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CMS Challenged Over Preliminary Fees for New Lab Codes

Lab and pathology groups say the science behind CMS's decisions is incorrect and fails to value most of the tests properly, resulting in lower reimbursement, especially for new chemistry codes.

Clinical laboratory and pathology organizations have strongly objected to preliminary payment rates that the Centers for Medicare and Medicaid Services has set for new CPT codes to be added to the 2009 Part B lab fee schedule, effective Jan. 1.

The groups fault CMS for ignoring its own policy requirements as well as the majority of recommendations they made on pricing for the new codes, and they urge the agency to reconsider before it publishes the final payment amounts.

The preliminary fee decisions cover six new CPT lab codes (*see table, p. 3*). One is a replacement code (88720) for the current bilirubin code 88400 that has been deleted from the CPT coding update for 2009 and renumbered. The other new codes are in chemistry, hematology and coagulation, microbiology, and in vivo lab procedures.

In announcing its initial decisions, CMS said, "Based on clinical judgment and public input gathered from and after the July 14, 2008 lab public meeting, these new codes were crosswalked to current codes that were sufficiently similar in process and outcomes." *Continued on p. 2*

INSIDE *NIR*

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Lab Fee Increase in 2009 May Be 'As Good as It Gets'

At the end of this year, the five-year freeze on annual updates to the Medicare Part B lab fee schedule expires and payment rates will increase by a hefty 4.5 percent on Jan. 1, 2009. But a gain of this size is likely the high water mark for clinical laboratories for the foreseeable future, given the economic outlook, the soaring federal deficit, and pressures to cut Medicare and other federal spending, industry analysts tell the *National Intelligence Report*.

The Medicare budget squeeze will get even tighter, analysts say, as the next Congress grapples with a physician fee fix and where to find the billions of dollars needed to pay for it. Physician fees have been raised 0.5 percent through 2009, but thereafter, double-digit cuts are scheduled under the statutory fee update formula.

Moreover, whoever wins the White House is expected to propose Medicare spending reductions. In Republican John McCain's health care reform plan, program savings would be achieved by reforming provider payment systems and eliminating fraud. Democrat Barack Obama's plan specifically calls for eliminating the 12 percent higher payment that Medicare managed care plans receive vs. traditional fee-for-service.

CMS is pricing the six new lab codes using the crosswalk method. None are being gap-filled. In a crosswalk, 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 cap. Most lab codes are paid at the cap.

New Lab Codes, *from p. 1*

But the crosswalks veer sharply for the most part from those recommended by the lab industry and result in lower test fees than the industry has advocated. This is notable for the new hematology and coagulation code 85397 for abnormal blood clotting, but is even more pronounced for the new chemistry codes—83876 for myocardial infarction and 83951 for chronic liver disease—which would see a drop of 50 percent or more in their payment amounts.

"The lower pricing that CMS is recommending for [these] codes could impact patient access because it jeopardizes a laboratory's ability to offer cutting-edge technology that will save lives, improve quality of life, and save the health care system money," the Clinical Laboratory Management Association warned in comments to the agency.

In their crosswalk recommendations, lab and pathology groups agree on pricing for chemistry code 83951 and in vivo code 88720. For the hematology and coagulation code 85397, they differ on code assignments, but the crosswalks equate to the same payment level. For the other codes, the groups split over favored crosswalks and related fees.

Where's the Public Input?

This is the overarching criticism that lab and pathology organizations have leveled at CMS. In comments to the agency, these groups say the rationale underlying the preliminary fee decisions ignores the clinical and technical information they submitted to back up their recommendations.

In its comments to the agency, the American Clinical Laboratory Association said, "If CMS is going to reject all of the recommendations that were made by industry representatives, then CMS should, at least, explain why its determinations are preferable to those proposed by all of the outside organizations who have the greatest experience and expertise in this area."

CLMA noted, "When CMS ignores expert public input, the underlying congressional intent that mandates this [public fee-setting] process is not being met. Finally, improper and inconsistent pricing decisions like these will affect new assays coming in the future if they are crosswalked to codes that were incorrectly crosswalked during this process."

The American Society for Clinical Pathology warned CMS that "ignoring information provided as part of the public comment process could undermine the agency's goal of gathering the charge, cost, and clinically detailed information . . . to determine reimbursement for new clinical lab tests in the future."

Another Chance to Ask CMS to Reconsider

Even if CMS makes final its recently released fee decisions, providers who disagree have another opportunity to ask the agency to reconsider. Under procedures adopted in the final 2008 physician fee schedule rule, clinical labs, other providers in the industry, and the public may request a reconsideration of the final fee determination for a new test, including the method used to derive the fee and the payment amount set.

