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Pathology Escapes SGR Fee Cut, But Not Other Reductions

Legislation preventing the SGR cut also extended for one year reasonable cost payments for lab tests in small rural hospitals in low population areas.

While pathologists are spared the 5% cut in Medicare physician payments scheduled to take effect January 1, 2007, under the statutory update formula, they still face a 6% reduction next year in total allowed charges due to regulatory changes to work and practice expense relative value units (RVUs) under the Part B physician fee schedule. For independent labs, however, the RVU changes translate to a gain of 2%. For diagnostic testing facilities, they translate to a cut of 2%.

Before the lame-duck session of the 109th Congress adjourned early this month, lawmakers blocked the 5% cut required by the sustainable growth rate (SGR) formula when actual Medicare physician spending exceeds a target rate. In a House-Senate compromise included in the Tax Relief and Health Care Act of 2006, Congress provides a zero update for 2007 (in effect, keeping fees frozen at 2005 levels, with an RVU conversion factor of $37.8975). But lawmakers also approved a new 1.5% bonus-incentive payment to physicians who voluntarily report quality measures, starting July 1, 2007.

Details on reporting quality measures remain to be fleshed out. Under its current voluntary reporting program for doctors, the Centers for Medicare & Medicaid Services will increase the number ➥ *p. 2*

INSIDE *NIR*

CMS Finalizes 2007 Lab Fee Schedule

The Medicare Part B lab fee schedule for 2007, released earlier this month, provides a zero update, keeping fees at their 2003 level in accord with the statutory five-year freeze on fee updates through 2008. The freeze also keeps the national minimum payment for Pap smears at $14.76.

The travel allowance to collect a specimen from nursing home or homebound beneficiaries remains at the 2006 level, $0.935 on a per-mile basis (HCPCS P9603) or $9.35 on a flat-rate basis (P9604). The personnel portion of the trip fee is $.45 (the 2003 level), while the standard mileage rate is $0.485 per mile, said the Centers for Medicare & Medicaid Services. The previous rate was $0.855 per mile (P9603) and $8.55 on a flat-rate basis (P9604).

New on the 2007 lab fee schedule are 11 CPT lab test codes for conditions such as liver cancer, heart disease, West Nile virus, and staphylococcus. In setting final payment rates for these codes, CMS crosswalked them to existing codes on the lab fee schedule, ➥ *p. 3*

Pathology Escapes SGR Fee Cut, *from p. 1*
and range of quality measures it will encourage physicians to report next year. CMS has identified 86 unique quality measures affecting 32 of 39 medical specialties expected to be available in 2007, from which it will select a subset for voluntary reporting. The list includes testing for blood glucose and cholesterol control in patients with diabetes, plus cytogenetics and flow cytometry services (*NIR, 28, 3/Nov 6 '06, p. 7*).

The 6% reduction that hits pathologists due to RVU changes is caused by a budget-neutral adjustment that shifts more dollars to primary care office visits following CMS's required five-year review of work RVUs (-5%) and the short-term effect of practice expense changes (-1%).

In one change welcomed by pathology and lab groups, flow cytometry technical component codes CPT 88184 and 88185 will increase significantly next year, thanks to higher practice expense RVUs that CMS adopted in line with supplemental data from the American Clinical Laboratory Association.

Some of the cost of changes in Medicare physician payment policy will be offset by reducing funds available in the Medicare Advantage stabilization fund, according to the House-Senate compromise.

'Grandfather' Protection Extended For Pathology TC Billings

As part of the Tax Relief and Health Care Act of 2006 enacted in the waning hours of the lame-duck session, Congress extended for one year, through 2007, the "grandfather" protection under which independent clinical labs are allowed to bill Medicare Part B directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. The protection was due to expire at the end of this year, and in the final 2007 physician fee schedule, the Centers for Medicare & Medicaid Services announced plans to eliminate it.

The "grandfather" provision applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end such billings on grounds that Medicare already pays for the TC as part of the hospital's DRG payment, and labs should seek payment from the hospital, not separately from Part B. Congress has intervened a number of times to block CMS from going ahead with its proposed policy.

The "grandfather" protection applies to the hospital, not the lab, CMS has noted. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology (Transmittal AB-01-47).

A coalition of healthcare provider groups, including the leading pathology and lab groups, had backed legislation (H.R. 6030, S. 3609) to make the protection permanent. Ending the protection would be particularly devastating to small and rural hospitals, warned the College of American Pathologists, because they cannot afford to do the work in-house and must contract it out. About 95% of 4,773 PPS hospitals and critical access hospitals outsourced some TC pathology services to labs that received direct payment for those services in 2001, according to the latest data from the Government Accountability Office. By eliminating direct payment, Medicare would have saved $42 million in 2001, the GAO estimated, while beneficiary cost sharing would have been cut by $2 million.

