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Lab Fees Flat In 2005, Code Change For Blood Draws

The freeze on fee updates impacts not only local Medicare fees and national fee caps, but also the minimum national payment for Pap smears and the personnel portion of the trip fee

In Medicare's Part B clinical laboratory fee schedule for 2005, finalized this month by the Centers for Medicare & Medicaid Services, payment rates remain frozen at 2003 levels, while the trip fee goes up by one penny, effective Jan. 1. Medicare also has made a switch in how labs should bill for blood draws.

Next year marks the second of a five-year freeze (through 2008) on lab fee updates, as required by the Medicare Modernization Act of 2003. Fees for CPT lab codes new to the fee schedule are established by crosswalks to existing codes frozen at 2003 levels (*see table, p. 2*). No codes have been deleted from the lab fee schedule.

For blood draws, the most frequently charged lab code, Medicare is replacing code G0001 with CPT 36415, Collection of venous blood by venipuncture. The fee remains at $3, unchanged since the lab fee schedule debuted in 1984. Under G0001, Medicare was charged for over 60 million venipunctures in 2002, according to CMS data. Carriers paid $181.5 million that year for this service, making it Medicare's fourth most reimbursed lab code. ➥ *p. 2*

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Lab Groups Wary Over Spending Cuts

Clinical laboratory lobbying groups expect renewed pressure on Congress next year to make further reductions in Medicare provider payments. Last year's successful battle to defeat restoration of a 20% lab co-pay could pale by comparison to what's ahead, given the funding needed for the new Medicare prescription drug benefit, the rising federal budget deficit, and any initiative to overhaul Social Security.

Still, there's opportunity for labs, says attorney Bob Waters, a partner in Gartner, Carton & Douglas (Washington, DC) who represents the American Association of Bioanalysts and leads the Clinical Laboratory Coalition. "I would like to believe that the more pressure that's put on our healthcare system, the wisdom of diagnosing and treating our Medicare patients early will be appreciated." Even though the economics of screening favor clinical labs in the long term, he adds, "we've got to be watchful that somebody doesn't do anything misguided in the short term," such as further lab fee cuts. While lab forces rallied to crush the co-pay last year, Congress did opt, at the last minute, to slap a five-year freeze on lab fee updates, from 2004 through 2008.

The re-election of President George W. Bush is expected ➥ *p. 6*

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Trip Fee: Due to a penny increase in the standard federal mileage rate, the Medicare travel allowance payable to collect specimens from homebound or nursing home patients will rise, as of Jan. 1, to $.835 on a per-mile basis (HCPCS code P9603) and $8.35 on a flat-rate basis (P9604). The personnel portion of the fee remains frozen at $.45; the mileage portion, which is updated by the Treasury Department, increases to $.385, from $.375 in 2004.

Pap Smears: In accord with the update freeze, the national minimum payment for the following Pap smear codes remains at $14.76: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148 and P3000.

Waived Codes: Added to next year's lab fee schedule are new CLIA-waived test codes CPT 84450QW for aspartate aminotransferase (AST/SGOT) and 80100QW for drug screens. The "QW" indicates that the test, which otherwise would be classified as CLIA moderate or high complexity, may be performed by labs certified only for waived testing. The fees for the waived codes are crosswalked to 84450 (capped at $7.22) and 80100 (capped at $20.32).

Blood Products: CMS has added code P9060 to the list of blood products payable on the basis of reasonable charges (or reasonable costs for hospital-based renal dialysis patients) and has dropped P9055 from a related list of codes that should be applied to the blood deductible.

The CMS memo implementing the 2005 lab fee schedule (Pub. 100-04, Change Request 3526, Nov. 5, 2004) is posted online at *cms.hhs.gov/manuals/pm_trans/R363CP.pdf*.

