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Quick Action Urged on Medicare Physician Fee Fix

Absent congressional intervention, the current increase in Medicare physician payments expires Nov. 30. A statutory cut of 23 percent takes effect the next day.

A broad array of medical groups, including 66 national organizations and 50 state medical associations, plus the District of Columbia, have called on congressional leaders to take up Medicare physician payment reform during the first week of the lame-duck session in November following the midterm elections.

The current 2.2 percent increase in the physician fee update expires Nov. 30. It has been in effect since June 1, blocking a 21 percent cut in fees required under the Sustainable Growth Rate (SGR) formula used to calculate the annual update to the Part B physician fee schedule.

But as of Dec. 1, the SGR will force a cut of more than 23 percent in Medicare and TRICARE payments for physician services unless lawmakers block it, the groups said in a letter to House speaker Nancy Pelosi (D-Calif.) and House Republican leader John A. Boehner (Ohio).

“To make matters worse, an additional cut of 6.5 percent will follow on Jan. 1, 2011. Physician practices simply cannot absorb cuts of this magnitude in programs as important as Medicare and TRICARE,” the groups said.

Continued on p. 2

INSIDE NIR

- Medicare physician fee fix: Indecision 2010.....2
- Top CLIA official Judy Yost receives G-2’s Lab National Leadership Public Service award.....3
- Box: Clinical lab fees: bottom line for 2011.....4
- Time running out to preserve pathology ‘grandfather’ protection5
- OIG to labs: ‘I’ve got my eyes on you’6
- Medicare coding and billing advisory: latest ICD-9 changes to lab national coverage policies7
- Names in the news at CMS...8
- Upcoming G-2 Events.....8
 - Webinars
 - Sales and Marketing Conference
- For registration or program information, visit our Web site

Key Medicare Changes in Store for Labs As Health Care Reform Law Unfolds

On the Medicare reimbursement front in 2011, it’s clear that the bottom line for clinical laboratories will be a 1.75 percent cut in their Part B fees.

That’s because of changes to the annual lab fee update formula that were enacted as part of the health care reform law, noted Alan Mertz, president of the American Clinical Laboratory Association, in his presentation at Lab Institute 2010, convened by Washington G-2 Reports Oct. 13-15 in Arlington, Va.

While not escaping fee reductions altogether, the lab industry did fend off harsher proposals raised in Congress to help pay for health care reform, he said. One would have restored the 20 percent lab copay under Part B. Another would have imposed a new annual lab tax based on revenue.

The industry was left with a new update formula: the consumer price index (CPI-U) minus a productivity adjustment (which could

Continued on p. 4

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Quick Action Urged, *from p. 1*

“Congress must break the cycle of forestalling a crisis in patient access to physician care for only a few months at a time and take action on legislation to provide stability and predictability for the program at least through 2011.”

Medicare Physician Fee Fix: Indecision 2010

Sharp differences over how to reform the Medicare physician payment system and how to pay for it have stymied legislative attempts to reach agreement on the issue. The House in late 2009 approved a repeal of the SGR, replacing it with an update tied to the gross domestic product, at an estimated cost of \$330 billion over 10 years. The bill was not fully financed, and the Senate rejected a similar bid, forcing lawmakers to wrangle over a series of short-term fixes at a lower cost, though critics say this has only exacerbated the depth of the cuts required under the SGR system.

Jan. 1: SGR cut of 21 percent blocked. Fees frozen at 2009 levels for two months, through Feb. 28. For the first time in 2010, CMS tells contractors to hold claims for up to 10 business days for 2010 dates of service, thereafter process claims at approved rates.

March 1: Two-month freeze expires, SGR cut kicks in. CMS alerts contractors to hold claims, pending legislative action. Congress cancels the cut retroactively and approves one-month extension of the freeze, through March 31.

April 1: One-month freeze expires, SGR cut kicks in. CMS again tells contractors to hold claims anticipating a legislative reprieve. Congress blocks the cut retroactive to April 1 and continues the fee update freeze through May 31.

June 1: Two-month reprieve expires. SGR cut takes effect. CMS again tells contractors to hold claims pending legislative action.

