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It's Down To The Wire For Pathology Fee Fix For 2006

If no action is taken on the physician fee issue prior to January 1, Congress could, according to one fallback scenario, signal the Centers for Medicare & Medicaid Services to delay the 4.4% cut while lawmakers work out details for an increase.

Unless Congress acts soon, a 4.4% Medicare cut in pathology and other physician fees will take effect on January 1. The Senate-passed budget reconciliation bill would avert the cut and approve a 1% increase; the House-passed version is silent on the issue. At press time, in preparation for a House-Senate conference to resolve differences between the bills, GOP leaders have been meeting to discuss a physician fee fix and a compromise over Medicare and Medicaid cuts needed to meet savings targets. Their goal is to complete work on the measure before adjourning for the holidays.

Veteran lab lobbyist Don Lavanty thinks Congress will back a Medicare increase in physician fees, adding that there is no indication at this point that Part B clinical laboratory reimbursement will be tapped to come up with needed savings. Still, until lawmakers wrap up their work, lab groups won't rest easy, remembering that they were successful in opposing a 20% Medicare lab co-pay in 2003, but at the last minute, got hit with a five-year freeze, through 2008, on any lab fee update.

➥ *p. 2*

Allied Health Training Funds Slashed

Funding for most Title VII health professions programs, including those that train medical technologists and medical laboratory technicians, has been drastically cut in the conference report on the HHS-Education-Labor appropriations bill for fiscal 2006. The House approved the report, 215-213, on December 14, and at press time, it was being considered by the Senate.

The conference report approves some $147 million for Title VII, 51% below the level for 2005. The allied health account, which includes a small portion for lab personnel training, is cut by 66%, to $4 million. The Senate had earlier approved $11.7 million for allied health, the same as for 2005, while the House had eliminated this funding (*NIR, 26, 18/Jul 11 '05, p. 3*).

Clinical laboratory groups say they will continue to fight for more lab personnel training support in next year's Congress, though with the GOP majority pushing to cut spending and taxes, it promises to be an uphill battle. They also will push for action on pending legislation designed to alleviate shortages in lab and other allied health personnel (*NIR, 26, 12/Apr 11 '05, p. 2*). This legislation has not moved since being introduced earlier this year.

INSIDE *NIR*

Pathology Fee Fix, *from p. 1*

Granting even a modest hike in physician fees for one year would cost upwards of $11 billion, and congressional GOP leaders are saying at this point that an offset must be found in other federal spending to pay for it. The White House this month gave its support to a two-year physician pay increase as long as an offset can be agreed to. And more recently, Rep. Pete Stark (D-CA) introduced a bill that would grant doctors a 1.5% increase for the next two years. Another issue to be resolved is whether to tie a physician pay increase to a pay-for-performance initiative, as the Senate bill would do. Physician groups are wary of such an initiative since much of the fine print remains to be worked out.

The House and Senate versions of budget reconciliation differ markedly in the amount of savings they aim to achieve and where cuts would be made. The House would cut $50 billion from entitlements and other domestic benefits; the Senate, $35 billion. The House would squeeze roughly $12 billion from federal Medicaid spending by tightening seniors' asset transfer rules, letting states impose higher cost-sharing on recipients, and relaxing some mandated preventive screening of children and pregnant women. The Senate would split $10 billion in savings between Medicaid and Medicare, mainly by prescription drug reforms and by scaling back the reserve fund to promote private health plans' participation in the new Medicare Advantage program, a move the White House has already threatened to veto.

Update: Corrections To Final 2006 Medicare Lab Fees

As suspected, the Centers for Medicare & Medicaid Services erred in the crosswalk used to establish a Part B fee schedule amount for new CPT code 87900 in 2006. In our previous issue (*27, 4/Nov 28 '05, p. 2*), we questioned whether the crosswalk to 87904 x 5, as listed in Change Request (CR) 4144 (November 10, 2005), was a mistake. The maximum allowable for 87904 is $182.11, so "x 5" would have yielded a total of $910.55. CMS officials declined to answer us until the fee schedule data files became publicly available.

Those files, since made public, show that the agency has acknowledged the mistake and has pegged the maximum allowable at $182.22 for 87900—Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics.

