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Medicare Proposes Increases In Pathology TC Codes For 2006

The proposed Part B physician fee schedule rule was published in the August 8 Federal Register. *CMS plans to issue a final version by November*

For pathologists and clinical laboratories, the big news in Medicare's proposed physician fee schedule for 2006 is the significant revision made to the technical component (TC) of flow cytometry services. Also up for a big change: the TC of the most frequently billed surgical pathology code, CPT 88305.

In the recently proposed fee schedule rule, the Centers for Medicare & Medicaid Services would increase the practice expense relative value units (RVUs) for these services, and if finalized, the result would be higher reimbursement next year, assuming Congress approves a fee update at least equal to that for 2005, or 1.5%.

While CMS says it must reduce pay rates per service by 4.3% in 2006, in line with the sustainable growth rate (SGR) formula used to calculate the update, most Hill watchers expect legislators to step in once more to prevent a fee cut, as they did for 2004 and 2005. ➥ *p. 2*

Quest To Acquire Major New Business Line

With the August 8 announcement that it plans to purchase LabOne, Quest Diagnostics, the nation's largest independent clinical laboratory, is branching out to secure a leading role in providing health screening and risk-assessment services to life insurance companies. LabOne, based in Lenexa, KS, gets most of its revenue from these services—$261 million, or 56%, of its total revenue of $468 million in 2004.

The deal is a cash transaction valued at $934 million and is expected to close in the fourth quarter. Some analysts say it's a conservative move by Quest which, though paying about 2-to-1, is buying a well-managed company with a steady revenue stream.

The deal will also strengthen Quest's drug abuse testing business and its routine lab testing business, especially in the Greater Cincinnati/Tri-State region. Quest's already large presence there will be expanded since LabOne owns the core lab operations of the Health Alliance of Greater Cincinnati, which provides reference work for six Alliance-affiliated hospitals, plus outreach for other clients. (Note: LabOne COO Michael Asselta will discuss hospital lab acquisitions at our October Lab Institute; register at *www.ioma.com/labinstitute05*).

INSIDE *NIR*

Pathology TC Increases, *from p. 1*

Several bills have been introduced to mandate a fee increase, most recently by Rep. Nancy Johnson (R-CT), who chairs the House Ways & Means health subcommittee. She has introduced a bill that would hike physician fees by 1.5% next year, eliminate the SGR, and beginning in 2007, reward doctors who report quality data with a full update based on the Medicare Economic Index, while those who don't report would get 1% less (*related coverage: National Intelligence Report, 26, 19/Jul 25 '05, p. 8*). Other bills pending in the House and Senate call for a minimum 2.7% update for 2006 (*NIR, 26, 16/Jun 6 '05, p. 3*).

Flow Cytometry Relief

Laboratory and pathology groups welcomed the prospect of higher TC payments for flow cytometry. In 2005, fees for both the TC and the professional component were reduced by as much as 50% when CMS priced the flow cytometry codes.

The CPT 2005 update replaced the old per-marker code 88180 with two new codes for the TC (88184-85) and three for the physician's interpretation (88187-89), but not until after CMS had published its proposed rule for the 2005 fee schedule. Since then, the American Clinical Laboratory Association and the College of American Pathologists have lobbied hard to get CMS to raise the fees (*NIR, 26, 5/Dec 16 '04, p. 8; 26, 7/Jan 24 '05, p. 7*).

ACLA concentrated on getting an increase in practice cost inputs on the TC side to account for the costs of instrumentation, reagents, and the need for cytotechnologists to handle the work. So, it was pleased with CMS's proposals. Said ACLA president Alan Mertz, "[This] will improve patient access to a critically important technology used to diagnose leukemia and lymphoma, monitor viral infection, and detect immune-altered states."