June 25: Obama signs law approving 2.2 percent increase to the fee update for six months, from June 1 through Nov. 30. CMS tells contractors to begin processing claims at the new rates.

Dec. 1: SGR cut of more than 23 percent scheduled. Congressional action: Pending.

Throughout 2010, lawmakers have enacted stopgap measures to block physician fee cuts, none addressing the underlying problem of the SGR, which has triggered negative payment reductions for most of the decade, forcing Congress to intervene.

On three occasions this year, Congress failed to act in time and the SGR cut took effect. Though later cancelled, CMS had to hold payments until the cut was reversed. The stop-start scenarios “were highly disruptive,” the letter noted. “Many practices were forced to seek loans to meet payroll expenses, lay off staff, or cancel capital improvements and investments in electronic health records and other technology. Further, when payments resumed, many physicians experienced long delays in receiving retroactive adjustments.”

Congress needs to avoid a repeat of these disruptive cuts, the groups said. This is an especially critical time, they pointed out, since the next fee cut is set to occur during the Medicare participation season, when physicians may change their status from one who accepts Medicare’s allowance as payment in full to one who does not participate and may bill patients more than the Medicare allowance.

“Hundreds of thousands of physicians will be considering whether they can

continue accepting Medicare rates at the same time that massive payment cuts are scheduled to take effect. We can anticipate that many physicians will be examining whether it makes any sense to continue their current relationship with Medicare given the severe disruptions of the past year.”

The College of American Pathologists, the American Society for Clinical Pathology, the American Medical Association, and all others signing the letter agree that the SGR must be axed. “Physicians are committed to taking the leadership in developing Medicare payment reforms to replace the SGR once and for all, and we are



counting on Congress to make permanent reform a reality. In the meantime, there is an imminent crisis. A statutory payment update that lasts at least through the end of 2011 will provide time for Congress and the physician community to develop a long-term solution.”

But the fee fix is competing on an already crowded legislative calendar for the lame-duck session, most notably the tax breaks that expire this year. So, Congress could fall back on a familiar pattern of punting on the fee update issue, letting the SGR cut go through, having CMS tell contractors to hold claims for two weeks, and then retroactively approving an increase for a longer term. 🏛️

G-2's 2010 Lab Public Service National Leadership Award



Award recipient Judy Yost with Dennis Weissman (right), and Kevin Ellison, president and CEO of Kellison and Co., which sponsors the annual award.

The recipient of this year's award honoring significant contributions to laboratory medicine and pathology is Judy Yost, M.T.(ASCP), the top official responsible for the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare and Medicaid Services (CMS). She was presented with this award, sponsored by Kellison and Co., at a special ceremony held during Lab Institute 2010, Oct. 13-15, in Arlington, Va.

In presenting her with this 17th annual award, Dennis Weissman, founder and former head of Washington G-2 Reports, noted, “Judy has been a staunch defender of quality in the clinical laboratory during her many years of dedicated service at the national level. As head of the CMS office for CLIA virtually since its inception, she is responsible for the oversight and administration of the regulatory program in a manner that promotes testing quality and accuracy.

“But on a more fundamental level, as expressed in one of our recipient's nominating letters, she has “been a tireless educator and communicator related to the application of CLIA regulations in the laboratory and never hesitates to make herself available to the public, an organization, or an individual for the purposes of promoting quality laboratory testing and helping people make sense of the complex and sometimes difficult regulations that govern laboratories.”

The award recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement.

Yost is currently director of the Division of Laboratory Services, responsible for the oversight and administration of the CLIA program, including certification, collection of fees, accrediting programs, state-exempt programs, proficiency testing programs, surveys and interpretive guidelines, enforcement of sanctions, and communications with labs and other stakeholders. Prior to joining CMS, she was the administrative director of progressively larger clinical laboratories and other clinical services in health systems.

Yost is a member of numerous professional societies, committees, and boards and has published several articles on laboratory quality oversight. She received her bachelor of science degree at Wilkes College and her master of arts degree in hospital management from Central Michigan University. 🏛️



Key Medicare Changes, from p. 1

never cause the CPI to fall below zero). Plus, for 2011 through 2015, an additional cut of 1.75 percent is required (which could cause the update to fall into negative territory).

