WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 30th Year of Publication

Vol. 09, Iss. 14, July 27, 2009

Negative Update Ahead for Medicare Lab Fees in 2010

Lab lobbyists hope they can at least persuade lawmakers to ameliorate the looming fee schedule cuts.

For the first time since the Medicare lab fee schedule debuted in 1985, its annual update is headed for negative territory in 2010—a cut of 1.9 percent—based on inflation figures released July 15 by the Bureau of Labor Statistics.

The update to local lab fees and national fee caps is based on the unadjusted Consumer Price Index for All Urban Consumers (CPI-U) for the 12-month period ending June 2009, or -1.4 percent. Under current law, the lab update is 0.5 percent less than that.

While the negative lab fee update may be revised, industry analysts tell *NIR*, the adjustment is likely to be small, "a few tenths of a percent higher or lower," but still a cut in test reimbursement, with clinical labs most reliant on Medicare revenue hit the hardest.

This year, for the first time in five years, lab fees got their yearly update, an increase of 4.5 percent. In the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), lawmakers approved an update for five years, from 2009 through 2013, but at a reduced rate: 0.5 percent below the full CPI-U. The update for 2009 is the highest since 1990, when fees rose 4.7 percent. The highest increase ever was 5.4 percent in 1987. *Continued on p. 3*

INSIDE *NIR*

www.g2reports.com

Should Medicare Provider Payments Be Set by an Independent Entity?

Congress currently controls Medicare provider payments, but in discussions with lawmakers over health care reform, the Obama administration has raised the idea of depoliticizing that job by having a new independent entity make the reimbursement decisions.

The idea has appeal among so-called House Blue Dogs, a coalition of fiscally conservative Democrats who have raised concerns about the rising costs of health care reform. Following a July 21 meeting at the White House, Rep. Mike Ross (D-Ark.), a member of the House Energy and Commerce committee and a Blue Dog, said "the idea is in its infant stages," but it is "common ground" to rein in long-term costs, noting that the Congressional Budget Office has said such an independent body could help do so.

One approach to an independent entity is contained in Senate legislation (S. 1110), introduced by John D. Rockefeller IV (D-W.Va.), to transform the Medicare Payment Advisory Commission into an executive branch agency that would determine *Continued on p. 8*

New Codes on the 2010 Lab Fee Schedule: What Should the Medicare Rates Be?

The Centers for Medicare and Medicaid Services (CMS) has begun the annual fee-setting process, as required by statute and regulations, for codes new to the Medicare lab fee schedule next year. At a July 14 public meeting, the agency opened the comment period on whether new test codes on the 2010 fee schedule, effective Jan. 1, should be priced using one of two approved methods: crosswalk or gap-fill.

The crosswalk is used to match a new test code to a similar existing code and pay at that code's rate. Payment for the new test is made at the lower of the crosswalk to the local fee schedule amount or the national limitation amount. Most lab fee schedule codes are paid at the national cap.

The gap-fill method is used when there is no comparable existing test. In this case, local carriers set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years.

New CPT Codes

These codes, developed and copyrighted by the American Medical Association, are (*last two digits to be finalized later*):

Chemistry

839XX, pH; exhaled breath condensate

841XX, Procalcitonin (PCT)

844XX, Thromboxane metabolite(s), including thromboxane if performed, urine

Immunology

863XX, Human epididymis protein 4 (HE4)

863XX, Cellular function assay involving stimulation (eg, nitrogen or antigen) and detection of biomarker (eg, ATP)

867XX, Antibody, Treponema pallidum

Tissue Typing

868XX, Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (eg., using flow cytometry; first serum sample or dilution)

868XX, Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (eg., using flow cytometry; each additional serum sample or dilution (list separately in addition to primary procedure))

Microbiology

871XX, Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed

871XX, Culture, typing; identification by nucleic acid sequencing method, each isolate

874XX, Infectious agent antigen detection by nucleic acid (DNA or RNA); Clostridium difficile, toxin gene(s), amplified probe technique.

Transcutaneous Lab Procedures

887XX, Hemoglobin (Hgb), quantitative, transcutaneous

Reproductive Medicine

893XX, Unlisted reproductive medicine laboratory procedure

New G Codes

CMS also is inviting input on additional new G codes for qualitative drug screens:
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

Finally, CMS wants feedback on a request by Abbott Diagnostics to change the crosswalk for CPT 83876, Myeloperoxidase (MPO), new on this year's lab fee schedule, to 83880, Natriuretic peptide. The current crosswalk is capped at $18.91 versus the cap of $49.56 for 83880.

Timetable for 2010 Lab Fee Schedule

CMS typically releases its preliminary fee determinations in the fall, followed by another round of comments, and publishes its final decisions in late October or November.

