WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 29th Year of Publication

Vol. 29, No. 19, July 28, 2008

Labs Score Big With Repeal of Medicare Bidding Demo

The death of the lab bidding demo was one of several laboratory and pathology "must-pass" priorities included in the final Medicare bill that became law this month. For details, see the Focus, pp. 4-5.

For the clinical laboratory industry, it was the long desired outcome of a four-year lobbying campaign. The Part B competitive bidding demonstration for independent clinical lab services was repealed when Medicare legislation (H.R. 6331) became law after Congress overrode the president's veto on July 15. The government had planned to launch the demo July 1 in San Diego, but a court order stopped the project earlier this year.

Repeal of the demo, coupled with the first increase in Medicare lab fees in five years (*related story below*), represents the most significant victory for the lab industry in decades, a Washington insider told *NIR*.

Labs and pathologists also gained from provisions in the new law that:

- ❑ Extend, through 2009, the TC "grandfather" protection that expired July 1. This allows qualified independent labs to continue to bill separately for certain anatomic pathology services to hospital patients.
- ❑ Reverse the cut in physician fees that took effect July 1 and replace it with a 0.5 percent increase through the rest of this year and a 1.1 percent increase for 2009.

INSIDE *NIR*

www.g2reports.com

Lab Fees Due to Rise 4.5 Percent in 2009

With the five-year fee freeze expiring Dec. 31, Medicare's Part B clinical laboratory payment schedule is projected to get a 4.5 percent update starting Jan. 1, 2009. This is the highest yearly update since 1990, when fees rose 4.7 percent. The highest was two decades ago, 5.4 percent in 1987.

The Centers for Medicare and Medicaid Services announced, in its proposed 2009 physician fee schedule rule, that the lab fee schedule will be updated next year by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) for the 12-month period ending June 30, 2008.

For this period, the unadjusted increase in the CPI-U is 5 percent, according to data just released by the Bureau of Labor Statistics. Since the new Medicare law reduces the lab fee update by 0.5 percent in 2009, the net increase for labs will about 4.5 percent (the adjusted figure could vary by a few tenths of a percent higher or lower). Until the release of the BLS data, the assumed CPI update was around 2 percent.

Continued on p. 7

Crosswalks Proposed for Medicare Pricing of New 2009 Lab Codes

Leading national clinical laboratory and pathology groups are all recommending that Medicare 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, 2009.

The groups submitted their crosswalk recommendations to the Centers for Medicare and Medicaid Services at the agency's July 14 open-door forum to obtain public input on the fee-setting process for new and revised tests, as required by statute and regulations.

Under the crosswalk method, a new test code is matched to a similar code on the fee schedule and is 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. The gap-fill alternative is used to set a fee when there is no comparable test and is based on local pricing patterns.

Making their debut in 2009 are two new CPT codes in chemistry, one in hematology and coagulation, one in microbiology, and three in a new subsection for in vivo laboratory procedures. The codes address conditions such as myocardial infarction, chronic liver disease leading to development of hepatocellular carcimona (HCC), the functional activity of proteases and other proteins in coagulation and fibrinolysis not currently specified in CPT, and detection of infectious agents other than virus by enzyme activity.

In their crosswalk recommendations, the lab and pathology groups agree on pricing for chemistry code 8395X and in vivo code 8872X. For the hematology and coagulation code 85XXX, they differ on recommended code assignments, but the crosswalks equate to the same payment level. For the other codes, there is a sharp split over favored crosswalks and related fees (*see table*).

At the CMS meeting, the American Clinical Laboratory Association and the Clinical Laboratory Management Association renewed their request that the agency reconsider its payment policy for CPT 80047, Basic metabolic panel (ionized calcium). Effective July 1, Medicare began paying for the panel at the rate for 80048, Basic metabolic panel (total calcium), or $11.83 in most regions. CMS also included the panel in composite rate payment for testing of end-stage renal disease patients.

ACLA and CLMA want the policy reversed, noting that the ionized calcium does not qualify under Medicare's definition of an automated chemistry test and must be run on a separate instrument. The groups also contend that the 80047 panel does not meet the definition for composite rate payment since it is not routinely performed for dialysis patients.