Clinical labs need to be alert to other major changes in 2011 and beyond as various Medicare provisions in the Patient Protection and Affordable Care Act (PPACA, Public Law No. 111-148) take effect, Mertz said, pointing out several areas of importance to labs, including wider coverage and payment for preventive services as well as new cost-control and quality initiatives aimed at transforming health care delivery and payment.

Expanded Prevention and Wellness Coverage

Increased testing is foreseen in this area as cost sharing is dropped for preventive services rated A (strongly recommended) or B (recommended) by the U.S. Preventive Services Task Force (USPSTF). The task force membership is broadened, as is the range of evidence considered for coverage. And in 2011, Medicare is to add an annual wellness visit to promote disease prevention, including referrals for lab and pathology screening where appropriate, with no cost sharing. Further, new network exchange plans can have no cost sharing for covered prevention and wellness services.

Complex Molecular Diagnostics Test Demonstration

Slated to begin July 1, 2011, this is a two-year project that would allow eligible hospital-based and independent labs to bill Medicare Part B for certain complex molecular diagnostic tests when performed within 14 days of a beneficiary's discharge. The project is authorized to pay up to a \$100 million ceiling. Under current Medicare rules, if a lab performs testing on blood or tissue samples collected by a hospital for inpatients and outpatients within the 14-day period, the lab must be paid by the hospital through its inpatient diagnosis related group payment, rather than a direct payment from Part B.

Bottom Line: Clinical Lab Fee Schedule 2011

Effective Jan. 1

- ❑ 0.5 percent reduction eliminated
- ❑ 1.2 percent productivity adjustment reduces the consumer price index (CPI-U) to zero
- ❑ 1.75 percent additional reduction to the lab fee schedule applied

Net change: Minus 1.75 percent

Patient Centered Outcomes Research Institute

This is the independent, nonprofit entity created to oversee the increased federal investment in comparative effectiveness research (CER), which got a \$1.1 billion boost under PPACA. Its goal is to assist patients, clinicians, purchasers, and policymakers in making informed decisions about the outcomes, risks, and benefits of two or more medical treatments, services, and items. The Institute's duties include identifying research priorities and carrying out a research project agenda.

The board of governors is comprised of 21 members, 19 of whom were appointed by the Government Accountability Office on Sept. 23. They include a diverse array of members from patient and consumer organizations, drug and medical device companies, insurers and providers, and academia. The two other members of the board are the directors of the Agency for Healthcare Research and Quality and the National Institutes of Health.

For clinical labs, the CER initiative is a new avenue to gain greater recognition of their essential role in disease diagnosis and management and thus a prominent role on the research and policymaking agenda, Mertz said.



The audio recording and transcript of the ACO session can be found under the Spotlight section at www.cms.gov/center/physician.asp.

Accountable Care Organizations (ACOs)

These are groups of providers and suppliers that agree to take part in a shared savings program, set to begin in 2012. If they meet quality thresholds, they can share in the cost savings they achieve for Medicare in coordinating Part A and Part B services, including clinical lab and pathology testing. Participating providers would be paid via fee-for-service but would be eligible for bonus payments when meeting performance benchmarks.

ACOs are entities with an established mechanism for joint decisionmaking, including practitioners in group practices, networks of practices, partnerships or joint ventures between hospitals and practitioners, hospitals that employ practitioners, and other groups as determined by the secretary of Health and Human Services. An ACO must enter into a three-year agreement to provide care to at least 5,000 Medicare beneficiaries (not including those enrolled in Medicare managed care).

The government is already gearing up for the advent of ACOs. CMS, the Federal Trade Commission, and the Health and Human Services Office of Inspector General jointly hosted an Oct. 5 workshop to air issues on how federal antitrust, anti-kickback, and self-referral prohibitions should apply to ACOs and the flexibility needed to spur innovation and achieve shared savings goals (NIR 10, 17/Sept. 23, p. 8). The audio recording and transcript of the ACO session can be found under the Spotlight section at www.cms.gov/center/physician.asp. 🏛️

Time Running Out on Pathology ‘Grandfather’ Protection

Unless Congress says otherwise, the current “grandfather” protection for certain pathology technical component (TC billings) will expire Dec. 31, and lawmakers are already under pressure to take up a host of more high-profile items during their lame-duck session, such as expiring tax breaks and a Medicare physician payment fix, before adjourning.

