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 18, October 12, 2009

The aim is to get a Senate bill that would replace the SGR update system, instead of canceling its effects but leaving it intact. The pending House legislation would replace the SGR and begin rollout of a new system in 2010.

Pathology Groups Push for Permanent Medicare Physician Fee Fix

Congress is on track to block a 21 percent cut in Medicare physician fees scheduled for Jan. 1, 2010 and approve a positive update, but it is uncertain whether lawmakers will go for a short-term fix to, or a fundamental overhaul of, the Sustainable Growth Rate (SGR) formula used to calculate the update.

In the Senate, the health care reform legislation being cleared by the Finance Committee at press time provides a short-term fix, while in the House, the reform bills passed by three health committees and awaiting merger into a single measure approve a basic overhaul.

The amended Finance bill, released Oct. 2 by chairman Max Baucus (D-Mont.), blocks the scheduled 2010 cut and grants a 0.5 percent increase for that year but contains no provisions for fixing or replacing the SGR beyond next year.

The College of American Pathologists and over 100 national and state medical societies have sent a letter to senators urging them to take further action as the legislation advances and replace the SGR with a new update system. *Continued on p. 2*

Another Cut Proposed for Lab Fee Update

The Medicare lab fee update would be sliced another $100 million under a provision in the amended health care reform bill that the Senate Finance Committee was considering at press time.

The new cut, contained in the bill released Oct. 2 by chairman Max Baucus (D-Mont.), is on top of other update reductions in the legislation, including a productivity adjustment and an additional cut of 1.75 percent for five years, starting in 2011. These reductions were made to offset the dropping of a previous proposal to impose a $750 million levy each year over 10 years on clinical laboratory services (*NIR, 09, 17, Sept. 28, p. 1*).

The bill does not specify how the extra $100 million is to be sliced and for how long, but presumably it is intended to offset the cost of a change to the "date of service" (DOS) policy for complex molecular tests, which provides that for a two-year period, in cases when a lab test is ordered less than 14 days after a beneficiary leaves a hospital, the lab furnishing the test may bill Medicare Part B for the test if certain criteria are met (*NIR 09, 12/June 22, p. 3*). *Continued on p. 6*

INSIDE *NIR*

www.g2reports.com

Medicare Fee Fix, *from p. 1*

The reform legislation in the House includes a provision to cancel the cumulative SGR cuts and base the fee update in 2010 on the Medicare Economic Index. Starting in 2011, the update would allow for growth based on the gross domestic product (GDP) plus 1 percent (2 percent for evaluation and management and preventive services).

Pathology 'Grandfather' Protection for TC Billings

Legislation being considered in both houses includes a two-year extension of the pathology "grandfather" provision, through 2011. The protection, which expires at the end of this year, allows independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of pathology services to hospital inpatients and outpatients.

The "grandfather" protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed to end the pathology TC billings. CMS said the TC is reimbursed as part of Medicare's Part A inpatient payment, and labs should seek TC payment from the hospital, not Part B. Congress has repeatedly blocked CMS from implementing this policy change by granting temporary extensions of the protection, most recently in the Medicare Improvements for Patients and Providers Act of 2008.

The "grandfather" protection applies to the hospital, not the lab, CMS says. 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.

Stark Weighs in on Specialty Groups Capturing Pathology Work

Stark is the architect of the physician self-referral ban, named after him and enacted to prevent unnecessary testing. It contains numerous exceptions for clinical laboratory and pathology medicine, including as part of in-office ancillary services.

In a question-and-answer session Sept. 24 at Lab Institute 2009, Congressman Pete Stark (D-Calif.), chairman of the House Ways and Means health subcommittee, was asked whether further steps are needed to prevent service overutilization by in-house histology labs that physician specialties, such as urologists and gastroenterologists, establish to increase Medicare revenue from anatomic pathology referrals.