Previously, since 80047 was added to the lab fee schedule on Jan. 1 of this year, it was reimbursed at the rate for a seven-test automated panel (paid by most contractors at $11.42) and the separate rate for 82330, ionized calcium (capped at $19.09), or a maximum of $30.51.

Next Steps in Lab Fee-Setting Process

CMS typically makes public its tentative fee decisions for new lab codes in September, followed by a two-week period for additional comments. Final fee decisions will be released when CMS publishes the 2009 Part B lab fee schedule, usually in October or November.

Pricing New CPT Codes on the 2009 Medicare Lab Fee Schedule
Crosswalk Recommendations by Lab, Pathology Organizations

Code/Descriptor	*Recommended Crosswalk*	*Current Fee Cap*
CHEMISTRY		
8372X, Myeloperoxidase (MPO)	AACC, 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
	ASM: No comment (n/c)	
8395X, Oncoprotein; des-gamma-carboxy-prothrombin (DCP)	AACC, ACLA, ASCP, CAP, CLMA: 83950, Oncoprotein; HER-2/neu	$89.99
	ASM: n/c	
HEMATOLOGY AND COAGULATION		
85XXX, Coagulation and fibrinolysis, functional activity, not otherwise specified (e.g., ADAMTS-13), each analyte	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		
879XX, Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)	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		
8872X, Bilirubin, total, transcutaneous	AACC, ASCP, CAP: 88400, Bilirubin, total, transcutaneous. Note: This code is deleted in CPT 2009 and renumbered to 8872X as part of a subsection for in vivo lab procedures.	$7.02
	ACLA, ASM, CLMA: n/c	
8874X1, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin (for in vitro carboxyhemoglobin measurement, use 82375)	ASCP: 88400, Bilirubin, total, transcutaneous	$7.02
	CAP: ½ of 88400	$3.51
	AACC, ACLA, ASM, CLMA: n/c	
8874X2, Hemoglobin, quantitative, transcutaneous, per day; methemoglobin (for in vitro quantitative methemoglobin determination, use 83050)	ASCP: 88400, Bilirubin, total, transcutaneous	$7.02
	CAP: ½ of 88400	$3.51
	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: The New Medicare Law

Lab, Pathology Priorities Enacted After Final Medicare Showdown

Congress this month overrode President Bush's veto of Medicare legislation and enacted major program changes advocated by clinical laboratory and pathology organizations. The changes include a physician fee fix and extension of the "grandfather" protection through next year, plus repeal of the lab competitive bidding demonstration and a delay in introducing competitive bidding for durable medical equipment suppliers.

The Medicare Improvements for Patients and Providers Act of 2008 became law July 15. The votes to override the veto were well above the two-thirds required. In the House, the vote was 383-41, with 153 Republicans joining 230 Democrats. In the Senate, the vote was 70-26, with 21 Republicans joining 42 Democrats and two independents.

President Bush has vetoed bills nine times but has been overridden only three times before. The president said he did not oppose the physician fee increase but rejected paying for it in part by reductions in Medicare managed care funding. The reductions target Medicare Advantage indirect medical education payments and include new provider network requirements for private fee-for-service plans, saving $12 billion over five years, according to Senate Finance Committee estimates.

Competitive Bidding

Competitive bidding has been touted by the Bush administration as a fee-for-service alternative intended to inject more market forces into the Medicare program. For clinical laboratory services, this effort is now at a dead end. The new Medicare law repeals the authority of the Centers for Medicare and Medicare Services to conduct a Part B lab bidding demonstration, as was required under the 2003 Medicare reform law passed by the GOP-controlled Congress.

The law also puts a halt on the national rollout of competitive bidding for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), which CMS began July 1. It imposes an 18-month delay in Round 1 involving 10 communities throughout the country and requires a corresponding 18 to 24 months' delay in subsequent rounds. National competitive bidding for DMEPOS was mandated by the GOP-run Congress, following reports of savings this payment method achieved in two pilot projects in Texas and Florida.

Pathologist/Physician Fees

Congress has replaced the cut of 10.6 percent in Medicare physician fees that took effect July 1 under the SGR (Sustainable Growth Rate) update formula with a 0.5 percent increase, retroactive to July 1 and effective through Dec. 31. For 2009, fees will rise an additional 1.1 percent.

