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New 2006 Lab Test Codes Unveiled, Pricing Input Sought

The final Part B lab fee schedule for 2006 is expected to be published after the last week of October 2005 and will become effective January 1

In advance of the July 18 public forum for receiving input on how fees should be established for new CPT lab codes on the 2006 Medicare Part B lab fee schedule, the Centers for Medicare & Medicaid Services has just released a list of these codes (*see p. 2*). The notice from CMS also includes revised codes as well as ones to be deleted from the fee schedule. The coding changes were developed by the American Medical Association's CPT Editorial Panel and will not be further discussed at the forum.

The meeting is open to the general public and is intended, CMS says, to obtain expert input on the assignment of payment levels for the new codes, using either the crosswalk or the gap-fill method. Under the crosswalk, a code is linked to an existing, substantially equivalent code and that code's fee amount and national payment limitation. When a code is gap-filled, the fee is based on local pricing patterns of Medicare contractors. ➥ *p. 2*

INSIDE *NIR*

Panel Okays Genetic Test Recommendations

The HHS Secretary's Advisory Committee on Genetics, Health & Society on June 15 approved a number of genetic testing coverage and payment recommendations from a task force charged with formulating them based on public comments.

Among the key recommendations:

- ❑ The Centers for Medicare & Medicaid Services should consider having a mechanism that would automatically trigger the Medicare national coverage decision process when a certain number of local contractors adopt local coverage policies for genetic tests.
- ❑ A benefit category to cover testing for genetic predispositions and other preventive services meeting evidence-based standards should be established under Medicare.
- ❑ Medicare now pays less for many genetic tests than it costs to perform them. Until the Part B lab fee schedule is overhauled, CMS should quickly establish a mechanism to adjust payments for such tests using its inherent reasonableness authority.

Committee members will have another opportunity to review the final report and recommendations on coverage and payment during the summer before they go to HHS Secretary Michael Leavitt this fall.

New 2006 Lab Test Codes, *from p. 1*

Below are the CPT coding changes noted by CMS. New codes are in bold; the final digit has yet to be finalized.

CHEMISTRY

- 82270 (*revised*) Blood, occult, by peroxidase activity (eg, 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)
- **8227x** single specimen, (e.g., from digital rectal exam)
- 83036 (*revised*) Hemoglobin; glycosylated (A1C)
- **8303x** glycosylated (A1C) by device cleared by FDA for home use
- **8363x** Lactoferrin, fecal; quantitative
- **8369x** Lipoprotein (a)
- **8370x** Lipoprotein, blood; electrophoretic separation and quantitation
- **8370x** high resolution fractionation and quantitation of lipoproteins including subclasses when performed (eg, electrophoresis, ultracentrifugation)
- **8370x** quantification of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy)
- 83898 (*revised*) Molecular diagnostics; amplification of patient nucleic acid, each nucleic acid sequence
- **8390x** amplification of patient nucleic acid, multiplex, first two nucleic acid sequences each
- 83901 (*revised*) amplification of patient nucleic acid, multiplex, each additional nucleic acid sequence (List separately in addition to code for primary procedure)
- **8390x** lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue)
- **8390x** signal amplification of patient nucleic acid, each nucleic acid sequence
- **8390x** separation and identification by high resolution technique (eg, capillary electrophoresis
- **8391x** Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE))

(Note: codes 83715 – 83716 deleted)

IMMUNOLOGY

- **8620x** Cyclic citrullinated peptide (CCP), antibody
- **8635x** B cells, total count
- **8635x** Natural killer (NK) cells, total count
- **8636x** Stem cells (i.e., CD34), total count
- **8648x** Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response

(Note: codes 86064, 86379, 86587 deleted)

MICROBIOLOGY

- **8720x** Smear, primary source with interpretation; complex special stain (eg, trichome, iron hemotoxylin) for ova and parasites
- **8720x** Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics

Further, CPT deleted code 86585, Skin test; TB, tine test, which is paid via the Medicare physician fee schedule, as well as two Category III (emerging technology) codes: 0010T and 0023T.