New CPT Lab Codes For 2005 Medicare Lab Fee Schedule

CODE	DESCRIPTOR	CROSSWALKED TO	FEE*
Chemistry			
82045	Albumin; ischemia modified	83880–Natriuretic peptide	$47.43
82656	Elastase, pancreatic (EL-1), fecal, qual. or semiquant.	83516–Immunoassay, non-antibody	$16.12
83009	H. pylori; blood test analysis for urease activity, non-radioactive isotope (*eg*, C-13)	83013–H. pylori (C-13), breath	$94.11
83630	Lactoferrin, fecal, qual.	83516–Immunoassay, non-antibody	$16.12
84163	Pregnancy-associated plasma protein-A (PAPP-A)	84702–hCG	$21.03
84166	Protein, e-phoresis, urine, CSF	84165–Protein, e-phoresis, serum + 87015–Specimen concentration	$24.34
Immunology			
86064	B cells, total count	86359–T-cells; total count	$52.70
86335	Immunofixation electrophoresis; other fluids with concentration (*eg*, urine, CSF)	86334–Immunofix, e-phoresis, serum + 87015–Specimen concentration	$40.54
86379	Natural Killer (NK) cells, total count	86359–T-cells; total count	$52.70
86587	Stem cells (*i.e.*, CD34), total count	86359–T-cells; total count	$52.70
Microbiology			
87807	Respiratory syncytial virus, with direct optical observation	87804–Influenza assay with optic	$16.76

*Natl. fee cap (maximum payable). Source: CMS. CPT codes © American Medical Assn.

Medicare Sets 2005 Fees For New Pathology Codes

In the final Medicare Part B physician fee schedule for 2005, finalized this month and effective Jan. 1, fees are established for new cytopathology and surgical pathology codes added to the CPT 80000 series. The fees below are based on relative value units (RVUs) for the various components of a service (work, practice expense, and malpractice expense) that are translated into a dollar amount using a national conversion factor. The CF for 2005 is $37.8975, up from $37.3374 in 2004 and $36.7856 in 2003.

	Code	Mod	Description	Work	PE Non-Facility	Malpract	Total Non-F	Fee*
Cytopathology	88164		Flow cytometry/tc, 1 marker	0.00	1.32	0.02	1.34	$50. 7826
	88165		Flow cytometry/tc, add-on	0.00	0.64	0.02	0.66	$25.0123
	88167		Flow cytometry/read, 2-8	1.36	0.45	0.01	1.82	$68.9734
	88168		Flow cytometry/read, 9-15	1.69	0.57	0.01	2.27	$86.0273
	88169		Flow cytometry/read, 16 & >	2.23	0.75	0.01	2.99	$113.3313
Surgical Pathology	88360	26	Tumor immunohistochem/manual	1.10	0.47	0.06	1.63	$61.7729
	88360	TC	Tumor immunohistochem/manual	0.00	1.26	0.02	1.28	$48.5088
	88367	26	In situ hybridization, auto	1.30	0.54	0.06	1.90	$72.0052
	88367	TC	In situ hybridization, auto	0.00	3.57	0.06	3.63	$137.5679
	88368	26	In situ hybridization, manual	1.40	0.60	0.06	2.06	$78.0688
	88368	TC	In situ hybridization, manual	0.00	2.90	0.06	2.96	$112.1766

*"Pure" fee, unadjusted for practice costs in specific Medicare payment locality

CPT codes © American Medical Assn. 26=Professional component. TC=Technical component.

Anatomic pathology code—CPT 88305-26, Gross and microscopic exam, Level IV—will increase by 2%, from $41.44 this year to $42.07 in 2005 (unadjusted for geographic practice cost differences). The global rate for 88305 will rise to $103.46 in 2005, from $95.21 in 2004, $93.39 in 2002, and $88.38 in 2001.

Medicare also is adopting a new add-on G-code, G0364, for bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service. Payment is based on a total of 0.34 RVUs for a "pure" fee of $12.88. The physician is to bill CPT 38221 for the biopsy and G0364 for the aspiration.

Genetic Test Modifiers Were Top Lab Issue, Says CPT Official

Enabling health insurers to determine the type of genetic testing they are being billed for was by far the most difficult task in the laboratory/pathology CPT 2005 update, Michael Beebe, CPT director for the American Medical Association, tells *NIR*. But it also was the most important. The move recognizes the proliferation of gene-based tests coming to market, with the potential to alter the practice of medicine profoundly.

Providers use process-oriented codes (83890-83912) that are identical for many genetic tests, but vary among some tests for the same condition. Insurers are reluctant to pay because it hasn't been clear what condition was being tested and whether it was medically necessary. The CPT Editorial Panel could have created a new code for each set of procedures for a particular gene type, but that would have quickly exhausted the reserve of unused codes. Instead, the panel opted for numeric-alpha modifiers that wouldn't conflict with CPT's existing two-digit modifier scheme or Medicare's HCPCS alpha modifiers. In the new scheme, the first digit is numeric, representing a disease category; the second is alphabetic, denoting gene type (*NIR, 26, 2/Oct. 25, '04, p. 1*).

