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Senate, House Bills Would Block July 1 Cut in Physician Fees

Both bills would buy time for Congress to come up with a long-term solution to the payment problem. The current fee update formula has triggered negative updates for most of this decade and will keep doing so well into the next.

Bills have been introduced in the House and the Senate to prevent a 10.6 percent cut in Medicare payments for pathologists and other physicians due to start July 1 and assure a modest increase for the next 18 months. Congress late last year staved off a 10.1 percent cut set for the first of this year and approved a 0.5 percent increase through June 30.

The Senate bill—S. 2785, introduced March 13 by Debbie Stabenow (D-Mich.)—would replace the looming fee cut with a 0.5 percent increase for the rest of this year and a 1.8 percent increase for 2009. The American Medical Association supports the bill, saying it hopes the measure will be a basis for action by the Finance Committee.

The House bill—H.R. 5445, introduced February 14 by Georgia Reps. Tom Price (R) and David Scott (D)—would block the impending cut and grant an increase of one percent for the remainder of this year and 1.8 percent for 2009. *Continued on p. 2*

House Energy & Commerce Committee Approves Overhaul of CLIA Cytology PT

A bill to overhaul the CLIA proficiency testing program for gynecologic cytology is ready to be scheduled for consideration by the full House, now that the Energy & Commerce Committee has reported H.R. 1237, a measure backed by a broad swath of national and state pathology groups.

The lobbying push now by the 66-member Cytology Proficiency Improvement Coalition is to muster additional Senate co-sponsors for an identical bill, S. 2510, introduced last December and pending before the Committee on Health, Education, Labor & Pensions.

Both bills would terminate the current CLIA cytology PT program in force nationwide since the start of 2005 and replace it with a continuing medical education alternative to assure patient health and safety in Pap testing. Each clinical laboratory would be required to:

- ❑ Ensure that all individuals who screen and interpret cytological preparations participate annually in an approved CME program that provides each participant with gynecologic cytologic samples designed to improve locator, recognition, and interpretive skills; and
- ❑ Maintain a record of program results. *Continued on p. 7*

INSIDE *NIR*

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The physician fee cut of 10.6 percent, set for July 1, is higher than the one blocked earlier this year (10.1 percent), CMS says, because the law requires that the conversion factor for periods after June 30 "must be computed as if the legislated increase for the first half of 2008 had never applied." For 2009, CMS estimates, payments would drop by another 5.4 percent under the SGR formula.

Cut in Physician Fees, *from p. 1*

The House and the Senate this month approved budget resolutions for fiscal 2009 with reserve funds for a Medicare physician fee fix, though the amount is not specified. The funds would become available only if the committees of jurisdiction enact spending offsets elsewhere, as required under pay-as-you-go rules. The budget blueprints are guides for lawmakers and are not binding.

The President's FY 2009 budget request, released February 4, was silent on the physician pay issue, but proposed a deep cut in Medicare spending, mostly from lower payments to hospitals and other Part A institutional providers; labs were spared, though national lab competitive bidding was proposed (*NIR, 29, 8/Feb 11 '08, pp. 3-6*). Democratic health leaders have said they will not go along with the proposed Medicare reductions.

The health leadership also dismissed Medicare spending reductions advanced by the Bush administration on February 15 to bring program outlays in line with a target established by the 2003 Medicare Modernization Act. The act requires the President to propose, and Congress to consider, legislation to rein in Medicare spending when the general revenue portion of the program's financing exceeds 45 percent. That provision was triggered last year when the Medicare Board of Trustees reported that this threshold would be reached in FY 2013. In response, the White House proposed to lower spending by charging higher-income beneficiaries more for Medicare prescription drug coverage, capping medical malpractice awards, and injecting more consumer control and efficiencies into the program.

The AMA, the College of American Pathologists, and other physician groups want Congress to repeal the Sustainable Growth Rate (SGR) formula used to update Medicare physician fees each year. The big question is how to pay for a long-range solution, let alone a short-term one. Even the fix through 2009 authorized in the newly introduced House and Senate bills would cost billions. The Stabenow bill could cost as much as $15 billion over five years, health care analysts have estimated.