Registration for the July 18 meeting begins June 20. To register, complete the Internet registration form by July 14 at *www.cms.hhs.gov/suppliers/clinlab*. A confirmation will be sent upon receipt of the registration. Individuals also may listen to the meeting by dialing 877-203-0044, conference ID 6097930. Registration is not required for audio listening. After the on-site presentations, a question and answer period will be opened to both the participants in the room and the audio listeners.

Pathology Groups Call For HHS Review Of Cytology PT

A broad spectrum of pathology groups say the current federal program is based on outdated science and obsolete procedures, but their arguments for needed changes have fallen on deaf ears

A coalition of 10 national pathology organizations and 48 state pathology societies, spearheaded by the College of American Pathologists, has asked Health & Human Services Secretary Michael Leavitt for a departmental re-evaluation of the validity and relevance of CLIA rules requiring gynecologic cytology proficiency testing for pathologists and cytotechnologists.

In a June 3 letter to Leavitt, the groups say the requirements, promulgated in the 1992 CLIA rules but not enforced until this year, are mired in the past and need to be modernized to reflect changes in medical practice guidelines and technological advances. A copy of the letter was sent to Mark McClellan, head of the Centers for Medicare & Medicaid Services, which administers CLIA PT activities.

The appeal to Leavitt escalates the campaign by coalition members to pressure the government to address their concerns following CMS's decision late last year to approve the national cytology PT program offered by MIME, the Indianapolis-based Midwest Institute for Medical Education (*National Intelligence Report, 26, 5/Dec 16 '04, p. 1*).

Along with urging a fast-track review of the cytology PT rules, the pathology coalition asked Leavitt: "If this well-intentioned but outdated program is to go forward, it [should] continue to be conducted on an educational basis and without individual punitive sanctions through the end of 2007, at a minimum."

The roll-out of cytology PT enforcement will impact some 3,800 laboratories that are CLIA-certified in this subspecialty, according to CMS. And it has riled many pathologists and laboratories because, for this year at least, MIME is virtually their sole avenue to satisfy the PT requirements (*NIR, 26, 8/Feb 7 '05, p. 1*). The enrollment deadline is June 30 and the initial testing must be completed by December 31, 2005. (Maryland's health department has run an approved program since 1994, but it's limited to labs that are located in the state or that test specimens from state residents.)

In defending the decision to go with MIME, CMS officials have said that once MIME came forward with a program that met the CLIA requirements and the filing deadline of July 1, they were required by the regulations to begin cytology PT enforcement. Since that decision, CAP and the American Society for Clinical Pathology have formally applied to become CMS-approved cytology PT providers, but the earliest they could qualify to begin testing would be 2006.

The pathology coalition acknowledges that CMS's decision is in accord with its CLIA responsibilities, but the broader concern is that the agency has not given sufficient attention to the issues repeatedly raised by

Key Challenges To Cytology PT Rules

In advocating revised CLIA rules for gynecologic cytology proficiency testing, the pathology coalition's June 3 letter to HHS Secretary Michael Leavitt questions specific CMS interpretations of what the CLIA statute requires:

- While the law mandates periodic examinations, the rules specify annual testing, even though CLIA routine inspections occur only every two years. Also, the rules provide for sanctions against individuals who fail to achieve a passing score of 90% after two attempts, but the law includes no such penalties. Moreover, the grading scheme is centered in triage and management guidelines that have changed substantially over the past 13 years.
- While all other general PT under CLIA is directed toward measuring results at the laboratory level, the cytology PT program targets individuals. "In reality, much of the work conducted within a laboratory is done so in consultation within a team of pathologists and trained medical staff," the coalition notes, concluding that the statutory requirement that PT testing take place, to the extent practicable, under normal working conditions "can be reflected only by including the collaborative team approach."

pathology and laboratory interests since the mid-1990s about the need to modernize cytology PT in line with "real-world" operations. One pathology source told *NIR* that there was "an unspoken agreement that the regs were not worded properly, so CMS's action caught everyone off-guard."