The most difficult tasks involved the disease categories and estimating the likely

proliferation of genetic tests in each so as to reserve enough codes for them. The panel anticipated the most growth in testing for neoplasia (solid tumor) conditions, so it reserved two numeric digits for this category—0 and 1. The two conditions with the least expected growth share a numeric digit, 9, with letters A-L reserved for metabolic-pharmacogenetics and M-Z for dysmorphology.

AMA may revisit the coding scheme as more molecular diagnostics come into play. "These modifiers could go into the thousands," Beebe notes, "but we only have room for 100s." Collaborating with the CPT panel to craft the modifiers was a Genetic Test Coding Workgroup, established by the College of American Pathologists and including the American Clinical Laboratory Association.

CMS Silent on Genetic Test Modifiers

Medicare's memo on the final Part B lab fee schedule for 2005 says nothing about the genetic test modifiers that the AMA approved. CMS is not yet recognizing these modifiers, but this won't interfere with claims that labs submit using these modifiers, an agency official tells *NIR*.

Labs shouldn't rush to alter their chargemaster to accommodate these modifiers until there's a better sense of how private payers view their use, advises coding expert Diana Voorhees, who heads DV & Associates in Salt Lake City, UT. Voorhees was the featured speaker in a Nov. 18 audioconference on CPT lab and pathology coding changes, sponsored by Washington G-2 Reports.

CMS Leaves Door Open For 'Pod' Labs, With Caveats

The Centers for Medicare & Medicaid Services has declined, for now, to slam the door on "pod" labs, a fast-spreading business arrangement in which specialty physicians such as urologists, dermatologists, and gastroenterologists take advantage of relaxed benefits reassignment rules to boost Medicare revenue from pathology referrals. The HHS Office of Inspector General has already sounded an alarm about possible overutilization (*NIR, 25, 17/Jun 21, '04, p. 1*).

Last August, CMS, in its proposed 2005 Medicare physician fee schedule rule, aired a similar concern about potential abuse, and many pathology and laboratory interests seized the opportunity to complain about "pod" labs. In the final Nov. 15 rule, the agency said it "shared the commenters' concerns" and would consider future rulemaking if necessary to prevent fraud and abuse. But for now, CMS is content to clarify, in Section 424.80(a), that nothing in the new provision allowing reassignment of claims from a contract supplier of physician services alters obligations under the anti-kickback statute, the Stark physician self-referral prohibition, and the rules for purchased diagnostic tests and for services and supplies "incident to" a physician's professional services (for more on the reassignment rules, see *NIR, 25, 11/Mar 22, '04, p. 1*).

CMS's stance "helps, but doesn't put the issue to rest," says attorney Jane Pine Wood, a shareholder with Cleveland-based McDonald Hopkins Co., LPA. "Though the OIG language stresses that groups still must comply with the Stark law," she told *NIR*, "the relaxed reassignment language still makes it easier for specialty groups to set up 'pod' labs or simply hire a part-time pathologist to perform only the professional interpretations on behalf of the group practices."

Attorney W. Bradley Tully, a principal in Los Angeles-based Hooper, Lundy & Bookman Inc., suggested to *NIR* that just because there is competitive pressure from "pod" labs, "this doesn't mean there is any abuse." If CMS considers the professional services the "pod" provides to be "purchased interpretations," it would not be allowed to also perform the technical component. However, it appears that CMS considers the leased "pod" lab's pathologist to be an independent contractor in the group's office, in which case he/she is not providing "purchased interpretations."

CMS Launches Council For Technology & Innovation

The American Association for Clinical Chemistry hopes the Council can streamline the process for getting new tests cleared for use by laboratories, says Vince Stine, director of government affairs. Of particular interest, he says, is the use of evidence-based medicine in coverage policy and a more seamless transition from FDA approval to CMS coverage

Officials with the Centers for Medicare & Medicaid Services on Oct. 22 introduced a new internal organization, the Council for Technology & Innovation, designed to promote use of new medical technologies. The entity, required by Section 942 of last year's Medicare Modernization Act, "is really there to help all of us gain transparency in the system … for coverage, coding, and payment," said co-chair Herb Kuhn, director of the CMS Center for Medicare Management. The other co-chair is Sean Tunis, MD, director of CMS's Office of Clinical Standards & Quality.