Flow Cytometry RVUs: Changes Proposed For 2006

CPT Code	*Work RVUs*	*PE RVUs ('06 vs. '05)*	*Malpractice RVUs*	*Fee**	*% Change*
88184, lst marker	.00	1.62/*1.32*	.02	$62.15	+22.4%
88185, add'l marker	.00	.86/*.64*	.02	$33.35	+33.3
88187, read 2-8 markers	1.36	.42/*.45*	.01	$67.84	-1.6
88188, read 9-15	1.69	.53/*.57*	.01	$84.51	-1.8
88189, read 16 & more	2.23	.69/*.75*	.01	$111.04	-2.0

*Assumes the same conversion factor for 2006 as in 2005 as applied to total RVUs—$37.8975; does not include adjustment for geographic overhead differences. The actual proposed update under the statutory formula is a negative 4.3%, unless Congress intervenes.

Even though CMS is proposing slighter lower practice expense RVUs for the physician's interpretation of flow cytometry services, the TC increases should help restore some of the pay cuts that pathologists and labs experienced this year (assuming congressional approval of a fee update). A myeloid/lymphoid panel, for

example, has 26 markers that typically would be reported, even though more were actually performed, including controls.

In another TC change, CMS proposes to pay more for surgical pathology code 88305 by increasing the practice expense value from 1.58 to 1.76 and the malpractice relative value from .03 to .04, resulting in an 11.1% increase in payment to $68.22 (assuming the conversion factor for 2005 and unadjusted for geographic differences). In Medicare's top 100 pathology and lab procedures, 88305 ranked #5 in terms of allowed services, according to Washington G-2 Reports, with 15.2 million allowed services and $868 million in allowed charges.

The cytopathology add-on code, 88141, would also see a boost in the practice expense value from .15 to .23, resulting in a 13.6% fee increase to $25.39 (assuming as above).

Other Fee Schedule Provisions

Under the proposed physician fee schedule, CMS calls for a series of other payment policy changes, including:

- Revise the list of designated health services subject to the Stark self-referral ban to include diagnostic nuclear medicine services and therapeutic nuclear medicine services.
- Provide supplemental payments to federally qualified health centers that contract with Medicare Advantage (managed care) plans. The payments would cover the difference, if any, between the amount the center gets for treating MA enrollees and its normal Medicare pay rate. The aim is to encourage these centers to participate in the new MA program.
- Expand the screening glaucoma benefit to include Hispanic-Americans age 65 and older because they are identified as an ethnic group at high risk for the disease. Currently, this benefit is limited to individuals with diabetes, those with a family history of glaucoma, and African-Americans age 50 and older.
- Expand Medicare telehealth services to include certain individual medical nutrition therapy. This is aimed at helping rural beneficiaries.

CMS To Host Open Forum On Lab Bidding Demo

The draft demonstration design to test Part B competitive bidding for independent laboratory services will hold center stage at a special public "listening session" scheduled by the Centers for Medicare & Medicaid Services on August 24 from 1:00 p.m. – 3:00 p.m. at CMS headquarters in Baltimore, MD.

The research contractor for the project, Research Triangle Institute International, will present the draft design. The project director is John Kautter, PhD. The overview includes the demo's structure, test menu, bidding, selection of winners, reimbursement, quality, access, and selection criteria for demo sites. The handout for the presentation will be posted at *www.cms.hhs.gov/researchers/demos/clinicallabdemo.asp*.

Two Ways To Participate In Bidding Forum

- **By phone:** Dial 1-800-837-1935, refer to conference ID 7085980. TTY communications relay services, dial 7-1-1 or 1-800-855-2880 and for Internet Relay services, go to *www.consumer.att.com/relay/which/index.html*.
- **In person:** An RSVP is required. RSVP (by close of business August 22) via e-mail to: *LAB_BID_DEMO@cms.hhs.gov*. Send your name, the name of your organization, and your contact information.

There will be an "Encore" recording you can access by dialing 1-800-642-1687 and entering the conference ID, beginning two hours after the forum has ended. The recording expires after four days.

The lab bidding demo is required by the Medicare Modernization Act of 2003. The Act does not specify an implementation date, but does require an initial report to Congress by December 31 of this year. CMS project director Linda Lebovic will present an update at Lab Institute 2005, October 19-22.

