WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 25th Year of Publication

Vol. 25, No. 22, September 27, 2004

Medicare Proposes Fees For New CPT Lab Codes In 2005

The new lab codes include testing for chest pain, pancreatic function, ulcers, Down's syndrome, and respiratory condition

The Centers for Medicare & Medicaid Services has announced proposed reimbursement rates for 11 new CPT codes to be added to the Part B lab fee schedule, effective Jan. 1, 2005. In line with recommendations from various lab groups, the rates would be established by crosswalking the new codes to existing CPT codes (*related coverage: National Intelligence Report, 25, 20/Aug. 16, '04, p. 10; 25, 18/July 5, '04, p. 1*).

Also in response to public recommendations, CMS said it would not propose placing 10 new and revised cytopathology and surgical pathology codes on the lab fee schedule. This idea had generated heated opposition from pathology and lab groups. Instead, these codes will be assigned to the Part B physician fee schedule, which bases payment rates on resource-based relative values subject to adjustments for differing geographic overhead costs.

The final lab fee schedule for 2005 and related instructions are slated to be sent to local carriers and fiscal intermediaries on or after the last week of October (to be online at *www.cms.hhs.gov/manuals*). ➥ *p. 2*

INSIDE *NIR*

Fallout Spreads Over Failure To Detect Lab Lapses

Controversy is snowballing over the effectiveness of the private accrediting process under CLIA (Clinical Laboratory Improvement Amendments) on the heels of major quality deficiencies in two Maryland clinical laboratories that were not detected during routine CLIA inspections by the College of American Pathologists, but came to light this year only after former lab workers complained. The labs involved were the Maryland General Hospital lab (*NIR, 25,16/June 7, '04, pp. 4-6*) and Reference Pathology Services of Maryland (*NIR, 25, 20/Aug. 16, p. 1*).

A Maryland legislative committee held a Sept. 21 hearing on clinical laboratory oversight, and another is planned for November. The state's health secretary, Nelson Sabatini, has questioned the collegial ties between accrediting agencies and the organizations they review; he favors more reliance on state regulators. The Centers for Medicare & Medicaid Services plans a Nov. 15 meeting of state, federal, and private accrediting officials and state regulators to discuss improvements to the CLIA accreditation and inspection process. And the Clinical Laboratory Improvement Advisory Committee last week examined voluntary programs such as those of CAP, the Joint Commission on Accreditation of Healthcare Organizations, and COLA, with an eye to exploring, at its meeting next February, whether a regulatory response is in order.

New CPT Lab Codes For 2005 Medicare Lab Fee Schedule

CODE	DESCRIPTOR	PROPOSED CROSSWALK TO	FEE*
Chemistry			
82045	Albumin; ischemia modified	83880	$47.43
82656	Elastase, pancreatic (EL-1), fecal, qual. or semiquant.	83516	$16.12
83009	H. pylori; blood test analysis for urease activity, non-radioactive isotope (*eg*, C-13)	83013	$94.11
83630	Lactoferrin, fecal, qual.	83516	$16.12
84163	Pregnancy-associated plasma protein-A (PAPP-A)	84702	$21.03
84166	Protein, electrophoretic fractionation and quantitation; other fluids with concentration (*eg*, urine, CSF)	84165 + 87015	$15.01 + $9.33
Immunology			
86064	B cells, total count	86359	$52.70
86335	Immunofixation electrophoresis; other fluids with concentration (*eg*, urine, CSF)	86334 + 87015	$31.21 + $9.33
86379	Natural Killer (NK) cells, total count	86359	$52.70
86587	Stem cells (*i.e.*, CD34), total count	86359	$52.70
Microbiology			
87807	Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus	87804	$16.76

*Natl. fee cap, 2004 (frozen thru 2008)

Source: CMS. CPT codes © American Medical Assn.

New CPT Lab Codes, *from p. 1*

The data file is to be available on or after the third week of November (online at *cms.hhs.gov/paymentsystems*).

Meanwhile, the American Medical Association has posted CPT 2005 codes online at *https://catalog.ama-assn.org/Catalog/cpt/cpt_home.jsp*. The print version is expected to be published shortly before the Nov. 11-12 CPT/RBRVS Joint Symposium in Chicago, where members of the CPT advisory committee and editorial panel, as well as AMA coding experts, will explain the coding changes. Sources confirm that CPT 2005 will include new modifiers for genetic tests.

Clinical laboratories should incorporate CPT 2005 changes sooner rather than later. As of Jan. 1, 2005, Medicare will no longer allow a 90-day grace period to accommodate coding revisions. Previously, labs had until Apr. 1 to retire codes that were active the previous year, but were discontinued for the current year. The demise of the grace period complies with the final HIPAA rule on electronic transactions and code sets, CMS notes. The rule requires use of the medical code set that is valid at the time the service is provided.

