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CMS Implements Changes To 2004 Laboratory Fees

While most lab fees are frozen at their 2003 level, CMS has revised its mapping of selected chemistry and microbiology codes, resulting in prices jumping by 100% to 300%

The Centers for Medicare & Medicaid Services has released a revised Part B fee schedule for laboratory services in 2004, reflecting changes required by the Medicare reform legislation signed into law last month (the Medicare Prescription Drug, Improvement & Modernization Act of 2003, or DIMA).

The key change from the original 2004 lab fee schedule issued by the agency in early November is the cancellation of the 2.6% Consumer Price Index update set for Jan. 1 of this year, in effect fixing virtually all lab fees at their 2003 price levels. Under DIMA, Part B lab fees get no CPI update for five years, from 2004 through 2008.

But certain procedures, mainly in chemistry and microbiology, will see a significant fee increase this year, doubling or tripling in price, based on CMS's revised mapping of these codes in response to comments received.

CMS also froze one component of the formula used to calculate the Medicare travel allowance to perform a specimen collection for either a nursing home or a homebound patient. The personnel cost is held to the 2003 level of $0.45, while the standard federal mileage rate ➟ *p. 2*

Hill Outlook For Labs Not Promising

That's the view of leading lobbyists for the clinical laboratory industry on the eve of the opening this month of the second and final session of the 108th Congress. A combination of crucial factors weigh heavily against further big changes in Medicare: the major program overhaul that became law last month, rising deficits, less spending leeway and the onset of presidential and congressional election campaigns.

Getting relief from the five-year lab fee freeze that began Jan. 1 will be difficult at best. Don Lavanty, who heads the Washington, DC area-based firm of J.T. Rutherford & Associates, doesn't think unfreezing fees will happen. "Anything that has a cost component will be difficult [to pass] unless there is an offset." And this could doom another lab priority: increasing the specimen collection fee from $3 to $5.25. Plus, securing additional funding to alleviate lab personnel shortages could be a tough-sell. ➟ *p. 7*

INSIDE *NIR*

Advance orders are now being accepted for our 2004 edition of the Medicare Reimbursement Manual, *which puts the revised 2004 lab fee schedule, plus pathology codes on the revised 2004 physician fee schedule, right at your fingertips for quick access. Also featured: a summary of Part B policy changes mandated by Congress. For more information, contact us at 1-800-522-7347 or visit our Website at* www.g2reports.com

2004 Laboratory Fees, *from p. 1*

rises from $0.36 in 2003 to $0.375 in 2004. As a result, the full payment rate on a per-mile basis (code P9603) is $0.825 and on a flat-rate basis (P9604) $8.25, effective Jan. 1.

Below are the major revisions CMS made to 2004 lab test fees in accord with DIMA. This updates the coverage in our Nov. 25 issue of the agency's original lab fee schedule for 2004. (CPT codes © American Medical Assn.)

NEW LAB CODES

CPT/ HCPCS Code	Descriptor	Natl. Fee Cap, 2004
84156	Protein; urine	$5.12
84157	Protein; other source	5.12
85055	Reticulated platelet assay	37.41
87269	Infectious agent antigen detection, immunofluorescence; giardia	16.76
87329	Infectious agent antigen detection, enzyme immunoassay; giardia	16.76
87660	Trichomonas vaginalis, direct probe	28.02

REASSIGNED LAB CODES

Descriptor	New CPT/HCPCS Code	Natl. Fee Cap, 2004
Starch granules, feces	89225	$4.67
Water load test	89235	7.69

FECAL OCCULT BLOOD: NEW SCREENING CODES

HCPCS Codes	Descriptor	Natl. Fee Cap, 2004
G0328, G0328QW	Fecal blood screen, immunoassay	$18.09

PAP SMEARS

The national minimum Medicare 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.

