codes, plus codes for multianalyte assays with algorithmic analyses, are posted at www.cms.gov/ClinicalLabFeeSched/. *Click on "Laboratory Public Meetings" to access the 2013 code download.*

Multianalyte Assays With Algorithmic Analyses

These are procedures that utilize multiple results derived from molecular pathology assays, as well as fluorescence in situ hybridization and other non-nucleic-acid based assays, and are then used in proprietary algorithmic analyses to derive a single result, reported typically as a numeric score or probability.

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 2013 coding list posted by CMS includes new codes for the MAAAs below (*Note:* numbering yet to be finalized.) MAAA is the AMA-preferred term for what the Food and Drug Administration has called in vitro diagnostic multivariate index assays (IVDMIAs).

815XX Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score

815XX Oncology (ovarian), biochemical assays of five proteins (CA-125, apoli proprotein A1, beta-2 microglobulin, transferrin and pre-albumin), utilizing serum, algorithm reported as a risk score

815XX Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adoponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score

815XX Fetal chromosomal abnormalities, biochemical assays of three proteins (PAPP-A, hCG (any form), DIA), utilizing maternal serum, algorithm reported as a risk score

815XX Fetal chromosomal abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

815XX Fetal chromosomal 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)

815XX Fetal chromosomal abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score

XXXX1M Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing se rum, prognostic algorithm reported as scores for fibrosis and necroin flammatory activity in liver

XXXX2M Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipo protein 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 ste atohepatitis (ASH)

XXXX3M Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipo protein 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)

Source: *www.cms.gov/ClinicalLabFeeSched/*. Click on "Laboratory Public Meetings" to access the 2013 code download.

New Members Named to Key Medicare Advisory Panel

Gene L. Dodaro, comptroller general of the United States and head of the U.S. Government Accountability Office (GAO), on May 24 announced the appointment of five new members and the reappointment of one existing member to the Medicare Payment Advisory Commission (MedPAC).

The newly appointed members, whose terms expire in April 2015, are:

- Alice Coombs, M.D., critical care specialist and anesthesiologist, South Shore Hospital, Weymouth, Mass.
- Jack Hoadley, Ph.D., research professor, Health Policy Institute, Georgetown University, Washington, D.C.
- David Nerenz, Ph.D., director of the Center for Health Policy and Health Services Research, Henry Ford Health System, Detroit.
- Rita Redberg, M.D., professor, clinical medicine, University of California at San Francisco Medical Center, San Francisco.
- Craig Samitt, M.D., president and chief executive officer, Dean Health System Inc., Madison, Wis.

The reappointed member, whose term expires in April 2015, is Glenn M. Hackbarth, J.D. (chair).

The newly appointed members are replacing Mitra Behroozi, Robert Berenson, Karen R. Borman, Ronald D. Castellanos, and Bruce Stuart.

Congress established MedPAC in 1997 and gave it a broad statutory mandate. In addition to advising Congress on payments to private health plans participating in Medicare and providers in traditional fee-for-service, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

MedPAC's 17 members are appointed to three-year terms (subject to renewal) by the comptroller general and serve part time. Appointments are staggered; the terms of five or six commissioners expire each year.

Terms for six existing commission members (Scott Armstrong, Katherine Baicker, Thomas M. Dean, Herb B. Kuhn, Mary Naylor, and Cori Uccello) will expire in April 2013, and terms for five existing commission members (Peter W. Butler, Michael Chernew, Willis D. Gradison, William J. Hall, and George N. Miller) will expire in April 2014.

Avoiding Common Version 5010 Claims Rejections

The Centers for Medicare and Medicaid Services has provided some tips on processing your Version 5010 claims and avoiding unnecessary rejections. Version 5010 has requirements different from those of Version 4010 and 4010A. For example:

- ❑ ZIP Code: You need to include a complete nine-digit ZIP code for the billing provider and service facility location. Work with your vendor to make sure your system captures it.
- ❑ Billing Provider Address: You need a physical address. Version 5010 does not allow use of a post office box for either professional or institutional claim formats. You can still use a P.O. box, however, as your address for payments and correspondence from payers as long as you report this location as a pay-to address.
- ❑ National Provider Identifier (NPI): Previously, you could report an Employer Identification Number (Tax ID) or Social Security number as a primary identifier for the billing provider. For Version 5010, you may only report an NPI. G2

The compliance deadline to upgrade to the Version 5010 electronic transaction standard is July 1, the agency said in an alert to entities covered under the Health Insurance Portability and Accountability Act.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

June 21

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Lucia M. Berte, MA, MT(ASCP), president, Laboratories Made Better!, Broomfield, Colo.

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