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Medicare Physician Fee Fix: Countdown to Looming Cut

Congress is under a self-imposed March 1 deadline to avert a scheduled 21 percent cut in fees and to decide on a payment increase and fundamental reform.

As of March 1, the freeze on the update to Medicare physician payments that began Jan. 1 comes to an end, and pathologists and other physicians are wondering what happens next.

The two-month freeze has blocked a 21 percent cut in the update under the Sustainable Growth Rate (SGR) formula and kept fees at their 2009 levels. Congress is widely expected to block the cut once again, but with only a few weeks left to act, it is unclear how lawmakers will proceed.

Under pressure to concentrate on jobs and the economy, and with little time left to avert a physician fee cut, lawmakers could continue the freeze for several months while they work out differences over changing the update system. But they are unlikely to want to go into the midterm elections without resolving the SGR issue, a top priority of medical groups.

Lawmakers already are being pressed by the College of American Pathologists, the American Medical Association, and other physician groups to repeal the SGR and not keep punting on overhauling the Medicare physician payment system. *Continued on p. 8*

Lab, Pathology Groups Urge Quick Legislative Action to Revive 'Grandfather' Protection for TC Billing

Eight national laboratory and pathology professional and scientific groups have urged congressional leaders to act quickly to restore the pathology "grandfather" protection that expired Dec. 31, 2009, saying it is needed to maintain quality testing and access to testing by Medicare beneficiaries, especially in rural areas.

The protection allows independent clinical labs to bill Medicare directly for the technical component (TC) of 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 eliminating separate billings. Congress has repeatedly blocked the agency from going ahead with this policy change.

In letters sent Jan. 28 to House speaker Nancy Pelosi and chairmen of the House health committees and to Senate majority leader Harry Reid and chairmen of the Senate health committees, *Continued on p. 2*

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Protection for TC Billing, *from p. 1*

the groups support extending the "grandfather" protection for two years, effective Jan. 1, 2010.

To expedite action, they further support attaching the extension to urgent legislation such as the debt limit bill or the Medicare physician fee update fix needed to block a 21 percent cut scheduled for March 1.

Signing the letter were the American Medical Technologists, American Association for Clinical Chemistry, American Clinical Laboratory Association, American Society for Clinical Laboratory Science, American Society for Clinical Pathology, American Society for Microbiology, College of American Pathologists, and the National Rural Health Care Association.

A Quandary for Qualified Providers

Since the start of the year, providers that qualify under the protection have been left in suspense about whether they will get paid. CMS has advised them to hold TC claims, but this was premised on the expectation that Congress would enact an extension as part of comprehensive health care reform legislation. The House reform bill approved a two-year extension, the Senate bill a one-year reprieve.

CMS told providers "to hold, to the extent possible, claims for services furnished on or after Jan. 1, 2010. If legislation is enacted, claims submission for affected services may resume. Otherwise, claims submitted with dates of service on or after Jan. 1 will not be paid" (*NIR 10, 1/Jan. 11, p. 1*).

CMS has repeatedly sought to end "grandfathered" TC billings, contending that the TC is paid through the hospital's inpatient DRG and labs should seek reimbursement from the hospital, not the Part B program.

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.

President's Budget Outlines HHS Priorities for 2011

President Obama's budget request for fiscal year 2011, released Feb. 1, includes a total of $911 billion for the U.S. Department of Health and Human Services (HHS). The money will be used, HHS secretary Kathleen Sebelius said, to "make many of the necessary investments our country has been putting off for years, including investments in fighting health care fraud, strengthening our public health infrastructure, and getting serious about health and wellness."

The budget continues to channel dollars into last year's priorities for health care reform as well as seeking funding for new initiatives. Here are the highlights:

Comparative Effectiveness Research

This priority gets an additional $261 million, including program support costs, for the Agency for Healthcare Research and Quality (AHRQ) to support new patient-centered health research projects. This will support the generation, translation, and dissemination of research to improve health care quality and efficiency by providing patients and clinicians with evidence-based information for medical decisionmak-

ing. The budget also continues to support research in this area within the National Institutes of Health.

For fiscal 2010, $1.1 billion was approved in the American Recovery and Reinvestment Act of 2009 (ARRA) to jump-start the comparative effectiveness research initiative.

Health Information Technology

To advance the president's HIT initiative, $78 million, an increase of $17 million, is requested for the Office of the National Coordinator for Health Information Technology (ONC). The increase will enable ONC to lead and coordinate federal HIT efforts while implementing and evaluating HIT infrastructure investments authorized by ARRA. That law also established Medicare and Medicaid HIT incentive programs to provide an estimated $20.6 billion over 10 years for the adoption and meaningful use of electronic health records (EHRs).