Providers 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 change the prior final fee determination. Either way, the agency's decision is final. There are no further rights to appeal. CMS's ultimate determination is effective in January of the following year.

Medicare Pricing of New 2009 CPT Lab Codes: CMS Preliminary Decisions vs. Lab, Pathology Crosswalks

Code/Descriptor	CMS Crosswalk	Natl Fee Cap
CHEMISTRY		
83876, Myeloperoxidase (MPO)	83520, Immunoassay for analyte other than infectious agent antibody or infection agent antigen, qualitative or semiquantitative, multiple step method; not otherwise specified	**$18.09**
Lab/Pathology Recommendations	ACLA: 82045, Albumin, ischemia modified	$47.43
	CAP: 82553, Creatine kinase (CK) (CPK); MB fraction only	$16.13
	ASCP, CLMA: 83880, Natriuretic peptide	$47.43
83951, Oncoprotein; des-gamma-carboxy-prothrombin (DCP)	82491/$25.23 plus 83520/$18.09	**$43.32**
Lab/Pathology Recommendations	AACC, ACLA, ASCP, CAP, CLMA: 83950, Oncoprotein; HER-2/neu	$89.99
HEMATOLOGY AND COAGULATION		
85397, Coagulation and fibrinolysis, functional activity, not otherwise specified (e.g., ADAMTS-13), each analyte	85230	**$25.02**
Lab/Pathology Recommendations	CAP: 85245, Clotting factor VIII, von Willenbrand factor, ristocetin cofactor	$32.06
	ACLA: 85246, Clotting factor VIII, VW factor antigen	$32.06
	ASCP, CLMA: 85247, Clotting factor VIII, VW factor, multimetric analysis	$32.06
	AACC, ASM: n/c	
MICROBIOLOGY		
87905, Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)	82657, Enzyme cell activity, nonradioactive substrate, each specimen, minus 87176, homogenization, tissue, for culture	**$17.01**
Lab/Pathology Recommendations	ASCP, ASM, CLMA: 82657, Enzyme cell activity, nonradioactive substrate, each specimen	$25.23
	AACC: 87808, Trichomonas vaginalis assay with direct optical observation	$16.76
	ACLA: 87810, Chlamydia trachomatis assay with direct optical observation	$16.76
	CAP: 82657/$25.23 less 87176, Homogenization, tissue, for culture/$8.22	$17.01
IN VIVO (E.G., TRANSCUTANEOUS) LABORATORY PROCEDURES		
88720, Bilirubin, total, transcutaneous. This code replaces 88400, which has been deleted from the CPT 2009 and renumbered as part of a subsection for in vivo lab procedures.	N/A	N/A
88740, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin (For in vitro carboxyhemoglobin measurement, use 82375)	½ of payment for 88720 ($7.02)	**$3.01**
Lab/Pathology Recommendations	ASCP: 88400, Bilirubin, total, transcutaneous	$7.02
	CAP: ½ of 88400	$3.01
	AACC, ACLA, ASM, CLMA: n/c	
88741, Hemoglobin, quantitative, transcutaneous, per day; methemoglobin	½ of payment for 88720 ($7.02)	**$3.01**
Lab/Pathology Recommendations	ASCP: 88400, Bilirubin, total, transcutaneous	$7.02
	CAP: ½ of 88400	$3.01
	AACC, ACLA, ASM, CLMA: n/c	

 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.

focus on: Medicare Policy Issues

Legislative Update on Lab, Pathology Priorities

Lobbying by clinical laboratory and pathology interests scored big wins on key legislative priorities this year, but with the second and final session of the 110th Congress winding down, prospects for passage are fading for a host of other bills supported by various industry groups.

Even if a lame-duck session is convened after the Nov. 4 elections, economic woes and work on another stimulus package are sure to eclipse all other congressional business. So the pending bills will likely die with this Congress and will have to be reintroduced in the 111th Congress, whose first session opens in January.