The demo is expected to have multiple winners in each of two geographic sites, with contracts up for re-bidding every three years; Pap smears and colorectal cancer screening are excluded (*NIR, 26, 1/Oct 11 '04, p. 1*). RTI is being advised on the demo by a panel of technical experts which it selected from among various laboratory interests (*NIR, 26, 5/Dec 16 '04, p. 2*).

Medicare Continues To Reward Hospitals For Quality Reports

The higher/lower pay scale is required by the Medicare Modernization Act of 2003. CMS says most hospitals already participate in the quality reporting program and get the full payment update

Acute-care hospitals that voluntarily report performance quality data will continue to get higher Medicare reimbursement in fiscal 2006 than hospitals that don't report. Reporting hospitals will get the full update for inpatient prospective payment, or 3.7%, effective October 1, while those that don't will get 0.4% less, or 3.3%.

The update was announced by the Centers for Medicare & Medicaid Services in a final rule in the August 12 *Federal Register*. The 3.7% increase is 0.5% above the market basket update projected in the inpatient PPS rule proposed earlier this year.

To get the full payment for 2006, hospitals must abstract and report clinical data on 10 quality measures in treating heart attack, heart failure, and pneumonia for two consecutive calendar quarters. Many hospitals are now reporting 17 quality measures for these three conditions, CMS says (*NIR, 26, 13/Apr 25 '05, p. 5*).

Medicare is working with the public-private Hospital Quality Alliance on additional measures related to patient satisfaction and care outcomes that could be added in the coming year. CMS administrator Mark McClellan recently announced that Medicare is participating in the Surgical Care Improvement Project whose goal is to see a 25% reduction in surgical complications by 2010.

The final inpatient PPS rule reduces the outlier threshold to $23,600 in 2006 from $25,800 in 2005. CMS says this will make it easier for hospitals to qualify for the extra payments. The threshold is used to determine how much a hospital's costs for a particular care must exceed the DRG payment before extra payments will be made for the case. The rule also replaces nine cardiac DRGs with 12 new ones in a move to discourage specialty hospitals from "cherry-picking" patients.

But the most controversial part of the rule is the increase in the number of DRGs subject to the post-acute transfer policy. The number jumps from 30 to 182 (down from the proposed 231 after provider groups raised concerns). CMS says the change will safeguard Medicare against "paying for the same care twice—first in the DRG hospital payment, then as payment to the post-acute facility." The American Hos-

pital Association wants legislative action to repeal the change, and 61 senators have expressed their concern over payment cuts to McClellan.

In provisions addressing rural hospital concerns, CMS defines how a critical access hospital that was designated by a state as a "necessary provider" can retain that status after relocating its facility. In its new location, the facility must meet all three of the 75% criteria: that is, 75% of patients must come from the same service area as before the relocation; 75% of the services must be the same as at the prior facility; and 75% of the staff must be same as at the prior facility.

Medical Error Reporting Bill Signed, Now It's "Fill In The Details"

The HHS Agency for Healthcare Research & Quality is charged with implementing the law. This includes providing technical assistance to patient safety organizations and addressing concerns about methodology, communication, data collection, and privacy

Long in gestation, patient safety legislation has passed Congress and been signed into law by the President; now the trick is to get it up and running. The Act moved quickly on the Hill, winning House approval on July 27; the Senate's on July 21. President Bush signed it into law on July 29.

The Act (S. 544) establishes a system of voluntary, confidential reporting by healthcare providers of medical errors. New entities called patient safety organizations (PSOs) will analyze data submitted by providers and give providers feedback to help them prevent future medical mistakes. The PSOs will also identify and track national and regional patterns reflected in the data.

A key obstacle that had stalled attempts to pass similar legislation in the previous Congress was removed by agreement to shield the reported data from use in civil and criminal proceedings. Patients may not use the data as evidence in medical malpractice lawsuits or other litigation; accrediting bodies or regulators may not use the data to take action against providers.

