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CLIA Advisory Panel Backs Major Cytology PT Changes

The panel's action is the first step toward revamping the CLIA PT program, but the College of American Pathologists is aggressively pushing an alternative, similar to the FDA's approach to assuring quality in breast cancer screening.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) is recommending major revisions to the CLIA cytology proficiency testing requirements, written in 1992 and implemented in 2005 amid much controversy, with critics assailing the rules as out of touch with current cytology science and practice.

CLIAC recommends expanding the testing interval from once each year to once every three years, doubling the slide set to 20 for all testing events (initial and repeat), and making the grading system the same for both cyotechnologists and cytopathologists.

The committee endorsed these and other changes at a June 20-21 meeting in Atlanta, GA, specially convened as a launch pad for revising the CLIA cytology PT rules *(National Intelligence Report, 27, 8/Feb 6 '06, pp. 4-5)*. CLIAC was established under CLIA (the Clinical Laboratory Improvement Amendments of 1988) to advise the government on CLIA scientific and technical issues. ➥ *p. 2*

Payment Proposal Is Mixed Bag For Pathology

Proposed changes to the Medicare physician fee schedule for calendar year 2007 would boost the work relative value units (RVUs) for certain pathology codes and increase the practice expense RVUs for the technical component (TC) of flow cytometry codes as well as the TC of the most frequently billed surgical pathology code, CPT 88305, but the combined impact of other policy changes would cut pathology payments overall by 6% next year and 7% by 2010.

The major factor driving down pathology payments is the increase proposed by the Centers for Medicare & Medicaid Services for primary care office visits. To fund the increase, the agency would redistribute $4 billion in Part B spending, according to an analysis by the College of American Pathologists.

If flow cytometry TC gains are finalized, the result would be a big increase for CPT code 88184, up about 22%, and 88185, up about 33%, while the TC for 88305 would rise by 6%, assuming Congress approves a fee update at least equal to that for 2006, or 0%. (Under the statutory update formula, a 4.6% cut is projected, though Congress is likely to intervene.)

The increases for CPT 88184 and 88185 are the same that CMS proposed last year, then cancelled as part of a broader problem the agency said it found with its PE methodology. Citing errors in calculating indirect PE RVUs and provider confusion over the new ➥ *p. 6*

INSIDE *NIR*

CMS releases list of new CPT codes for 2007 Part B lab fee schedule 3

Providers urged to join new campaign to boost seniors' use of Medicare preventive services—see *Focus* 4-5
— Screening tests payable under lab fee schedule
— Cancer screening payments under lab fee schedule

Table of Medicare-proposed RVUs for flow cytometry .. 6

House committees split over transition to ICD-10 coding system by 2009 6

CDC expected to recommend HIV testing as part of routine care 7

Citizens' group urges core health benefits for all Americans by 2012 8

Lab competitive bidding: Has CMS 'put the cart before the horse'? 8

The CLIAC recommendations do not touch on legislative fixes to the CLIA statute. The panel was advised by government officials that these were off the table and to stick to regulatory revisions.

CLIA Advisory Panel, *from p. 1*

In other recommendations, CLIAC would retain the four diagnostic categories for PT testing (unsatisfactory, normal or benign, low-grade squamous intraepithelial lesions or LSIL, and high-grade squamous intraepithelial lesions or HSIL), require at least one challenge per category, and eliminate the automatic five-point penalty for failure to distinguish between LSIL and HSIL. The PT slides would have to be field-validated, and PT vendors would be required to disclose their methods for validation. CLIAC also redefined "slide" as "challenge" to allow for new technologies, such as virtual slides, in addition to glass slides.

Next Steps

A team from the Centers for Medicare & Medicaid Services and the Centers for Disease Control & Prevention will draft proposed rules for public comment, based on CLIAC's work and data from the first year of cytology PT (2005), Judy Yost, the top CLIA official at CMS, told *NIR*. There is no timeline to complete the work, she acknowledged, but said CLIAC will stay involved. The committee will get an update on progress at its next meeting in September.

But there is an urgency for federal officials to "fast track" the proposed rulemaking, observers note. The regulatory route allows more flexibility to make changes, continue the existing program, and ward off a legislative threat to suspend it altogether until the rules are rewritten. That threat is the House-passed bill, H.R. 4568, championed by CAP and requiring that the PT program "reflect the collaborative clinical decision-making of lab personnel involved in screening or interpreting cytological preparations" (*NIR, 27, 6/Jan 9 '06, p. 3*). The bill has been referred to the Senate HELP Committee, which reportedly has deferred action, pending the outcome of the CLIAC meeting.

