G2 INTELLIGENCE

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New Year Revives Old Threats to Labs, Pathologists

Lab and pathology priorities are caught in the undertow as Congress and the White House battle over reducing the federal budget deficit, a fight intensified this year by the fall elections, increasing the possibility that lawmakers could punt on major Medicare reform and other big-ticket items until voters decide who should be in charge of the government in 2013.

Clinical laboratories and pathologists entered the new year with only a two-month reprieve from major Medicare reimbursement cuts.

Congress canceled the 27.5 percent cut in Medicare physician payments scheduled for Jan. 1, 2012, under the sustainable growth rate (SGR) formula and froze the physician fee update at 0 percent until March 1. For the freeze period the conversion factor is $34.0376.

It also extended from Jan. 1 to March 1 the grandfather protection that allows qualified independent clinical labs to bill Medicare directly for the technical component of pathology services to hospital inpatients and outpatients.

Provisions blocking these payment cuts were contained in legislation (H.R. 3765, the Temporary Payroll Tax Cut Continuation Act of 2011) that cleared the House and the Senate by unanimous consent and was signed into law Dec. 23, 2011. The measure also extends expiring Medicare payment provisions for numerous providers, including hospitals, nursing homes, and ambulance service providers.

The rationale for the short-term SGR and grandfather extensions was to avoid disruptions on Jan. 1 and provide time for further negotiations on financing longer-term extensions.

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Who Should Regulate Lab-Developed Tests?

The Food and Drug Administration (FDA) has already announced its decision to regulate laboratory-developed tests (LDTs), citing its jurisdiction over medical devices.

In contrast, pending House legislation, supported by leading clinical laboratory and pathology groups, would assign LDT oversight to the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare and Medicaid Services (CMS).

"The FDA has recently suggested that it has three draft guidances on LDT regulation under review," noted attorney Peter Kazon, senior counsel with Alston & Bird in Washington, D.C., who spoke at a Jan. 5 webinar sponsored by G2Intelligence:

- ❑ A guidance discussing a general regulatory framework.
- ❑ A guidance to address some type of registration or notice requirement for LDTs.

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- A guidance comparing quality-control requirements under both FDA law and the CLIA program at CMS.

"It is unclear when they will be issued for comment," Kazon said.

But Rep. Michael Burgess (R-Texas) would put CLIA in the driver's seat in regulating LDTs, and he has introduced legislation to do just that (H.R. 3207), with 11 GOP co-sponsors to date. The bill also would clarify that LDTs are not medical devices subject to FDA oversight.

Provisions of the bill, summarized by Kazon, would:

- Establish a test registry data bank of all new LDTs and direct-to-consumer DNA tests.
- Require laboratories to notify CMS of new LDTs or direct-to-consumer DNA tests.
- Require test-offering entities to register. These are entities that offer direct-to-consumer tests but do not actually perform the testing.
- Allow CMS, acting through CLIA, to review the tests for clinical validity. Where clinical validity was not shown, CMS could force the test to be withdrawn.
- Finance the program with fees paid by laboratories as part of the CLIA process.

The Burgess bill, the Modernizing Laboratory Test Standards for Patients Act, was introduced Oct. 14, 2011 (*NIR 11, 19/Oct. 20, p. 1*). It has the "full and strong" backing of the American Clinical Laboratory Association (ACLA), said President Alan Mertz. "This legislation offers a modern, innovative, and flexible approach that builds on the success of CLIA. It avoids regulatory overlap and redundancy, while assuring consumers that LDTs are reliable and accurate. This is a balance that will encourage continued innovation and protect consumers."

The question of who has jurisdiction—FDA or CMS/CLIA—is important because LDTs—in vitro diagnostics manufactured by and offered in the same CLIA-certified laboratory—are estimated to number in the thousands and are used for a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions.