In FY 2011, these programs will begin providing incentive payments to eligible providers. CMS recently issued proposed rules on qualifying for the payments, including a definition of the"meaningful use" qualifier (*NIR 10, 2/Jan. 25, p. 3*).

Strengthening CMS

The budget calls for $3.6 billion, an increase of $186 million, to meet current administrative workload demands on CMS from recent legislative requirements and continuous beneficiary growth. It provides targeted investments to revamp HIT systems and optimize staffing levels.

Specifically, $110 million of the increase is for a new Health Care Data Improvement Initiative to transform CMS's data environment from one focused primarily on claims processing to one also focused on state-of-the art data analysis and information sharing.

Health Care Fraud

The president requests $1.7 billion for fraud fighting at HHS, including $561 million in Health Care Fraud and Abuse Control (HCFAC) discretionary funding, an increase of $250 million over the FY 2010 enacted level. The emphasis will be on fighting fraud in the field and increasing Medicaid audits.

Estimates indicate that these investments will generate $9.9 billion in savings from increased recoveries and prevention efforts. Also proposed is a set of new program integrity tools to help CMS beef up provider enrollment scrutiny, increase claims oversight, improve Medicare's data analysis capabilities, and reduce overutilization of Medicaid prescription drugs. These proposals would save an estimated $14.7 billion over 10 years.

Biomedical Research

The National Institutes of Health (NIH) would get $32.2 billion, an increase of $1 billion, to support innovative projects from basic to clinical research, including personalized medicine, and to capitalize on the Human Genome Project. The focus is on five areas: supporting genomics and other high throughput technologies, translating basic science into new and better treatments, support for the biomedical research community, using science to enable health care reform, and focusing on global health.

In FY 2011, NIH estimates it will support a total of 37,001 research project grants, including 9,052 new and competing awards.

focus on: Clinical Lab Oversight

What's Ahead for the CLIA Program in 2010?

We put this question to the top CLIA official, Judy Yost, director of laboratory services at the Centers for Medicare and Medicaid Services (CMS), who listed "some of the key projects (in no particular order) for this year," along with "numerous others as well as ongoing responsibilities associated with managing this program."

The key projects include:

- ❑ Updating proficiency testing (PT) regulations for labs and PT providers
- ❑ Addressing quality concerns in waived testing
- ❑ Planning for the new EP-23 quality control policies, following release of new guidance from the Clinical and Laboratory Standards Institute on customizing QC for the lab
- ❑ Clarifying CLIA guidance on test ordering and reporting to facilitate implementation of electronic health records (EHRs). Sections 493.1241 and 493.1291 of the CLIA rules are the key areas to be addressed
- ❑ Updating all of the interpretive guidelines for lab surveyors
- ❑ Enhancing oversight of foreign labs subject to CLIA
- ❑ Finalizing the cytology PT proposed rule

The CLIA program, established by the Clinical Laboratory Improvement Amendments of 1988 and in operation since 1992, oversees a vast universe of clinical laboratories—a current total of 214,875 registered labs.

Updating Proficiency Testing Regulations

A work group is set to meet in March to begin this effort, Yost told *NIR*. It is being convened under the auspices of the Clinical Laboratory Improvement Advisory Committee (CLIAC) and will be representative of all industry stakeholders.

This is the first step in the plan by CMS, in collaboration with the Centers for Disease Control and Prevention, to take account of changes in lab medicine and technology since the CLIA rules were published in 1992. Clinical testing protocols have evolved, and so too has PT for tests like those that identify genetic mutations. All labs performing certain tests must annually enroll in a CMS-approved PT program for the primary test method utilized by the lab for regulated analytes and perform them successfully.

The task for the work group is to re-evaluate PT requirements for labs, PT programs, grading criteria, and target values; to develop a technically sound mechanism for analyte selections; and to clarify standards for PT referral to help labs avoid the severe mandatory penalties for sending PT samples to another lab for testing or communicating about PT results prior to the closing of the PT event. (Current policy is posted at *cms.hhs.gov/clia*. Click on Brochures and select PT.)

Cytology PT Proposal

The agency is reviewing comments received on this proposed rule and there is no estimated time for finalizing it, Yost said. The rule was proposed in the Jan. 16, 2009 *Federal Register*.