Recap of Major Gains

The final Medicare reform measure and the new genetic anti-discrimination law incorporated these top pathology and laboratory objectives:

- Preventing further cuts in pathology and other fees payable under the Part B physician fee schedule and gaining a fee increase. Congress granted a 0.5 percent hike through 2009. But with another round of deep cuts looming in 2010 under the current SGR (Sustainable Growth Rate) update formula, the College of American Pathologists and other physician groups want lawmakers to jettison the SGR formula and redo the system that Medicare uses to reimburse physician services to avoid the need for "Band-Aid" fixes. Paying for the change would require cuts elsewhere in the Medicare budget.
- Extension of the "grandfather" protection for technical component billings by independent labs for anatomic pathology services to hospital inpatients and outpatients. The Centers for Medicare and Medicaid Services first proposed eliminating this protection in 1999, but Congress has repeatedly blocked the move. The latest extension runs through 2009, and pathology and lab groups favor making the protection permanent.
- Securing a Consumer Price Index update for the Part B lab fee schedule, the first since the update was frozen at the start of 2004 at the previous year's levels. Congress granted the CPI update minus 0.5 percent, which equates to a 4.5 percent increase in 2009. In the coming year, the lab industry aims to forestall any move to reduce the update further to help pay for other Medicare reforms.
- Repeal of the competitive bidding demonstration for independent lab services that CMS had planned to launch in San Diego last July.
- The Genetic Information Non-discrimination Act (GINA) prohibits employers and health insurers from discriminating against individuals based on their genetic information and test results. The ban applies to employment agencies, labor unions, and Medicare supplemental policy plans as well. While GINA establishes uniform national safeguards, it does not preempt state protections against genetic discrimination. GINA removes major barriers to use of genetic testing in personalized medicine, advocates say, by encouraging people to get tested without fear of reprisal and enabling physicians to customize care to the patient's unique genetic profile.

Recap of Pending Pathology, Lab Bills

• *CLIA Cytology PT Overhaul*

Senate bipartisan support continues to grow behind legislation that would overhaul CLIA cytology proficiency testing (S. 2510), with five new co-sponsors signing on in the last two weeks of September and one more at the start of this month, reports the College of American Pathologists.

The new senators signing on are: Democrat Byron Dorgan (N.D.), and Republicans Jeff Sessions (Ala.), John Sununu (N.H.), Jim Bunning (Ky.), Lindsey Graham (S.C.), and John Cornyn (Texas) As of press time, S. 2510, introduced by Sen. Mary Landrieu (D-La.) had a total of 42 co-sponsors.

Despite gains in the Senate, the bill's chances for passage this year are "up for speculation," an industry source told *NIR*, adding that final action is unlikely given the overriding concern in Washington about the economy. The House approved an identical version of the bill earlier this year.

But CAP and others in the 60-member Cytology Improvement Coalition of national and state pathology groups plan to push the legislation next year, building on the momentum gained thus far in the House and the Senate.

The legislation would terminate the current CLIA program for gynecologic cytology PT, in force nationwide since the start of 2005, and replace it with a continuing medical education (CME) alternative to assure patient health and safety in Pap testing. The clinical laboratory would be required to ensure that:

- ❑ All individuals who screen and interpret cytological preparations participate annually in an approved CME program that provides each participant with gynecologic cytologic samples designed to improve locator, recognition, and interpretive skills.
- ❑ A record is maintained of program results and available for inspection.
- ❑ The laboratory director considers such results and other performance metrics in reviewing the performance of individuals involved in screening and interpreting cytological preparations.
- ❑ The laboratory director submits the continuing education program results for each individual and plans for corrective action or remedial training in a timely manner to the laboratory's accrediting organization for purposes of review and ongoing monitoring.

The current CLIA cytology PT program has been highly controversial since the government began enforcing PT requirements nationwide. The coalition says the program is outdated, based on rules written in 1992, and does not reflect changes since then in cytology science and practice. The House and Senate bills offer a better approach, CAP argues, "by challenging screening and interpretation skills in a constructive learning environment and, over time, keeping pace with advances in science and technology."

Meantime, cytology PT testing continues under the current CLIA program. CAP and the American Society for Clinical Pathology are the two nationally approved PT providers. The Maryland health department runs an approved program for specimens of state residents.

• *Lab Fee Modernization*

House legislation (H.R. 6761), introduced July 31 and backed by the American Society for Clinical Laboratory Science and the Clinical Laboratory Management

Association, would require a negotiated rulemaking process to revamp the Medicare lab fee schedule based on the value of the testing, the resources required, and geographic cost differences. The bill is sponsored by Reps. Bart Stupak (D-Mich.) and Michael Burgess (R-Texas).

No action is expected this year, but CLMA said the bill was introduced "to get the idea out there and gain ground to push hard for it next year when the new Congress is expected to take up health care reform." H.R. 6761 is intended to start a process to obtain input from all stakeholders, CLMA said. While it contains provisions to guide the rulemaking (such as tapping the Institute of Medicine report on lab payment alternatives), it does not prescribe the outcome. "The Medicare lab fee schedule was adopted in 1984," CLMA noted, "and has not been subject to a fundamental review and updating since then to reflect changes in the delivery of clinical lab medicine, resulting in real reductions in reimbursement."