Paying for a physician fee increase is the thorny issue that led to the current six-month fix after House and Senate negotiators failed to agree on where to find the money. House Democratic health leaders favor tapping funds from Medicare managed care, noting that Medicare Advantage (MA) plans get rates 12 percent higher than traditional Medicare. The House last year reduced MA payments to 100 percent of fee-for-service levels, but this provision was stripped from the final compromise Medicare, Medicaid & SCHIP Extension Act passed in late December. The White House and most congressional Republicans, along with private health plans, continue to oppose reductions in the MA program. Meantime, MA payments are due to rise an average 4.8 percent in 2009, according to a preliminary estimate by the Centers for Medicare & Medicaid Services. The final figure, to be announced by May, could be higher or lower depending on final data calculations.

The political dynamics also mean that other Medicare providers would likely be tapped to finance the physician fee fix. And this prospect has made clinical laboratory interests heighten their vigilance to protect Medicare lab fees, currently set to emerge from a five-year freeze at the beginning of 2009. Absent congressional intervention, lab fees are due for a Consumer Price Index update next January 1, the first increase since 2003.

focus on: CLIA Lab Oversight

Current CLIA 'Hot Spots' & What They Mean for Labs

This year marks the 20th anniversary of the CLIA program, the most sweeping change in the regulation of clinical laboratory testing in the nation's history. For the first time, all testing of human specimens for disease or health status was made subject to federal oversight. Currently, 200,667 labs are enrolled in CLIA (in 1994, 150,000), according to the Centers for Medicare & Medicaid Services.

Congress moved with uncharacteristic speed in 1988 to enact the Clinical Laboratory Improvement Amendments (CLIA) in response to widespread media coverage of the life-threatening hazards posed by inaccurate results of Pap smears to detect cervical cancer. The government began implementing the law in 1992 by regulating labs based on the complexity of the testing they perform.

This year, several major policy "hot spots" have come into the limelight for labs that perform CLIA moderate and high complexity testing:

- ❑ Enforcement of revised quality control standards.
- ❑ Tighter lab inspection procedures, in follow-up to recommendations of the Government Accountability Office (GAO).
- ❑ Changes in proficiency testing for gynecologic cytology.

Updates on these issues were presented by the top CLIA official at CMS, Judy Yost, at a briefing of the Clinical Laboratory Improvement Advisory Committee (CLIAC) during its February 20-21 meeting in Atlanta, and in a March 18 LABLine audio conference sponsored by the American Clinical Laboratory Association and also featuring R. Bruce Williams, MD, FCAP, who chairs the College of American Pathologists' Lab Accreditation Commission.

Quality Control Policy Changes

In revamping CLIA quality control requirements in 2003, CMS made three major revisions to the Analytic Systems Section affecting verification of performance specifications for moderate complexity tests, clarification of calibration checks, and requiring two levels of external QC every day of testing (with equivalent QC options). Initially, inspectors rated compliance with these revisions via an "educational" approach to help with the transition to testing that was "new to the lab."

CLIA Lab Universe

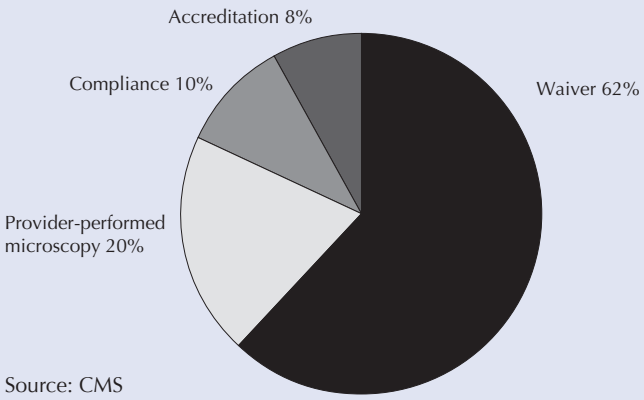
Total Number of Labs	200,667
Waived	119,839
Provider-performed microscopy	38,903
Compliance	19,827
Accredited	16,098
Exempt states	approx. 6,000*

*New York (2,952), Washington (3,065).
Source: CMS

But since the start of this year, this approach will continue only for external QC requirements in Section 493.1256, Yost told CLIAC. CMS will discontinue as "educational" rules for test method verification (Section 493.1253), maintenance and function checks (Section 493.1254), and calibration and calibration verification (Section 493.1255). Labs that do not meet these requirements will be written up for a deficiency and will get a letter requiring corrective action, though CMS could impose sterner sanctions if it thinks serious quality issues are involved.

Yost added one caveat: labs that are CLIA-certified through CLIA-approved accreditation organizations will be required to continue to meet their accrediting body's QC requirements. CMS is working with accrediting bodies to standardize inconsistent policies, she said.