REVISED PRICING FOR SELECTED CODES

CPT/HCPCS Code	Descriptor	Natl. Fee Cap, 2003	Natl. Fee Cap, 2004	% Chg
80157	Carbamazepine, free	$13.89	$18.52	+33
83663	Fetal lung maturity assessment; fluorescence polarization	13.22	26.43	+100
83664	Fetal lung maturity assessment; lamellar body density	6.61	26.43	+300
87046	Culture, bacterial; stool, aerobic, addtl. pathogens, isolation/presumptive ID of isolates	3.30	13.18	+300
87071	Culture, bacterial; aerobic, isolation/presumptive ID of isolates, any source except urine, blood, stool	6.59	13.18	+100
87073	Culture, bacterial; quant., anaerobic, isolation/ presumptive ID of isolates, any source except urine, blood, stool	6.59	13.18	+100
87254	Viral isolation; centrifuge enhanced (shell vial) technique, includes ID with IF stain	6.83	27.32	+300
87300	Infectious agent antigen detection, IF technique, polyvalent for multiple organisms	8.38	16.76	+100
88400	Bilirubin, total, transcutaneous	3.51	7.02	+100

NEW HCPCS CODES FOR CBCs

Code	Descriptor	Natl. Fee Cap, 2004
G0306	Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count) and automated differential WBC count	$10.86
G0307	Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count)	9.04

Physician Fees Up 6% In 2004 Over Earlier Announced Cut

CMS has extended to Feb. 17 the deadline for physicians to decide whether to enroll to participate in Medicare this year

Thanks to congressional intervention, Medicare payments for pathology and other physician services will be 6% more on average this year than they would have been under a now-scrapped fee schedule that the Centers for Medicare & Medicaid Services published last Nov. 7 (*NIR, 25, 3/Nov. 10, '03, p. 3*). In the new Medicare reform law, Congress approved a physician fee update of not less than 1.5% in each of 2004 and 2005. This averts a 4.5% update reduction this year, based on the formula in Medicare law.

Under the revised physician fee schedule published in the Jan. 7 *Federal Register*, the 2004 conversion factor—which is used to translate a procedure's relative value units (RVUs) into a dollar amount—is $37.3374, effective Jan. 1, vs. $35.1339 in the previous rule and $36.7856 in 2003. The higher update this year will trigger about $800 million more in Medicare spending for physician services than originally expected. An additional $200 million will be spent on changes Congress mandated to recognize area cost differences. Physicians in many areas will get more than last year, from 0.1% more in New Orleans and much of New York to 7.9% more in Puerto Rico. Generally, the most significant increase is 2-3% in primarily rural Midwestern states. Within each area, the percentage increases vary by specialty, depending on the mix of work, practice and malpractice expenses. The largest increase on average—52%—will go to Alaska physicians.

For pathologists, the Medicare fee for CPT 88305, Gross and microscopic exam, Level IV, continues its string of annual increases. 88305 is the most commonly billed anatomic pathology code, comprising over half of the total billable volume and allowed charges paid by the program to pathologists. In 2004, the global rate for 88305 will total $95.21, up from $94.54 in 2003, $93.39 in 2002, $88.38 in 2001, and $76.15 in 2000. For other frequently billed pathology codes, changes in RVUs will trigger either fee increases or declines this year, as depicted below.

Medicare Fee Changes: Selected Pathology Procedures

		2003		2004	
CPT Code		*Total RVUs*	*Pure Fee**	*Total RVUs*	*Pure Fee*
88141	Cytopath, c/v, interpret	1.42	$52.24	0.61	$22.78
88180	Cell marker study	1.59	58.49	1.82	67.95
88304	Tissue exam	1.15	42.30	1.12	41.82
88305	Tissue exam	2.57	94.54	2.55	95.21
88307	Tissue exam	4.42	162.59	4.37	163.16
88311	Decalcify tissue	.46	16.92	.46	17.18
88312	Special stains	2.18	80.19	1.92	71.69
88313	Special stains	1.45	53.34	1.35	50.41
88325	Comp. exam	5.23	192.39	5.22	194.90
88342	Immunocytochemistry	2.21	81.30	2.26	84.38

Source: Medicare physician fee schedules, 2004 and 2003. *Unadjusted for geographic practice cost differences. CPT codes © American Medical Assn.

CMS Establishes Discount Drug Card Benefit

Inside the Final Medicare Reform Law MRL

Just one week after President Bush signed into law the landmark Medicare reform bill, his Administration took the transitional step toward creation of a new outpatient prescription drug benefit. On Dec. 15, the Centers for Medicare & Medicaid Services issued an interim final rule authorizing government-endorsed, privately offered drug discount cards. The aim is to offer Medicare beneficiaries some immediate savings on spending for medications while CMS works out details of the comprehensive drug benefit to begin Jan. 1, 2006.