CMS invited comments on a series of changes to the CLIA proficiency testing program for gynecologic cytology and its requirements for pathologists and cytotechnologists who perform Pap testing:

Current rule	***Proposed rule***
10 slides/test	20 slides/test
2 hours/test	4 hours/test
Annual test	Biennial testing
Test Composition:	***Test Composition:***
• 1 unsatisfactory challenge	1 unsatisfactory challenge
• 1 normal challenge	1 normal challenge
• 1 low grade (LSIL) challenge	1 low grade (LSIL) challenge
• 1 high grade (HSIL) or cancer (CA) challenge	2 high grade (HSIL) or cancer (CA) challenge
1 missed HSIL/CA = automatic failure	2 missed HSIL/CA = automatic failure
Glass slide test	Glass slide test and opportunity for new technologies
Field validation of slides not required	Continuous field validation required
Appeals process not required	Appeals process required
Different scoring grids for pathologists, cytotechnologists	Same

Left unchanged is CMS's position that the CLIA statute requires PT testing of individuals and thus this issue is not included in the rulemaking. Critics contend that this is too narrow a reading of the law and that testing the lab as a whole, as is the case with noncytology PT, is a better way to assure Pap smear quality results.

The rulemaking has been controversial. In its comments, the College of American Pathologists asked CMS to withdraw the proposed rule and consider a continuing medical education (CME) alternative (*NIR 09, 6/March 30, p. 1*). Under the CME alternative backed by CAP, along with the more than 60 organizations in the Cytology Improvement Coalition:

- ❑ All individuals involved in screening and interpreting Pap tests must participate in a federally mandated annual CMS testing program in gynecologic cytology.
- ❑ All CMS PT programs must be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.
- ❑ Each lab director must use results from the annual test, along with other CLIA required metrics, to assess individual performance and, if necessary, take appropriate action for remedial training or further continuing medical education.

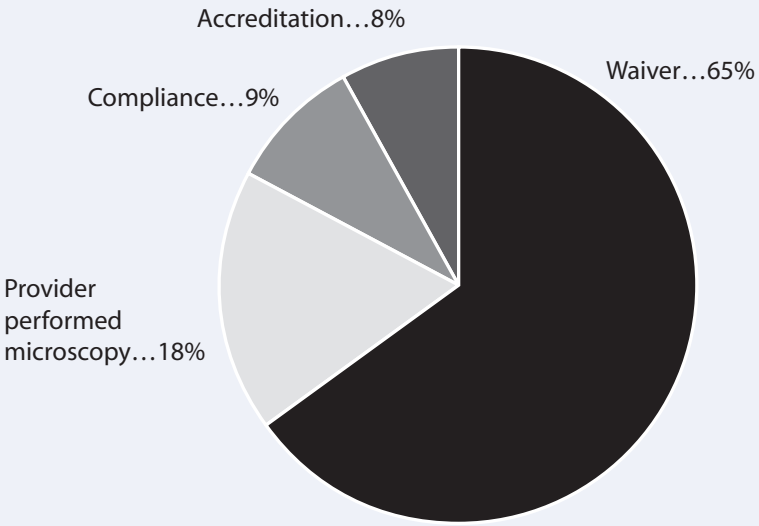
Under the current CLIA cytology PT program, there are two approved national PT providers: the College of American Pathologists and the American Society for Clinical Pathology. The state of Maryland runs a separate PT program for those testing specimens of state residents.

Quality of Waived Testing

CMS surveys of waived testing labs under the Certificate of Waiver (CW) project have identified quality concerns in this least regulated category, requiring only that the test user follow the manufacturer's instructions. Waived labs account for 65 percent of CLIA-certified labs.

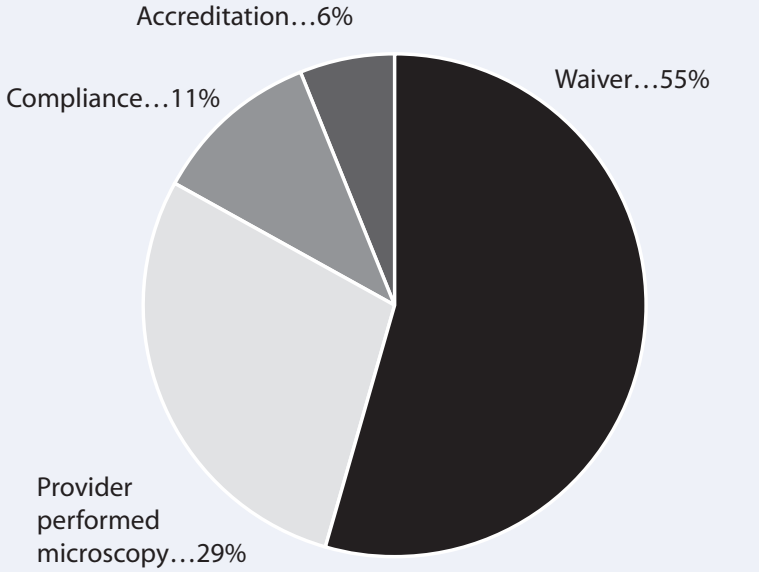
The problem areas included not performing quality control as the manufacturer requires, testing personnel not trained or evaluated, and not having the manufacturer's instructions on proper test device use. "We have presented our concerns to CMS management," Yost said, "and are proceeding with some plans [to address those concerns] that are possible under the existing law and regulations. We also are exploring other options with CLIAC, our Partners in Lab Oversight, the accreditation organizations, exempt states, and Veterans Affairs."

