WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 09, Iss. 15, August 2009

Health Care Reform: Labs Battle Old, New Threats

Whether a productivity adjustment proposed in the House or a lab copay being weighed in the Senate will survive the next stage of health care reform is unclear. When lawmakers return in September, House Democratic leaders will have to reconcile reform bills passed by three committees. In the Senate meanwhile, the HELP committee has passed its bill, while Finance committee negotiators have pledged to work through August to craft a bipartisan compromise.

As Congress left town for its annual August recess, the clinical laboratory industry fended off a new threat to Medicare reimbursement rates, while lobbying heavily against an old one.

In the House, the industry got an agreement from the Energy and Commerce committee that when applying a new productivity adjustment to the annual update to the Part B lab fee schedule, the result could never fall below zero.

In the Senate, the industry faces an old nemesis, this time in Finance committee proposals under consideration that would require a 20 percent copayment for Part B covered lab services for the first time in the fee schedule's 25-year history.

The 26-member Clinical Laboratory Coalition (CLC), along with the AARP seniors' lobby, has registered its "strongest opposition" to the idea.

The CLC told key senators it would oppose any measure that includes this proposal. In a July 31 letter to Finance committee chairman Max Baucus (D-Mont.) and ranking Republican Charles Grassley (Iowa),

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New Certification Route to Open for Medical Lab Personnel

Under an agreement, effective Oct. 23 of this year, two national credentialing organizations will form a single agency to certify medical technologists and medical laboratory technicians. The new entity is called the ASCP Board of Certification (BOC).

The change was announced by the Board of Registry (BOR) of the American Society for Clinical Pathologists (ASCP) and the National Credentialing Agency for Laboratory Personnel (NCA) at the annual meeting of the American Society for Clinical Laboratory Science (ASCLS) in July. When the agreement takes effect, the NCA, formed in 1978, will be dissolved as a corporation.

The current certification designations for medical technologist (MT) and clinical laboratory scientist (CLS) will be replaced with a new title: medical laboratory scientist (MLS). The designation will be MLS(ASCP). The BOC also will offer an exam to support a certification program for a doctorate in clinical laboratory sciences (DCLS).

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The Clinical Lab Coalition is composed of leading clinical laboratory and pathology professional associations, national and regional labs, and test manufacturers and distributors.

Health Care Reform, *from p. 1*
the CLC noted that Congress has rejected this idea in the past and urged the committee to spurn it as a "financing mechanism" for health care reform.

Cushioning Impact of the Productivity Factor

Under the Energy and Commerce agreement, lab fees would be "held harmless" in 2010, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR*. They would get the inflation update under current law (the Consumer Price Index-U minus 0.5 percent), though it is projected to be minus 1.9 percent, the first time the update has fallen into negative territory in its 25-year history.

But beginning in 2011, the CPI-U update would be replaced by a productivity adjustment, and while the final result may not always be positive, it could never be negative. The productivity adjustment is an economywide factor estimated by the Bureau of Labor Statistics that the committee proposes to apply to all Part A and Part B providers not already subject to it. The theory is that fees should be adjusted annually to reflect savings from productivity gains.

The inflation rate to 2015 is currently projected to be 1.1 percent, while the productivity adjustment is expected to range from 1.2 percent to 1.4 percent over that period.

Copay Means New Costs to Seniors, Labs

In opposing the 20 percent copay, the CLC said it does not yield savings for health care reform but shifts $24 billion in new costs to beneficiaries and adds new administrative costs to labs that must collect the copay. It frequently costs more to collect the copay than what the lab can expect to receive. For the majority of the top 100 lab procedures, the copay is less than $2, the coalition said.

The copay will result in a costly "paper blizzard," said Dr. Mark Birenbaum, administrator for the American Association of Bioanalysts and the National Independent Laboratory Association, which are coalition members. "If passed, it will result in over a quarter of a million bills to be mailed every single day."

Seniors in rural areas, nursing homes, and home health settings served by small local labs would be hardest hit, said the CLC. These labs have tight operating margins and can "ill afford what is, in essence, a 20 percent to 25 percent cut in their reimbursement."