The files also price new code 86480—Tuberculosis test, cell mediated immunity measurement—at $86.59, one cent more than the $86.58 figure cited in our crosswalk table, a difference due to rounding.

For all the other crosswalked codes in our table, the final data file amounts and the CR figures match, except for new code 83704—Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy). The data files show a maximum allowable of $44.08, or $0.36 more than the $43.72 indicated in our table, based on the CR crosswalk to 83716 + 85004. In explaining the discrepancy, CMS officials told us that the CR indicates the fee-setting method, but "is not meant to recalculate fees in the data files." Rather, this is done "by using the base year fee for each code in each geographic area, updating the fee to the fiscal period, crosswalking, and then applying the national limitation amount." For code 83716, the base year was 1999; for 85004, 2003.

CAP Unveils More Changes To Lab Accreditation Program

CAP accredits more than 6,000 labs worldwide.

The College of American Pathologists held a media advisory on December 1 to announce more changes to its laboratory inspection and accreditation program next year. Initiatives already underway in the wake of the Maryland General Hospital quality failures include a move in 2006 to unannounced routine CLIA inspections for labs the College accredits, protections for whistleblowers, and abiding by an information-sharing protocol to target federal, state, and private resources to detect or prevent problem cases (*NIR, 27, 2/Oct 31 '05, p. 2*).

In a statement summarizing the changes, R. Bruce Williams, MD, FCAP, who chairs the CAP Commission on Laboratory Accreditation, said, "We believe these initiatives will enhance the consistency and effectiveness of our inspection process, strengthen the monitoring of lab quality between inspections, and reaffirm public confidence in the accreditation process. The unfortunate incidents at Maryland General Hospital that came to light in 2004 prompted the College to re-evaluate its accreditation process. We believe the changes we announced today, and those made earlier, will go far toward preventing another case like Maryland General from occurring."

Specifically, CAP will:

- ❑ Institute new techniques that emphasize direct interaction with personnel, observation of the testing process, and other best practices.
- ❑ Provide new tools to evaluate the lab director's role, including:
  - —A checklist to assess his/her effectiveness, including institutional impediments to his/her authority, execution of the lab quality management program, and ensuring that the lab has sufficient and properly trained personnel.
  - —A patient safety inspection checklist that focuses on patient and sample identification throughout the specimen collection and testing stages.
- ❑ Monitor problem labs to ensure sustained compliance. In 2006 and 2007, the College will invest more than $9 million to support the development of a knowledge management system that integrates quality factors, including proficiency testing results and trend analysis, inspection findings and complaints. The aim is to get a broader, multi-dimensional assessment of how a lab is performing.

In the wake of Maryland General, it is also CAP policy that the labs it accredits must prominently display a poster promoting CAP's toll-free reporting line for confidential routing of complaints and quality concerns. CAP also will revoke a lab's accreditation if it harasses or threatens workers who report lab quality concerns.

U.S. Rep. Elijah Cummings (D-MD), in whose district Maryland General is located, hailed CAP's announcement, noting in a December 1 statement that he has worked with CAP to strengthen oversight of accredited labs. Cummings is the sponsor of a bill (H.R. 686), introduced in the aftermath of Maryland General, that would require unannounced inspections and safeguard whistleblowers.

New Training Requirements For Inspectors

To ensure that CAP inspections are carried out with consistency, the College is requiring enhanced training for its volunteer inspectors. Team leaders and team members will have to complete training every two years, in addition to update activities. Mandatory training for all team leaders will begin in July 2006, and will be phased in later for team members.

In response to a question during the media advisory, R. Bruce Williams, MD, who heads CAP's lab accreditation program, said the inspectors will have several options to fulfill the training requirements, for example:

— A live seminar typically for one day.
— A regional workshop plus a modified e-learning module.
— A live workshop at a CAP meeting plus e-learning.
— Complete training online.

Following completion of training, inspectors will receive a competency assessment, he said, adding that this is *not* a test.

COLA Gears Up For Lab Inspection Changes

Starting in January, COLA will perform unannounced routine CLIA inspections of clinical laboratories it accredits under its cooperative accreditation initiative with JCAHO (*NIR, 27, 2/Oct 31 '05, p. 1*). A subset of roughly 100 labs of the 6,800 labs that COLA accredits will be affected. *NIR* contacted Max Williams, the director of policy and external affairs at COLA, for an update on plans for the change. Below are his replies.