The coalition's letter to Leavitt notes that scientific and technological advances, such as computer-assisted screening, location-guided screening, digital imaging, and others, have had a significant impact on the practice of gynecologic cytology since the 1992 CLIA rules. Also, quality assurance has improved due to CLIA limits on the number of Pap test slides that a pathologist or cytotechnologist may screen in a 24-hour period. In contrast, the letter continues, the federal cytology PT rules have "stood still."

Earlier this year, the Clinical Laboratory Improvement Advisory Committee weighed into the controversy at the urging of pathology and lab groups. The panel, which advises the government on CLIA scientific and technical matters, passed by unanimous vote a recommendation that CMS consider revising the cytology PT rules, based on updated comments from professional organizations and the public to reflect current practice, evidence-based guidelines, and anticipated changes in technology (*NIR, 26, 10/Mar 7 '05, p. 1*). CMS officials speaking on the issue at the CLIAC meeting said they were aware of the issues posed by the pathology and lab groups, would monitor the implementation of the new program, and take corrective action as needed.

HHS To Lead Drive For National E-Health Record System

To learn more about Web-based connectivity between labs and physician clients, the benefits to be gained and the pitfalls to avoid, join in our June 23 'hot topic' audio conference. For registration and program details, go to our Website, www.g2reports.com

Health & Human Services Secretary Michael Leavitt has unveiled a national strategy that would use federal leverage as a dominant healthcare purchaser and provider to engage the private sector in an ambitious effort to meet the President's call for most Americans to have electronic health records within 10 years. To underscore his point, Leavitt noted that federal agencies now pay for more than one-third of all the healthcare in this country.

In related Capitol Hill action, new bipartisan legislation has been introduced to provide incentives—increased Medicare reimbursement, among them—to help healthcare providers and suppliers adopt and use health information technology (HIT).

Putting The National Strategy In Play

At an HIT conference earlier this month in New York City, Leavitt noted that "use of e-health records and other HIT will reduce medical errors, minimize paperwork, lower costs, and improve quality of care." These benefits are so vital to the U.S. economy and to patient safety that the Federal Government must take the lead, he said, adding "we expect major private payers will join ranks quickly in this effort."

To kick off the national strategy, HHS will appoint a 17-member advisory panel, with Leavitt serving as chairman. The task of the panel—a public-private collaboration called the American Health Information Community—will be to recommend how to make patients' health records digital and interoperable while safeguarding their privacy and security. To aid in this undertaking, HHS will contract with outside entities to help set data standards, certification, and architecture for an Internet-based national health information exchange.

HHS plans for the AHIC to be succeeded within five years by a private-sector health information community initiative to set additional needed standards, certify new HIT, and provide long-term governance.

The strategy announced by Leavitt reflects the recently released findings of the HIT Leadership Panel, which emphasized that "without a strong, explicit federal role, private sector efforts will be insufficient to achieve widespread adoption and use of HIT." Current efforts are highly fragmented, so incentives must be aligned to foster the adoption of HIT, the panel stressed.

The leadership panel, which included executives from companies that purchase substantial levels of healthcare for their employees as well as other industries that utilize IT, was established as part of the HHS Framework for Strategic Action. That blueprint for national adoption of HIT was issued in July 2004 by the national coordinator for HIT, David Brailer, MD, PhD. The President established Brailer's position by executive order in April 2004.

Not long after the leadership panel's findings were made public, the General Accountability Office issued its report, saying HHS still needed detailed plans and milestones for each phase of the Framework for Strategic Action, and HHS agreed. The first phase, now in progress, targets development of market institutions to foster HIT investment and reduce related risks, as well as looking at infrastructure prototypes such as regional health information exchanges. The second phase will focus on actual investment in clinical management tools and capabilities such as e-health records and telehealth. The third phase will support market shifts to reward providers for quality.

Legislative Incentives

S. 1227, introduced this month by Sens. Olympia Snowe (R-ME) and Debbie Stabenow (D-MI), would authorize $4 billion over five years in grants and tax incentives to help healthcare providers adopt HIT and related hardware and software upgrades. Roughly half of the funds would go to physicians, while $1.25 billion would go to hospitals, $500 million to skilled nursing facilities, and the rest to other providers. The bill also would allow Medicare payments to be adjusted for providers who use HIT to boost the quality of care and reduce costs. Snowe said the measure includes provisions to promote HIT adoption in rural and provider shortage areas.