The grandfather provision allows an independent lab to bill Medicare directly for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed to eliminate such billings, contending that the TC is reimbursed through the hospital’s prospective payments and labs should seek payment from the hospital, not Part B. CMS has repeatedly sought to impose this new policy, but Congress has repeatedly blocked it with a series of moratoria.

Clinical laboratory and pathology groups are advocating for extension of the protection. But getting it on the fast track in the short time scheduled for the lame-duck session is a big concern. The likely legislative vehicle, industry sources speculate, is an extenders bill that would encompass the grandfather protection along with other Medicare payment and policy changes.

The protection is of special benefit to rural hospitals that cannot afford to perform the pathology work in-house but must send it to an outside clinical lab.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology. 🏛️



OIG to Labs: 'I've Got My Eyes on You'

Clinical laboratories are once again in the sights of the Health and Human Services Office of Inspector General (OIG) on several fronts, according to its fiscal 2011 work plan released this month. Below are some major targets:

Laboratory Test Unbundling

Review the extent to which clinical labs have unbundled profile or panel tests to maximize Medicare payments. Scrutinize claims for multiple dates of service or drawing specimens on sequential days. Also, determine the extent to which Medicare contractors have controls to block inappropriate payments.

The full *OIG fiscal 2011 work plan* is at www.oig.hhs.gov/publications/workplan/2011/.

Medicare Part B Payments for Glycated Hemoglobin A1C Tests

Review contractor procedures to screen for the frequency of claims for glycated hemoglobin A1C tests. Under national coverage policy, this test is not considered reasonable and necessary more often than every three months on a controlled diabetic patient unless documentation supports the medical necessity of testing in excess of this limit. Preliminary OIG work at two Medicare contractors showed variations in procedures for checking test frequency.

Trends in Laboratory Utilization

Review these trends under Medicare, which pays only for lab tests ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary. In 2008, Medicare paid about \$7 billion for clinical lab services, a 92 percent increase from 1998. Much of the growth was the result of increased service volume. The OIG will examine the types of tests, the number ordered, and how test ordering is affected by physician specialty, diagnosis, and geographic difference.

Lab Test Payments: Medicare versus Other Public Payers

Review the extent to which Medicare payment rates for laboratory tests vary from other public payers. Excessive payment rates can be costly for Medicare. In 2009, it paid nearly \$10 billion for lab tests. The OIG will compare Medicare lab payment rates for the 10 most utilized lab tests with those of other public payers, including the Department of Veterans Affairs and state Medicaid programs.

Medicare Billings With Modifier GY

Review providers' use of modifier GY on claims for services that are not covered by Medicare. The modifier is to be used for coding services that are statutorily excluded or do not meet the definition of a covered service. Beneficiaries are liable, either personally or through other insurance, for all charges associated with the provision of these services. Providers are not required to give them advance notice of charges for services that are excluded from Medicare by statute. As a result, beneficiaries may unknowingly acquire large medical bills for which they are responsible. In fiscal 2008, Medicare received over 75.1 million claims with a modifier GY totaling approximately \$820 million.

FDA Medical Device Approval

Review the Food and Drug Administration's 510(k) device clearance process, including policies and procedures at the FDA Center for Devices and Radiological Health (CDRH) for resolving scientific disputes about approval of devices that may arise between FDA and industry or within FDA, such as between reviewer and manage-

ment. Examine a sample of administrative files for disputed decisions and assess the extent to which procedures were followed during the resolution process. Also assess whether CDRH managers and staff are aware of and trained in policies and procedures for resolving scientific disputes. 