CLIA Labs by Certificate Type *(non-exempt only)*



Source: CMS

In terms of equivalent QC, Yost noted there was recognition at the 2005 meeting of the Clinical Laboratory & Standards Institute that labs need more information from test manufacturers and that one-size-fits-all QC does not work for different test systems and methods. As a result, CLSI is developing documents on alternative QC for labs and risk management for manufacturers, she said, adding that CMS will revise its interpretive guidelines accordingly, though it has not yet determined if Options 1 to 3 will remain.

Lab Inspections: Response to GAO Recommendations

During the LABLine audio conference, Yost and Williams discussed their respective programs' actions following criticism from the GAO that lab oversight was not sufficient to ensure quality. The GAO report, issued in 2006, said a better job could be done in problem areas in inspection, complaint, and enforcement procedures and recommended steps to beef up CLIA oversight by CMS and survey organizations (*NIR, 27, 18/Jul 17 '06, pp. 1, 3-6*). Congress requested the report in the aftermath of widely publicized quality failures at Maryland medical testing facilities, most notoriously at Baltimore's Maryland General Hospital in 2004 where lapses went undetected by federal, state, and private accrediting inspectors and came to light only in a whistle-blower suit.

Yost noted that the GAO made 13 recommendations to CMS. Some overlap, so they can be rolled up into 10, she said. CMS disagrees only with the GAO's advice to require proficiency testing four times a year. The agency contends the current method is scientifically valid. It requires PT three times a year, with five challenges for a test total of 15.

The GAO urged CMS to find ways to compare survey findings across survey organizations, so problems do not fall through the cracks. Yost said CMS is working with its survey partners to collect and compile data for a crosswalk. One issue to resolve is a common definition of "serious deficiency." CLIA recognizes standard-level and condition-level deficiencies, the latter being the most serious, exposing the lab to stricter sanctions. Yet some feel that any deficiency should be regarded as "serious," she observed. Work on the definition is continuing via Partners in Lab Oversight, an initiative launched soon after the Maryland lab incidents to improve information sharing among survey organizations and coordinate follow-up on quality problems.

Number of Labs Subject to Routine Inspections

Compliance (inspections under the federal program by state survey agencies under contract with CMS)	19,827
CLIA-Accredited Labs by Accreditation Organization	
COLA	6,434
CAP	5,357
JCAHO	2,834
AABB	223
ASHI	129
AOA	65

Source: CMS

CMS has agreed to provide no more than two weeks' advance notice to labs it inspects, in line with the GAO's recommendations, Yost said. CAP and JCAHO have already switched to unannounced inspections, as has COLA for facilities it accredits under its cooperative agreement with JCAHO. As of October 1 this year, CAP will go from a six-month to a three-month window in its inspection program, with a focus on constant preparedness.

Both CMS and CAP have taken steps, Yost and Williams said, to improve the education and training of lab surveyors and to help labs prepare for an inspection, as well as publicize ways to file complaints confidentially, areas the GAO said needed strengthening. And to monitor survey deficiencies, including repeat deficiencies, CMS is upgrading the entire CLIA data system so that all entities can track repeat offenders and repeat enforcement actions.

Identity theft has popped up as a problem, Yost said, with individuals or entities using stolen identities to apply for CLIA enrollment so they can bill Medicare for tests that are not performed. To curb such fraud, "We may do a drive-by to verify the existence of the lab," she said. In some cases, CMS has found only empty lots and empty buildings at the address given.

Top Deficiencies Found in Lab Surveys: Helpful Corrective Hints from CMS

— Don't forget that analytes not listed in the regulations as requiring proficiency testing require a twice yearly accuracy check. Monitor your test menu so you don't miss any.

— Follow the manufacturer's instructions for test performance, in addition to meeting CLIA quality control requirements. Remember, CLIA supersedes if its requirements are more stringent.

— Have a quality assurance plan in place and have it followed for each phase of testing: general, pre, analytic, and post.

— The test report requires certain elements. This is critical with the advent of e-health records and the pervasiveness of laboratory information systems. Include the date the report was issued on the report.

— Avoid using expired reagents; monitor inventory and workload; develop and follow purchasing and storage policies.

— A procedure manual is required for all tests. Have one available, follow it, and have it signed by the laboratory director. Retain for each procedure for two years following its demise with initial and final dates.