CLIA Labs by Certificate Type (nonexempt only)



Source: CMS CLIA database

Physician Office Labs by Certificate Type* (nonexempt only)



*Rounded. Source: CMS CLIA database

The CMS Division of Laboratory Services will:

- ❑ Continue the CW project based on the concerns identified.
- ❑ Provide educational materials by mail to all CW laboratories upon enrollment, on the CMS Web site, and on an ongoing basis.
- ❑ Initiate the collection of test menus/methods to verify that CW laboratories are only performing waived testing.
- ❑ Enlist the support of medical professional groups and patient advisory groups to solicit support in educating these laboratories.
- ❑ Solicit and analyze data from accredited facilities that are performing waived testing subject to their standards. Compare performance data from these facilities and generate oversight ideas for the long term.

Also being considered are several steps that CMS presented to CLIAC last fall, including possible changes to the CLIA statute: the definition of a waived test, a PT requirement, personnel qualifications, and routine biennial surveys.

Supreme Court Upholds Ruling on Forensic Lab Testimony

The U.S. Supreme Court has dismissed a challenge to its ruling last year that lab analysts and other forensic specialists must be available to testify in person at trials. The court ordered the case, *Briscoe v. Virginia*, back to state court for further consideration.

In a Jan. 25 one-line order, the court said, "We vacate the judgment of the Supreme Court of Virginia and remand the case for further proceedings not inconsistent with the opinion in *Melendez-Diaz v. Massachusetts*."

Last year, in *Melendez-Diaz v. Massachusetts*, the court ruled, 5-4, that analysts who create crime lab reports must be available to be cross-examined on how they reached those results. 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 lab report and to the qualifications and skills of personnel who produce the test results cited in the report (*NIR 09, 14/July 27, p. 7*).

Right to Confront Witnesses

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" and "forensic evidence is not uniquely immune from the risk of manipulation."

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."

Issue in *Briscoe* Legal Challenge

The issue in *Briscoe v. Virginia* was whether the state met its obligation under the confrontation clause by giving a defendant the right to call the lab expert as his own witness, and if the defendant declines to do so, must the state present the lab expert for cross-examination.

The defendant was convicted on cocaine charges based in part on "certificates of analysis" from the state lab attesting to the amount and type of drugs found during his arrest. During the trial, the defense argued that the drug evidence needed to be presented in live testimony to allow for cross-examination, but the judge admitted the testimonials. The defense did not call the lab analyst as its own witness.

The conviction was upheld by a state appellate court, which consolidated the case with a similar appeal (*Magruder v. Commonwealth*), and subsequently by the Virginia Supreme Court, which stated, "Because the defendants in these appeals failed to call the lab experts, they waived the challenges under the confrontation clause to the admissibility of the certificates of analysis."

The U.S. Supreme Court in *Melendez-Diaz* indicated that an approach like Virginia's, shifting the burden of calling the witness to the defendant, would not satisfy the state's obligation under the Sixth Amendment confrontation clause.

Medicare Physician Fee Fix, *from p. 1*

The SGR has triggered fee cuts for most of the past decade and will force ever-deeper cuts in the future, the groups note. While Congress has blocked the cuts and granted increases instead, the short-term fix has not addressed the SGR at the root of the problem. Declining Medicare payments threatens beneficiary access to services, the groups warn, as more doctors drop Medicare.

The Senate's health care reform bill would block the 2010 cut and grant a 0.5 percent increase at a cost of an estimated $10.9 billion. It would make no changes to the SGR. The House physician payment bill would repeal the SGR and institute a new update system. In 2010, the fee update would be based on the Medicare Economic Index. In 2011 and beyond, it would be tied to growth in the gross domestic product, plus 1 percent (2 percent for prevention and primary care services). But the net cost of $210 billion over 10 years is not paid for, a sticking point with Republicans and conservative Democrats.

The debt ceiling bill, an industry source noted, waives the Senate pay-go rules for a physician fee fix, with spending up to $82 billion without offset cuts. However, this would require an authorizing bill.

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