CAP Advocates Alternative Approach

While CAP is a CLIA-approved cytology PT provider, along with the American Society for Clinical Pathology, the College has fundamental objections to CMS's interpretation of the CLIA statute—in particular, the agency's stance that individuals must undergo PT. CAP reads the statute broadly, saying proficiency should be measured at the lab level since under normal working conditions, the screening is performed by a team of pathologists and trained medical staff.

Commenting on CLIAC's action, Thomas Wheeler, MD, FCAP, chairman of CAP's Council on Scientific Affairs, told *NIR* that it confirms what the College has been saying all along—the current program is seriously flawed and needs a makeover, not just a facelift. Dr. Wheeler, who is a professor and interim chair with the pathology department at Baylor College of Medicine in Houston, TX, testified on behalf of CAP at the CLIAC meeting. He said CAP favors the quality assurance approach adopted by the Food & Drug Administration under the Mammography Quality Standards Act (MQSA). That approach uses annual medical outcomes data audits that allow for voluntary training and/or testing, relies on internal corrective action vs. external enforcement, and rejects proficiency testing of the individual. The MQSA outcomes audit is similar to CLIA re-screening protocols, which enable a lab to evaluate its performance based on actual outcomes, he said. The existing cytology PT program, in contrast, judges an individual's competency in isolation and at only one point in time.

Under the CAP-favored approach, there is a lab responsibility on a day-to-day basis for what is going on, Wheeler said. "Individuals would be tested in the setting

where they normally operate, but we would not pass or fail them—corrective action would be up to the lab director." The CLIA rules already require the lab director to assure personnel competency, he noted. "The lab director would use the PT results as another tool to assess the lab's performance, and accrediting bodies would review the results based on the lab director's documentation."

The FDA rejected individual proficiency testing under the MQSA, citing lack of consensus on testing standards and measurements and because it was costly and duplicative, CAP argues. "The College thinks the reasoning for MQSA applies equally to CLIA," John Scott, vice president of CAP's division on advocacy, told *NIR*. "We see no reason for the significant [regulatory] differences, given that the CLIA lookback is probably more strict than under the MQSA." CAP will keep pressing for a legislative solution, he said. "We now have rules that stand to be significantly reworked, yet we continue to test under [them]. Why continue to test utilizing this regime? We think Congress should pick up the bill and suspend the program until they get it right."

New 2007 Lab Test Codes Unveiled, Pricing Input Sought

In advance of the July 17 public forum for receiving input on how payment levels should be established for new CPT codes on the 2007 Medicare Part B lab fee schedule, the Centers for Medicare & Medicaid Services has released a list of these codes (*see below*). The codes 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 rates to the new codes, using either the crosswalk or the gap-fill method (*NIR, 27, 16/Jun 12 '06, p. 1*). Under the crosswalk method, 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 carriers.

The July 17 forum will run from 10 a.m. to 3 p.m. (Eastern). To listen in, dial 410-786-3100 and, at the prompt, respond conference ID 178976. The CMS contact is *anita.greenberg@cms.hhs.gov*.

New CPT Codes For Which Fee Recommendations Are Sought
(Fifth digit to be finalized later)

Chemistry

1) 8210x:	Alpha-fetoprotein; AFP-L3 fraction isoform and total AFP (including ratio)
2) 8369x	Lipoprotein-associated phospholipase A2, (Lp-PLA2)
3) 8391x	Molecular diagnostics; RNA stabilization

Immunology

4) 8678x	Antibody; West Nile virus, IgM
5) 8678x	Antibody; West Nile virus

Microbiology

6) 8730x	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; Aspergillus
7) 8749x	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique
8) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
9) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique (For assays that detect methicillin resistance and identify Staphylococcus aureus using a single nucleic acid sequence, use 87641)
10) 8765x	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
11) 8780x	Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis

Source: CMS, June 19 notice.

focus on: *Disease Prevention, Early Detection*

Providers Urged To Promote Medicare Preventive Services

Over the past decade, Congress has greatly expanded the Medicare Part B preventive care and screening benefit, but many beneficiaries do not take advantage of these services. While beneficiaries visit their physician six or more times a year on average, many are not aware of their risk for disease or even that they may have a condition that preventive services are intended to detect, says the Centers for Medicare & Medicaid Services.

The agency has launched a new initiative to close this "prevention gap" and is urging healthcare providers to help spread the word. Healthcare professionals play a crucial role, CMS says, in educating Medicare patients about the benefits of clinical laboratory and other medical services to prevent disease from developing or to prevent serious complications of disease: "As a trusted source, your recommendation is the most important factor in increasing use of appropriate preventive services."

