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Lab, Pathology Groups Propose Pricing For New Lab Codes

For an analysis of the practical implications of the new CPT codes, see the Medicare Coding Advisory in this issue, p. 7.

The leading national clinical laboratory and pathology organizations are unanimous in recommending use of the crosswalk method to set Medicare fees for 11 new CPT codes that will be added to the 2007 Part B lab fee schedule. The unanimity continues the trend in recent years for these groups to coalesce behind the crosswalk method vs. the "gap-fill" alternative.

The groups' recommendations were submitted at the July 17 public forum held by the Centers for Medicare & Medicaid Services to get pricing input. CMS released the list of new lab codes last month. They include three in chemistry, two in immunology, and six in microbiology (*see table, p. 2*).

Under the crosswalk method, a new CPT lab code is matched to an existing, substantially equivalent code on the lab fee schedule and its reimbursement rate. CMS uses the "gap-fill" method when there is no comparable existing test. In this case, local carriers set their own fee for the first year, based on local pricing patterns. CMS then uses these amounts to arrive at a national price for following years.

At the July 17 forum, AdvaMed, the leading trade group for medical device makers, asked CMS for more explicit guidance ➥ *p. 3*

Senators Unite Behind Physician Fee Fix

Eighty of 100 Senators have urged their leadership to step in soon to prevent a projected Medicare cut in physician payments next year, saying, "At a minimum, we must provide a positive fee update for 2007."

In a July 17 letter to Majority Leader Bill Frist (R-TN) and Minority Leader Harry Reid (D-NV), the Senators warned that if Congress does not act soon, the statutory SGR (sustainable growth rate) formula used to update physician fees will impose a pay cut of about 5%, effective January 1. The Senators advocate a 2.8% increase, consistent with that recommended by the Medicare Payment Advisory Commission.

Congress prevented a scheduled 4.4% cut in 2006 but granted only a zero update, freezing fees at their 2005 levels. "The average 2006 Medicare rates for physicians are about the same as in 2001," the letter said. "If the 2007 cut is imposed, aggregate payment rates since 2001 will have fallen 20% below the government's conservative measure of inflation for medical practice costs." The Senators asked the leadership to work on a physician fee fix "on an expedited basis with the Finance Committee."

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Medicare Fee Recommendations For New 2007 CPT Lab Codes: Laboratory & Pathology Organizations

Code	*Descriptor*	*Recommended Crosswalk, Related Medicare Fee Cap*
CHEMISTRY		
1) 8210x:*	Alpha-fetoprotein; AFP-L3 fraction isoform and total AFP (including ratio)	**83950/$89.99:** AACC, ACLA, ASCLS, ASCP, CAP, CLMA. No recommendation: ASM.
2) 8369x	Lipoprotein-associated phospholipase A2, (Lp-PLA2)	**83880/$47.43:** AACC, ACLA, ASCLS, ASCP, CAP, CLMA. No recommendation: ASM.
3) 8391x	Molecular diagnostics; RNA stabilization	**83907/$18.66:** AACC, ACLA, ASCLS, ASCP, ASM, CAP, CLMA.
IMMUNOLOGY		
4) 8678x	Antibody; West Nile virus, IgM	**86645/$23.54:** AACC, ACLA, ASM, ASCP, CAP, CLMA. **86696/$27.05:** ASCLS.
5) 8678x	Antibody; West Nile virus.	**86644/$20.11:** AACC, ACLA, ASM, CLMA. **86651/$18.43:** ASCP, CAP. **86696/$27.05:** ASCLS.
MICROBIOLOGY		
6) 8730x	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; Aspergillus	**83790/$16.10:** ASCLS. **87301/$16.76:** ACLA, CLMA. **87327/$16.76:** ASCP, CAP. **87338/$20.10:** ASM. **87449/$16.76** + **87015/$9.33:** AACC.
7) 8749x	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique	**87496/$49.04:** ASCP, CAP, CLMA. **87651/$49.04:** ACLA. **87798/$49.04** + **83902/$19.83:** AACC, ASM. **87798/$49.04:** ASCLS.
8) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique	**87651/$49.04:** ACLA, ASM, ASCP, CAP, CLMA. **87798/$49.04:** AACC, ASCLS.
9) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique	**87651/$49.04:** ACLA, ASM, ASCP, CAP, CLMA. **87798/$49.04:** AACC, ASCLS.
10) 8765x	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique	**87651/$49.04:** AACC, ACLA, ASM, ASCP, CAP, CLMA. **87798/$49.04:** ASCLS.
11) 8780x	Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis	**87660/$28.02:** AACC. **87802/$16.76:** ACLA, ASM. **87880/$16.76:** ASCP, CAP. **87899/$16.76:** ASCLS, CLMA.

