



CMS Drops Proposed Cytology Proficiency Testing Rule

In explaining its decision, CMS said there was a lack of consensus and support for the changes envisioned in the rulemaking.

In an April 8 memo to state survey agency directors, the Centers for Medicare and Medicaid Services (CMS) said it is withdrawing its proposed rulemaking to revise requirements for gynecologic cytology proficiency testing under the Clinical Laboratory Improvement Amendments (CLIA).

CLIA officials had said during the September 2010 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) that the agency was considering this move (*NIR 10, 16/Sept. 9, p. 1*).

In making the withdrawal official, Thomas E. Hamilton, director of the CMS survey and certification group, said in the memo, "CMS was acting in response to comments it received on the proposed revisions, the greater percentage of which requested replacement of the current proficiency testing (PT) program with a continuing education program."

This conflicts with CMS's interpretation that the CLIA statutory language requires the testing of individuals, he said. Critics contend 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 ensure Pap smear quality results.

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Lab Copay Proposal Could Be Resurrected

A perennial threat to the clinical laboratory community could return—namely, the introduction of a copayment for Medicare-covered lab tests.

Clinical lab groups have fought off numerous attempts in Congress over the years to institute a lab copay but may have to mobilize once again to squelch this highly unpopular—and controversial—proposal.

Speaking at the annual meeting of the American Clinical Laboratory Association (ACLA) April 19, Chuck Clapton, health policy director for the Senate Health, Education, Labor, and Pensions (HELP) Committee, predicted that the copay could resurface in congressional discussions to offset Medicare costs.

Beneficiary cost sharing for Medicare-covered lab services was dropped in 1984 as part of the switch to the Part B clinical lab fee schedule. But reviving a copay for these services has been bandied about at least twice in recent years, the last time in 2009 when the Senate Finance Committee proposed it as one option to help finance health care reform legislation.

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Ryan's Plan Promises Medicare Physician Fee Fix, Critics Fault It for Lack of Specifics

Republican Rep. Paul Ryan (Wis.), chairman of the House Budget Committee, says one of the objectives of his proposed Medicare reforms is to “fix the physician payment formula for the next 10 years so that beneficiaries continue to have access to health care.”

Critics have fired back that Ryan's plan does not spell out how it would be paid for and further does nothing to fix the underlying problem—the sustainable growth rate (SGR) formula that has triggered ever-steeper cuts in physician fee updates that Congress has repeatedly blocked.

Unless Congress intervenes, Medicare physician payments are scheduled for an SGR cut of approximately 30 percent in 2012. President Obama's budget for 2012 would block the cut and extend the current freeze on the payment update for two years, through Jan. 1, 2014.

Ryan's promise to fix physician payments is included in the budget blueprint for fiscal 2012 that he crafted and that the GOP-controlled House passed April 15. The blueprint also would repeal the health care reform law and overhaul both Medicare and Medicaid (*related story, p. 3*).

According to the House Budget Committee Report (H. Rept. 112-158), “the inclusion of an SGR reserve fund in the budget resolution accommodates a fix to the SGR, providing proce-

dural flexibility to allow for SGR reform legislation as long as it did not increase the deficit” over the next 10 years.

But Democratic leaders of the House Energy and Commerce and Ways and Means committees scoffed that “the Republican budget simply establishes a deficit-neutral reserve fund, which means that it has to be fully paid for with yet-unidentified cuts (most likely from Medicare).”

They also pointed to a footnote in the Congressional Budget Office's analysis of the budget resolution that says CBO assumed no change in the SGR when it prepared its estimates based on specifications from the staff of Ryan's committee.

For pathologists and other physician groups, repeal of the SGR is a longstanding priority. House health leaders recently agreed that the SGR is “broken” and in a bipartisan letter to 51 physician organizations asked for their ideas on a permanent fix to the Medicare formula. In a March 28 letter they said they were committed to finding a permanent, sustainable solution this year (*NIR 11, 7/April 8, p. 3*).

Congress established the SGR system in the 1997 Balanced Budget Act because of concern that the Medicare physician fee schedule would not adequately constrain overall increases in spending for physicians' services.