The bill also "enhances public transparency and strengthens reporting of adverse events—all without additional government expenditures," ACLA said in a letter to Burgess. Further, it would accelerate progress on personalized medicine by encouraging the clinical lab industry to keep innovating with new tests "that detect and diagnose disease as well as inform the treating physician whether a drug or biologic is an effective means of treating a particular patient" based on that patient's genetic profile, including predisposition to certain diseases and optimal response to drug therapy.

In introducing the bill, Burgess said, "It is important that we relieve restrictions while providing regulatory reform that positively impacts and protects patients while promoting job growth. Adding additional and duplicative FDA regulations to industries that are not under the agency's jurisdiction will further burden an overstretched institution that cannot currently process its substantial backlog due to its own regulations being a hindrance." G2

Persistence Pays Off in Fight to Save CLIA Certification

It took nearly two years, but a small laboratory has prevailed in its appeal against having its certificate under CLIA (Clinical Laboratory Improvement Amendments) revoked for one year for sending proficiency testing (PT) samples to another lab for analysis in violation of the CLIA statute and regulations.

The Centers for Medicare and Medicaid Services (CMS) opted not to contest the finding of Richard J. Smith, an administrative law judge (ALJ) for the Health and Human Services Departmental Appeals Board, that "what happened during the time period at issue was not an intentional referral and not for purposes of analysis."

"To my knowledge, this is the first case in which CMS's determination that a lab violated PT referral prohibitions has been reversed," the attorney representing the lab, Robert E. Mazer, with Ober/Kaler in Baltimore, told *NIR*.

The Facts of the Case

At issue in the case, *J.B. and Greeta B. Arthur Comprehensive Cancer Center Laboratory v. CMS* (DAB No. 2436), were PT samples involved in three testing events in 2008 and one testing event in 2009.

After testing its PT samples, the Cancer Center (Mexico, Mo.), which was CLIA-certified in the subspecialties of chemistry and hematology, sent unused portions to the lab operated by the hospital with which the center is affiliated, Audrain Medical Center (also in Mexico, Mo.), for proper storage and eventual disposal. AMC and the center have different CLIA certificates and basically operate independently of each other, including having separate directors for each lab.

Certificate revocation, the most severe sanction under CLIA, would bar the lab from performing diagnostic testing on human specimens and from receiving Medicare payments for its services. It also would prohibit its owners and operators from owning or operating any lab for at least two years from the date of the revocation.

The hospital, however, tested the unused portions before the Cancer Center reported its PT results to its PT provider, the American Association of Bioanalysts. This was noted in a September 2009 routine survey by the Joint Commission (TJC) that interpreted the circumstance as not an intentional referral and granted the center its accreditation. However, based on the finding of a potential PT referral, TJC advised the center that it had to report this to CMS, which followed up with a complaint investigation. After that survey was completed in October 2009, CMS determined that the center improperly referred PT samples to another lab for analysis. In a letter to the center on Jan. 14, 2010, CMS proposed to revoke its CLIA certificate and cancel its approval to receive Medicare payments as of Jan. 29, 2010. On Jan. 21, 2010, the center asked the agency to reconsider. In a Feb. 9, 2010, response, CMS refused to do so, prompting the center on March 11, 2010, to request an ALJ hearing. The ALJ decision upholding the center's position was issued on Sept. 21, 2011. CMS then had 60 days to respond, but by the time that period expired, the agency opted not to pursue the matter further.

Mazer noted that the ALJ "found it significant that the cancer center laboratory did not *direct* the hospital to test its PT samples and it did not require or suggest that the hospital advise it of its own test results." ALJ Smith ruled that AMC performed tests to check its own equipment, not to verify Cancer Center's results.

Significance of the Case

The ALJ decision is significant in one respect, Mazer said in comments to *NIR*. "The

Departmental Appeals Board has frequently permitted CMS to revoke CLIA certificates of various laboratories that have claimed to have accidently or unintentionally referred PT specimens to other labs. This decision demonstrates that the fact that a lab may have sent its PT samples to another lab does not mean it violated CLIA's PT referral prohibition, even if the other lab retested the PT specimens.