The day after the veto override, CMS announced that physicians should begin to receive payment at the 0.5 percent update rate in 10 business days or less, noting that Medicare contractors are working to incorporate the new rates in their payment system. To avoid disruption to claims payment, contractors will continue to process

claims that have been on hold on a rolling basis (first in/first out) for payment at the -10.6 percent level, CMS said. After contractors begin to pay claims at the 0.5 percent rate, they will automatically reprocess, to the extent possible, any claims already paid at the lower rates.

Claims with dates of service July 1 and later billed with a submitted charge at least at the level of the Jan. 1 to June 30, 2008 fee schedule amount (reflecting a 0.5 percent increase in effect over that period) will be automatically reprocessed, CMS said. Any lesser amount will require providers to contact their local contractor for direction on obtaining adjustments. Nonparticipating physicians who submitted unassigned claims at the reduced nonparticipation amount also will need to request an adjustment, the agency said.

The new law also extends through Dec. 31, 2010, the Physician Quality Reporting Initiative (PQRI), which authorizes bonus payments for reporting on CMS-approved quality performance measures. Moreover, the bonus is increased to 2 percent in 2009 and in 2010. Meantime, CMS has announced that physician bonuses for the 2007 program topped $36 million and payments should be received no later than August. More than 56,700 physicians and other health professionals satisfactorily reported quality information. The highest incentive totals went to providers in Florida ($3 million) and Illinois (over $2 million).

Laboratory Services Reimbursement

For the first time in five years, the Part B lab fee schedule will get a positive update starting Jan. 1, 2009, though it will not be the full Consumer Price Index update currently projected to be 5 percent. Congress reduced the CPI update to the lab fee schedule by 0.5 percent, for a net gain of 4.5 percent (*see story, p. 1*).

Also, critical access hospitals serving rural areas will receive 101 percent of reasonable costs for clinical lab services to beneficiaries, regardless of whether the lab specimen was taken in the hospital or off-site at another facility operated by the hospital.

Pathology TC "Grandfather" Protection

The new law extends for 18 months, from July 1, 2008 through Dec. 31, 2009, the "grandfather" provision that allows qualified independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. The protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end such billings on grounds that the TC is reimbursed as part of Medicare's Part A inpatient payment and that labs should seek TC payment from the hospital, not Part B.

The "grandfather" protection applies to the hospital, not the lab, CMS has noted. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology.

Expanding the Preventive Services Benefit

Until now, coverage of Part B preventive services required an act of Congress, but in the new law, CMS is given authority to cover new services, via the Medicare national coverage decision process, that are recommended by the U.S. Preventive Services Task Force. Moreover, Congress modified the "Welcome to Medicare" physical exam by waiving the deductible and extending coverage from six months to one year after enrollment in Part B.

FDA Okays New Genetic Test for Breast Cancer Patients

The SPOT-Light test is manufactured by Invitrogen Corp. of Carlsbad, Calif. Herceptin is made by Genentech of San Francisco.

The Food and Drug Administration has approved a novel genetic test for determining whether patients with breast cancer are good candidates for treatment with the drug Herceptin (trastuzumab).

The SPOT-Light HER2 CISH kit is a test that measures the number of copies of the HER2 gene in tumor tissue. This gene regulates the growth of cancer cells.

A healthy breast cell has two copies of the gene, which sends a signal to cells telling them when to grow, divide, and make repairs. Patients with breast cancer may have more copies of the gene, prompting them to overproduce HER2 protein, so that more signals are sent to breast cells. As a result, the cells grow and divide much too quickly. Patients who overproduce are typically treated with the drug Herceptin, which targets HER2 protein production. This helps to stop the growth of HER2 cancer cells.

"When used with other clinical information and laboratory tests, this test can provide health care professionals with additional insight on treatment decisions for patients with breast cancer," said Daniel Schultz, M.D., director of the FDA's Center for Devices and Radiological Health.

The SPOT-Light test counts the number of HER2 genes in a small sample of removed tumor. The removed piece is stained with a chemical that causes any HER2 genes in the sample to change color. This color change can be visualized under a standard microscope, eliminating the need for the more expensive and complex fluorescent microscopes required to read assays already on the market, the FDA said. Unlike existing tests, the agency added, SPOT-Light allows labs to store the tissue for future reference.