New Pathology CPT Codes That CMS Declined To Put On Lab Fee Schedule*

Cytopathology

88184 .... Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
88185 .... Each additional marker (list separately in addition to code for first marker)
88187 .... Flow cytometry, interpretation; 2-8 markers
88188 .... 9-15 markers
88189 .... 16 or more markers

Surgical Pathology

88360 .... Morphometric analysis, tumor immunohistochemistry (*eg*, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semiquant., each antibody; manual
88367 .... Tissue in situ hybridization (quant. or semiquant.), each probe; using computer-assisted technology
88368 .... Tissue in situ hybridization (quant. or semiquant.), each probe; manual

*Codes to be placed on Medicare physician fee schedule (proposed in Aug. 5 *Federal Register*; final version to be published by Nov. 1, with effective date of Jan. 1, 2005)

Source: CMS. CPT codes © American Medical Assn.

Labs Aren't Guilty Of Gouging Medicare, Says ACLA Study

ACLA and other lab groups fear the OIG's plan, if finalized in its current form, could limit discounts to doctors and other third-parties, and could force labs to accept less than Medicare fee schedule rates to avoid accusations that they are overcharging Medicare

The American Clinical Laboratory Association has come up with new ammunition in its challenge to the controversial Medicare discriminatory billing rule proposed by the HHS Office of Inspector General (*NIR, 24, 22/Sep 29, '03, p. 1*). The OIG threatened enforcement action, including exclusion from Medicare and Medicaid, against labs and other providers that billed these programs "substantially in excess" of (or 120% of) their "usual charges" for the same item or service; a "good cause" exception would be allowed, for example, to cover the higher costs of serving Medicare/Medicaid beneficiaries, but the burden of proof for this would be on the provider.

ACLA says the proposal should not apply to clinical laboratories. Labs aren't guilty of overcharging Medicare or Medicare; in fact, they get paid less by these programs than by other third-party payers, the association argues. A study, commissioned by ACLA and conducted by the accounting firm of Ernst & Young, finds that labs charge Medicare 13% less than they charge other third-party payers per CPT code billed and that Medicare pays, in the aggregate, about 17% less per CPT code billed. This calculation excluded "client-billing" arrangements under which labs sell tests to physicians at a discount and doctors in turn charge full price to patients or third-party payers (but not to Medicare, which requires direct billing by the person or entity performing or supervising the testing).

In a written analysis of the survey, ACLA argued that the OIG should not include client billing in the "usual charge" calculation. Laboratories can charge less for such testing because physicians agree to pay promptly and fully and because the paperwork is much simpler (clients usually are billed monthly for all lab services to a patient or entity with minimal data reporting, whereas Medicare is billed per CPT code for each encounter and much more extensive data must be reported). Nevertheless, ACLA asserted, even with client-billing arrangements included, "Medicare and Medicaid still pay less than other third-party payers." The survey report did not show client-billing data on a CPT code basis.

To control for differences in test mix or complexity, Ernst & Young compared average charge and reimbursement per CPT code. The report said this shows that "even if the differences in complexity are factored in, Medicare still is paying less than [other] third-party payers." The survey was sent to ACLA members in March. Respondents included two national labs, two esoteric labs, and one smaller entity. Ernst & Young promised not to disclose the identities of any of the respondents and to report data only in the aggregate.

Lab Averages As Percentage Reduction From Highest Amount (Baseline)

Finding	*Private 3rd Parties*	*With Clients*	*Medicare*	*Medicaid*
Charges per requisition	Baseline	N/A	(15.55%)	(14.85%)
Reimb. per requisition	Baseline	(13.17%)	(19.32%)	(32.14%)
Charges per CPT code billed	Baseline	N/A	(12.97%)	(5.11%)
Reimb. per CPT code billed	Baseline	N/A	(16.87%)	(24.35%)
# of CPT codes per requisition	Baseline	N/A	(02.96%)	(10.26%)

Source: Ernst & Young study

ACLA argued that if the OIG rule is finalized in its original form, Medicare could unfairly "cherry-pick" CPT codes for fee reductions. Every payer pays more for some codes, less for others, the association noted. While in the aggregate Medicare pays less on a CPT code basis, it is possible to find codes where Medicare pays more. It would be unfair, ACLA concluded, to force labs to accept lower payment for those codes or face exclusion from Medicare. The association said the OIG should rely instead on its "inherent reasonableness" authority to adjust payments per CPT code because this allows for correction of underpayments as well as overpayments.