The copay would add "to already unacceptable cuts in payment for lab services" and impede advances in promising areas of lab medicine, the coalition concluded. "Medicare lab payments have been reduced by about 40 percent in real (inflation-adjusted) terms. The annual fee update has been eliminated in 10 of the last 12 years, and over the past 21 years, clinical labs have only received five full updates."

Medicare Trip Fee to Drop

As of Oct. 5, your local Medicare contractor will implement a new and lower Part B travel allowance to collect specimens from homebound or nursing home patients.

For code P9603, where the average trip exceeds 20 miles round trip, the new total is $1.00 per mile ($0.55 per mile, plus an additional $0.45 per mile to cover the technician's time and travel costs). Contractors have the option to pay more than the $1.00 minimum if local conditions warrant.

For code P9604, payable on a flat-rate trip basis, the new allowance is $10.00.

Current payment for P9603 is $1.035 per mile and for P9604 $10.35 (*NIR, 09, 1/Jan. 12, p. 6*).

The lower rates are effective back to Jan. 1 of this year, but contractors are not to search and adjust claims that have already been processed to either retract payment for claims or to retroactively pay claims. They are to adjust claims brought to their attention, however, the Centers for Medicare and Medicaid Services said in Change Request 6524 (Aug. 7, 2009).

focus on: Lab Payment Policy

Lab, Pathology Groups Propose Pricing for New CPT Codes on Medicare's 2010 Lab Fee Schedule

Leading national clinical laboratory and pathology groups are recommending that in most cases, Medicare should use the crosswalk method to establish payment rates for new CPT codes to be added to the Part B lab fee schedule, as of Jan. 1, 2010.

The groups presented their proposals (*see table, pp. 4-5*) to the Centers for Medicare and Medicaid Services (CMS) for pricing 13 CPT lab codes new to next year's fee schedule, in response to the agency's call for comment from the industry and the public.

CMS began the comment period at the July 14 open-door forum held to obtain input on whether to use the crosswalk method or the gap-fill method to establish fees for the new tests, as required by statute and regulations (*NIR, 09, 14/July 27, p. 2*).

Under the crosswalk method, a new test code is matched to a similar code on the fee schedule and paid at that rate. Payment is the lower of the local fee schedule amount or the national limitation amount (NLA). Most lab codes are paid at the NLA. The gap-fill alternative is used to set a fee when there is no comparable test and is based on local pricing patterns.

The New CPT Codes

Making their debut in 2010 are three new CPT codes in chemistry, three in immunology, two in tissue typing, three in microbiology, one for in vivo (eg, transcutaneous) lab procedures, and one in reproductive medicine (last two digits of codes to be finalized).

The test codes address conditions such as asthma and other pulmonary disease, bacterial infections and sepsis, cardiovascular disease, ovarian cancer, immunosuppression in organ transplant recipients, syphilis, pretransplant risk assessment, staph infections (including methicillin resistant S. aureas or MRSA), and Clostridium difficile associated disease.

Pricing Method Proposals

In their crosswalk recommendations, the lab and pathology groups represented in the table on pages 4 and 5 agree on pricing for chemistry code 839XX, immunology code 867XX, microbiology codes 871XX1 and 871XX2, and transcutaneous lab procedure code 887XX.

They differ over recommended code assignments for microbiology code 874XX and immunology code 863XX1 (HE4), but the crosswalks to the NLA equate to the same payment level, $30.38.

The groups split over proposed crosswalks, with resulting NLA highs and lows, for chemistry codes 841XX (a swing of $28.30 to $49.56) and 844XX ($18.91 to $26.47) and tissue typing codes 868XX1 ($86.02 to $124.79) and 868XX2 ($39.09 to $124.79).