Will COLA follow the same guidelines as JCAHO?
"Yes, we will generally follow the same guidelines as to which labs will be subject to unannounced inspections and what timeframes are applicable. We're also looking at different test volume thresholds that would be applicable to the smaller labs."

For the vast majority of labs it accredits under CLIA, including physician office labs, COLA will stay with announced inspections. Why is that?
"In general, COLA will continue routine biennial accreditation inspections with advance notice for these labs. Unannounced inspections are by design intrusive and disruptive, and, therefore, not routinely used for labs unless complaints or risk of harm warrant such action. We employ trained staff surveyors. They are able to work closely with the labs to maintain a preventive environment that embraces the learning culture. Lab personnel are less intimidated and more free to ask questions when they are speaking with a knowledgeable, trained professional who can help them reduce errors.

"Importantly, there is no evidence to suggest that routine unannounced inspections yield findings different from announced [ones]. We should not confuse an educational approach to mean that the inspection is any less stringent."

What's the latest on your inspectors and their training?
"COLA is not a peer-review program. Rather, all our lab surveyors are COLA employees, each of whom routinely performs over 200 surveys a year. Each surveyor has at least a bachelor's degree in medical science, must have a minimum of six years' bench experience, and must qualify (at a minimum) as a lab technical supervisor under CLIA.

"Surveyors complete a six-month training program when they start with COLA and are brought in for three weeks of in-house training each year. This involves more than just technical work and updates to COLA standards. We spend a significant amount of time working on coaching, mentoring, and communication techniques so that our on-site surveys are educationally oriented, process-based, and a platform for a lab's continuous improvement.

"COLA currently employs 16 staff surveyors to perform accreditation surveys of our 6,800 laboratories. We have immunohematologists, cytotechnologists, pathologists, microbiologists, and laboratory generalists on our survey staff. We use sophisticated logistics programming to track labs in need of surveys and to assign surveyors to particular labs. This helps keep our costs down. COLA surveyors are prohibited from consulting to, or otherwise working for, a laboratory they survey."

West Nile Virus: FDA Licenses First Blood Screening Test

The Food & Drug Administration has licensed the first blood test to screen donors of blood, organs, cells, and tissues for infection with the West Nile virus (WNV). The approval came after two years of trial use. The Procleix WNV Assay, developed by Gen-Probe Inc. (San Diego) and marketed by Chiron Corp. (Emeryville, CA), detects viral genetic material (ribonucleic acid, or RNA) in the window of time prior to antibody production.

Since 2003, under an FDA research protocol that has been dubbed a "universal clinical trial," the nation's blood supply has been screened for WNV using nucleic acid tests made by Gen-Probe Chiron and by Roche Molecular Systems (Pleasanton, CA). To date, said the FDA, there have been 30 documented cases of people who most likely acquired the virus from a blood transfusion; nine of them died.

According to a Gen-Probe statement, the company's test has been used to screen more than 29 million units of donated blood since June 2003, detecting WNV in more than 1,500 cases.

WNV typically is transmitted to humans by mosquito bites and can lead to mild, flu-like symptoms and, in some cases, encephalitis and meningitis. The virus, first detected in the United States in 1999, has reoccurred each year since, moving from east to west, with infection occurring in almost every area of the country. The virus has caused close to 20,000 human cases of disease and at least 762 deaths since 2002, the FDA noted, adding that an estimated one million to two million people have been infected with WNV. In 2002, it was discovered that WNV could be transmitted in blood, and a concerted public-private campaign began to develop investigational tests that could be deployed nationwide as an interim measure to protect the blood supply.

"This approval is the result of a tremendous cooperative effort among the FDA, other public health agencies, the test kit manufacturers, and the blood industry," said Jesse Goodman, MD, MPH, director of the FDA Center for Biologics Evaluation & Research. "To develop an investigational test to screen blood, tissue, and organ donors, and get this test in blood banks throughout the country, and then licensed this quickly is a remarkable achievement for public health and patient safety."