CMS, JCAHO Get In Sync On Hospital Quality Reporting

The Centers for Medicare & Medicaid Services and the Joint Commission on Accreditation of Healthcare Organizations have agreed to align their respective hospital quality measures, starting with a technical manual they jointly released on Sept. 15. The manual establishes common definitions for hospitals to use, beginning with January 2005 discharges, when reporting under CMS's National Voluntary Reporting Initiative and for JCAHO accreditation.

The effort involves the reporting of performance measures for three medical conditions that are relatively common among the Medicare population (*see box*). There had been differences in the format of specifications for data elements, types of cases excluded, and calculation algorithms. CMS and JCAHO say that, in the future, they intend to modify the goals on a common schedule as well.

Meantime, CMS says the new hospital pay-for-performance requirement, mandated by the Medicare Modernization Act of 2003, is paying off. Of the 3,906 inpatient acute care hospitals eligible, some 3,839 (or 98.3%) met the voluntary quality-reporting deadline of Aug. 15. They will be rewarded with the full 3.3% market basket update to their DRG prospective payments for fiscal 2005 (which begins this Oct. 1). Hospitals that failed to report voluntarily will get 0.4% less (*NIR, 25, 20/Aug. 16, '04, p. 4; 15/May 24, '04, p. 1*). Next year, CMS intends to add more clinical quality and patient satisfaction measures, but no payment incentives are currently associated with these.

Hospital Quality Measures For Three Clinical Conditions

For a heart attack (acute myocardial infarction), did the hospital:
—Give aspirin to the patient upon arrival?
—Prescribe aspirin upon discharge?
—Give a beta-blocker to the patient upon arrival?
—Prescribe a beta-blocker upon discharge?
—Give an ACE inhibitor to the patient with heart failure?

For heart failure, did the hospital:
—Assess the patient's heart function?
—Give the patient an ACE inhibitor?

For pneumonia, did the hospital:
—Give the patient an antibiotic in a timely fashion?
—Find out if the patient received a pneumococcal vaccination?
—Assess the patient's oxygen level?

Beginning early in 2005, CMS will publish its quality data at *www.medicare.gov* to help healthcare consumers choose the best hospitals (currently, this information is posted at *cms.hhs.gov*). Similarly, JCAHO has begun publishing its quality data at *www.qualitycheck.org*. Users can search the JCAHO Website for accredited laboratories and see whether individual labs complied with JCAHO's national patient safety goals. Users also can view a short history of JCAHO survey results for each lab's parent organization.

HHS Panel Recommends Blood Safety, Supply Initiatives

Noting that bacterial contamination of room-temperature stored platelet components is one of the greatest remaining infectious risks of blood transfusion, a federal advisory committee has urged the U.S. Department of Health & Human Services to improve the safety and supply of platelets by encouraging the development and adoption of techniques for bacterial screening.

The HHS Advisory Committee on Blood Safety & Availability called on the Department to fund studies to develop bacterial screening methods suitable for release testing of platelets in routine practice. HHS has proposed a two-year study of screening for release control of platelets stored as long as seven days, but the committee wants the Department to expedite licensure of 7-day platelets in significantly less than two years. In 1986, the Food & Drug Administration, citing concerns about bacterial contamination, reduced the platelet storage limit from seven to five days, but this has since curbed platelet supply.

The committee also discussed several other major topics and approved related recommendations at its Aug. 26-27 meeting in Washington, DC. Among them:

Whole Blood Platelets: Because there is no way to assay individual whole-blood derived platelets (WBDP) for bacterial contamination (they are merely checked by dipstick for pH and glucose levels), this source of platelet supply is riskier than apheresis platelets. This has led to a dual level of safety for platelets readied for transfusion and a threat to the platelet supply as the inventory of WBDP declines. In response, the committee said, HHS should adopt strategies to expedite the licensure of a pre-storage pooled WBDP component for transfusion, and the effort should be based on a critical review of information from Canada, Europe, and *in vitro* data.

Transfusion-Related Lung Injury: The committee called on HHS to support further inquiry into whether the Department should do more to prevent transfusion-related acute lung injury (TRALI). Though the panel saw no compelling scientific evidence to recommend an intervention at this time, it advised HHS Secretary Tommy Thompson to quickly develop a standardized definition, implement clinical education and effective surveillance, model the impact of deferral or screening interventions, and study the etiology, diagnostic testing, epidemiology, and treatment of TRALI.