CLMA and ASCLS would like to get a Senate counterpart bill introduced this year and have also sought backing from other groups in the 10-member Clinical Laboratory Coalition.

• *Another Alternative to the Lab Fee Schedule*

Bipartisan House and Senate bills, H.R. 1321 and S. 2404, supported by AdvaMed, the leading trade group for medical device manufacturers, would establish a demonstration project to evaluate new approaches to Medicare payment for clinical lab tests, starting with new molecular diagnostic tests. The bills also call for new rules on the gap-filling method, which uses local pricing patterns to establish fees, increased transparency in how fees are set for new tests, and advance notice of test fees being considered for adjustment under inherent reasonableness authority.

Relying on the crosswalk method is flawed, AdvaMed argues, because the fee schedule lags behind new technologies and does not reward their value, raising barriers to innovation and beneficiary access. Also, when considered in light of fee limits enacted by Congress since the current fee schedule was introduced in 1984, it is way out of date, says AdvaMed.

• *Increase in Specimen Collection Fee*

Rep. Phil English (R-Pa.) has sought repeatedly to get Congress to raise the Medicare fee for specimen collection, but this year, as in the past, his legislation has languished since being introduced. The fee has remained at $3 per encounter since 1984. His bill, H.R. 1501, introduced in March last year with five co-sponsors, would set "the fee at $6.07 for 2008 and be adjusted for inflation in subsequent years to cover the appropriate cost of collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made."

• *Lab Personnel Training*

Bipartisan Senate legislation—S. 605, the Allied Health Reinvestment Act, backed by the American Society for Clinical Laboratory Science, among others—would authorize funding for Title VII programs to promote careers in allied health and to educate and train allied health personnel, especially in critical shortage areas. Support would include grants to facilitate and expand student enrollment and to develop internship and resident programs, loans for faculty development, and scholarships for students who agree to provide service in rural and other medically underserved areas. S. 605 specifically includes clinical lab sciences, medical technology, and cytotechnology.

♦ Medicare Claims *Advisory*

New Interest Rate for Overpayments, Underpayments

Effective Oct. 22, Medicare has increased the rate of interest it will pay you for claims that were underpaid or collect from you for claims that were overpaid.

The new interest rate is 11.375 percent, up from 11.125 percent from July 24 through Oct. 21 and back to the level it was in the period from April 18 through July 23. At the start of this year, the rate was 12.5 percent. The highest rate over the last eight years was in early 2001—14.125 percent.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (5 percent for calendar 2008) or the private consumer rate fixed by the Treasury Department. The Centers for Medicare and Medicaid Services announced the effective date of the new private consumer rate in Change Request 6238.

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2009

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Crystal Gateway Marriott ★ Arlington, Va.

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More Time Needed for ICD-10 Switch, Say Provider Groups

The change would require providers to go from having 17,000 procedure and diagnosis codes in ICD-9 to more than 155,000 in ICD-10.

An array of provider groups is urging the federal government to reassess its timeline to replace the ICD-9 diagnosis and procedure coding systems used in HIPAA transactions with ICD-10 code sets. The government has proposed to make the switch by Oct. 1, 2011 (*NIR, 29, 21/Sep 15 '08, p. 1*).

According to a study commissioned by 11 health care provider groups, including the American Clinical Laboratory Association, the costs for the transition in such a short time are "markedly higher than what [the government] has estimated and will place a major burden on providers, taking valuable time away from patients and straining other resources needed to invest in health information technology." For a 10-physician practice, the estimated cost is more than $285,000; for a three-doctor practice, $83,290; for a 100-doctor practice, more than $2.7 million.

The study was released Oct. 14, the same day that the Centers for Medicare and Medicaid Services initiated a series of conference calls to explain ICD-10. In that session targeted to hospitals, CMS said no final decision has been made on the implementation date. The next calls are Nov. 12 for other Part A/B providers and Nov. 17 for physicians. To register, go to *www.cms.hhs.gov/ICD10*.

Latest on Lab Competitive Bidding Lawsuit

Although Congress this year killed the Medicare competitive bidding demonstration for independent lab services, there is still unfinished business in the lawsuit that local labs filed in federal district court to stop the demo's planned July 1 launch in San Diego.

The Centers for Medicare and Medicaid Services has asked the court to dismiss the case as moot now that lawmakers have terminated the demo. But the lab plaintiffs have opposed this motion. They want CMS to return the bid applications submitted and make no use of the bid information for Medicare pricing purposes.

Judge Thomas Whelan opted not to hold a hearing on Sept. 22 to air the dueling motions; instead, he will decide the case based on the briefs submitted by the rival parties. At press time, both sides were awaiting his ruling.

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