— Specimen integrity is vital to producing good results. Have procedures to monitor specimens from collection to results reporting.

The *lab director is usually cited* when serious problems are found, CMS warns.

Changes in Cytology PT Rules

Proposed revisions to the cytology proficiency testing rules are "in clearance in the Department of Health & Human Services," Yost told CLIAC. The draft reflects 17 recommendations by CLIAC, she said. CLIAC urged a series of changes to the rules, including the frequency of testing, diagnostic categories and scoring systems, and the number of challenges (*NIR, 27, 17/Jun 29 '06, p. 1*).

CMS agreed to revisit the cytology PT rules after the House in December 2005 passed a bill to suspend the current program until certain changes were considered. While the revisions were in the works, CMS said it would use PT to emphasize improvements vs. punitive sanctions, as long as all affected sites and personnel participated in a CMS-approved cytology testing program (*NIR, 27, 8/Feb 6 '06, pp. 4-5*).

The CLIA cytology PT program has been highly controversial since CMS began enforcing it nationwide in January 2005, triggering opposition from a broad coalition of pathology and lab groups. CMS said it had no choice, since the law stated that labs are to be subject to cytology PT when commercially available. One organization, MIME, stepped forward and, in late 2004, was approved as the first national cytology PT provider (and was later bought by the American Society for Clinical Pathology).

In opposing the current program, the 66-member Cytology Proficiency Improvement Coalition, which includes national pathology groups and all state pathology societies, argues that the rules, written in 1992, don't reflect changes in cytology science and practice since then. The process of revising the rules began in 2006, CAP has pointedly noted, and CMS has repeatedly postponed the deadline for publishing a proposed rule. The pathology groups also object to CMS' directive that only regulatory changes could be considered; changes to the statute were off the table.

The coalition is spearheading a lobbying drive to terminate the current program and replace it with a continuing medical education alternative. The House Energy & Commerce Committee this month approved a bill (H.R. 1237) to do just that. A companion bill (S. 2510) is pending in the Senate (*related story, p. 1*).

New Warning Against Referral of PT Samples

Both Yost and Williams said clarification is being issued to end confusion that has arisen recently over the rules barring referral of proficiency testing samples to other labs.

Gains have been registered under the current cytology PT program, CMS says, as passing scores have risen, from 91 percent passed in 2005 to a 96 percent pass rate in 2007, with pathologists showing the most significant rate gain (67% in 2005 to 89% in 2007).

Yost reiterated the prohibition against sending any PT sample or part of a sample to another lab for testing, "Better wait until after you get the results from your PT provider." The prohibition also applies to communicating with another lab about PT results for that same time frame, she emphasized. Further, a lab should report to CMS any PT samples it gets from another lab during the PT event.

Williams said CAP is alerting its members to clarify that any lab may report for PT only testing actually done at the lab. "For example, if a lab performs HIV screening and routinely sends positive samples to another lab for confirmation, it is not allowed to do this for PT as it would be considered referral of PT. PT is meant to assess the testing done in one specific lab, not the testing done in an outside facility." The penalty for violating this rule is severe, he pointed out—revocation of the lab's certification for at least one year and the potential suspension of the medical director's license for two years.

CAP has identified common areas where labs may inadvertently refer PT, Williams noted:

- *Reflex and confirmatory testing:* For a patient sample, if a lab does not perform the confirmatory or reflex portion of a test battery or other testing, the sample would typically be sent to a different lab for that testing. For a PT sample, however, a lab may not send it outside the participating lab. The lab must complete the PT result forms using the appropriate code.
- *If multiple CLIA numbers exist within the same institution or ancillary lab:* Special caution is advised when labs get PT samples with more than one CLIA/CAP number. If the specimens are tested in the wrong area, this could be perceived as referral or "sharing" of PT if both labs test the PT sample. This could also occur if the wrong lab does the testing and reports the results to the PT provider.
- *Slides for pathologist review:* Certain patient slides, like abnormal differentials, involve patients and require a pathologist's review. These slides may go to an outside lab for review, but PT slides cannot. Rather, the pathologist must review the slide at the lab's physical address.

Connecticut, New York To Get New Medicare Part A/B Contractor

The Centers for Medicare & Medicaid Services has awarded National Government Services (NGS, headquartered in Indianapolis) a contract of up to five years for the combined administration of Medicare Part A and Part B claims payment in Connecticut and New York. The contract has an approximate value of $323 million over five years, CMS said.