Hepatitis B Testing: The committee recommended against proceeding with proposed mini-pool nucleic acid testing of donor blood for hepatitis B virus, even though the risk of infection via transfusion is higher for HBV than for HIV or hepatitis C. Members agreed that the money would be better spent on expanding HBV immunization, an option not available for HIV or HCV. Nevertheless, the committee encouraged HHS to promote the development of multiplex direct pathogen testing that would include a test for HBV.

Rare Blood Disorders: The panel called for HHS to promote the development and licensing of products for treating rare blood disorders, such as deficiencies of Protein C or Factors V, VII, XI, or XIII. Often, such patients must import products licensed in Europe for personal or off-label use in the U.S., which the committee deemed unacceptable as a long-term solution.

Joint Commission Boosts All Accreditation Survey Fees

The increases range from $300 for triennial surveys of critical access hospitals to $3,000 for networks. For hospitals, the increase averages $2,700 vs. the $24,000 paid on average this year

The Joint Commission on Accreditation of Healthcare Organizations is hiking survey fees by 9.5% for most types of healthcare organizations in 2005, the second fee increase in a decade and by far the largest. For larger hospitals, the increases can be up to 17%. The Commission's central office initially had sought an even greater increase of 20-22%, but had to "whittle it down" to win the approval of JCAHO's commissioners. The increases will vary by program and within programs, says JCAHO, which also has unveiled a subscription billing model (start date, 2006) to help accredited organizations spreads fee payments over the accreditation cycle.

For clinical laboratory certification, JCAHO figures, the biennial survey fees will increase on average by $590, or about 10% of the $5,900 average fees that the Commission has charged labs in an 18-month period beginning January 2003, JCAHO spokesman Mark Forstneger told *NIR*. The increase in survey fees substantially exceeds the 3.5% increase for labs in 2000, which averaged $170. Fees vary by type and size of provider and by the number of services requested.

The Commission's expense management "made possible the recent value-enhancing investments in the Joint Commission's accreditation products," JCAHO president Dennis O'Leary, MD, said in a statement. He added, however, that such cost-cutting "can no longer alone permit us to provide the level of support and service that accredited organizations are, quite appropriately, seeking." For that, the commission needs "new resources."

JCAHO also will begin adding a certified healthcare engineer to surveys of hospitals with 200 or beds to help evaluate the hospital's compliance with life safety code and physical plant requirements. The additional fee for this survey team will be $3,500, according to the Commission. In a July report, the General Accounting Office cited life safety violations as a significant area for program improvements.

Last January, JCAHO established a new "Shared Visions—New Pathways" approach to surveys that involved following samples throughout the lab workflow and interacting with front-line staff, rather than simply poring over reams of documents with lab managers (*NIR, 25, 11/Mar 22, '04, p. 3*). The College of American Pathologists is implementing similar enhancements in an effort to avoid situations like the one at Maryland General Hospital, where it accredited the lab based on a paper review, only to learn later from whistleblowers that the proficiency testing results had been doctored (*NIR, 25, 16/Jun 7, '04, p. 4*).

The Commission has also added Web-based mid-cycle performance assessments, which accredited organizations want available on demand, rather than only at the midpoint between their triennial surveys. JCAHO has not yet added these performance assessments for labs, whose surveys are biennial to conform with the CLIA survey process.

More information on the survey fees is available by contacting the Joint Commission Pricing Unit, 630-792-5115.

♦CODING A·D·V·I·S·O·R·Y

Crucial Deadline For Diagnosis Coding Update—October 1

There will be no 90-day grace period to ascertain the new ICD-9 codes and learn about discontinued ones, says CMS. This is in accord with the final HIPAA rule on electronic transactions and code sets, which requires use of the medical code set that is valid at the time the service is provided

Your laboratory must be ready, as of this Oct. 1, to bill Medicare Part B claims using the latest update to the ICD-9-CM diagnosis coding system; claims lacking a valid ICD-9 code will be returned as "unprocessable," the Centers for Medicare & Medicaid Services has warned. Diagnosis codes have been required on all paper and electronic claims billed to Medicare carriers since Oct. 1, 2003; the only exception is for ambulance supplier claims.