"In another respect, the decision is less significant," he noted. "The ALJ did not make new law. His decision reflected application of particular facts to the terms of the statute and regulations and previous interpretations that indicated that the prohibition was violated only if the purpose of sending the PT specimens to another lab was so that they would be tested. Although in this case another lab did test the PT specimens, that was not the reason why it was sent the unused PT specimens. They were provided only so they might be properly stored.

"Obviously, it would have been better for everybody if CMS had not attempted to revoke the lab's certificate," Mazer said. "But CMS should be commended for not pursuing an appeal after the ALJ found that the facts did not support a finding that there had been an intentional referral of PT samples for analysis."

The ALJ ruling can be found at *www.hhs.gov/dab/decisions/civildecisions/cr2436.pdf.*

New From CMS: the Independence at Home Demonstration

The health care reform law (the Patient Protection and Affordable Care Act of 2010) authorized a series of Medicare demonstration projects to test various coordinated care models that reward health care providers for furnishing high-quality care while reducing costs.

And the Centers for Medicare and Medicaid Services (CMS), through its Innovation Center, has been energetic in getting these projects off the ground. First, there was the shared savings program for accountable care organizations (*NIR 11, 20/Nov. 3, p. 4; 11, 7/April 8, p. 1*). Then there was the bundled payment initiative (*NIR 11, 16/Sept. 8, pp. 4-5*).

"This program gives new life to the old practice of house calls, but with 21st century technology and a team approach"—Marilyn Tavenner, acting CMS administrator

The latest is the Independence at Home Demonstration to encourage better coordination of care through home-based primary care for Medicare beneficiaries with multiple chronic conditions and functional limitations. CMS issued a call for applications on Dec. 21, 2011. The deadline for applications and letters of intent is Feb. 6, 2012.

The project will reward health care providers that show a reduction in Medicare expenditures through an incentive payment if they succeed in providing high-quality care while reducing costs. CMS will use quality measures to ensure that beneficiaries experience this care.

Medical practices that are eligible to participate in the demonstration must include physicians or nurse practitioners who have experience delivering home-based primary care. Teams may also include pharmacists, social workers, and other supporting staff.

Up to 50 medical practices will be selected to participate for a three-year period, and during each year of the project each practice must serve at least 200 Medicare fee-for-service beneficiaries with multiple chronic conditions and functional limitations in two or more activities of daily living. In all, the demo aims to benefit up to 10,000 of these Medicare patients.

New Year Revives Old Threats, *from p. 1*

When Congress returns later this month, time is short for a House-Senate bipartisan committee to negotiate an agreement on extending the payroll tax cut and other expiring provisions, including the SGR fix and the grandfather protection.

Pathology and other medical groups continue to push hard for repeal of the SGR, which has triggered negative updates for most of the last 10 years. The SGR sets a target growth rate for Medicare physician spending. When actual spending exceeds the target, a fee cut is required. Congress has repeatedly intervened to block a fee reduction but has authorized only a series of short-term patches to the problem. Under the current formula, cuts even steeper than the 27.5 percent required for 2012 are on track for future years.

Now is the time, these groups argue, to make a permanent fix to the SGR by scrapping it and turning to payment based not on service volume but on service quality and efficiency. Delaying SGR repeal only hikes the costs in the long run, they say.

Who's Who on the Extensions Conference Committee

A 20-member conference committee is set to begin meeting the week of Jan. 16 on a full-year extension of the payroll tax holiday and another block of an SGR cut scheduled in Medicare physician payments scheduled for March 1.

House Ways and Means Committee Chairman Dave Camp (R-Mich.) is expected to chair the committee. A majority of conferees from each chamber is needed for the conference report to be approved and sent for a floor vote in each chamber.