Under the card program, the government estimates that seniors will save up to 25% on individual prescriptions and 15% on total drug costs. Projected enrollment: 7.3 million seniors, of which 4.7 million will meet low-income eligibility requirements

CMS plans to enroll beneficiaries in the discount card program between June 1, 2004, and Dec. 31, 2005. After that, it will continue to honor the cards until beneficiaries enroll in the new Medicare Part D drug benefit or until the initial Part D enrollment period ends.

Private-sector interest in offering the discount cards appears encouraging. More than 500 people attended a Dec. 18-19 pre-application conference in Baltimore, MD, including representatives of insurance companies, pharmacy benefit managers, software vendors and drug makers. CMS urged attendees to state their intent to apply by Jan. 7.

Card sponsors will be allowed to charge seniors an annual fee of up to $30. Low-income seniors will pay no fee and have $600 added to their card every year by CMS. The government will monitor card sponsors' drug prices to ensure they don't increase faster than the average wholesale price or the sponsor's cost structure, notes CMS official Teresa DeCaro. Sponsors also must show how they will meet a requirement to inform seniors, at the point of sale, about cheaper generic alternatives.

CMS had already done much of the work on the discount program. Two earlier proposals were blocked in federal court by drugstore interests fearing that the program would shift prescriptions to mail-order pharmacies (*NIR, 24, 8/Feb. 10, '03, p. 6*). CMS is optimistic it can avoid a lawsuit this time, now that it has explicit congressional authority for the program; however, the National Community Pharmacists Association has not ruled out a legal challenge.

Senate Poised To Restore Most Allied Health Training Money

Increased funding for clinical lab personnel training is a key priority for ASCLS and other lab groups in the upcoming session of Congress

Federal training funds for clinical laboratory and other allied health personnel will decline less than 1% under a measure awaiting Senate action, a far cry from the 93% cut the Senate initially proposed for allied health and other Title VII training programs (*NIR, 24, 22/Sept. 29, '03, p. 3*). The measure is the House-passed conference report on the fiscal 2004 omnibus appropriations bill, H.R. 2673, that includes funding for operations of the U.S. Department of Health & Human Services.

The bill is expected to be the Senate's first order of business when it reconvenes Jan. 20. But there's a growing sense in Washington that debate on it could become protracted. If so, Congress would have to approve another continuing resolution to keep operations of HHS and other affected agencies running. The current continuing resolution, which provides funding at FY 2003 levels, expires Jan. 31.

Under H.R. 2673, funding of Title VII allied health professions training is slated to drop 0.59% to $11.852 million from $11.922 million in FY 2004, which began Oct. 1, 2003. Funding would have been level but for the 0.59% across-the-board cut to provide additional money for the Department of Veterans Affairs, says Erica Froyd of the Association of American Medical Colleges.

"Clinical laboratory education programs do not gain much from the bill," comments Elissa Passiment of the American Society for Clinical Laboratory Science. In any given year, most of Title VII money goes toward educating physicians, dentists, nurses and other allied health professionals, with programs for medical technologists and technicians getting only $800,000 to $1 million.

CMS To Clarify "Date of Service," Streamline NCD Updates

Comments on the proposed changes are due Feb. 23, 2004. Send to: CMS, Attn: CMS-3119-PN, P.O. Box 8011, Baltimore MD 21244-8011. Contact: Jackie Sheridan-Moore, 410-786-4635

The Centers for Medicare & Medicaid Services has proposed to define more clearly the "date of service" for laboratory tests performed in certain situations, and to simplify routine updates to the National Coverage Decisions (NCDs) affecting some 23 frequently ordered lab tests. The proposal appeared in the Dec. 24, 2003 *Federal Register*.

Under the negotiated rulemaking that developed the NCDs, the date of service for stored specimens was specified as the date of retrieval from the archive, rather than the collection date. This prompted questions over how long a specimen had to be stored before it was considered "archived." CMS had given local Medicare contractors discretion on this point, but regional labs cited concerns about programming their systems to accommodate different contractor interpretations. CMS now proposes to define specimens stored for more than 30 days as "archived."

For specimens collected over a period that exceeds 24 hours—such as commonly occurs with fecal occult blood tests and urine collections for hormone analysis in pregnant women—CMS proposes to define the date of service as the collection end date. Currently, it is defined as the date the collection began.