The SGR is a target that is intended to control the growth in the volume of physician services by tying Medicare reimbursement levels to a number of factors, including growth in the volume of services relative to growth in the national economy. The formula compares actual spending to target spending and adjusts the update. If expenditures exceed the target, the update is reduced.

Since 2002, spending has been above the target, triggering cuts in reimbursement. With the exception of 2002, when a 4.8 percent decrease was applied, Congress has enacted a series of bills to override the reductions (last year on five separate occasions). 

GOP Budget Calls for Radical Medicare, Medicaid Surgery

The Republican budget blueprint for fiscal 2012, which passed the House April 15 by a vote of 235-193, would replace Medicare's fee-for-service system with premium support and would change federal Medicaid payments into block grants to states, though it does not specify how such grant amounts would be calculated. It also would repeal the health care reform law, the Patient Protection and Affordable Care Act (PPACA).

Overall, the budget resolution, developed by Rep. Paul Ryan (R-Wis.), chairman of the House Budget Committee, envisions \$6 trillion in spending cuts and more than \$4 trillion in tax cuts over the next 10 years.

The GOP road map for overhauling Medicare and Medicaid stands little chance of getting through the Democratic-controlled Senate, but it sets the stage for debate over spending on federal entitlement programs and how to rein it in to help reduce the federal deficit.

Toward a New Medicare

The shift to Medicare premium support would start in 2022 for people currently younger than age 55. When eligible for Medicare, they would choose from a menu of private insurance plans, and the government would provide about \$15,000 to cover the cost of premiums. The federal payments would go to the insurers selected by beneficiaries. "It gives consumers choice," Ryan has said. "It has insurers competing against each other for their business. We want to harness the power of patient choice."

In its assessment, the Congressional Budget Office said the use of Medicare funds for seniors to shop for private insurance would likely mean seniors would bear a larger share of their health care costs than under the current program. "That greater burden would require them to reduce their use of health care services, spend less on other goods and services, or save more in advance of retirement than they would under current law."

President's Counter Proposal

On April 13, President Obama offered his deficit reduction framework that calls for hundreds of billions of dollars in Medicare and Medicaid savings without making drastic changes to the programs.

It would expand the power of the Independent Payment Advisory Board, which was created under PPACA to make recommendations to Congress on Medicare policy. It also would streamline the federal funding formulas for Medicaid and the Children's Health Insurance Program.

Further savings would be sought by reducing Medicare prescription drug spending by making the generic versions of biologic drugs available more quickly and prohibiting "pay-for-delay" patent settlements between brand-name and generic drug companies.

According to a White House fact sheet, the proposal would save \$340 billion by 2021, \$480 billion by 2023, and at least \$1 trillion in the following decade, on top of the savings found in PPACA. Overall, the proposal would reduce the deficit by \$4 trillion over the next 12 years.

Obama has drawn a sharp contrast between his plan and the House Republican budget resolution (H. Con. Res. 34). "Their plan essentially lowers the government's health care bills by asking seniors and poor families to pay them instead. Our approach lowers the government's health care bills by reducing the cost of health care itself," he said. 

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Despite withdrawal of the proposal, Hamilton noted, the CLIA program will implement the majority of CLIAC-endorsed PT recommendations “where the comments from the public and the cytology community demonstrate consensus and CMS sees benefit.”

Changes to Be Made

Using surveyor interpretive guidance and administrative policy, CMS will implement the following:

- Encourage labs to participate in educational lab programs in addition to individual PT;
- Change the current term of “slides” to challenges;
- Define a challenge as case equivalent;
- Retain four response categories and continue to require at least one challenge from each of the four categories in each test;
- Require field validation, monitor challenges continuously, and remove challenges that fail field validation;
- Require vendors to disclose field validation procedures;
- Provide educational feedback for result discrepancies;
- Continue to allow PT providers to determine proctor requirements;
- Require PT providers to disclose their appeals process in writing; and
- Change language to state “individuals who score <90” as opposed to using the word “fail.”