He demurred on whether more action is needed, saying he did not see overutilization as a problem when, for example, the testing helps the physician and the patient get a speedy diagnosis. Further, he said, "You don't want the government intruding in every physician practice to see its business model."

Pathology groups say the government needs to do more to limit the spread of in-house histology labs, contending that they exploit a loophole in the Stark exception for in-office ancillary services. There already is ample guidance on acceptable conduct, the congressman noted, including the Stark regulations as well as new Medicare anti-markup rules that allow a referring practice to satisfy the "sharing a practice" requirement and bill for technical component pathology services performed in its in-house lab. Under Alternative 1, a supervising physician is deemed to share a practice with the referring practice if he or she furnishes substantially all (at least 75 percent) of professional services through the billing/referring practice. Under Alternative 2, the focus is on where the diagnostic test is performed and supervised.

FDA and Lab-Developed Tests: Policy Change in the Offing?

That was the question posed to a senior Food and Drug Administration (FDA) official and clinical laboratory industry representatives in back-to-back sessions Sept. 24 at Lab Institute 2009.

As the FDA continues to look into the level of oversight appropriate for lab-developed tests (LDTs), the policy could change, but it would not be done quickly and not without open discussions with stakeholders, said Don St. Pierre, deputy director of the agency's office of in vitro diagnostic device evaluation and safety.

The agency will act wherever patients are found to be at risk, he said, but the main concern now is not with traditional labs, but with a small number of "outliers" who game the system to escape FDA oversight.

St. Pierre acknowledged the unequal regulation field under current FDA policy that requires agency review of distributed in vitro diagnostics (test kits) prior to marketing, while LDTs enter the market without review.

But he reiterated the FDA's long-standing position that it has jurisdiction over LDTs as a medical device. "If a lab makes an LDT, then it is a medical device manufacturer. Just because you have a CLIA certificate does not mean you are not a medical device maker, and everything you do is under FDA enforcement discretion."

The agency has used this discretion for most LDTs, he pointed out. It currently regulates analyte-specific reagents (ASRs) used in LDTs and has issued guidance for a category of genetic tests, In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), that use a proprietary algorithm to produce a patient-specific result.

FDA Focused on Proving Claims Made

In a follow-up panel discussion, St. Pierre stressed the bulk of his unit's workload is on the labeling of products and the claims made for them. "If you are offering an LDT that is truly an LDT, be sure you have good data to back up the claims you make in promoting it," he advised.

He also was asked about the petitions pending to change the two-tiered regulatory framework. Genentech and the Advanced Medical Technologies Association (AdvaMed) have asked the FDA to subject LDTs to the same scientific and regulatory standards applied to test kits, thus leveling the playing field. A number of other groups have joined in support of the petitions.

"It is great that we have the petitions to begin to make decisions on the issues," he said. "They provide a mechanism to address the issues." He would not speculate on the time frame for any response, only noting that there is not time to have an open process and reach a decision this year. Moreover, the final call will be made at a level higher than his unit.

Disputing FDA Oversight Claims

The FDA's claim to have jurisdiction over medical devices is a fundamental premise disputed by the American Clinical Laboratory Association and is an unresolved legal issue, said panelist David Mongillo, vice president for policy and medical affairs. LDTs are developed in house for use only by that lab and the results are sold as a service, not marketed as a test kit.

LDTs are of significant value in improving patient outcomes in clinical practice today, he said, comprising thousands of tests done daily on patients ranging from molecular diagnostics to guide treatment and therapy to modified test kits to detect common disease conditions.

ACLA contends that CLIA regulations along with standards of accrediting bodies are sufficient to assure quality of LDTs. If there are issues regarding clinical validity, they should be addressed through CLIA, Mongillo said, "and if necessary, strengthen the bar but do not add another layer of federal oversight, given how tightly regulated the industry already is."