CMS also wants to make it simpler to manage the list of codes covered under the lab NCDs. At present, the agency can alter these only through the formal notice-and-comment process outlined in the Sept. 26, 2003 *Federal Register*. CMS proposes to make clerical and ministerial changes, such as annual CPT/HCPCS coding updates, without waiting for comments, and to let the general public request such changes by writing to the director of the CMS Coverage & Analysis Group. All such changes would be announced prior to CMS's subsequent quarterly software edit.

Further, in response to lab requests, CMS would institute a simpler notice-and-comment process for seeking changes to the NCDs' narrative indications, one that would not require submission of scientific literature. The agency also would incorporate only the narrative portion of the NCDs in its new NCD Manual print version, but would post the complete manual, including lists of covered and non-covered codes, online.

♦CODING A·D·V·I·S·O·R·Y

In addition to six new lab codes recognized by Medicare (*see p. 2*), the CPT 2004 update made a variety of other changes, listed below, in the pathology/laboratory 80000 series, effective Jan. 1. For revised codes, the deleted text is indicated by a strikethrough; the new text is in italics. CPT codes © American Medical Assn.

CHEMISTRY

Revised

83716 Lipoprotein, blood; high resolution fractionation, quantitation of ~~lipoprotein cholesterols~~ *lipoproteins including lipoprotein subclasses when performed* (eg, electrophoresis, nuclear magnetic resonance, ultracentrifugation)

84155 ~~Protein; total, except refractometry~~ *Protein, total, except by refractometry; serum*

84160 ~~Protein; refractometric~~ *Protein, total, by refractometry, any source*

84165 ~~Protein; electrophoretic fractionation and quantitation~~ *Protein,* electrophoretic fractionation, quantitation

HEMATOLOGY & COAGULATION

New

85396 Coagulation/fibrinolysis assay, whole blood (eg, viscoelastic clot assessment), including use of any pharmacologic additive(s), as indicated, including interpretation and written report, per day

MICROBIOLOGY

Revised

87040 Culture, bacterial; blood, *aerobic,* isolation/presumptive ID of isolates (includes anaerobic culture, if appropriate)

87045 ~~feces~~ *stool, aerobic,* isolation/preliminary exam (eg, KIA, LIA), Salmonella and Shigella species

87046 stool, *aerobic,* additional pathogens, isolation and ~~preliminary examination (eg, Campylobacter, Yersinia, Vibrio, E. coli 0157), each plate~~ *presumptive ID of isolates*

87070 any other source except urine, blood or stool, *aerobic,* isolation/presumptive ID of isolates

87075 any source, *except blood,* anaerobic, isolation/presumptive ID of isolates

87272 Infectious agent antigen detection by IF technique; cryptosporidium~~/giardia~~

87328 by EIA technique, qual. or semiquant., multiple step method; cryptosporidium~~/giardia~~

CYTOPATHOLOGY

New

88112 Selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal

SURGICAL PATHOLOGY

New

88361 Morphometric analysis; tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semiquant.

Revised

88312 Special stains (List separately in addition to code for ~~surgical pathology examination~~ *primary service*); Group I for microorganisms (eg, Gridley, acid fast, methenamine silver), each

88342 ~~Immunocytochemistry~~ *Immunohistochemistry* (including tissue immunoperoxidase), each antibody

88358 Morphometric analysis; tumor *(eg, DNA ploidy)*

OTHER PROCEDURES

New

89220 Sputum, obtaining specimen, aerosol induced technique, separate procedure. (Previously coded as 89350, deleted in 2004)

89230 Sweat collection, iontophoresis. (Previously coded as 89360, deleted in 2004)

89240 Unlisted miscellaneous pathology test. (Previously coded as 89399, deleted in 2004).

Revised

89055 ~~Leukocyte count, fecal~~ *Leukocyte assessment, fecal, qual. or semiquant*

REPRODUCTIVE MEDICINE

New

89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	greater than 10 oocytes
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	greater than 5 embryos
89335	Cryopreservation, reproductive tissue, testicular
89342	Storage (per year); embryo(s)
89343	sperm/semen
89344	reproductive tissue, testicular/ovarian
89346	oocyte
89352	Thawing of cryopreserved; embryo(s)
89353	sperm/semen, each aliquot
89354	reproductive tissue, testicular/ovarian
89356	oocytes, each aliquot

Revised

89250	Culture ~~and fertilization,~~ oocyte(s)*/embryo(s), less than 4 days;*
89251	Culture ~~and fertilization,~~ oocyte(s)*/embryo(s), less than 4 days*; with co-culture of embryos oocyte(s)/embryos
89258	Cryopreservation; embryo*(s)*