2007 Lab Fee Schedule, *from p. 1*

consistent with the majority pricing recommendations of the leading clinical laboratory and pathology organizations (*NIR, 27, 19/Jul 31 '06, p. 2*). The 2007 lab fee schedule also adds existing CPT 86901, Blood typing; Rh(D), crosswalked to 86900, Blood typing; ABO, with a fee cap of $4.17.

Also next year, as required by the Medicare reform law, CMS is codifying in regulations the public process it uses to invite and respond to comments on setting fees for new test codes on the lab fee schedule. CMS is adopting the process it has used since 2002, typically beginning the cycle in June and ending in November (*NIR, 28, 4/Nov 20 '06, p. 1*).

MEDICARE FEES FOR NEW CPT LAB CODES

Code	Descriptor	Crosswalk, Medicare Fee Cap	Supported by
CHEMISTRY			
1) 82107	Alpha-fetoprotein; AFP-L3 fraction isoform and total AFP (including ratio)	83950/$89.99	AACC, ACLA, ASCLS, ASCP, CAP, CLMA
2) 83698	Lipoprotein-associated phospholipase A2, (Lp-PLA2)	83880/$47.43	AACC, ACLA, ASCLS, ASCP, CAP, CLMA
3) 83913	Molecular diagnostics; RNA stabilization	83907/$18.66	AACC, ACLA, ASCLS, ASCP, ASM, CAP, CLMA
IMMUNOLOGY			
4) 86788	Antibody; West Nile virus, IgM	86645/$23.54	AACC, ACLA, ASM, ASCP, CAP, CLMA
5) 86789	Antibody; West Nile virus	86644/$20.11	AACC, ACLA, ASM, CLMA
MICROBIOLOGY			
6) 87305	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; Aspergillus	87327/$16.76	ASCP, CAP
7) 87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique	87496/$49.04	ASCP, CAP, CLMA
8) 87640	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique	87651/$49.04	ACLA, ASM, ASCP, CAP, CLMA
9) 87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique	87651/$49.04	ACLA, ASM, ASCP, CAP, CLMA
10) 87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique	87651/$49.04	AACC, ACLA, ASM, ASCP, CAP, CLMA
11) 87808	Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis	87802/$16.76	ACLA, ASM

 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.

focus on: National Healthcare Policy

What's Ahead For Clinical Labs, Pathologists In '07?
A Quick Guide To Key Medicare Policy Changes

Effective January 1

1. MEDICARE COVERAGE

New Test Codes on the Lab Fee Schedule

Eleven new CPT lab codes will be added to the Part B lab fee schedule. They include three in chemistry, two in immunology, and six in microbiology (*see table, p. 3*). Also added: an existing CPT blood typing code.

New & Revised Preventive Services Benefits

❑ ***Abdominal Aortic Aneurysm Screening***

Medicare will add abdominal aortic aneurysm (AAA) screening to the list of covered Part B preventive services, as required by the Deficit Reduction Act of 2005. Coverage is limited to a one-time only ultrasound screening upon referral from the physician who provided the beneficiary's initial "Welcome to Medicare" physical exam. The annual Part B deductible is waived.

To bill for AAA screening, use HCPCS code G0389, *Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm screening*. Payment will be made under the Medicare physician fee schedule at the same rate as CPT 76775.

Eligible beneficiaries include those at risk for AAA, including anyone with a family history of AAA; a man aged 65 to 75 who has smoked at least 100 cigarettes in his lifetime; and any other individual who manifests risk factors for which screening is recommended by the U.S. Preventive Services Task Force.

Reminder: *For labs and all other Part B providers, there is no grace period to implement active valid CPT codes on the lab fee schedule and active valid ICD-9 diagnosis codes required on claims. As of January 1, 2007, Medicare will recognize only active valid CPT and ICD-9 codes as payable.*

❑ ***Fecal Occult Blood Screening***

To bill for this screening, use CPT 82270—*Blood, occult, by peroxidase activity (e.g., Guaiac) qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)*. This code replaces HCPCS G0107. Fecal occult blood screening is part of the Part B colorectal cancer screening benefit and is payable under the lab fee schedule.

❑ ***Colorectal Cancer Screening***

Medicare will waive the annual Part B deductible for colorectal cancer screening procedures reimbursed via the physician fee schedule, in accord with a requirement in the Deficit Reduction Act of 2005. Co-pay will continue to apply. Affected services include flexible sigmoidoscopy (G0104), colonoscopy (G0105 and G0121), and barium enemas (G0106 and G0120).