For the new immunology code 863XX2, Cellular function assay (ATP), ASCP and CAP said they could not find an appropriate item on the lab fee schedule to recommend as

New CPT Codes on the 2010 Medicare Lab Fee Schedule: *Pricing Recommendations by Lab, Pathology Organizations*

Code/Descriptor*	Proposed Crosswalk	Current National Limit Amount (NLA)
CHEMISTRY		
839XX, pH; exhaled breath condensate	AACC, ACLA, ASCP, CAP, CLMA: 82800, Blood gases, pH only/$12.37 + 87015, Concentration, any type, for infectious agent/$9.75	$22.12
	ASM: No comment	N/A
841XX, Procalcitonin (PCT)	AACC, ACLA: 83880, Natriuetic peptide	$49.56
	ASCP, ASM, CAP, CLMA: 84146, Prolactin	$28.30
844XX, Thromboxane metabolite(s), including thromboxane if performed, urine	AACC, ACLA, ASCP, CAP: 83520, Immunoassay, analyte, quantitative; not otherwise specified	$18.91
	CLMA: 83520/$18.91 + 82570, Creatinine; other source/$7.56	$26.47
	ASM: No comment	N/A
IMMUNOLOGY		
863XX1, Human epididymis protein 4 (HE4)	AACC, CAP, CLMA: 86304, Immunoassay for tumor antigen, quantitative; CA-125	$30.38
	ACLA, ASCP, ASM: 86316, Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each	$30.38
863XX2, Cellular function assay involving stimulation (eg, nitrogen or antigen) and detection of biomarker (eg, ATP)	AACC, ACLA, ASM: 86353, Leukocyte transformation, mitigen or antigen induced blastogenesis/$71.58 + 82397, Chemiluminescent assay/$20.63	$92.21
	ASCP, CAP: 86353 + 82397 + XX	$92.21 + XX
	ASCP and CAP noted in their comments that they could not find an appropriate item on the lab fee schedule to recommend as the third code to represent the beads used as part of the assay. Recognizing that this is an incomplete crosswalk, they are supportive of using the gap-fill method if recommended by the manufacturer.	
	CLMA: No comment	N/A
867XX, Antibody, Treponema pallidum	AACC, ACLA, ASCP, ASM, CAP, CLMA: 86781, Treponema pallidium, confirmatory test (eg, FTA-abs.)	$19.34
TISSUE TYPING		
868XX1, Human leukocyte antigen (HLA) crossmatch, noncytotoxic (eg., using flow cytometry; first serum sample or dilution	AACC: 86361, T cells; absolute CD4 count/$39.09 x 3	$117.27
	ACLA, ASCP: 87536, HIV-1, quantification	$124.24
	ASM: 88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker	N/A. Code payable via physician fee schedule. Mean of limiting charge: $86.02
	CAP: 86356 ($39.03) x 3, Monoculear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen	$117.27

	CLMA: 88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker/$78.26 pure fee + 88185, each additional marker (list separately to code for the first marker)/$46.53	N/A. Paid on the physician fee schedule, $124.79 pure fee, unadjusted for locality.
868XX2, Human leukocyte antigen (HLA) crossmatch, noncytotoxic (eg., using flow cytometry; each additional serum sample or dilution (list separately in addition to primary procedure)	AACC, CAP: 86356, Mononuclear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen	$39.09
	ACLA, ASCP: 86361, T cells; absolute CD4 count	$39.09
	ASM: 88185, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (list separately to code for the first marker)	N/A. Mean of physician fee schedule limiting charge: $51.10
	CLMA: 88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker/$78.26 + 88185, each additional marker (list separately to code for the first marker)/$46.53	N/A. Paid via physician fee schedule, $124.79 pure fee, unadjusted for locality.
MICROBIOLOGY		
871XX1, Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed	AACC, ACLA, ASCP, ASM, CAP, CLMA: 87798, Infectious agent antigen detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique	$51.25
871XX2, Culture, typing; identification by nucleic acid sequencing method, each isolate	AACC, ACLA, ASCP, ASM, CAP: 87902, Infectious agent genotype analysis; hepatitis C virus	$375.88
	CLMA: 83890-83912 range; no specific code recommended	N/A
874XX, Infectious agent antigen detection by nucleic acid (DNA or RNA); Clostridium difficile, toxin gene(s), amplified probe technique	AACC, ACLA, ASCP, ASM, CLMA: 87798, Infectious agent antigen detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique	$51.25
	CAP: 87500, Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe techniques	$51.25
TRANSCUTANEOUS LAB PROCEDURES		
887XX, Hemoglobin (Hgb), quantitative, transcutaneous	AACC, ACLA, ASCP, CAP, CLMA: 88740, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemglobin	$7.33
	ASM: No comment	N/A
REPRODUCTIVE MEDICINE		
893XX, Unlisted reproductive medicine laboratory procedure	AACC: Unlisted codes not included on Medicare lab fee schedule	N/A
	ACLA: NLAs are not assigned to “unlisted” codes	N/A
	ASCP: Not applicable	N/A
	ASM, CAP, CLMA: No comment	N/A