H.R. 2234, introduced in May by Reps. Tim Murphy (R-PA) and Patrick Kennedy (D-RI), would authorize some $50 million in grants and loans in fiscal 2006 and such sums as necessary in the succeeding four years, to assist the development and operations of regional health informa-

KEY Q&As on HIT

- *What is health information technology?* It's information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of healthcare information, data, and knowledge for communication and decision-making.
- *What's included?* Applications such as use of the Internet and telemedicine.
- *What's a central component?* The electronic health record. This is a patient's medical file, which is stored electronically and maintained by a healthcare provider.
- *What does the e-health record support?* It supports ordering prescriptions and tests, informing clinical decisions, and developing a longitudinal record of events, decisions, and information pertaining to a patient's care.
- *What capabilities do e-health record systems include?* They include such capabilities as viewing, ordering, messaging, documenting, care management, analysis and reporting. Functionalities vary by software vendor, though efforts are underway to standardize them.

Source: *HIT Leadership Panel: Final Report.* Prepared by The Lewin Group, Inc.

tion organizations. The bill also would increase Medicare payments to physicians who participate in such networks and federal Medicaid matching funds to states that invest in such networks. Murphy and Kennedy said use of HIT will help prevent medical errors and curb the rising costs of care by reducing the need to repeatedly perform expensive testing on patients whose medical histories are difficult to locate. Their bill also would mandate an anti-kickback safe harbor and a Stark self-referral exception to encourage investment and participation in regional and community health information exchanges. The measure has support in the Senate from Hillary Rodham Clinton (D-NY) and Mel Martinez (R-FL).

Patient Safety Bill Promised By August

Prospects for a new voluntary, confidential system for reporting medical errors and near misses, including quality failures in laboratory testing, took a positive turn this month when Nathan Deal (R-GA), head of the House Energy & Commerce health subcommittee, said he aims to pass a bipartisan patient safety bill before Congress takes its August recess.

Deal said his staff is working with Senate counterparts to move the legislation, which has been stalled by partisan deadlock for several years. The Senate HELP Committee approved a bipartisan patient safety bill (S. 544) in March.

Current legislative efforts envision certifying a number of public and private organizations to act as patient safety organizations to analyze data and promote education on lessons learned and best practices. Previous efforts to enact patient safety protections have been stymied by issues involving confidentiality, litigation, and preemption of state laws. The American Medical Association says it's time to move from "the existing culture of blame, which suppresses information about errors, to a culture of safety, which focuses on sharing information to prevent future errors."

HIPAA Claims Attachment Proposal Expected This Fall

In September, the Centers for Medicare & Medicaid Services plans to propose HIPAA standards for electronic healthcare claims attachments, according to the semi-annual regulatory agenda recently published by the Department of Health & Human Services. The standards currently are in the departmental clearance process, a CMS official told *NIR*.

The proposed rule is expected to follow the lead of Health Level 7 and the Accredited Standards Committee X12N, which have been working to develop HIPAA claims attachment standards through industry consensus processes:

- HL7 has proposed standards and specifications for attachments to several types of claims, including lab claims.
- X12N has proposed use of a 004050 implementation guide of the 277 electronic data interchange format to request an attachment and the 275 format for sending an attachment, using HL7 as the messaging standard and LOINC as the code set.

Washington Publishing Co. (North Bend, WA)—the publisher of all the ASC X12N implementation guides under HIPAA—encourages HIPAA-covered entities to assess these documents soon, "so that feedback can be received by the standards

developing organizations in time to effect necessary and relevant changes before a final rule is published." The company sells copies of the documents at *www.wpc-edi.com/products/publications/attachments*.

Earlier this year, the National Committee on Vital & Health Statistics, which advises the HHS Secretary on HIPAA and other matters related to information technology, urged HHS "to encourage and support several different claims attachment demonstration projects and pilots" that would address issues such as cost, benefit, workflow requirements, implementation challenges, privacy concerns, and best practices.