Changes Not to Be Made

What will not be implemented at this time, Hamilton said, are:

- Reduce the frequency of testing to a three-year cycle;
- Use 20 challenges for every test (initial test and retest);
- Change the grading scheme to a new model that is the same for both technical supervisors and cytotechnologists;
- Require biopsy confirmation of category D (HSIL/cancer) challenges but not category C (LSIL) challenges;
- Add a transition phase for new technology such as virtual slides when the individual can request retesting with the previous platform or format (e.g., glass slides); and
- Require oversight organizations and agencies to determine if labs participate in educational programs and provide labs with identification of available resources.

PT Proposal Controversial From the Start

The cytology PT rulemaking, issued Jan. 16, 2009, called for lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies, for example, digital images, as they become available.

CMS estimated it would impact 2,142 cytology laboratories and 12,831 individuals who screen or interpret 65 million gynecologic cytology preparations in the United States each year.

The proposals were based on recommendations of a work group convened by CLIAC and later endorsed by the full committee. But the rulemaking triggered opposition from the cytology community at the outset when CMS insisted that the CLIA statute requires PT testing of individuals and any change in this regard was off limits.

In refusing to budge, Hamilton's memo faulted cytology continuing education programs for not meeting the law's requirements for the number and frequency of slides to be tested. "Additionally, the evaluation of results performed by [these] programs is not sufficient to satisfy the statute and regulations, as participation in continuing education is voluntary, and the programs have no oversight authority. The educational challenges provided by continuing education programs are initially performed independently by each individual who reads and interprets cytology slides, but a consensus answer is provided to the educational program on behalf of the entire lab. Credits earned for participation are granted to participants even when there is a failure to successfully identify the challenge, which may disguise poor performers.

"Replacing the current requirements with continuing education would introduce risk to the CLIA program. The current system already includes continuing education tailored to individual areas of failure, and the proposed change would diminish CMS' ability to oversee, monitor, and enforce quality testing through cytology PT which has demonstrated proven success."

In calling for an alternative PT approach, the broad-based 60-member cytology PT coalition has argued that the current regulations, initially written in 1992, have not kept pace with the latest science and technology. The coalition asserts that the statutory language can accommodate alternative education-based programs to assess proficiency. In the 110th Congress the coalition gathered bipartisan support behind legislation for this purpose. The measure passed the House and got 43 cosponsors in the Senate but no further action was taken before the session closed in January 2009.

CMS resolutely defends the current cytology PT program, citing success in improving quality and reducing errors, based on PT results since nationwide testing began in 2005. According to the April 8 memo, "The number of individuals who scored less than the passing score of 90 percent has decreased significantly over time." Improvements in participant scores may be due to post-failure continuing education and greater comfort with the testing process, the memo concluded.

There are two CMS-approved national PT providers: the College of American Pathologists and the American Society for Clinical Pathology. The state of Maryland runs an approved program for testing individuals who examine Pap smears from Maryland residents. 

Lab Copay Proposal, from p. 1

The committee proposed a uniform 20 percent coinsurance for all Medicare Part B services, including preventive and diagnostic clinical laboratory services.

The lab industry lobbied vigorously against such copays, arguing that they would shift an entirely new cost burden to beneficiaries. The AARP also explicitly rejected lab copays. Ultimately, the Finance Committee withdrew the copay proposal.

While many in the industry hoped the issue was laid to rest, Clapton explained that given the current federal budget deficit, all potential sources of savings will come under close scrutiny. 

Revocation of Texas Lab's CLIA Certificate Upheld

The Centers for Medicare and Medicaid Services (CMS) was legally authorized to revoke a Texas laboratory's certificate under the Clinical Laboratory Improvement Amendments (CLIA) because its owner had another CLIA certificate revoked in the previous two years.

That was the decision by an administrative law judge (ALJ) for the Departmental Appeals Board of the Health and Human Services Department in *Southlake Emergency Care Center v. CMS*. The center may continue to provide patient care services, but lab testing must be sent elsewhere to a CLIA-certified facility.

ALJ Joseph Grow found it undisputed that Dr. Charles J. O'Hearn owned and operated both the Southlake Laboratory and the Coppell Laboratory. CMS revoked Coppell's CLIA certificate on June 22, 2010. This triggered the agency's move against Southlake because it had the same owner as Coppell.