CPT codes © American Medical Assn. *Last two digits to be finalized.
Acronyms: AACC-American Assn. for Clinical Chemistry, ACLA-American Clinical Laboratory Assn., ASCP-American Society for Clinical Pathology, ASM-American Society for Microbiology, CAP-College of American Pathologists, CLMA-Clinical Laboratory Management Assn. The American Association of Bioanalysts and the American Society for Clinical Laboratory Science did not submit comments.

the third code to represent the beads used as part of the assay. Recognizing that this results in an incomplete crosswalk, they are supportive of using the gap-fill method if recommended by the manufacturer.

New G Codes

None of the groups had recommendations for new G codes for qualitative drug screens that CMS will add to the 2010 lab fee schedule:

- ❑ GXXX1, Drug screen, qualitative; multiple drug classes, any method, each procedure (eg, multiple drug test kit)
- ❑ GXXX2, Drug screen, qualitative; single drug class method (eg, immunoassay and enzyme assay), each drug class

Reconsideration Request

CMS invited feedback on a request by Abbott Diagnostics to change the crosswalk for CPT 83876, Myeloperoxidase (MPO), introduced to the lab fee schedule this year, to 83880, Natriuretic peptide (BNP). The MPO test is a quantitative marker used to predict myocardial infarction in patients with chest pain. The current crosswalk is capped at $18.91 versus the cap of $49.56 for 83880.

The American Association for Clinical Chemistry, the American Society for Clinical Pathology, and the Clinical Management Association agree that the crosswalk should be to 83880, as they recommended last year for the 2009 lab fee schedule, noting that the tests are similar in method and clinical application. Both use enzyme-linked immunosorbant assay (ELISA) technology and are cardio markers used to evaluate risk in patients with chest pain.

Next steps in lab fee-setting process: CMS typically makes public its tentative fee decisions in September, followed by a two-week period for additional comments. Final decisions will be announced in the 2010 Part B lab fee schedule via a program transmittal to local contractors. The final fee schedule is typically released in November.

CLMA noted in a letter to CMS that the agency's decision to crosswalk the MPO code to 83520 at a significantly lower payment rate ($18.91) "has seriously impacted a lab's ability to offer this test and provide patients at risk for myocardial infarction (MI) access to this cutting-edge technology. Preventing MI costs less than the complications."

The American Clinical Laboratory Association supports crosswalking the MPO code to CPT 82045, Albumin; ischemia modified (currently capped at $49.56), as it had proposed for the 2009 lab fee schedule. ACLA noted that "in conjunction with clinical history and electrocardiogram, MPO provides different information than either BNP or troponin and thus can identify patients with chest pain who are at risk of MI but have neither a positive troponin level or EKG changes. Other than 82045, the other cardiac measurement assays/CPT codes do not represent the same type of measurement as MPO."

The College of American Pathologists advocates a crosswalk to CPT 82553, Creatine kinase (CK), (CPK); MB fraction only (currently capped at $16.86), saying it represents a corresponding condition to 83876 for use in the diagnosis of MI.