"We see [the Council] as a place for manufacturers who need an entry point for coding and reimbursement questions," Stephanie Mensch of AdvaMed told *NIR*. Manufacturers often are more attuned to the regulatory approval processes of the Food & Drug Administration than to the coding and payment processes at CMS.

The Council, which replaces the existing Medicare Technology Council, is comprised of senior-level CMS professional staff and consists of two working groups:

- The Effective Innovation Working Group. Its aim is to improve the timeliness and efficiency of coverage, coding, and payment processes. It will review procedures for identifying new technologies and work to overcome barriers, for example by expediting Medicare's national coverage determination process.
- The Better Evidence Working Group. Its purpose is to promote comparative effectiveness studies and other innovative procedures for gathering additional medical evidence about new technologies.

The Council is working on one proposal of interest to laboratories—it would have CMS publish guidance documents to enable the agency to decide more quickly and more openly whether it intends to cover new tests and other medical innovations. The Council also is at work on a coverage, coding, and payment "white paper" to show "how it all flows together," Kuhn said. Tunis added that the Council is responding to initial feedback with plans to explain what triggers internal decisions to develop Medicare national coverage determinations, as well as what triggers the agency to request Medicare Coverage Advisory Committee reviews.

Tom Gustafson of the CMS Center for Medicare Management noted, in response to a question, that CMS intends to issue a notice of proposed rulemaking by early 2005 regarding the processes the agency uses for establishing appropriate payment levels for new clinical laboratory tests. There are two ways CMS currently does this: by crosswalking new codes to existing codes or by gap-filling based on local pricing patterns. The Council's key staff contact is Janet Anderson Brock at 410-786-2700, *janderson@cms.hhs.gov*.

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to translate into "continuity in the leadership of the departments we deal with," comments Alan Mertz, president of the American Clinical Laboratory Association, which represents large national and regional labs. With Republicans remaining in control of Congress and increasing their majority in both Houses, "it increases the chance of a deficit reduction bill next year … We've got to keep up the pressure to keep from getting caught in it."

HHS Secretary Tommy Thompson and CMS chief Mark McClellan declared in a Nov. 6 press conference that they believe Congress isn't likely to cut Medicare spending next year because this would hurt the new prescription drug benefit. But three days later, Pricewaterhouse Coopers predicted big cuts for hospitals. Sandy Lutz, director of the firm's Health Research Institute, told reporters, "Hospitals should start bracing for the next Balanced Budget Act"

Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science, says she'd be "very surprised if there is anything helpful to healthcare providers, especially laboratorians," in the next session of Congress, which opens in January. To pay for the Medicare drug benefit, the Bush Administration and Congress "either will have to increase the debt or go after providers." And when it comes to the lab fee schedule, "everything will be back on the table," she fears.

Pathology groups are wary too about the potential for reimbursement cuts. They and other physicians face an expected 5% reduction in fees ahead unless Congress changes their fee update formula. Congress did intervene to avert projected fee cuts in 2004 and 2005 by granting a 1.5% update for each of those years in the Medicare Modernization Act of 2003. Denise Bell of the College of American Pathologists says fixing the statutory formula for fee updates is a priority.

Medical Liability Reform

The President talked up this issue during the campaign and soon after his re-election, leading many to believe he will seek action. "I definitely think capping medical malpractice awards will be a top priority of this Administration," says Bell. Republican gains in the Senate, where they expanded their majority to 55, "make it a close vote [there]," Mertz notes. But whether a bill can squeak through the Senate, where the GOP lacks the 60 votes needed to defeat a filibuster, "is a tough call," Passiment thinks.

Leadership Change On the Senate HELP Committee

Waters says it's too early to tell how clinical labs will be affected if, as expected, Sen. Mike Enzi (R-WY), succeeds Judd Gregg (R-NH) as chairman of the Health, Education, Labor & Pensions Committee, a post Gregg left to head the Budget Committee. Gregg has championed patient safety legislation that has neared, but likely won't reach, final passage in the lame-duck session of the 108th Congress.

Patient safety remains a big concern for many Americans, however, according to a national survey just released. More than half of the 2,000 adults surveyed are dissatisfied with the quality of healthcare, up from 44% in 2000, and 92% approve of mandatory reporting of medical errors. A large majority think that safety report cards on hospitals, for example, would go far toward addressing the issue; few think that more lawsuits are the answer. The survey was conducted by the Kaiser Family Foundation, the Harvard School of Public Health, and the HHS Agency for Healthcare Research & Quality.