Celso Bianco, MD, executive vice president of America's Blood Centers, said, "We need to celebrate our success. This shows that we can respond to emerging viruses that threaten the safety of the blood supply. Within a record time period, joint efforts, helped by powerful diagnostic tools, effectively addressed the risk presented by WNV."

The biggest implication of the Gen-Probe Chiron test approval to screen for West Nile virus is what the cost will be, said Jane Starkey, director of information services for America's Blood Centers. When in trial use, the company could charge only on a cost recovery basis. Now, the test can be sold at market rates.

Chiron spokesman John Gallagher told *NIR* that the company will set the price in the next month or so, but it will be below the $10 to $15 range the company now charges for its nucleic acid assays for HIV and hepatitis C viruses. Chiron has 80% of the U.S. market of 13 million to 14 million annual blood donations, he said.

The fully automated Roche nucleic acid test for West Nile virus is still under investigational use in blood banks, and studies continue. The company is in the process of meeting FDA licensure submission requirements, Roche Diagnostics spokesperson Dowia Turner told *NIR*.

Earlier this year, the FDA advised blood establishments to defer donors suspected of or diagnosed with WNV infection for 120 days after diagnosis or the onset of illness, whichever is later; previously, the deferral period was 28 days (*NIR, 26, 18/ Jul 11 '05, p. 4*).

New, Virulent *C. Difficile* Strains Spreading, Warns CDC

The new strains are geographically dispersed in this country, and while not yet a public health emergency, CDC officials urge health professionals to be aware of the risk so that cases can be treated quickly and steps taken to limit spread of the infection.

Clinicians and laboratory personnel should be on the alert for new, more toxic strains of *Clostridium difficile*, according to warnings sounded this month by the Centers for Disease Control & Prevention and *The New England Journal of Medicine*. The bacillus *C. difficile* has long been associated with diarrhea in hospital patients and in long-term care residents; the primary risk factor has been antibiotic use for other conditions.

But a more severe form of *C. difficile*-associated disease (CDAD) has been recently identified in otherwise healthy persons living in the community and in peripartum women, two populations thought to be at low risk for infection, researchers point out in the December 2 issue of CDC's *Morbidity & Mortality Weekly Report*.

The researchers looked at 33 such cases reported from four states—New Hampshire, New Jersey, Ohio, and Pennsylvania—during May-June 2005, with all but one of the cases occurring during 2004-2005. Of the cases studied, 23 occurred in otherwise healthy people with minimal or no exposure to healthcare settings or antibiotic use (the age range was from six months to 72 years, with a median of 23 years). The remaining 10 cases occurred in peripartum women who had had brief hospital stays, and in four cases, there was evidence of transmission to close family contacts. One of the women died, and many of the other cases developed chronic and debilitating infections.

Cultures from two patients were available for characterization, the researchers said, and did not match the "epidemic strain" that has been detected as the cause of severe hospital-associated cases of CDAD in 16 states, according to unpublished CDC data.

In a related study in the December 8 *New England Journal of Medicine*, researchers said recent reports suggest that the rate and severity of CDAD are on the rise and may be associated with a new, more virulent strain of *C. difficile*, resistance to drugs, or both. The authors analyzed 187 samples from eight healthcare facilities in six states—Georgia, Illinois, Maine, New Jersey, Oregon, and Pennsylvania—with outbreaks of CDAD between 2000 and 2003. At each site, they found the same, previously uncommon strain. This strain caused a severe outbreak in several hospitals in Quebec in 2003 that may have killed 200 patients.

Considered together, the different studies suggest that the epidemiology of CDAD might be changing. The *MMWR* article cites, in particular, certain features of CDAD that have been uncommon in the past: close-contact transmission, high recurrence rate, young patient age, bloody diarrhea, and lack of exposure to antibiotics. Accordingly, the article concludes, doctors should consider the diagnosis of CDAD in patients with severe diarrhea even if the patients do not have the traditional risk factors such as recent hospitalization or antibiotic use. Patients with severe diarrhea lasting more than three days and accompanied by blood and fever should see their physician.