The FDA based its approval of the test on a study of tumor samples from patients with breast cancer in the United States and Finland. The findings confirmed that the test was effective in determining how many HER2 genes were in these patients.

Senate Support Grows for CLIA Cytology PT Overhaul

The House passed identical legislation (H.R. 1237) April 8 (NIR/ 29, 12/Apr 14 '08, p. 1).

Bipartisan support for a Senate bill to revamp the CLIA cytology proficiency testing program is on the upswing, with eight more co-sponsors signing on in the last several weeks, bringing the total to 25 at press time.

The bill, S. 2510, 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 alternative to assure patient health and safety in Pap testing. It is pending before the Committee on Health, Education, Labor, and Pensions.

New Senate cosponsors this month include Republicans Roger Wicker (Miss.) and Pat Roberts (Kans.), Joseph Lieberman (Conn.), an independent, and Democrat Daniel Inouye (Hawaii).

Cosponsors added in June included Democrats Claire McCaskill (Mo.), Patrick Leahy (Vt.), Ron Wyden (Ore.), and Republican Norm Coleman (Minn.)

Under S. 2510, introduced by Mary Landrieu (D-La.) on Dec. 18, 2007, the clinical

laboratory is 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 is available for inspection.

Congressional enactment of the CLIA PT overhaul is a top legislative priority this year for the 60 national and state pathology groups represented in the Cytology Proficiency Improvement Coalition, including the College of American Pathology, which held a members' Washington fly-in last month to lobby senators for the measure.

The current CLIA cytology PT program has been highly controversial since the government began enforcing its 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 Fees Due to Rise, *from p. 1*

The Part B lab fee schedule receives an automatic CPI update each year unless Congress decrees otherwise, as it has repeatedly. Since the schedule was established in 1984, lab fees have gotten a zero update in 12 of the years from 1994 to the present:

1985 .....4.1%	1992.....2.0%	1997 ..... 2.7%
1987 .....5.4%	1993.....2.0%	1998-2002 ..... 0.0%
1989 .....4.0%	1994.....0.0%	2003 ..... 1.1%
1990 .....4.7%	1995.....0.0%	2004-2008..... 0.0%
1991 .....2.0%	1996.....2.8%	2009 (projected) 4.5%

The current freeze, required by the Medicare Modernization Act of 2003, canceled the scheduled 2.6 percent increase for 2004 and has kept fees at their 2003 levels. The freeze affects both local fees and national fee caps.

The end of the freeze should also translate to a gain for Pap smear testing for both diagnostic and screening purposes. The national minimum payment now is frozen at the 2003 level of $14.76. These tests are paid at the lesser of the local fee or the national fee cap, but never below the national payment floor and never more than the actual charge. Affected codes include:

88142/G0123	88150	88164	88174/G0144
88143/G0143	88152	88165	88175/G0145
88147/G0147	88153	88166	P3000
88148/G0148	88154	88167	

OIG Finalizes New Payment Rules for Advisory Opinions

Most requests for advisory opinions involve anti-kickback law or the safe harbor regulations, though the OIG may also advise on its exclusion authorities, as well as civil money and criminal penalties.

As of July 17, a deposit of $250 is no longer required when requesting an advisory opinion from the HHS Office of Inspector General about kickback and other legal risks to a current or proposed business arrangement. Instead, those asking for an opinion will pay the costs of preparing it in one lump sum to the U.S. Treasury via electronic funds transfer—checks and money orders will no longer be accepted. Once the OIG gets confirmation of payment in full, the opinion will be released to the requesting party.

The new policy was promulgated in a final rule in the July 17 *Federal Register*. The rule adopts in final form, without change, an interim final rule published March 26, 2008. The OIG received no comments on the interim final. According to the OIG, the new policy better reflects current electronic payment methods, will increase efficiency in processing payments from requestors, and will benefit requestors by consolidating their payment obligations into one final payment.

An advisory opinion is a legal opinion by the OIG to one or more requesting parties about how the OIG's fraud and abuse authorities apply to an existing or proposed business arrangement. It is binding only on the U.S. Department of Health & Human Services and cannot be relied on by anyone else.

 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.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.