Acronyms in table: AACC-American Association for Clinical Chemistry; ACLA-American Clinical Laboratory Association; ASCLS-American Society for Clinical Laboratory Science; ASCP-American Society for Clinical Pathology; ASM-American Society for Microbiology; CAP-College of American Pathologists; and CLMA-Clinical Laboratory Management Association. (Note: The American Association of Bioanalysts did not submit comments.)

*Fifth digit to be finalized later. CPT codes © American Medical Assn.

Pricing For New Lab Codes, *from p. 1*

on how carriers should use the "gap-fill" method. Specifically, said Teresa Lee, vice president for payment and policy, AdvaMed wants step-by-step instructions on how pricing data should be collected and reported—and also wants the instructions released for public comment before being issued to carriers. The group also asked CMS to bar carriers from using a "least costly alternative" standard when fees are "gap-filled."

In response, CMS official Amy Bassano, director of the ambulatory services division, said the agency is closely monitoring the "gap-fill" process and indicated additional guidance may be needed in the future.

Tentative pricing for the new lab codes will be proposed by CMS in September, followed by a short comment period. Final fee decisions will be announced in the 2007 lab fee schedule, to be released in late October or early November. The July forum was the sixth such public meeting CMS has held in accord with requirements of the 2000 budget law.

CMS Keen To Test Consumer-Run Health Plans In Medicare

The Centers for Medicare & Medicaid Services plans to run a demonstration program to expand consumer-directed health plan options under the Medicare Advantage program in 2007 and 2008. In its bidding solicitation, CMS says it wants to test products similar to health savings accounts (HSAs) for Medicare beneficiaries as well as products for employers who now offer HSA plans to their pre-Medicare employees and retirees. The bidding period ends next month.

A special presentation on the outlook for consumer-driven healthcare and why quality and pricing transparency count will be featured at Lab Institute 2007, September 27-30, by market expert Kerry Hicks, chairman & CEO, Health Grades Inc. For more on Institute registration and program information, go to www.g2reports.com.

Until now, CMS notes, HSA-type plans have not been available to Medicare beneficiaries. The agency's move to test these plans as an option alongside HMOs, PPOs, and private fee-for-service plans is in line with the Bush administration's priority to use HSAs to help lower rising healthcare costs and empower consumers as "smart shoppers," stimulating competition on price and quality among providers. The 2003 Medicare reform law authorized health savings accounts, and the President has repeatedly asked Congress to revise requirements to encourage more individuals and employers to sign up.

CMS also points to growing market interest among employers and individuals in HSAs and other types of consumer-directed health plans (CDHPs). While these plans represent a small share of the 177 million Americans with private health insurance coverage, the number of enrollees last year increased from about three million to between five and six million, the Government Accountability Office recently reported.

Types Of Consumer-Run Plans

The Internal Revenue Service recognizes various CDRHs designed to give individuals tax advantages to offset healthcare costs. They include HSAs, medical savings accounts (MSAs), health reimbursement arrangements (HRAs), and health flexible spending arrangements (FSAs).

The GAO cautions that several factors may diminish the appeal of CDHPs. Federal requirements, for example, limit annual tax-free contributions to HSAs. Certain state insurance requirements or income tax laws in eight states do not reflect federal statutory provisions for HSAs.

An HSA may receive contributions from an eligible individual or any other person, including an employer or a family member, on behalf of the eligible individual. Funds in an HSA are tax-free when used for qualified medical expenses and roll over to subsequent years. An HSA also is completely portable—it follows the individual wherever he or she goes. In an HRA, however, the contribution is provided only by an employer for an employee and the account is not portable. The main difference between an FSA and an HSA is that FSA funds must be used within a calendar year; otherwise, they are forfeited.