The "prevention gap" initiative comes as CMS has wrapped up work on the initial enrollment period for the Part D prescription drug benefit. Over 38 million beneficiaries—90% of people with Medicare—have the drug coverage, HHS Secretary Michael Leavitt announced this month. Of the additional 4.4 million who did not enroll, over three million are expected to meet low-income criteria and can sign up now without incurring a penalty, he said.

Medicare Part B covers the following preventive services and screening (subject to certain eligibility and frequency limits):

- ❑ A "Welcome to Medicare" initial physical exam by a physician.
- ❑ Screening for cancer (breast, cervical, colorectal, and prostate), cardiovascular disease, diabetes (plus diabetes self-management training, medical nutrition therapy, and supplies), glaucoma, and osteoporosis.
- ❑ Adult immunizations for influenza, pneumonia, and hepatitis B.
- ❑ Smoking and tobacco use cessation counseling services.

While many of the above are covered and payable under the Part B physician fee schedule, several crucial screenings are covered and payable under the lab fee schedule (*see table, p. 5*).

Utilization rates for some of the covered services are low, notes CMS. For example, in 2003, only

Cancer Screening: Medicare Lab Fee Schedule

HCPCS Code	*Allowed Services*	*Allowed Charges*	*Payment*
PROSTATE CANCER			
G0103	1,641,302	$42,070,568.76	$42,001,024.58
PAP SMEARS			
P3000	259,186	$3,796,892.45	$3,793,447.33
G0123	794,976	$21,816,114.15	$21,790,801.77
G0143	17,854	$493,480.02	$492,415.11
G0144	1,829	$53,675.17	$53,478.75
G0145	86,377	$3,039,160.80	$3,025,208.74
G0147	1,658	$26,056.68	$26,048.73
G0148	11,667	$231,707.58	$230,595.93
COLORECTAL CANCER			
G0107	1,826,251	$8,126,291.12	$8,106,056.07
G0328, G0328QW	33,044	$575,229.63	$560,047.26

Source: CMS, BESS data, calendar 2004.

36.3% of eligible beneficiaries had the Pap test and pelvic exam. According to other CMS data, the rate for prostate cancer screening is 54%; for mammography, 55%. The highest rate, 83%, is for cholesterol screening, added to the Part B benefit as of January 1, 2005. The lowest rate, 2%, is for the "Welcome to Medicare" physical exam, also added in 2005. As part of that exam, physicians are to provide education, counseling, and referral to clinical lab and other covered preventive services, including a brief written plan (such as a checklist) for obtaining these services.

Along with calling on providers to encourage seniors to tap the preventive services benefit, CMS wants to use the partnerships it developed with advocacy, volunteer, and other groups nationwide for enrollment outreach on the drug benefit, says agency administrator Mark McClellan, MD, PhD. The campaign will make a special effort to reach minorities age 65 and older, a population that is among the least likely to receive preventive services and that has higher rates of chronic illnesses.

Medicare Preventive Services: Screening Tests Payable Under Lab Fee Schedule, 2006

Code	*Test*	*Natl Fee Cap*
• Cardiovascular Disease (all beneficiaries, once every five years)		
82465	Cholesterol, total	$6.08
83718	HDL cholesterol	$11.44
84478	Triglycerides	$8.04
80061	Lipid panel (*includes above tests*)	$18.72*
• Diabetes (at-risk beneficiaries, once a year; those with pre-diabetes, twice a year)		
82947	Glucose; quant., blood (except reagent strip)	$5.48
82950	Post glucose dose (includes glucose)	$6.64
82951	Glucose; tolerance test (GTT), three specimens includes glucose	$17.99
• Prostate Cancer (all male beneficiaries age 50 and older, once a year)		
G0103	Screening PSA	$25.70
• Cervical, Vaginal Cancer (all female beneficiaries, once every two years; those at high risk, annually)		
P3000	Screening Pap smear, cervical or vaginal, by technician under physician supervision, any system	$14.76
G0123	Screening cytopathology, cerv/vag (any system), automated thin layer prep, by cytotechnologist under physician superv.	$28.31
G0143	Screening cytopathology, cerv/vag (any system), automated thin layer prep, with manual screening and rescreening, by cytotech under physician superv.	$28.31
G0144	Screening cytopathology, cerv/vag (any system), automated thin layer prep, by automated system, physician superv.	$29.85
G0145	Screening cytopathology, cerv/vag (any system), automated thin layer prep, by automated system and manual rescreening under physician superv.	$37.01
G0147	Screening cytopathology smear, cerv/vag, by automated system, under physician superv.	$15.90
G0148	Screening cytopathology smear, cerv/vag, by automated system, with manual rescreening	$21.23
• Colorectal Cancer (all beneficiaries age 50 and older; fecal occult blood test once a year)**		
G0107	FOBT, 1-3 simultaneous determinations	$4.54
G0328, G0328QW	As alternative to G0107, FOBT, immunoassay, 1-3 simultaneous determinations	$22.22

*Not capped, but most carriers pay at this rate. **Additional screening covered, but payable under the physician fee schedule: colonoscopy (once every two years for all beneficiaries, no minimum age limit), flexible sigmoidoscopy (once every four years), and barium enema as alternative to either.