For laboratory services, there are significant revisions in the latest annual ICD-9 update. Among those of special note:

New Pap smear codes

—795.03: Pap smear of cervix with low grade squamous intraepithelial lesion
—795.04: Pap smear of cervix with high grade squamous intraepithelial lesion
—795.05: Cervical high risk human papillomavirus (HPV) DNA test positive
—795.08: Unsatisfactory smear, inadequate sample

Changes to covered codes under the laboratory National Coverage Decisions

1) Alpha-fetoprotein
—Code added: 273.4

2) Blood counts
—Addition of codes that do *not* support medical necessity: 521.06, 521.07, 521.08, 521.10-521.15, 521.20-521.25, 521.30-521.35, 521.40-521.42, 521.49, 524.07, 524-20-524.37, 524.39, 524.50-524.57, 524.59, 524.64, 524.75, 524.76, 524.81, 524.82, 524.89, 525.20-525.26, 618.00-618.05, 618.09, 618.81-618.83, 618.89, 692.84, V72.40, V72.41
—Deletion of codes from the list: 521.1, 521.2, 521.3, 521.4, 524.2, 524.3, 524.5, 524.8, 525.2, 618.0, 618.8, V72.4

3) Blood glucose testing
—Codes added: 491.22, 707.00-707.07, 707.09, V58.67
—Code deleted: 707.0

4) Collagen crosslinks
—Codes added: 252.00-252.02, 252.08
—Code deleted: 252.0

5) Digoxin therapeutic drug assay
—Codes added: 588.81, 588.89
—Code deleted: 588.8

6) Fecal occult blood test
—Code added: V58.66

7) Gamma glutamyl transferase
—Codes added: 070.70, 070.71, 252.00-252.02, 252.08, 273.4, 453.40-453.42, 588.81, 588.89
—Codes deleted: 252.0, 588.8

8) Glycated hemoglobin
—Code added: V58.67

9) Hepatitis panel
—Codes added: 070.70, 070.71

10) HIV testing (diagnosis)
—Coverage terminated: V01.7, 588.8
—Codes added: 070.70, 070.71, 588.81, 588.89, V01.71, V01.79

11) Lipid testing
—Codes added: 588.81, 588.89
—Code deleted: 588.8

12) Partial thromboplastin time
—Codes added: 070.70, 070.71, 453.40-453.42. Also, in accord with a separate Medicare coding analysis, CMS will cover 729.81.

13) Prostate-specific antigen
—Code covered under separate Medicare coding analysis: 600.01

14) Prothrombin time
—Codes added: 070.70, 070.71, 453.40-453.42, 530.86, 530.87. Also, in accord with a separate Medicare coding analysis, CMS will cover 729.81.

15) Serum iron studies
—Codes added: 070.70, 070.71

16) Urine culture
—Codes deleted: 584.5, 584.9, 586
—Code added: 788.38

CMS posts the new, revised, and discontinued ICD-9 codes on its Website at *cms.hhs.gov/medlearn/icd9code.asp*. Providers can also visit the Website of the National Center for Health Statistics, *www.cdc.gov/nchs/icd9.htm*. CMS urges providers to purchase a new ICD-9 book or CD-ROM annually.

New Lab Test Cleared To Screen Newborns For Congenital Disease

The Food & Drug Administration has approved for marketing a new laboratory blood test that physicians can use to screen newborn infants for a variety of inherited diseases. The test is performed on blood from heel-stick samples, the same kind of sample used for state-required newborn screening tests. The blood sample is measured for levels of amino acids and substances called free carnitine and acylcarnitines.

While everyone has small amounts of these substances, abnormally high amounts or patterns may indicate different disease states called inborn errors of metabolism. They include (but aren't limited to) phenylketonuria and maple syrup urine disease, medium chain Acyl-CoA dehydrogenase deficiency, isovaleric acidemia, homocystinuria, and hereditary tyrosinemia. While each of these disorders is relatively rare, as a group they are fairly common and can cause developmental delay, seizures, mental retardation, and death. With early identification, many of the effects can be significantly reduced, FDA said.

The test—NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit—is manufactured by PerkinElmer Life and Analytical Sciences, Inc. (Norton, OH). It is not a stand-alone test for predicting inborn errors of metabolism. It provides screening information when used with clinical evaluation and other tools to determine a newborn baby's risk.

NIR Subscription Order or Renewal Form

❑ ***YES***, enter my subscription to *National Intelligence Report* at the rate of $389 for one full year (22 issues). My subscription includes the *National Intelligence Report* newsletter, the in-depth *Focus* insert, news extras as major stories break, and exclusive discounts on other Washington G-2 Reports products.

❑ Check enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

MAIL TO: Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Or call 212-629-3679 and order via credit card or fax order to 212-564-0465 9/04B

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December which are one-issue months) by Washington G-2 Reports, 1111 14th Street NW, Suite 500, Washington DC 20005-5663. Tel: (202) 789-1034. Fax: (202) 289-4062. Website: www.g2reports.com

Order Line: (212) 629-3679. *Publisher:* Dennis W. Weissman. *Editor:* D.J. Curren. *Managing Editor:* Bowman Cox.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 200.