CDHPs typically combine a qualified high-deductible policy with an HRA or an HSA, with protection against catastrophic healthcare costs. For 2006, the minimum annual deductible is $1,050 for a self-only plan or $2,100 for a family plan. Because health savings accounts shift more of the financial risk to individuals, CDHPs typically offer a series of decision-support tools to help patients assess price and quality, though not required to do so, noted the GAO.

Expanding Medicare Coverage Choices

Medicare Advantage plans can offer MSAs under current program authority, but the number of accounts opened has been relatively small, noted the GAO, and no new accounts could be opened after December 31, 2005. In an MSA, Medicare pays for a high-deductible health insurance plan for beneficiary enrollees and puts money in an account set up for the beneficiary, generally at the beginning of the year. This money and the earnings on it are tax-free as long as used for qualified healthcare expenses.

The CMS demonstration is intended to give Medicare Advantage plans the flexibility to market other coverage options, including accounts with features similar to HSAs. The agency said it is particularly interested in testing a product design that includes a minimum deductible, a cap on out-of-pocket expenses, and protection against catastrophic healthcare costs.

CMS says account-based plans in Medicare would be attractive to beneficiaries who want more control over their healthcare spending, with protection from catastrophic healthcare expenses at a lower premium cost, and to beneficiaries who had an HSA prior to becoming eligible for Medicare.

Abbott's Hepatitis B Test Approved For Blood Screening

The test is the first fully automated product that combines screening and confirmatory tests for hepatitis B surface antigen, said the FDA.

Abbott Laboratories' PRISM HBsAg assay was approved this month by the Food & Drug Administration to test people who donate blood, blood components, and organs for transplant for the hepatitis B virus. The test also may be used to screen blood from cadavers for organ and tissue donation. A blood test is the only way to determine if a donor has HBV infection.

The FDA cleared the test to confirm samples found to be reactive by the Abbott PRISM HBsAg assay. Currently, the screening and confirmatory tests are performed separately.

The automated test system increases the efficiency and convenience of screening blood, tissue, and organ donors for hepatitis B, the FDA said. The fully automated features reduce the potential for operator error; the test is tamper-resistant, with redundant checks to ensure the integrity of the testing system; and the test is highly sensitive and specific for HBsAg, the agency noted.

HHS Announces 'Seal Of Approval' For Ambulatory E-Health Records

The first round of ambulatory (outpatient) electronic health record products (EHRs) have been certified by the federally recognized Certification Commission for Healthcare Information Technology (CCHIT), said Michael Leavitt, Secretary of Health & Human Services July 18. The list is posted at *www.cchit.org*.

This "seal of approval" will remove a major barrier to widespread adoption of e-health records, Leavitt said. "It gives healthcare providers peace of mind to know they are purchasing a product that is functional and interoperable and will bring higher quality, safer care to patients." The Bush administration has made the adoption of health IT a priority, calling for e-health records for most Americans by 2014.

Certification by CCHIT means that the EHR products meet baseline levels of functionality, interoperability, and security, in accord with published criteria. This limits the risk associated with investing in health IT, a major upfront cost for physician practices, CMS noted. In response to Leavitt's announcement, the American Medical Association gave wholehearted backing to CCHIT's work, saying it is an important tool to help doctors make buying decisions.

Health IT products will be certified in three stages: first, ambulatory EHRs; second, inpatient or hospital EHRs; and third, architecture to enable information exchange between and among healthcare providers and institutions. CCHIT, a private, nonprofit organization, received a $2.7 million contract from HHS in September 2005 to develop standards for certifying health IT products.

Pathology, Lab Codes Excluded From Launch Of MUEs

The MUEs are limits on the units of service that a healthcare provider can bill a particular CPT/HCPCS code per Medicare beneficiary per day. Claims for services that exceed these limits would be automatically rejected.

Medicare's initial round of "medically unlikely" edits, scheduled for January 2007, will not include pathology and clinical laboratory codes, according to a July 24 letter from the private contractor, Correct Coding Solutions, LLC (Carmel, IN), which is handling this highly controversial claims processing change for the Centers for Medicare & Medicaid Services.