Deleted

89252	Assisted oocyte fertilization, microtechnique (any method)
89256	Preparation of cryopreserved embryos for transfer (includes thaw)

Looking farther out, the prospects for 2005, when the 109th Congress begins, could be even worse if, as many veteran Hill observers predict, the worsening federal budget crunch demands spending cuts, and Medicare provider reimbursement becomes a tempting target again

Hill Outlook, *from p. 1*

Attorney Bob Waters, a partner in DC-based Arent Fox who also represents the American Association of Bioanalysts and chairs the Clinical Laboratory Coalition, says that despite the gloomy outlook, lab interests need to be alert for opportunities that may arise "as the year unfolds." But it will be tough-going. "Because of Democratic pressure to change the [new] Medicare law, the [GOP] leadership is against even introducing a technical corrections bill, because it would be a Pandora's box." Rumors are circulating that other legislative proposals could become a vehicle for pushing the priorities of labs and other interest groups, such as a measure the Bush Administration is said to be preparing to tackle the problem of the medically uninsured. Waters, however, thinks these are "not likely vehicles for significant modification."

Alan Mertz, president of the American Clinical Laboratory Association, agrees that rolling back the lab fee freeze is a major priority, adding "we're not wild about the competitive bidding [demonstration required under the Medicare reform law]." Though a legislative vehicle for modifying Medicare reform provisions may be hard to find this year, he notes, "As complicated as the drug benefit is, by 2005 or 2006, they are going to need to make some adjustments." When that happens, "we'll [be ready] to make our case on the freeze."

"Patient safety is at the top of [our legislative] list," says Jason DuBois of the American Society for Clinical Pathology, noting that a patient safety bill, S. 720, has cleared the Senate HELP Committee. The lab fee freeze and competitive bidding pilot "are at the forefront of our agenda," he adds, along with revamping the physician fee update formula to prevent future payment reductions.

FDA Ends Four-Year Ban On Many Abbott Immunoassays

FDA says "some quality systems issues persist," but adds that Abbott can address them through voluntary action. FDA also will further evaluate three corrective actions Abbott recently initiated

The Food & Drug Administration informed Abbott Laboratories on Dec. 18 that it has improved quality systems enough at its Lake County, IL, manufacturing operations to re-introduce dozens of immunoassays that the company had pulled from the market in January 2000 under terms of a Nov. 19, 1999, consent decree. In the dispute over alleged repeated violations of good manufacturing practices, the government had required Abbott to stop marketing all but 54 "essential" tests.

Abbott plans to re-launch products within weeks on a rolling basis, starting with tests for vitamin B-12, ferritin and folate, and is also anxious to introduce more than 10 new products to the U.S. market, many of them successors to pulled products, according to Abbott spokeswoman Rhonda Luniak.

Abbott has made "a substantial investment in compliance, and will continue to [do so]" at its Abbott Park and K2 manufacturing facilities in Lake County, which she said are the largest, most complex manufacturing facilities in the world. The company brought the facilities into compliance mainly by reorganizing manufacturing operations that had been split up according to process, with each product subject to a different mix of processes. Now there are five "focused factories," each producing one type of product at a time.

Commenting on FDA's green light, Steve Gutman, head of the agency's Office of In Vitro Diagnostic Device Evaluation & Safety, notes, "Companies are like human beings—they're not always perfect and there'll always be failures." He urges labs to sound an alert when tests don't work properly. "Labs can help the manufacturer, themselves and a lot of others by identifying problems."

G-2 SPECIAL AUDIO CONFERENCE

Reimbursement & Compliance Alert Scheduled Jan. 21 & 22

Washington G2 Reports will host a two-part audio-conference Jan. 21-22 at 2:00-3:30 pm (EST) each day, "2004 Reimbursement & Compliance Alert for Labs & Pathologists," that provides an in-depth look at changes ahead in Medicare reimbursement, billing and coding, plus critical priorities for compliance programs.

Day 1 features coding and billing experts Diana Voorhees, D&V Associates, and Christopher Young, Lab Management Support Services. ***Day 2*** features lawyers Hope Foster, Esq., Mintz Levin, and Judy Waltz, Esq., Foley & Lardner.

To register, call 1-800-651-7916 or go online to http://glyphics.quickconf.com/sem-online/ioma or e-mail registration@glyphics.com.

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