The President alluded to the new legal safeguards when he noted, "To maintain the highest standards of care, doctors and nurses must be able to exchange information about problems and solutions. Yet in recent years, many doctors have grown afraid to discuss their practices because they worry that the information they provide will be used against them in a lawsuit."

The PSOs must be approved by the Department of Health & Human Services and must have a primary focus on patient safety and quality of care; they cannot be part of a health insurer. JCAHO–the Joint Commission on Accreditation of Healthcare Organizations has said it plans to apply for PSO recognition.

The law takes effect immediately and one big challenge will be to develop a common reporting language so data can be aggregated. Facilitating data exchange among state reporting systems, most of them mandatory and gathering data differently, will be a major effort. Twenty-three states have medical error reporting systems; all but one are mandatory. Some states identify the reporting hospital, some track errors but don't identify the hospitals.

Other hurdles to overcome include creation of a public-private partnership to run the reporting system and getting startup money since the Act contains no appropriations or cost estimates. Last March, the Congressional Budget Office estimated $58 million in costs over the next five years.

House Passes Medical Liability Reform Bill

The House has cleared similar legislation repeatedly, only to see the reform effort falter in the Senate

The House on July 27 passed, 230-194, a bill that would impose a federal limit on the amount of damages a plaintiff could collect against a physician or manufacturer of medical products during litigation. The measure is a priority for the President and the American Medical Association. There is yet no companion bill in the Senate.

Under the House-approved bill (H.R. 5):

- Jury awards for non-economic damages (or pain and suffering damages) would be capped at $250,000. No cap would be imposed on economic damages.
- Each party would be liable only for the amount of damages directly proportional to that party's percentage of responsibility.
- Plaintiffs generally would have to sue within three years of the alleged injury or one year after discovery of the alleged injury.
- The court may restrict the payment of attorney contingency fees. Fees would be limited to a decreasing percentage based on the increasing value of the amount awarded.
- Authorizes the award of punitive damages in limited cases: (1) where it is proven by clear and convincing evidence that a person acted with malicious intent to injure the claimant or deliberately failed to avoid the unnecessary injury the claimant was substantially certain to suffer; and (2) where compensatory damages are awarded. Punitive damages would be limited to the greater of two times the economic damages or $250,000.
- Limits the liability of manufacturers, distributors, suppliers, and providers of medical products that comply with standards of the Food & Drug Administration.

Medicare Sets October Deadline For HIPAA-Compliant Claims

As of June, only 0.5% of fee-for-service providers submitted non-compliant claims. Clinical labs had the highest rate, 1.72%; for hospitals, it was 1.45% and for physicians, 0.45%

All laboratories, pathologists, and other healthcare entities filing fee-for-service claims to Medicare Part B must, as of October 1, submit them in a format compatible with requirements under HIPAA (the Health Insurance Portability & Accountability Act). Claims that don't comply with the final standards for electronic transactions and code sets will be returned to the filer to resubmit.

This marks the end of the grace period that the Centers for Medicare & Medicaid Services granted providers to achieve compliance. The initial deadline was October 16, 2003, but less than one-third of providers were compliant, so CMS implemented a contingency plan to accept non-compliant claims beyond that date as long as the provider made a diligent, reasonable effort to come into full compliance.

CMS expects to end the contingency plan for other transactions in the near future. The next target is the remittance advice.

CODING A·D·V·I·S·O·R·Y

Duplicate Claim Edit Expanded For Lab Services

Since April 1 of this year, the Medicare program has been checking for duplicate claims submitted to more than one carrier for referred clinical diagnostic laboratory services and purchased diagnostic tests/interpretations. This software edit did not check line items that contained the "90" modifier for referred testing.

Starting January 1, 2006, the edit will be expanded to include all claims, with or without the "90" modifier (Change Request 3946, July 29, 2005). Accordingly, Medicare will reject all lab service claims submitted to carriers when it has been determined that another carrier has already paid for the same service on the same date of service, with the exception of line items that contain the "91" modifier (which denotes repeat clinical lab services for the same beneficiary on the same date of service).