Beneficiaries can learn about covered preventive services and screening, along with recommendations based on their personal characteristics, McClellan adds, by calling the Medicare hotline (800-633-4227) or going to *www.medicare.gov/health/overview.asp*. The 2007 Medicare handbook also will focus on preventive care.

CMS has developed various educational products and resources to help healthcare professionals and their staff become familiar with Medicare coverage and payment for preventive services. For more on each service, go to *www.cms.hhs.gov*, select "Medicare," and scroll down to "Prevention." For products to share with Medicare patients, go to *www.medicare.gov*.

Payment Proposal, *from p. 1*

proposed PE methodology, the agency scuttled all PE RVU changes and valued all physician services at 2005 levels (*NIR, 26, 21/Sep 12, '05, p. 1; 27, 3/Nov 14 '05, p. 1*).

Leading pathology and laboratory organizations, including the American Clinical Laboratory Association, have long lobbied for higher flow cytometry payments. In 2005, when CMS priced CPT's new coding system for flow cytometry, fees for both the TC and the physician's interpretation fell by as much as 50%. The system 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).

Independent laboratories that bill for physician fee schedule services would be clear winners under the combined impact of the proposed physician work and PE RVU changes: up 3% next year and 19% in 2010. Diagnostic testing facilities that bill for these services would see a decline of 2% in 2007 and 5% in 2010.

Though CMS proposes lower PE RVUs for the physician 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 at least a zero update).

The CMS proposal, published in the June 29 *Federal Register* (with a comment deadline of August 21), includes the required five-year review of physician work values, resulting in higher office visit payments, and an overhaul of the PE methodology. Practice expense includes the direct costs of running a practice such as clinical staff and equipment and indirect costs such as administrative staff and rent. PE RVUs account for $30 billion in physician fee schedule payments or about 45% of overall payments under the fee schedule.

Currently, CMS establishes PE RVUs by allocating aggregate specialty practice costs to specific procedures (the "top-down" approach). Now, the agency wants to adopt a "bottom-up" approach over a four-year transition period, calculating direct expenses by using procedure-level data for clinical staff time, supplies, and equipment. The agency also would modify the way indirect PE is determined and would eliminate the non-physician work pool, pricing these services instead under the standard PE methodology.

Flow Cytometry Codes:
RVUs Proposed For Determining Medicare Payments, 2007

CPT Code	Work	PE: Final '06/ Proposed '07	Malpractice	Total RVUs: Final '06/ Proposed '07	Fee: '06 vs. '07*
88184	0.00	1.32/1.62	0.02	1.34/1.64	$50.78/$62.15
88185	0.00	0.64/0.86	0.02	0.66/0.88	$25.01/$33.35
88187	1.36	0.45/0.43	0.01	1.82/1.80	$68.97/$68.21
88188	1.69	0.57/0.54	0.01	2.27/2.24	$86.03/$84.89
88189	2.23	0.75/0.68	0.01	2.99/2.92	$113.31/$110.66

Sources: CMS Notice of Proposed Rulemaking, *Federal Register,* June 29, 2006, and Medicare's final 2006 Physician Fee Schedule. *"Pure" fee, assumes no update to the conversion factor for 2006, $37.8975; does not include geographic practice cost adjustment.

Legislative Split Persists Over Switch To ICD-10

House committees that share jurisdiction over Medicare remain divided over the issue of replacing the current ICD-9 diagnosis and procedure coding system with the ICD-10 version by 2009. The changeover involves going from 13,000 diagnosis codes and 11,00 procedure codes under ICD-9 to approximately 120,000 diagnosis codes and 87,000 procedure codes. Moreover, ICD-9 data sets cannot be converted to ICD-10 data sets or vice versa, requiring a major coding/billing systems overhaul.

The Ways & Means Committee adopted its health subcommittee's bill (H.R. 4157), calling for an all-payer shift to ICD-10 by 2009, a provision opposed by a host of insurer, medical, and laboratory groups, including the American Clinical Laboratory Association, which argued for a deadline no sooner than 2012. The Energy & Commerce Committee approved its health panel's substitute H.R. 4157, which has no mandate for an ICD-10 transition (*NIR, 27, 16/Jun 12 '06, p. 1*).