Change in the Equation

In the era of personalized medicine, there has been a profound shift in the weight given to laboratory testing in screening and diagnosis, observed panelist Laura van't Veer, Ph.D., chief research officer at Agendi, and head of molecular pathology at Netherlands Cancer Institute.

It has gone from being one of many components in medical decisionmaking to now having a central role, she said, and as a result, more rigorous studies are needed of the analytic and clinical validity and utility of LDTs so that the information can be integrated into a result tailored to a patient's genetic profile.

Because of the increasing complexity of genetic testing, there is a place for FDA review, she concluded, but alongside CLIA, the Centers for Disease Control and Prevention, and other involved parties. "Our discussion should always be about what is the best way to assure quality test results for the patient."

CAP Proposes Risk-Based Oversight

Separately, in a Sept. 24 announcement, the College of American Pathologists (CAP) recommended a three-tier risk-based approach to regulating LDTs, defined as medical tests performed by the laboratory in which the test was developed, and the test is neither FDA-cleared nor FDA-approved.

The proposed changes would encompass claims of clinical validity and specify scientific and regulatory standards to be applied to all LDTs. The risk-based classification would be divided into three categories—low, moderate, and high. The ranking would be based on claims made for the test, the potential risk to patients, and the extent to which results could be used in the determination of diagnosis or treatment.

"While the preponderance of LDTs present relatively low risk to patients, the increasing use and complexity of some LDTs underscores the need for increased oversight," said CAP president Jared N. Schwartz, M.D., Ph.D., in a statement. "CAP's risk-based model employs a public-private partnership to address oversight of these tests in an inclusive, systematic way."

In addition, CAP recommends strengthening CLIA accreditation standards on labs using low- and moderate-risk LDTs and requiring FDA review of all high-risk LDTs.

CAP said the FDA should continue to exercise enforcement discretion in regulating LDTs, asserting authority only in specific instances where regulators believe implementation of an LDT without direct FDA oversight is not appropriate.

New Report Touts Value of Lab Testing in Prevention, Quality

As Congress wrestles with health care reform legislation, a new report from the American Clinical Laboratory Association (ACLA) and the Advanced Medical Technologies Association (AdvaMed) says laboratory screening and diagnostic tests play an integral role in advancing prevention and wellness initiatives that are supported on both sides of the political aisle.

These goals include wider patient access to early detection and treatment, support for personalized medicine to guide patient-specific therapy, and more cost-effective care for chronic conditions.

But realizing the full potential of lab testing in a reformed health care environment will require overcoming obstacles that pose risk and uncertainty to labs and test manufacturers alike, such as varying evidence standards and varying coverage, payment, and coding complexities for new tests.

The report was released at a Sept. 29 Results for Life briefing in Washington, D.C., sponsored by ACLA and AdvaMed. The study was conducted by the Lewin Group, which is owned by UnitedHealth, one of the nation's largest insurers.

Report Highlights

"Screening and diagnostic tests contribute to health care value across the spectrum of care," says the report. It addresses the cost and clinical implications of lab testing by focusing on four areas:

- *Rapid diagnostic tests for hospital-acquired MRSA infections:* Hospital-acquired infections (HAIs) cause 99,000 deaths and $20 billion to $45 billion in health care costs annually. Antibiotic-resistant staph infections, called MRSA, cause half of HAIs. Rapid MRSA lab tests allow hospitals to identify the infection quickly and take action to limit its spread.
- *KRAS genetic testing:* In metastatic colorectal cancer, the genetic test for the KRAS gene mutation can now determine which patients will benefit from specific drugs and which will not. This allows many patients to avoid serious side effects and enables physicians to select the most effective treatment from the start. The test could save $740 million per year, according to one estimate.
- *HbA1c blood glucose testing:* Substantial evidence supports the value of HbA1c testing as a screening and diagnostic tool for diabetes and prediabetes. Delaying the onset of diabetes and improved management of the disease can reduce complications, the risk of death, and costs for treatment. The total cost of diabetes is $174 billion a year, about $58 billion of that attributable to lost worker productivity.
- *HPV DNA testing for cervical cancer:* Genetic tests for the HPV viruses that cause cervical cancer are improving diagnostic accuracy in identifying the disease at its earliest stages. The tests are leading to improved disease-free survival and quality of life, along with reductions in disease occurrence, death, and progression to advanced cancers.