Under reconsideration request procedures adopted in the final 2008 physician fee schedule rule, clinical labs, other providers in the industry, and the public may ask CMS to review a final fee for a new test, including the method used to derive the fee and the payment amount. "New test" is defined as "any test for which a new or substantially revised HCPCS code is assigned on or after Jan. 1, 2008." Affected parties who think the final fee should be gap-filled instead of crosswalked or vice versa have 60 days following release of the final rates to request a reconsideration. It is up to CMS to decide whether to reconsider and, if so, whether to make the change. Either way, the agency's decision is final. There are no further rights to appeal.

New Certification Route, *from p. 1*

The associate-level certification designation will be medical laboratory technician or MLT(ASCP), while the cytogenetics designation will be technologist in cytogenetics or CG(ASCP). The ASCP suffix will attach to each certification designation offered by the board.

In dealing with the BOR and NCA exams, the board will evaluate whether to hybridize them into one or offer two exam levels. The new credential is MB(ASCP).

Benefits of the Accord Touted

ASCP BOR chair Kathleen Becan-McBride, MT(ASCP), said the agreement "will increase the credibility of the clinical lab profession when advocating on legislative and regulatory issues. Also, a single credential and single standard of qualification will simplify entry into the profession for new graduates, and employers will find it easier to set standards for entry-level competency that will ensure patient safety."

What Does the Changeover Mean for You?

How is my current status affected?

If you are due to recertify this year, recertify on schedule. By maintaining your active credential you will ensure the transfer of your credential to the new BOC. No examinations will be required for the transfer.

Can I get a credential from the BOC without taking an examination?

If you are not currently certified with the ASCP Board of Registry or the NCA, you cannot get a credential without taking an exam. This would be a violation of the certification board's accreditation.

Do I need to take both exams?

You can register to take NCA exams up until Aug. 21, 2009. After that date, there will be only one combined agency offering examinations.

When will I get my newly designated credential?

The new credentials of MLS(ASCP)^{cm} or MLT(ASCP)^{cm} will be conferred at the time of mandatory or voluntary recertification for the current certification designation of CLS/MT and CLT/MLT. (The superscript indicates certification maintenance, i.e., recertification.)

Governance of New Certification Board

The board of governors of the new agency will be composed of five ASCP Fellows (pathologists), five ASCP lab professionals, four representatives of the ASCLS, two representatives of the Association of Genetic Technologists, eight representatives from the eight participating societies respectively, and one public representative.

The participating societies are the American Association of Bioanalysts, American Association for Clinical Chemistry, American Association of Pathologists' Assistants, American College of Microbiology, American Society for Cytopathology, American Society of Hematology, CLMA, and the National Society for Histotechnology.

The new BOC will operate with complete autonomy from all parent organizations, as required for continued accreditation by the American National Standards Institute (ANSI).

Connecticut Requires Direct Billing for Anatomic Pathology

Connecticut Governor M. Jodi Rell (R) signed into law on July 8 legislation that prohibits an ordering physician from billing patients for anatomic pathology services performed or supervised by another physician. This prevents a treating physician from profiting by charging a patient the full price for a service he or she received at a discount.

Enactment of the markup prohibition was a key priority of the Connecticut Society of Pathologists, in partnership with the College of American Pathologists.

A violation would exempt a patient or third-party payer from reimbursing the provider submitting the claim. Further, a provider engaged in illegal conduct under the state's law can be sanctioned by the Connecticut Medical Examining Board resulting in the restriction, suspension, or revocation of a medical license.

Connecticut is the 16th state to enact a pathology direct billing law, notes the College of American Pathologists. The others are Arizona, California, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Montana, Nevada, New Jersey, New York, Ohio, Rhode Island, South Carolina, and Tennessee. Direct billing has been a Medicare requirement since 1984.

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

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27th Annual Lab Institute: Advancing in the Eye of the Storm
Crystal Gateway Marriott Hotel
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Nov. 12
Lab Leaders Summit Driving Growth in Your Business
The Princeton Club of New York
New York City

Dec. 7-9
Laboratory Sales and Marketing Conference: Scaling New Heights in a Volatile Market
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 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com. Order Line: (212) 629-3679.

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