The ICD-10 transition is part of broader legislation to promote the adoption of health information technology and e-health records by providers, including anti-kickback and Stark safe harbors that allow providers to furnish HIT resources to physician referral sources. ACLA is lobbying to ensure that clinical labs are included in the ranks of protected providers.

At press time, the differences between the two bills were to be negotiated by committee leaders and staff. One big concern is how much the ICD-10 transition and expanded safe harbors would cost Medicare. The House committees are awaiting further word on the "scoring" issue from the Congressional Budget Office. In a June 15 analysis, the CBO said the safe harbors would increase the volume of services and thus raise Medicare and Medicaid spending, but the agency did not specify by how much. The CBO also noted that moving to ICD-10 by 2009 would mean substantial transition costs to providers. House GOP leaders have said they do not want HIT legislation to increase federal spending.

Energy & Commerce did, however, approve an ICD-10 related amendment by its health subcommittee chairman, Nathan Deal (R-GA), stipulating that "in any regulation or action implementing ICD-10, the HHS Secretary shall ensure that no healthcare provider is required to code to a level of specificity that would require documentation of non-medical information on the external cause of any given type of injury."

New Guidelines Expected To Expand HIV Testing

Testing for the virus that causes AIDS would become part of routine medical care for most Americans, under changes proposed by the CDC to help further curb the spread of the infection.

The Centers for Disease Control & Prevention is at work on finalizing new HIV testing guidelines and expects to publish them in late summer, a CDC media spokesperson confirmed to *NIR*. Under proposed changes, HIV testing would become a standard part of routine medical care for every American, ages 13-64, regardless of risk or prevalence, unless the patient declines.

The testing is recommended as part of a general physical exam, and there would be no need for separate consent—general consent for medical care would suffice. Counseling is recognized as a critical part of HIV testing, but in the healthcare setting, it would be focused on individuals who test positive; pre-test counseling would not be required. For persons at high risk, annual testing is recommended. Adoption of the guidelines is voluntary, but they do influence how physicians care for patients and what insurers will pay for.

According to the CDC, about 25% of the one million Americans infected with HIV do not know it, and this group is most responsible for its spread. Routine testing has been successful in perinatal HIV prevention, the agency notes. Universal screening of pregnant women has led to dramatic declines in mother-to-child HIV transmission in the United States—from about 1,650 HIV-children born in the 1990s to about 144-236 today. "We hope to extend that success to other adults as well," said a CDC spokesperson.

Citizens' Group Weighs In On Healthcare Reform

The challenge ahead is to put "meat on the bones," said Sen. Ron Wyden (D-OR) who, along with Sen. Orrin Hatch (R-UT), added the working group provision to the Medicare reform law.

In a bid to go beyond policymakers and pundits, Congress, in the 2003 Medicare reform law, set up and financed a Citizens' Health Care Working Group to poll the public on reforms desired for the nation's healthcare system. That group released its 12-page report and interim recommendations this month, calling for "affordable healthcare" and "core health services for all" by 2012.

The group also backed guaranteed financial protection against high medical costs, development of integrated community health networks, more intensive efforts to improve the quality of care and efficiency, and new ways to help people with advanced incurable conditions get end-of-life care in the environment they choose.

The initial recommendations, posted at *www.CitizensHealthCare.gov* (with a comment deadline of August 31), reflect input from over 20,000 citizens who participated in more than 75 community meetings nationwide or who shared their views online. A final version is expected to be issued at the end of September and will go to the President for review and to the Congress, which is to hold hearings on the issues.

washington WATCH

Lab Competitive Bidding: 'Putting The Cart Before The Horse'

That's what the American Clinical Laboratory Association thinks of the request by the Centers for Medicare & Medicaid Services for comments on a new form for labs to bid under the pending Part B lab competitive bidding demonstration.

"We would expect this … to have been the last thing to be drafted so it would have actually reflected the bidding process," said ACLA president Alan Mertz. "We are being asked to comment on a form to implement a program that has yet to be formulated or subject to [additional] public comments by stakeholders."

The proposed demo sites have yet to be announced, so "it is impossible to envision submitting a bid without knowing the geography, approximate testing volume and mix, or the potential number of winners," Mertz noted.

For ACLA's full comments submitted to CMS, go to *www.clinical-labs.org.* For more on CMS's initial bidding demo report and the draft application, see *NIR, 27, 14/May 8 '06, pp. 1, 4-5.*

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