The report, The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement, *is posted on the ACLA Web site, www.clinical-labs.org.*

The report notes that lab testing plays a prominent role in the new federal priority given to comparative effectiveness research. It also calls for investment in more studies to consider the tradeoffs between the costs of greater testing frequency and the yield of cases detected.

Lab Fee Update, *from p. 1*

The American Clinical Laboratory Association, while long advocating for regulatory or legislative change in the DOS policy, does not favor doing so at the expense of further reductions to the lab fee update. Prior to news of the extra $100 million cut, the College of American Pathologists, the Association for Molecular Pathology, and the Association of Pathology Chairs came out against the DOS provision unless modified to apply to all lab settings, not just independent labs.

Currently, lab fees get the full Consumer Price Index update (CPI-U) minus 0.5 percent. This year, it was an increase of 4.5 percent. The Finance bill would leave the current formula in place for 2010, when the update is projected to be a cut of 1.9 percent. But beginning in 2011, the update would be further reduced by a productivity adjustment (currently pegged at a negative 1.3 percent), but this could not reduce the lab fee update below zero. Applying it to the lab fee update would save an estimated $5 billion over 10 years. Legislation in the House applies a productivity adjustment to the lab fee update, beginning in 2010, but with no guarantee that the result would never fall below zero. It does not, however, call for additional reductions to the update.

♦ Medicare Claims *Advisory*

New Waived Tests and Billing Codes

The list of CLIA waived tests and billing codes is typically updated quarterly. For the Oct. 1 update, which includes a complete list of all currently waived tests, see CMS Change Request 6570 at www.cms.hhs.gov/transmittals.

The Oct. 1 update by the Centers for Medicare and Medicaid Services to the list of CLIA waived tests includes the latest approved by the Food and Drug Administration for this category. New waived tests are approved on a flow basis and are valid as soon as approved. When billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived in accord with CLIA (the Clinical Laboratory Improvement Amendments). Your claims are edited at the CLIA certificate level prior to approval for payment.

CPT Code	*Effective Date*	*Description*
82274QW, G0328QW	Dec. 4, 2008	Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT)
84703QW	Jan. 26, 2009	Siemens Clinitek Status Urine Chemistry Analyzer
82962, 82465QW	Jan. 29, 2009	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}
82274QW, G0328QW	March 5, 2009	Henry Schein One Step+ iFOBT
81003QW, 82044QW, 82570QW	March 5, 2009	Siemens Clinitek Status Urine Chemistry Analyzer
87804QW	March 10, 2009	EarlyDetect Pro Influenza A Test
87804QW	March 10, 2009	EarlyDetect Pro Influenza B Test
83986QW	March 16, 2009	Lil' Drug Store Products Inc. VagiScreen Vaginal Health Test
86308QW	April 14, 2009	Acceava Mono II {Whole Blood}
80101QW	April 30, 2009	1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II
87880QW	May 21, 2009	Inverness Medical Signify Strep A
86318QW	May 21, 2009	Inverness Medical Signify H. Pylori Whole Blood
86318QW	May 21, 2009	EarlyDetect H. Pylori Whole Blood Rapid Test

2009 Lab Public Service National Leadership Award

Franklin Cockerill III, M.D., received this Washington G-2 Reports award, sponsored by Kellison and Co., for his contributions to laboratory medicine and pathology at a special ceremony Sept. 24 during Lab Institute 2009.

Dr. Cockerill is chair of the laboratory medicine and pathology departments at the Mayo Clinic and is president and CEO of Mayo Collaborative Services Inc./Mayo Medical Laboratories. He is board-certified in internal medicine, infectious diseases, and clinical microbiology and has held numerous leadership positions in professional associations and on government advisory panels.