Pennsylvania Medicaid Decides Against Lab Co-Pay

Medicaid recipients in Pennsylvania won't have a co-payment imposed for their laboratory services, the state Department of Public Welfare has decided. In a letter to Alan Mertz, president of the American Clinical Laboratory Association, DPW Secretary Estelle R. Richman said the decision was made "following a review of lab services." The state legislature earlier this year dropped a proposed lab co-pay of up to $3 from the final budget the governor later approved, but the lawmakers gave the DPW the authority to change Medicaid rates, benefits, and co-pay requirements until December 31 of this year (*NIR, 26, 19/Jul 25 '05, p. 7*). ACLA, along with the American Association of Bioanalysts and others in the Clinical Laboratory Coalition, lobbied hard to defeat any legislative or regulatory change that would have required a lab co-pay for nearly 900,000 adult Medicaid recipients in the state (*NIR, 26, 13/Apr 25 '05, p. 3*).

♦CODING A·D·V·I·S·O·R·Y

ICD-9 Changes To Uniform Lab Payment Policies: The January 2006 release of the Medicare edit module for the 23 laboratory national coverage decisions (NCDs) will contain several changes to the list of covered ICD-9-CM diagnosis codes, the Centers for Medicare & Medicaid Services has announced:

- *All 23 NCDs:* Remove V76.44 (special screening for malignant neoplasms, prostate) from the list of ICD-9 codes not covered by Medicare.
- *NCD for Blood Counts:* Add V76.44 (special screening for malignant neoplasms, prostate) to the list of ICD-9 codes that do not support medical necessity.
- *NCD for Tumor Antigen by Immunoassay CA-125:* Add 158.8 (malignant neoplasms, specific parts of peritoneum) and 158.9 (malignant neoplasms, peritoneum, unspecified) to the list of ICD-9 covered codes.

The 23 NCDs were developed by the lab negotiated rulemaking committee and published in a final rule in the November 23, 2001 edition of the *Federal Register*. Since January 1, 2003, lab claims subject to these NCDs have been processed uniformly nationwide. The Medicare contractors' NCD edit module is updated quarterly as necessary to reflect coding updates and other changes. The previous update, which included many more ICD-9 additions and deletions, was effective October 1, 2005 (*NIR, 26, 21/Sep 12 '05, p. 7*).

Surrogate UPINs To Be Scrapped: Effective for dates of service on or after April 1, 2006, physicians, laboratories, and other healthcare providers will not be able to use surrogate or "dummy" UPIN identifiers on their Medicare claims. They must submit the referring physician's actual UPIN or the claims will be returned as "unprocessable." This change will affect teaching medical center pathologists, notes Dennis Padget, head of DLPadget Enterprises (Simpsonville, KY), because of the relatively high turnover of attending staff, making it difficult for hospitals to keep up with the UPIN registry and because of the high number of outside consultation cases, which often don't think to send UPIN information. The surrogate UPIN OTH000 was intended for interim use when a UPIN had been requested but not yet received. But a Medicare probe last year found that an excessive number of claims had the surrogate when in many cases, UPINs had been assigned.

CDC Issues 'Good Lab Practices' Guide For Waived Tests

The CDC report is designed as an educational and training tool for personnel to improve lab practices and enhance patient safety as the number of waived tests and the sites that perform them continue to increase dramatically.

As part of the government's effort to weed out quality problems and improve test performance in clinical laboratories with a CLIA certificate of waiver, the Centers for Disease Control & Prevention has published a document on good laboratory practices that includes a checklist of crucial steps throughout all phases of the testing process—pre-analytic, analytic, and post-analytic—with special attention to the manufacturer's instructions for quality control.

The document emerged from previous discussions and work of the Clinical Laboratory Improvement Advisory Committee (*NIR, 26, 10/Mar 7 '05, p. 5*). It presents the findings of quality surveys of CLIA-waived labs by the Centers for Medicare & Medicaid Services and by CDC since 1999, along with recommendations from CLIAC on how to promote quality testing in these sites. The document can be found in the *Morbidity & Mortality Weekly Report* online at *www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm*.

Of the quality deficiencies in 4,214 sites surveyed by CMS over 2002-2004, the major problem was in not following the test manufacturer's instructions, especially with regard to quality control. CLIA officials at CMS say that return surveys show improvement and that the educational approach is working. Nonetheless, they plan to continue to survey waived labs for quality issues in 2006 (*NIR, 26, 22/Sep 26 '05, p. 3*).

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

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