NGS is the sixth Part A/B MAC award by Medicare. By 2011, a total of 15 A/B will cover every state and the District of Columbia, CMS says, replacing the old payment system that split claims processing between fiscal intermediaries and carriers. The new system consolidating A/B work was authorized in the 2003 Medicare reform law.

As the Medicare Administrative Contractor (MAC) for this jurisdiction (#13), NGS will be the first point of contact for handling Medicare fee-for-service claims from hospitals, skilled nursing facilities, physicians, and other health care practitioners in the two states. Currently, the work for the states is split among two fiscal intermediaries and four carriers. NGS is scheduled to take over no later than November 2008.

The contract includes a base period and four one-year options, with an opportunity to earn award fees according to NGS' ability to meet or exceed CMS-set performance requirements in provider customer service, payment accuracy, improved provider education leading to correct claims submissions, and cost savings from efficiencies and innovation.

Previous MAC Awards

- Highmark Medicare Services Inc. (Camp Hill, Pa.):
  Jurisdiction 12—Delaware, Maryland, New Jersey, Pennsylvania, and the District of Columbia. CMS restored the award to Highmark following a protest lodged by Palmetto GBA with the Government Accountability Office on November 5, 2007. The agency took corrective action, and the GAO dismissed the protest. As a result, CMS expects Highmark to take over the workload by the end of this year.
- Palmetto GBA (Columbia, S.C.):
  Jurisdiction 1—California, Hawaii, Nevada, American Samoa, Guam, and the Northern Mariana Islands.
- Noridian Administrative Services, LLC (Fargo, N.D.).
  Jurisdiction 3: Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming.
- TrailBlazer Health Enterprises (Richardson, Texas).
  Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas.
- Wisconsin Physicians Health Insurance Corp. (Madison, Wis.).
  Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska.

MAC contracts must be reopened for competitive bidding every five years. For more information, see *http://www.cms.hhs.gov/MedicareContractingReform/*

CLIA Cytology PT, *from p. 1*

The College of American Pathologists argues that this is a better approach "because it challenges screening and interpretation skills in a constructive learning environment and, over time, keeps pace with advances in science and technology." CAP and other coalition members say the current PT requirements are outdated, based on rules written in 1992, and do not reflect changes in cytology science and practice since.

Meantime, cytology PT testing continues under the current CLIA program. CAP and the American Society for Clinical Pathology are the two nationally approved PT providers. The Maryland health department runs an approved program for specimens of state residents.

Coverage Expanded for Home Testing for Anticoagulant Therapy

Medicare previously provided home test coverage only for beneficiaries with mechanical heart valves who are on warfarin.

In a policy change announced March 19, the Centers for Medicare & Medicaid Services has expanded Medicare coverage for home blood testing of prothrombin time (PT) International Normalized Ratio (INR). As a result, coverage will extend to beneficiaries using the drug warfarin, an anticoagulant medication, for chronic atrial fibrillation or venous thromboembolism.

Atrial fibrillation is an electrical disturbance of the heart that produces an irregular heart rhythm and increases the risk of stroke from blood clots forming in the heart chambers and then traveling to the brain. Patients with venous thromboembolism experience blood clots, usually in the legs, which may break off and travel to the lungs—a potentially fatal complication.

Patients use PT/INR blood testing to determine how well their anticoagulant medicine is working to prevent blood clots. PT measures the speed of blood coagulation, while INR provides a way to standardize such measurement. Tests can be performed at home as long as patients work with their health care provider as part of anticoagulation management. The new National Coverage Determination is posted at *cms.hhs.gov/mcd/viewdecisionmemo.asp?id=209*.

Don't Miss These Upcoming G-2 Events!

April 23—Audio Conference, Strategies for Optimizing Transfusion Safety & Quality
Learn how to avoid patient safety risks and inefficient practices by effective communication and cooperation among nursing, clinical lab, and blood bank staff.

April 30-May 2: Molecular Diagnostics: Making $ & Sense in Operating an MDx Lab
Hyatt Regency, Cambridge, Mass.
Get the lowdown on different business models, plus financial and technical trends driving this fastest growing area of the U.S. lab industry.

June 18-20: Laboratory Outreach 2008, Winning with the Right Numbers
The Bellagio, Las Vegas.
Profit from expert know-how on building state-of-the-art group, hospital, and health system outreach programs.

For registration and other information, go to ***www.g2reports.com***.

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