His current research interests range from basic discovery to applied science on the phenotypic and genotypic identification of antimicrobial resistance. Recently, he and his research team at Mayo developed numerous real-time PCR assays versus conventional culture-based assays and include the first commercially available rapid PCR test for anthrax. This work has resulted in eight U.S. patents, two foreign patents, and 56 licensed technologies.

As head of Mayo Collaborative Services, he oversees the largest for-profit company associated with the Mayo Clinic. The major service line, Mayo Medical Laboratories, is the third largest provider of esoteric lab services in the United States and in total serves over 4,000 clients around the world. Dr. Cockerill has held numerous leadership positions in professional associations and on government advisory panels and is the recipient of multiple awards and honors, including the BD Award sponsored by the American Society for Microbiology.

G-2 Scholarship Award for 2009

Erica Godwin, a senior medical technology major with a biological sciences minor at the University of Delaware, was presented with the sixth annual Dennis Weissman/Washington G-2 Reports Scholarship, sponsored by McKesson and Washington G-2 Reports, on Sept. 24 during Lab Institute 2009. The $5,000 scholarship, given annually for excellence in clinical laboratory science, is intended to help develop future leaders and qualified medical technology professionals.

Erica Godwin with Perry Patterson (left), vice president and publisher, Washington G-2 Reports, and Bob Weathers, specialty vice president, pathology and outreach, McKesson.

Godwin has a 3.757 GPA, has been on the Dean's list each of the past six semesters, received the General Honors Award in 2008, and is pursuing an Honors Degree. Since 2007, she has been a member of the Alpha Lambda Delta Academic Honor Society. In 2008, she was recognized with the university's Women of Promise Award. In 2009, she received the ASCP National Student Honor Award for academic excellence and potential to contribute to the medical technology profession. She is a student member of the American Society for Clinical Pathology and the American Society for Clinical Laboratory Science.

Lab Testing, Billing Under the OIG's Microscope

The OIG work plan is posted at www.oig.hhs.gov.

Lab test unbundling by clinical laboratories, Medicare billings with the modifier GY, and compliance with assignment rules are on the long list of projects in the HHS Office of Inspector General's work plan for the federal fiscal year 2010, released Oct. 1. The annual plan is a guide to projects throughout the Department of Health and Human Services Department that the agency expects to undertake (though not necessarily complete in the year ahead).

The OIG says it will look at whether labs have unbundled profile or panel tests to maximize Medicare payment by submitting claims for multiple dates of service or by drawing specimens on sequential days. Also under scrutiny: the controls that Medicare contractors have in place to prevent such inappropriate payments.

The office also will assess providers' compliance with Medicare assignment rules, including rules on assigned lab services, and will review providers' use of the modifier GY on claims for services that are not covered by Medicare. Providers do not have to provide advance notice of these charges, and beneficiaries may not know they are liable to pay. In fiscal 2008, the OIG said, Medicare received over 75.1 million claims with a modifier GY, totaling approximately $820 million.

Upcoming G-2 Events

Webinars

Oct. 20
Increasing the Market Value of Pathology: How Technology and Practice Trends Are Driving Business Growth
2:00 p.m. (Eastern)

Oct. 29
Bringing Social Media Into the Lab: Integrating Facebook, Twitter, and YouTube Into Your Growth Strategy
2:00 p.m. (Eastern)

Virtual Symposium

Oct. 27
The Future of Health Care: Capitalizing on Emerging EMR Opportunities
Online 10:30 a.m. – 6:00 p.m. (Eastern)

Conferences

Nov. 12
Lab Leaders Summit
Driving Growth in Your Business
The Princeton Club of New York

Dec. 7-9
2nd Annual LabCompete: 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, including special savings, go to www.g2reports.com

 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.