With the letter to the American Medical Association, Rosen sent a revised file of MUEs for further review, noting that it incorporates comments about specific criteria that were submitted by national organizations by June 26. The deadline to submit comments on the revised file is September 25. The revised MUE list contains 2,828 edits, and most are for surgical procedures, Rosen said. The original list, released last January, included nearly all CPT/HCPCS codes.

No CPT codes in the 80000 series for pathology/laboratory services are in the initial phase-in of MUEs, according to a preliminary analysis by the College of American Pathology. But the list does include several HCPCS "G" codes for pathology and laboratory services covered under the Part B preventive services benefit and subject to frequency limits, CAP points out. These include Pap smears, fecal occult blood testing, and prostate-specific antigen (PSA) testing.

Rosen's letter confirms what CMS Program Integrity Group officials from the previously told the Clinical Laboratory Coalition during a June 29 meeting (*NIR, 27, 18/Jul 17 '06, p. 2*).

Modest Gains Reported For Pathology Compensation

Pathologists' salaries ranged from a low of $183,253 to a high of $359,615 in 2006, according to *Modern Healthcare's* recently released annual survey of physician salaries. The top amount for pathologists was reported by the Medical Group Management Association—$359,615, up 3% over 2005-06—followed by the American Medical Group Association, which reported a 2% rise to $284,000. The bottom amount, $183,253, was reported by the Hospital & Healthcare Compensation Service.

MGMA, AMGA, and HHCS are among the 15 trade groups and physician recruitment firms that took part in this year's *Modern Healthcare* survey, whose findings were analyzed by Michael Romano in the July 12 issue. The top five earners in the study were orthopedics (at the upper end of the salary range, with an average of about $403,000) radiologists, non-invasive cardiologists, urologists, and anesthesiologists. Family practitioners were at the bottom of the scale.

Overall, said Romano, the survey shows increases, especially in primary care (typically among the bottom earners) in the range of 7% to 13%, but rising inflation has cut into pay raises in most medical specialties. Among the specific findings:

- ❑ The increase for all physicians surveyed in 2006 by the HHCS is 3.9%, a slight decline from 2005.
- ❑ Cardiologists saw the biggest increase between 2005 and 2006. Their average salary rose by 7.5%, to about $370,000.
- ❑ Radiologists saw a boost of 3.8% to just over $394,000.

In recent years, Romano noted, physicians in many specialties have said their reimbursement rates have not kept pace with their operating costs or inflation. Last month, he noted, the Center for Studying Health System Change (Washington, DC) reported a drop of 7% in the average net income for doctors, after accounting for inflation from 1995 to 2003. During that period, increases in Medicare pay rates amounted to 13%, well below the 21% rate of inflation.

Nonetheless, doctors remain among the most highly paid professionals in the nation, the Center study found. At least half of all patient-care physicians earned more than $170,000 in 2003. The average salary for all patient-care physicians that year was almost $203,000.

Two More States Enact Pathology Direct-Bill Requirements

Under direct billing, payment is made only to the person or entity that performs or supervises a service, with few exceptions. Medicare Part B has had this policy since 1984.

Massachusetts and Tennessee are the latest states to mandate all-payer direct billing for pathology services. The Massachusetts legislation became law on July 24 and takes effect in 90 days. It covers anatomic pathology, defined as "histopathology, surgical pathology, cytopathology, hematology, sub-cellular pathology, molecular pathology, and blood banking services performed by a pathologist."

The Tennessee law, which took effect July 1, prohibits client billing for cytopathology. The original measure covered anatomic pathology, but in a compromise to ensure passage, it was

Direct-Bill States

- Arizona
- California
- Iowa
- Louisiana
- Massachusetts
- Montana
- Nevada
- New Jersey
- New York
- South Carolina
- Rhode Island
- Tennessee

Source: College of American Pathologists, July 27, 2006.

amended to encompass only cytopathology, defined as "the examination of cells from fluids, aspirates, washings, and brushings, or smears, including the Pap test performed by a physician or under the supervision of a physician." Tennessee also has on the books a disclosure law, requiring physicians who contract with a hospital or clinical lab for anatomic pathology and then bill the patient or another third party to disclose on the bill the net amount paid to the lab for the services.