'Welcome to Medicare' Exam Expected To Increase Lab Screenings

A beneficiary is eligible for the exam within six months after his/her first Part B coverage period, but only if that period begins on or after Jan. 1, 2005

The new "Welcome to Medicare" physical exam, to be covered as of Jan. 1, 2005, is likely to increase referrals for follow-up laboratory screening benefits already covered by the Part B program. The key definition of the benefit, published in the final 2005 physician fee schedule (*Federal Register*, Nov. 15, 2004), requires physicians to provide new beneficiaries with education, counseling, and referral, including a brief written plan such as a checklist for obtaining lab screenings and other preventive services that are separately payable.

These services currently include screenings for breast, vaginal, and cervical cancer as well as colorectal and prostate cancer and for glaucoma, plus diabetes outpatient self-management training; bone mass measurements; and medical nutrition therapy for beneficiaries with diabetes or renal disease. Starting Jan. 1, screening for cardiovascular disease and diabetes will also be covered.

In addition to information on the above, the physician or other qualified non-physician practitioner must provide, as part of the initial preventive physical:

- ❑ A review of medical and social history, potential risk for depression, functional ability and level of safety (hearing, activities of daily living, risk of falls, and home safety). Social history is to include, at a minimum, any history of alcohol, tobacco, and illicit drug use, diet, and physical activities.
- ❑ Measurement of vital signs (height, weight, blood pressure, visual acuity).
- ❑ Performance and interpretation of an electrocardiogram.

Both deductible and coinsurance apply to the baseline exam. In related policy, Medicare specifies that:

- ❑ The exam must include the EKG, regardless of whether a diagnostic EKG was recently performed.
- ❑ It is dropping its proposed limit on the level of a medically necessary office visit when performed and billed with the baseline exam. The proposed limit was a Level 2 visit code, but Medicare now says CPT 99201-99215 may be used, depending on the circumstances and appended with CPT modifier "25" identifying the office visit as a separately identifiable service from G0344.
- ❑ A digital rectal exam is not separately payable when performed during the baseline exam. Payment for the DRE is bundled into the office visit fee.
- ❑ When a physician refers to an outside source for the EKG, the physician is expected to incorporate the results into the beneficiary's medical record. Both components of the baseline physical—the examination and the EKG—must be performed in order for either to get paid.
- ❑ When the physician has genuine doubt whether the exam will be covered as an initial physical, an Advance Beneficiary Notice should be obtained, alerting the beneficiary that he/she may be financially liable if Medicare denies the claim.

"Welcome to Medicare" Exam Fees

*Code**	*Description*	*Fee/Non-Facility*
G0344	Initial preventive exam	$97.40
G0366	EKG for initial prevent exam	27.29
G0367	EKG tracing for initial prev	17.81
G0368	EKG interpret & report prev	$9.10

*Crosswalked to CPT 99203, 93000, 93005, and 93010, respectively.

Plans To Tighten Lab Oversight Aired At Maryland Hearing

State Sen. Paula Hollinger, who chairs the committee that held the hearing, intends to propose legislation for the committee's consideration when it meets Dec. 7, staff said

State legislation is in the works in Maryland that would require organizations to accredit clinical laboratories based on surprise visits. The legislation was prompted by testing quality problems at Maryland General Hospital and Reference Pathology Services (both in Baltimore) that regulators said threatened patient health and safety (*NIR, 25, 22/Sep 27, '04, p. 1*). The bill also would protect whistleblowers and require improved communications between government and private oversight agencies to handle complaints.

The Maryland Senate Education, Health & Environmental Affairs Committee laid the groundwork for the bill at a Nov. 9 hearing in Annapolis, where U.S. Rep. Elijah Cummings (D-MD) described similar federal legislation he is sponsoring (*NIR, 26, 3/Nov 8, '04, p. 8*).

In related reforms, the Joint Commission on Accreditation of Healthcare Organizations will stop announcing regular surveys in January 2006, says Mark Crafton, executive director for state and external relations. "We believe this will help accredited organizations focus on providing safe, high-quality care at all times and reduce unnecessary costs that facilities incur in preparation for a survey." JCAHO also adopted a policy, effective Jan. 1, 2005, to consider accredited organizations out of compliance if they threatened retaliation against a whistleblower. The College of American Pathologists supports federal legislation to shield whistleblowers who alert accrediting organizations about problems, said president Mary Kass, MD, FCAP. But she was silent on the idea of requiring unannounced inspections.

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