Could the opportunity for public comment on the proposed rule become a vehicle for objections to a recommendation by the Medicare Payment Advisory Commission that laboratory test results be required on lab claims, an idea opposed by lab groups (*NIR, 26, 10/Mar 7 '05, p. 1*)? During the April 25 lab open-door forum, one CMS official seemed to suggest so. In response to a question about MedPAC's advice, that official said labs should make their views about it known when the rule is proposed. *NIR* later spoke with a different CMS official who was more circumspect, cautioning that top agency brass have yet to consider the proposed policy change, whether to agree with it, and, if so, what mechanism would be appropriate for reporting test results.

♦ QUESTION *of the* M·O·N·T·H

Our hospital lab often processes samples sent from a physician network. Medicare often denies coverage on grounds of lack of medical necessity. Can we shift the risk of non-payment for lack of medical necessity to the physician responsible for ordering the test? Can we charge the physician for performing the test and tell the physician to seek reimbursement directly from Medicare?

"This is a common problem," says attorney Robert Mazer with Ober/Kaler in Baltimore, MD. He noted that in June 1996, Barbara Wynn, deputy director of the Bureau of Policy Development at what was then the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services), advised a laboratory trade organization that Medicare policy doesn't bar a lab from assessing a penalty against a physician for the laboratory's loss (as opposed to claiming payment from the physician which could raise regulatory issues).

In the real world, however, Mazer continued, that won't work for a number of reasons—the physician will likely find another lab, and it's unclear whether this might result in a financial arrangement with the physician under the Stark self-referral prohibitions. And Medicare's direct billing law won't permit the physician to bill Medicare for tests performed by the hospital lab.

"If the physician doesn't provide a diagnosis code, the lab should remind the physician that he or she is legally required to do so by Section 4317(b) of the Balanced Budget Act of 1997," Mazer said. "Educational efforts regarding diagnosis codes, medical necessity, and use of the advance beneficiary notice (ABN) would also appear appropriate. If nothing works and the lab is losing money, the lab might advise the physician that it will not continue with the arrangement. Again, this may not be practically feasible, particularly for a hospital lab."

OIG Warns Labs Against Blood Collection Deals

These deals pose significant risk of fraud and abuse, the OIG says, including overutilization and inappropriate higher costs to federal healthcare programs

Laboratories that furnish physician clients with free blood collection samples, then pay the physicians to collect the samples risk violating the federal anti-kickback statute as well as possible exclusion from Medicare/Medicaid and civil money penalties, according to an advisory opinion from the HHS Office of Inspector General, posted June 13.

The lab that sought the opinion said that it draws blood from referred patients and does the testing on-site, then submits claims for these services to the patients' insurers, including federal healthcare programs. Some of the referring physicians want to draw the blood themselves during office visits and asked the lab to provide the supplies at no charge and pay them a per-patient amount for the draws. The per-patient amount would be negotiated, but would likely be no more than $3-$6 per patient and no more than once each day for each patient. The lab wants to enter this proposed arrangement because competing labs are doing so.

washington WATCH

There is substantial risk, warns the OIG, that the blood draw remuneration to the doctors—which could be twice as high as Medicare's $3 collection fee, along with the free supplies—is being offered in exchange for referrals. Moreover, any claims the lab submits for blood draws by the doctors would implicate the False Claims Act since Medicare pays only the person or entity that actually does the draw.

CMS Education or Propaganda?

The Centers for Medicare & Medicaid Services says it's revising a draft 2006 edition of *Medicare & You*, the annual handbook for beneficiaries. The draft drew harsh criticism from some consumer groups and from congressional Democrats who complained it contained errors and omissions that might mislead beneficiaries, such as how much they might have to pay under the new Part D drug benefit and their options in selecting a health plan.

Critics, including the Medicare Rights Center, say the draft served as a propaganda vehicle for the Bush Administration's privatization ideology by favoring HMOs and Medicare Advantage plans over traditional fee-for-service coverage. CMS officials stress that the agency has already made some revisions and will make more before finalizing the handbook.

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