♦MEDICARE CODING A·D·V·I·S·O·R·Y

Practical Implications Of The New 2007 CPT Lab Codes

By Charles Root, president, CodeMap®, Barrington, IL

The new CPT code for AFP-L3 Fraction and Total AFP testing will presumably eliminate expensive imaging and liver biopsy procedures in patients with a high probability of developing liver cancer. Usually, such patients already suffer from cirrhosis or hepatitis and must be carefully monitored to detect any new neoplastic disease at an early stage. Since an oncoprotein similar to HER-2/neu is determined using a complex chromatographic method, most comments submitted by clinical laboratory and pathology organizations on proposed pricing supported a crosswalk to 83950 at $89.99 (*see table, this issue, p. 2*).

Lipoprotein-associated phospholipase A2 is a marker for cardiovascular disease and stroke and is representative of a number of new and more specific tests for both determining risk and managing patients with existing cardiovascular disease. The unanimous recommendation to crosswalk this code to Natriuretic peptide at $47.43 should establish a new and more realistic payment level for subsequent cardiac markers. Reimbursement for first-generation assays such as troponin and hsCRP remain in the $10-$20 range, leaving little room for profit.

The new molecular diagnostics code for RNA stabilization represents the continued evolution of the molecular diagnostic method codes and allows the additional cost of RNA stabilization to be separately reimbursed. This code will be used with other existing molecular diagnostic codes to describe complex RNA-based procedures.

The two new codes for West Nile virus antibodies allow the accurate identification of such tests by their own specific code. Previously, West Nile virus tests had to be reported with non-specific method codes, which are often denied by payers.

Four new codes for DNA-based assays illustrate the rapid evolution of molecular diagnostic techniques for infectious agents, in this case, enterovirus, Staphylococcus aureus, Group B Strep, and methicillin-resistant Staphylococcus aureus (MRSA). The advent of rapid definitive tests for MRSA will enable hospitals to identify both carriers and infected patients so that proper isolation steps can be taken to prevent hospital-based infections.

The new code for Trichomonas vaginalis by direct optical observation applies to a new CLIA-waived, point-of-care test for the rapid diagnosis of vaginitis. Similar to the other new infectious agent codes described above, this new code will allow providers to report specific payable codes, rather than generic method codes which are often denied by Medicare and private payers.

Update On Impending Medicare Payment Hold

The payment delay will affect cash flow for providers, but not in a big way, say industry analysts.

Medicare payments of Part A and Part B claims will be suspended for the last nine days of the current fiscal year, the Centers for Medicare & Medicaid Services has announced. The payment hold will run from September 22 to the 30th.

The delayed payments will be paid on October 2, the first day of fiscal 2007, the agency said (*NIR, 27, 15/May 22 '06, p. 7*). No interest will be accrued or paid, and no late penalty will be paid to any entity or individual for payment delays caused by the hold. The payment hold is required under the Deficit Reduction Act of 2005.

The effect on the federal budget is to shift an estimated $5.2 billion in Medicare spending from the current fiscal year to the next, according to the Congressional Budget Office. But the one-time shift will not affect total spending over the two-year period, concluded the CBO.

Analysts say the shift is an accounting trick that Congress used to contain the cost of the bill and stay within spending goals. But Congress has used this type of spending shift before, analysts note, and state Medicaid agencies have done likewise to reach a balanced budget.

washington WATCH

Budget Blues For Lab Personnel Training

Federal support for allied health programs, including the training of medical lab personnel, would be essentially flat in fiscal year 2007, under provisions approved by House and Senate appropriators.

The House Appropriations health subcommittee has approved $3.96 million for allied health, about the same level as this year. For health professions training overall, the subcommittee bill earmarks $313 million and restores a big cut in scholarships for disadvantaged students.

The Senate Appropriations Committee has included $4 million for allied health in its FY 2007 spending bill for HHS, Labor & Education. For health professions training overall, the bill provides $304 million, an increase of $9 million over the President's request.

Meantime, legislation to target more money to lab personnel training programs has languished on Capitol Hill since being introduced last year. It has gained more co-sponsors following lobbying by the American Society for Clinical Laboratory Science and other groups, but not enough traction to get committee action.

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