Medicare Lab Fees in 2010, *from p. 1*

Prior to MIPAA, lab fees were automatically adjusted by the full CPI-U update, in accord with the Deficit Reduction Act of 1984. But Congress has cancelled it for most of this decade, from 2000 to 2002 and from 2004 to 2008, as part of curbs on Medicare spending growth. Only this year did lab fees rise above their 2003 levels.

CPI-U Updates to Lab Fee Schedule

1985	4.1%
1987	5.4%
1989	4.0%
1990	4.7%
1991	2.0%
1992	2.0%
1993	2.0%
1994	0.0%
1995	0.0%
1996	2.8%
1997	2.7%
1998-2002	0.0%
2003	1.1%
2004-2008	0.0%
2009	4.5%
2010 (projected)	-1.9%

The negative update means a cut next year for Pap smear testing for both diagnostic and screening purposes. The national minimum payment in 2009 is $15.42 , up from $14.76 where it had been frozen since 2004. 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	

focus on: Lab Payment Policy

Is It Time to Reset the Medicare Lab Fee Schedule?

The HHS Office of Inspector General (OIG) thinks so. In a report released this month, the OIG recommends that the Centers for Medicare and Medicaid Services (CMS) "should seek legislative authority to establish a new process for setting accurate and reasonable payment rates for clinical laboratory tests."

The current system of 56 local fee schedules used to pay for Part B covered lab services is based on "suspect data" that may not reflect the actual costs of these services, the OIG said. Variations in carrier rates were present at the start of the fee schedule system and have been carried forward and possibly increased in subsequent adjustments.

The OIG report examined carrier payment rates and test utilization in 2007 and found variation across and within carriers that did not appear to reflect geographic cost differences. The OIG recommended that new legislation should set a base payment rate for each lab test that CMS could adjust to account for these differences.

In response, CMS said it did not concur, noting that the Obama administration's budget does not propose any change in the current fee schedule system. The agency further noted that it lacks the statutory authority to standardize lab payment rates. But CMS said it would take the OIG's advice into consideration as it continues to monitor the effects of current fee schedule policy.

The OIG is the latest voice this year to call for an alternative to the current Part B fee schedule methodology. Legislation pending in the House (H.R. 1452) and championed by the American Society for Clinical Laboratory Science and the Clinical Laboratory Management Association would require a negotiated rulemaking process to move to a single national lab fee schedule that would align reimbursement with actual testing costs. Proponents say this is long overdue for genetic and genomic testing advances (*NIR, 09, 7/Apr. 13, p. 5*). Similar legislation was introduced in the previous Congress, but no further action was taken.

Back in 2000, in a congressionally mandated report on alternative lab payment methods, the Institute of Medicine recommended a national Medicare lab fee schedule adjusted for geographic costs, but this was never acted on.

The Deficit Reduction Act of 1984 mandated the switch to local lab fee schedules, known collectively as the Clinical Laboratory Fee Schedule. Carriers set fees based on local prevailing charge data. Since then, Congress has imposed constraints on lab fees by canceling their annual inflation update (12 times since 1994) and by establishing a national limitation amount (NLA) for each test, first set in 1985 at 115 percent of the national median but subsequently reduced to the current 74 percent. (For tests capped after Jan. 1, 2001, the median is 100 percent, but this has been applied only to 12 diagnostic and screening Pap smear codes.)

The OIG's Findings

In 2007, 97 percent of lab tests had at least one carrier rate that varied from the NLA (fee cap). However, 83 percent of all carrier rates were at the NLA, and 89 percent of laboratory test claims were paid at the NLA.

The 10 Most Utilized Lab Tests: Carrier Rates Below the Fee Caps

Test	*Natl. Fee Cap*	*Carrier Rates Below the Cap*
Basic metabolic panel	$11.83	$8.93 – Ind., N.Y. 2, N.Y. 3, Wash. $9.37 – Ky. $9.64 – Tenn. $10.25 – Ohio $10.74 – Wyo. $11.20 – N.C., N.Y. 1
Comprehensive metabolic panel	$14.77	$11.92 – Wash. $11.74 – Ky. $11.80 – N.C. $12.05 – Tenn. $13.36 – N.J., N.Y. 2, N.Y. 3, S.C. $14.55 – Ind., Miss.
Lipid panel	$18.72	$15.34 – Vt. $15.56 – Wyo. $15.88 – Ala., Ind. $15.91 – Ky. $16.69 – La. $17.05 – Md., N.D. $17.16 – N.H. $17.69 – S.C. $17.77 – Ohio $17.95 – Mich.
Urinalysis with scope	$4.43	$3.57 – Wyo. $4.41 – Del., S.C.
Urinalysis automated with scope	$4.43	$3.57 – Wyo. $4.41 – Del., S.C.
Urinalysis without scope	$3.57	$2.49 – Vt. $2.87 – Wyo. $2.92 – Mo. 2 $3.30 – Ohio $3.28 – Okla.
Glycosylated hemoglobin	$13.56	$9.77 – Idaho $10.61 – Wyo. $12.08 – Okla. $12.22 – R.I. $13.08 – Md., S.D.
Thyroid Stimulating Hormone	$23.47	$21.98 – Ind. $22.73 – Miss. $22.77 – N.C. $22.93 - Wyo. $23.29 – Wash.
CBC with automated differential	$10.86	$6.50 – Ind., Neb. $7.39 – Utah $8.97 – Ariz. $9.88 – Colo. $10.36 – S.C. $10.79 – N.Y. 1
Prothrombin time	$5.49	$4.44 – Wyo. $4.89 – Iowa $5.25 – Md.