Medicare Coding and Billing Advisory

Lab National Coverage Policies: Latest Coding Changes

The Oct. 1 quarterly update to contractor edits of claims for tests subject to Medicare’s clinical laboratory national coverage determinations (NCDs) makes numerous additions and deletions to the list of covered diagnosis codes for 14 of the 23 NCDs.

The NCDs affect frequently ordered clinical laboratory procedures and specify the circumstances under which Medicare will pay for a test, the appropriate CPT and ICD-9-CM codes to use, coverage limitations (such as frequency of testing), and other guidelines. Medicare requires an ICD-9-CM code on all clinical laboratory testing services in order for the claim to be processed.

Effective for services furnished on or after Oct. 1, 2010, the changes to the list of ICD-9-CM covered codes for the following lab NCDs are (for blood counts, the list of codes that do not support medical necessity):

<i>NCD</i>	<i>ADD</i>	<i>DELETE</i>
Urine Culture, Bacterial	780.66	None
HIV Testing (Diagnosis)	780.66, 786.30, 786.31, 786.39	786.3
Blood Counts	832.2, V11.4, V25.11, V25.12, V25.13, V49.86, V62.85	V25.1
Partial Thromboplastin Time (PTT)	275.01, 275.02, 275.03, 275.09, 287.41, 287.49, 786.30, 786.31, 786.39	275.0, 287.4, 786.3
Prothrombin Time	275.01, 275.02, 275.03, 275.09, 287.41, 287.49, 786.30, 786.31, 786.39, 999.80, 999.83, 999.84, 999.85	275.0, 287.4, 786.3
Serum Iron Studies	237.73, 237.79, 275.01, 275.02, 275.03, 275.09, 287.41, 287.49, 999.80, 999.83, 999.84, 999.85	275.0, 287.4
Blood Glucose Testing	275.01, 275.02, 275.03, 275.09, 276.61, 276.69, 780.33, 787.60, 787.61, 787.62, 787.63	275.0, 276.6, 787.6
Glycated Hemoglobin/ Glycated Protein	275.01, 275.02, 275.03, 275.09	275.0
Lipids Testing	278.03	None
Digoxin Therapeutic Drug Assay	276.61, 276.69	276.6
Alpha-fetoprotein (190.25)	275.01, 275.02, 275.03, 275.09	275.0
Gamma Glutamyl Transferase	237.73, 237.79, 275.01, 275.02, 275.03, 275.09, 560.32, 780.66, 970.81, 970.89	275.0, 970.8
Hepatitis Panel/Acute Hepatitis Panel	780.33	None
Fecal Occult Blood Test	287.41, 287.49, 560.32	287.4

The national coverage policies were developed by a lab negotiated rulemaking and published in a final rule on Nov. 23, 2001. Lab claims for each of the policies have been processed uniformly nationwide since April 1, 2003. The policies are posted at www.cms.gov/CoverageGenInfo, click on Lab NCDs. 



Names in the News at CMS

The Centers for Medicare and Medicaid Services (CMS) recently announced appointments to two new posts created by the health care reform law, the Patient Protection and Affordable Care Act (Pub. L. No. 111-148).

Richard Gilfillan, a former executive at the Geisinger health plan and its hospital system in Pennsylvania, has been named acting head of the new **Center for Medicare and Medicaid Innovation**, charged with testing payment and delivery system models that will improve quality and control costs in public health insurance programs.

Gilfillan, director of the performance-based payment policy staff at CMS, has been a consultant for Geisinger Consulting Services, president and chief executive officer of Geisinger Health Plan, and executive vice president of insurance operations for Geisinger Health System. Gilfillan began his career as a family practice physician.

Melanie Bella has been appointed director of the **Federal Coordinated Health Care Office**, created to improve and integrate care for beneficiaries eligible for both Medicare and Medicaid. She joins CMS from the nonprofit Center for Health Care Strategies (Hamilton, N.J.), where she was senior vice president for policy and operations. Before that she was Medicaid director for Indiana from 2001 through 2005. 🏛️

• Upcoming G-2 Events •

Webinars 2 p.m. – 3:30 p.m. (Eastern)

Nov. 4
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Nov. 16
Lab and Pathology Coding, Billing, and Reimbursement: Practical Planning and Preparation for 2011

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