❑ ***Osteoporosis Screening***

Beneficiaries at risk for osteoporosis are eligible for bone mass measurements (BMM) once every two years, though coverage may be more frequent when medically necessary. In the final 2007 physician fee schedule rule, the Centers for Medicare &

CMS is expanding the number of beneficiaries who qualify for osteoporosis screening due to long-time steroid therapy by reducing the dosage equivalent required for eligibility from an average of 7.5 milligrams per day of prednisone for at least three months to 5.0 mg/day.

Medicaid Services announced that it will no longer cover single-photon absorptiometry, saying newer techniques are superior in accuracy and precision, and the agency revised "bone mass measurement" to read: "Is performed with either a bone densitometer (other than a single-photon or dual-photon absorptiometry) or with a bone sonometer system cleared for this use by the FDA" and includes a physician's interpretation of the results.

For a medically necessary BMM to be covered for an individual being monitored during FDA-approved osteoporosis drug therapy, the monitoring must be performed using a dual energy x-ray absorptiometry system (axial system).

Lab National Coverage Policies

Medicare will cover additional ICD-9 diagnosis codes under its National Coverage Decisions (NCDs) for 23 of the most frequently ordered clinical laboratory tests. The NCDs were developed via a negotiated rulemaking between CMS and lab industry groups. For tests covered under the NCDs to be payable, active valid ICD-9 codes must be used on Part B lab claims to document that the testing is medically necessary.

ICD-9 codes added to the Lab NCDs as of the start of 2007 are:

❑ Prothrombin Time	V58.83 (Encounter for therapeutic drug monitoring)
❑ Partial Thromboplastin Time	V58.83
❑ Thyroid Testing	783.0 (Anorexia); 793.99 (Other nonspecific abnormal findings on radiological and other exams of body structure)
❑ Fecal Occult Blood Test	995.20 (Unspecified adverse effect of unspecified drug, medicinal and biological substance)

Blood Glucose Testing In Nursing Homes

In the final 2007 Medicare physician fee schedule, CMS reiterated its existing policy on blood glucose testing in nursing homes—the test-ordering physician must be the one who treats the beneficiary and uses the test results in the care of that patient. For each blood glucose test provided to a beneficiary residing in a skilled nursing facility, the treating physician must certify that the test is medically necessary. A standing order is not sufficient to order a series of blood glucose tests.

2. MEDICARE PAYMENT

Lab Fee Schedule

Reimbursement remains frozen through 2008, in accord with the five-year update freeze mandated in the 2003 Medicare reform law. Fees for 11 new CPT lab codes added to the fee schedule were determined by crosswalking (*related story, p. 1*).

Pathology Payment

While spared from the 5% cut scheduled for Medicare physician payments in 2007, pathologists still face a 6% cut as a combined impact of regulatory changes to work and practice expense RVUs (*related story, p. 1*). Congress also continued the "grandfather" protection for certain pathology TC billings by independent labs (*related story, p. 2*).

'Medically Unlikely' Edits

CMS is inaugurating a new system of coding edits for Part B claims—called "medically unlikely" edits or MUEs—designed to weed out what the agency calls improper payments. 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 are automatically rejected.

The initial phase-in of the MUEs will be limited to anatomical edits (*e.g.*, billing for more than one appendectomy per patient). Pathology and clinical lab services are not included, except for five "G" codes for Pap smear screening—G0123, G0124, G0143, G0144, and G0145—whose MUEs are set at one.

The next MUE implementation is set for April 2007 and will concentrate on "typographical edits," CMS has said. CMS has contracted with Correct Coding Solutions, LLC (Carmel, IN), to handle this highly controversial claims processing change.

Effective May 23

National Provider Identifier

In order to get reimbursed, clinical laboratories, pathologists, and other healthcare providers must include their National Provider Identifier (NPI) on all Medicare electronic claims sent on and after May 23, 2007 (for small health plans, May 23, 2008). Medicare legacy numbers will no longer be accepted thereafter.

From January 2, 2007 through May 22, Medicare recommends that providers submit both their NPIs and legacy provider numbers. The NPI system has been established in accord with HIPAA (the Health Insurance Portability & Accountability Act). Every healthcare provider must obtain an NPI. The NPI is a 10-digit numeric identifier that does not expire or change. To apply online for an NPI, go to *https://NPPES.cms.hhs.gov*.

Effective July 1

Diagnosis Coding On Claims

CMS is requiring local carriers to process all diagnosis codes reported on claims. For claims processed as of this date and later, carriers are to process up to eight diagnosis codes reported on a claim vs. the current limitation of four and are to accept all diagnosis codes reported on a claim.

Also Ahead in '07

New Claims Processing Structure

Medicare is continuing its multi-stage transition to the Medicare Administrative Contractor (MAC) system that will replace the current system of carriers and fiscal intermediaries. CMS will designate 15 MACs nationwide to combine Parts A/B claims processing. The first MAC contract was awarded to Noridian Administrative Services (Fargo, ND) in July 2006, and the contractor is expected to implement consolidated A/B claims processing in March 2007 for Jurisdiction 3, which includes Arizona, Montana, North and South Dakota, Utah, and Wyoming.