When the lab fee schedule debuted in 1985, carriers used lab charge data that may not have reflected the actual costs. Since then, the crosswalk and gap-fill methods used to update carrier rates have incrementally added to the variation in these rates. As a result, carrier rates in 2007 were inconsistent both across carriers and within each carrier. The variation did not appear to reflect geographic differences in cost.

❑ **Carrier rates for nearly all lab tests varied, but 83 percent were at the NLA.**

Lab utilization generally declined as the amount moved farther below the NLA, with a noticeable drop when the amount paid was 25 percent or more below the NLA. Carrier rates below the NLA were most prevalent when the percentage below the NLA was the smallest. The percentage of rates below the NLA generally declined as the rates moved farther from the NLA.

❑ **Variation in rates did not appear to reflect geographic differences in cost.**

No carrier consistently had all rates at the same percentage below the NLA. Instead, each had rates dispersed at varying percentages below the NLA. For example, Florida's carrier, the carrier with the highest utilization of lab tests, had 21 percent below the NLA. These rates ranged between less than 1 percent and 92 percent at different percentages below the NLA.

If a geographic assessment of costs had been consistently factored into the establishment of each carrier's rates, each carrier might have been expected to have most, if not all, rates at the same percentage below the NLA.

❑ **Methods for setting carrier rates created inconsistent variations across carriers.**

Variation in carrier rates started with the methods used to establish and update the lab fee schedule. When carriers set rates, they used lab charge data from their localities. Although the OIG did not assess the charge data, it cited studies indicating that the data may have reflected a lab's decisions on profit levels and market share. As a result, the data may also not have reflected the real differences in cost from carrier to carrier.

❑ **Variation was greater for some carriers than others.**

At one end, Alaska's carrier had 3 percent of its rates below the NLA. At the other end, Utah's carrier had 31 percent of its rates below the NLA. Most carriers (34 of 56) had between 10 percent and 24 percent of their rates below the NLA.

Variation of rates across carriers means that some paid different amounts for the same test. The rate for one genetic test, for example, was $12.82 in California and $95.84 in Wyoming. Similarly, the rate for one breath analysis test was $60.66 in New Jersey and $94.11 in Kentucky.

❑ **Carriers pay different rates for the same lab test, so Medicare payments also vary.**

Medicare paid over $3.4 billion for lab tests in 2007. Payments would have been $3.5 billion if all tests had been paid at the NLA or $2.4 billion if the NLA had been reduced to 50 percent of the national median. Setting all carrier rates at 73 percent of the median would have eliminated variation without a change in overall Medicare payments.

The OIG report, *Variation in the Clinical Laboratory Fee Schedule* (OEI-05-08-00400), is posted at www.oig.hhs.gov/oei/reports/oei-05-08-00400.pdf

Supreme Court Ruling Puts Lab Analysts in the Hot Seat

In a 5-4 decision, the U.S. Supreme Court ruled that analysts who create crime laboratory reports must be available to testify in court and be cross-examined on how they reached those results. Submission of the paperwork alone is not sufficient. Prosecutors can no longer rely on the crime lab report as *prima facie* evidence of what they assert.

The ruling applies to testing for blood alcohol, narcotics, or any substance whose results are included in a crime laboratory report and to the qualifications and skills of personnel who produce the test results cited in the report.

The majority opinion, written by Justice Antonin Scalia, held that a criminal defendant has the right under the Sixth Amendment "to be confronted with the witnesses against him." Cross-examination of witnesses "is designed to weed out not only the fraudulent analyst, but the incompetent one as well." Serious deficiencies have been found in the forensic evidence used at criminal trials, he wrote, adding that "forensic evidence is not uniquely immune from the risk of manipulation."