The expanded edit for duplicate claims will apply only to claims containing a CPT code on the Part B clinical lab fee schedule or a HCPCS code on the abstract file for purchased diagnostic tests/interpretations paid under the Part B physician fee schedule that Medicare implemented last April.

Medicare Contractors Notified Of New Waived Tests

The Centers for Medicare & Medicaid Services has sent to local Medicare contractors an updated list of test kits that have been recently waived by the Food & Drug Administration in accord with CLIA (the Clinical Laboratory Improvement Amendments of 1988).

The new waived tests were identified in Change Request 3984 (August 5, 2005) and must be billed with the "QW" modifier to be recognized as a waived procedure.

CPT Code/ Modifier	*Description*
81003QW	Physician Sales & Services, Inc. PPS Select Urine Analyzer
83721QW	LDL cholesterol testing performed using the Polymer Technology Systems Cardiochek PA Analyzer
86308QW	Clearview Mono-Plus II McKesson Medi-lab Performance Infectious Mononucleosis Test
86318QW	Germaine Laboratories, Aimstep H. pylori (whole blood) Wampole Laboratories Clearview H. pylori II (fingerstick or whole blood)
87807QW	Binax Now RSV Test (K032166/A005)
87880QW	McKesson Medi-Lab Performance Strep A Test Dipstick Biotechnostix Rapid Response Strep A Rapid Test Strip Biotechnostix Rapid Response Strep A Rapid Test Device RAC Medical Clarity Strep A Rapid Test Strips
87899QW	Genzyme OSOM Trichomonas Rapid Test

CMS Rolls Out Roadmap For Quality Improvement

Businesses and providers are showing "new willingness to come together in partnerships with CMS", says the agency, and CMS wants to meet "the responsibilities of its influence" on assuring quality in healthcare systems

Achieving quality is the big buzz in healthcare, and the major players, Medicare and Medicaid, have spelled out five strategies to help ensure "the right care for every person every time." The strategies are outlined in the quality improvement "roadmap" recently issued by the Centers for Medicare & Medicaid Services (*www.cms.hhs.gov/quality/quality%20roadmap.pdf*). "These are highways, not destinations," CMS emphasized. "The [goal] is safe, efficient, effective, patient-centered, timely, and equitable care. But the strategies are critical to getting us there." They include:

- ❑ Work through public-private partnerships.
- ❑ Publish quality measurements and information targeted to both beneficiaries and providers.
- ❑ Develop pay-for-performance (P4P) programs for each major care setting.
- ❑ Help providers make greater use of electronic health systems.
- ❑ Help develop information on the effectiveness of healthcare technologies.

CMS also has revamped the Quality Council, chaired by agency head Mark McClellan, and formed workgroups to support the above efforts. In terms of crafting physician P4P, a CMS spokesperson said Medicare would consider the National Quality Forum's new set of 36 voluntary standards for outpatient care. Among them are measures for treating asthma, behavioral health, heart disease, hypertension, osteoarthritis, and for prenatal care, immunizations, and screening services.

washington WATCH

CMS Grilled On Poor Medicare Quality Oversight

Responding to news reports that private Medicare contractors are inadequately investigating patient complaints about quality, Senate Finance Committee chairman Charles Grassley (R-IA) is seeking documents about Quality Improvement Organizations (QIOs) from the Centers for Medicare & Medicaid Services. CMS now pays $1.3 billion over three years for the operations of 53 QIOs whose job is to investigate complaints about the quality of care Medicare patients receive.

Grassley's request followed a series of articles last month in *The Washington Post* that found that QIOs—largely dominated by physicians—probe few patient complaints and impose few sanctions against doctors. The *Post* reported that even when complaints are reviewed, patients have less than a 25% chance of having them confirmed. Grassley told CMS he's concerned that the QIOs "have misplaced their priorities."

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

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