CMS also has issued an RFP for bids for more jurisdictions, with contracts scheduled to be awarded in July 2007:

- ❑ Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas
- ❑ Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska
- ❑ Jurisdiction 12: Delaware, the District of Columbia, Maryland, New Jersey, and Pennsylvania

The switch to MACs was mandated by the 2003 Medicare reform law. The statute gave CMS six years (until 2011) to competitively bid and transition all Medicare fee-for-service workloads to MACs. The law also requires that MAC contracts be reopened for competitive bidding every five years.

New Practice Guideline For HER2 Testing For Breast Cancer

The College of American Pathologists and the American Society of Clinical Oncology on December 11 announced the release of a clinical practice guideline to improve the accuracy of HER2 testing for breast cancer patients and to guide therapy selection. This is the first time the two groups have joined to address a critical issue affecting all patients with a new diagnosis of invasive breast cancer, said CAP and ASCO in a joint statement.

Two methods are most commonly used to test for HER2: immunohistochemistry (IHC) and fluorescence in-situ hybridization (FISH). IHC testing can show how much of the HER2 protein is present on the surface of tumor cells, while FISH testing measures the number of HER2 gene copies in the nucleus of each cell. This gene is responsible for high levels of expression of the HER2 protein on the tumor cells. The guideline recommends a testing algorithm that defines positive, negative, and equivocal values for both the IHC and FISH tests. Equivocal results form a new category and require repeat testing or use of a different test. The guideline does not recommend initial use of one test over another in general circumstances.

Of special note to clinical labs, the guideline recommends adherence to stringent quality improvement standards, including assessment of HER2 testing concordance of 95% with another validated HER2 test for both positive and negative assay values, participation in ongoing internal testing performance evaluation, and participation in external proficiency testing. Biannual examination of these activities will occur through lab accreditation by a valid accrediting agency like CAP. As a result of the panel's recommendations, CAP will require all the labs it accredits to participate in HER2 proficiency testing if they wish to conduct HER2 testing. For a copy of the guideline and companion pieces, visit *www.asco.org/guidelines/HER2* or call 703-299-1180.

♦CLIA A·D·V·I·S·O·R·Y

New Waived Tests & Billing Codes

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The CPT codes for the following new tests must have the modifier QW to be recognized as a waived test, effective January 1, 2007:

82274QW, G0328QW	Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test
87899QW	Gryphus Diagnostics BVBlue
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)

Also for 2007, the new CPT/HCPCS code 87808 QW (Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis) replaces code 87899QW that was assigned to the Genzyme OSOM Trichonomas Rapid Test.

For the complete list of CLIA waived tests and billing codes as of January 1, 2007, see CMS Change Request 5404 (November 24, 2006), which can be downloaded at *www.cms.hhs.gov/transmittals*.

Medicare Recovery Audit Project To Go Nationwide

Healthcare providers billing Medicare will come under greater scrutiny now that Congress has extended the recovery audit project and is expanding it to all states. Currently, the project is a demo operating in California, Florida, and New York. Its aim is to identify and collect inaccurate Medicare overpayments and underpayments using six specialized Recovery Audit Contractors (RACs).

A recent progress report on the three-year demo, which began in March 2005, showed that the RACs had found $303.5 million in improper payments in the Medicare fee-for-service program. According to CMS statistics in the report, "CMS RAC Status Document FY 2006," $68.6 million in overpayments have been collected, $2.9 million in underpayments have been paid back, and an additional $232 million is in the collection or repayment process. The cost of the program thus far has been $14.5 million, the report said.

Congress approved expansion of the RAC project in enacting the Tax Relief and Health Care Act of 2006 as members wrapped up the lame-duck session and adjourned this month.

All of us at Washington G-2 Reports/IOMA wish you Happy Holidays!

washington WATCH

After Contentious Struggle, FDA Gets Permanent Head

In one of his final acts as Senate Majority Leader, Bill Frist (R-TN) overrode the time-honored tradition of senatorial holds, plus members of his own party, and allowed a Senate vote on the President's nomination of **Andrew von Eschenbach** to be permanent Commissioner of the Food & Drug Administration. He has been acting commissioner for the past year.

The Senate voted 80-11 to confirm him. He had cleared the Senate's HELP Committee without objection on September 20, but did come under fire from some Senators over the FDA's stance on drug importation and birth control devices.

Three GOP Senators placed holds on the nomination: Charles Grassley (IA), Finance Committee head, Jim DeMint (MO), and David Vitter (LA). Grassley has been especially vocal in criticizing von Eschenbach for disregarding congressional oversight of the FDA, including failure to respond to requests for information.

Reminder: December is a one-issue month for *NIR*.

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