The Innocence Project filed an amicus curiae brief in the case, noting that in roughly half of the 240 DNA exonerations nationwide, faulty forensic science was a contributory factor to the wrongful convictions. In February, the National Academy of Sciences concluded that forensic scientists for law enforcement agencies "sometimes face pressure to sacrifice appropriate methodology for the sake of expediency."

Scalia dismissed dissenters' arguments that producing analysts in court would be burdensome and costly. "The confrontation clause may make the prosecution of criminals more burdensome, but that is equally true of the right to trial by jury and the privilege against self-incrimination."

The case, *Melendez-Diaz v. Massachusetts* (No. 07-591), arose when Luis E. Melendez-Diaz was convicted on cocaine trafficking charges in Massachusetts. Part of the evidence against him was a lab report stating that bags of white powder said to have belonged to him contained cocaine. He objected, saying he had the right to confront the analyst about the report. The trial court disagreed, he was convicted, and the state appeals court affirmed the lower court ruling, rejecting his claim that the paperwork submission violated his right under the Sixth Amendment. Thirty-five states and the District of Columbia sided with Massachusetts as the case advanced.

Justice Anthony M. Kennedy, writing for the dissenters, said the majority decision upends 90 years of settled law. Scientific evidence should be treated differently from statements from witnesses to a crime. He warned that the decision would subject the nation's criminal justice system to "a crushing burden" and that it means "guilty defendants will go free, on the most technical grounds."

"The defense bar today gains the formidable power to require the government to transport the analyst to the courtroom at the time of trial," Kennedy wrote. As an example, he cited the FBI's laboratory in Quantico, Va., which employs 500 and conducts more than a million scientific tests each year. "The court's decision means that before any of those million tests reaches a jury, at least one of the laboratory's analysts must board a plane, find his or her way to an unfamiliar courthouse, and sit there waiting to read aloud notes made months ago."

Joining Scalia in the majority decision were Justices Clarence Thomas, John Paul Stevens, David H. Souter, and Ruth Bader Ginsberg. Dissenting, in addition to Kennedy, were Chief Justice John G. Roberts Jr. and Justices Samuel A. Alito Jr. and Stephen G. Breyer.

Medicare Provider Payments, *from p. 1*

provider payments but not deliver payments to providers. Under the bill, the Centers for Medicare and Medicare Services would consult with the commission and implement provider payment changes through normal regulatory processes (*NIR, 09, 11/June 8, p. 8*).

Meantime, with criticism mounting over the $1 trillion or more that health care reform is projected to cost and with a Senate Finance bill still being negotiated, President Barack Obama has jumped into the fray, prodding lawmakers to keep up momentum for comprehensive legislation this year. Markup of bills has already been completed by the Senate Health, Education, Labor, and Pensions (HELP) committee and by the House Ways and Means and the Education and Labor committees, while at press time, Energy and Commerce was working on the details of its provisions.

Eyes now are on what the Senate Finance committee will produce. Leaders have expressed confidence that it will be a bipartisan bill, but this means tackling controversial issues approved by the other committees over Republican objections, such as the requirement that individuals obtain health insurance coverage, employers offer affordable coverage or face financial penalties, the proposed creation of a new public plan option to compete with private insurers, and new spending on comparative effectiveness research.

Upcoming G-2 Events

Webinar

Aug. 11
Medicare Changes in the Works: What They Mean for Labs, Pathologists, and Diagnostic Imaging Providers

Conferences

Sept. 23-25
27th Annual Lab Institute: Advancing in the Eye of the Storm
Crystal Gateway Marriott Hotel, Arlington, Va.

Nov. 12
Lab Leaders Summit
Driving Growth in Your Business
The Princeton Hotel, New York City

Dec. 7-9
Laboratory Sales and Marketing Conference: Scaling New Heights in a Volatile Market
Sheraton Wild Horse Pass Resort and Spa, Chandler, Ariz.

For details on the above, plus subscriber discounts and other special savings, go to **www.g2reports.com**

NIR Subscription Order or Renewal Form

- ❑ ***YES***, enter my one-year subscription to the *National Intelligence Report (NIR)* at the rate of $489/yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues at *www.ioma.com/g2reports/issues/NIR*. Subscribers outside the U.S. add $100 postal.*
- ❑ AAB & NILA members qualify for special discount of 25% off — or $366.75 (Offer code NIRI1).
- ❑ I would like to save $196 with a 2-year subscription to *NIR* for $782.*
- ❑ ***YES***, I would also like to order the *Lab Industry Strategic Outlook 2009: Market Trends & Analysis* for $1,495 ($1,195 for Washington G-2 Reports subscribers). (Report #3308C).

Please Choose One:

❑ Check enclosed (payable to Washington G-2 Reports)
❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

MAIL TO: Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Or call 973-718-4700 and order via credit card or fax order to 973-718-0595 NIR 7/09B

 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.

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.