For all you need to know on how to safeguard your CLIA certificate, see the chapter on "CLIA Sanctions and Other Legal Issues" in the latest update to CLIA Compliance: The Essential Reference for the Clinical Laboratory, 3rd Edition. It offers in-depth analysis by attorneys Robert E. Mazer, J.D., and Kristin Cilento Carter, J.D., with Ober/Kaler in Baltimore. Details on the handbook are available at www.G2Intelligence.com.

"The most interesting aspect of the case," attorney Robert Mazer with Ober/Kaler in Baltimore, told *NIR*, "is the ALJ's rejection of the argument that CMS should not have revoked the CLIA certificate of Coppell Lab because it had already closed. CMS appears to have argued that while Coppell Lab may have been closed, its CLIA certificate was not surrendered."

O'Hearn said he submitted a plan of correction for Coppell Lab on April 20, 2010, but then closed the facility that same month, citing "present economic

conditions and shrinking health care reimbursements." He said he did not appeal Coppell Lab's revocation since the notice came two months after he had closed it and he saw no reason to take further action.

ALJ Grow found that "the voluntary closure of a lab, however, does not preclude CMS from proceeding to revoke the lab's CLIA certificate. The Board has held that revocation under such circumstances may form the basis of the two-year prohibition against that laboratory's owners or operators operating another CLIA laboratory. *Sentinel Med. Labs., Inc.*, DAB No. 1762 (2001), *aff'd*, *Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-70236 (9th Cir. May 22, 2002). If laboratories were allowed to close to escape revocation and their owners to then open another laboratory, the relevant CLIA regulations would be null, and the government's enforcement powers could be evaded."

A lab may withdraw from CLIA by going out of business, the regulations stipulate. However, as the ALJ noted, CMS may revoke a lab's CLIA certificate even

after it has gone out of business if the agency decides that the lab's performance warrants going ahead with the enforcement action. In this light, Mazer observed, "Once the agency issued a notice of proposed revocation, it may not have made a difference—the lab may not have been able to escape revocation by giving up its CLIA certificate." 

New National Coordinator Named for HIT Office

Farzad Mostashari, M.D., has been named to head the Office of the National Coordinator (ONC) for Health Information Technology at the U.S. Department of Health and Human Services (HHS), succeeding Dr. David Blumenthal who has returned to Harvard University to teach. HHS Secretary Kathleen Sibelius made the announcement this month.

Mostashari previously was deputy national coordinator for programs and policy at ONC. Prior to joining ONC in July 2009, he served in various health IT roles throughout New York City, most recently as assistant commissioner for the primary care informatics project in the city's health and mental hygiene department, where he facilitated the adoption of prevention-oriented health IT by more than 1,500 providers in underserved communities. In addition, he led the city's Center of Excellence in Public Health Informatics funded by the Centers for Disease Control and Prevention and an Agency for Healthcare Research and Quality project to measure quality at the point of care. 

Medicare *Claims Advisory*

Changes in Drug Screening Codes

Effective April 1, 2011, the Centers for Medicare and Medicaid Services has updated the status of two codes on the 2011 Medicare Part B laboratory fee schedule:

- ❑ Deleted: G0431QW, Drug screen, qualitative; multiple drug classes by high-complexity test method (*e.g.*, immunoassay, enzyme assay), per patient encounter. Code G0431 describes a high-complexity test and should not be reported with a QW modifier; this modifier indicates a CLIA-waived test.
- ❑ Added: G0434QW, Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived or moderate-complexity test, per patient encounter. Code G0434 can describe a CLIA-waived test. The use of the QW modifier to indicate a CLIA-waived test is necessary for accurate claims processing.

Codes G0431 and G0434 remain on the lab fee schedule. 

Interest Rate Drops for Medicare Overpayments, Underpayments

Effective April 19, 2011, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has dropped to 11 percent from 11.25 percent in effect since Jan. 24.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar year 2011) or the private consumer rate fixed by the Treasury. Upon notification from the Treasury of the new private consumer rate of 11 percent, the Centers for Medicare and Medicaid Services announced the quarterly update to the Medicare interest rate in Transmittal 187 (April 12, 2011). The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent. 



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