Roster of Committee Members

House	Senate
Democrats	
Allyson Schwartz (Pa.)	Max Baucus (Mont.)
Sandy Levin (Mich.)	Jack Reed (R.I.)
Xavier Becerra (Calif.)	Ben Cardin (Md.)
Chris Van Hollen (Md.)	Bob Casey (Pa.)
Henry Waxman (Calif.)	
Republicans	
Kevin Brady (Texas)	John Barrasso (Wyo.)
Nan Hayworth (N.Y.)	Jon Kyl (Ariz.)
Tom Reed (N.Y.) Mike	Mike Crapo (Idaho),
Dave Camp (Mich.)	Republican Whip
Renee Ellmers (N.C.)	
Tom Price (Ga.)	
Fred Upton (Mich.)	
Greg Walden (Ore.)	

Though most lawmakers agree that the SGR is broken, the cost of its repeal, an estimated $300 billion over 10 years, has been a stumbling block in the deficit-cutting climate. Absent congressional action, that cost would get higher, accumulating to more than $500 billion in only a few more years, the American Medical Association has warned.

Negotiating the payroll tax cut and other extensions appears even harder this year, Hill watchers say, with the fall elections looming large in political calculations. Congress remains sharply divided on partisan lines over how to reduce the federal deficit. The GOP supports expenditure cuts and no tax increases, while Democrats and the Obama administration call for a mix of cuts and increased tax revenue.

Legislative Outlook for Labs, Pathologists

This year poses more challenges to lab and pathology reimbursement, and what happened last year sets the stage, said Alan Mertz, president of the Ameri-

can Clinical Laboratory Association, who spoke at the Jan. 5 G2Intelligence webinar, Labs and Pathologists in the Crosshairs Again.

In the political environment on Capitol Hill and the continuing struggle over reducing the federal deficit and stimulating job growth, the mood is likely to be "it doesn't matter if it is bad policy, we just need the money," he said.

And the political difficulty of direct beneficiary cuts makes providers a more likely target for deficit-reduction measures.

The good news for clinical labs is that in 2011 neither the White House nor the House and Senate proposed any cuts to the Medicare lab fee schedule or the introduction of a 20 percent coinsurance for tests on the schedule.

The bad news is that labs could be targeted this year for fee cuts to help pay for an SGR fix. The two-month reprieve was paid for by nonhealth savings of $4 billion. Blocking the SGR cut through the rest of 2012 would require at least an estimated $20 billion in offsetting savings. "The SGR will likely continue to be the 'pay-for' threat well into the future," he said.

But if Congress moves to a deficit-reduction deal that includes broad cuts in Medicare, lab providers could be tapped to pay the bill, as the Medicare Payment Advisory Commission (MedPAC) said last year when it recommended paying for SGR repeal with cuts to physician specialists, a freeze on primary care, and clinical labs pegged for $21 billion in savings over 10 years (*NIR 11, 21/Nov. 17, p. 6*).

"It is unfair to cut lab payments to bail out other providers," Mertz told the webinar audience, noting that Medicare lab fees have received zero or negative updates in 14 of the last 22 years. Moreover, under current law, these fees face a cut of 11.3 percent over the next five years.

A broader deficit-reduction package with entitlement cuts could resurrect the threat of a 20 percent coinsurance for tests payable under Medicare's Part B lab fee schedule. This is one option in MedPAC's report to Congress. Another would require both coinsurance and a deductible for Medicare lab services, saving $24 billion over 10 years, according to the Congressional Budget Office.

In another priority area, clinical labs and pathologists intend to keep lobbying lawmakers to remove anatomic pathology from the in-office ancillary services exception under the Stark physician self-referral law. This will curb overutilization by preventing medical specialties from bringing pathology work in-house to boost Medicare revenue and result in major savings, according to the Alliance for Integrity in Medicare, whose members include ACLA, the College of American Pathologists, and the American Society for Clinical Pathology.

CMS Announces New Waived Tests, Billing Codes

The official instruction, including a complete list of waived tests, is found on the CMS Web site at www.cms.gov/transmittals/downloads/R2321CP.pdf.

The Jan. 1, 2012, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 16 more devices, the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

The Centers for Medicare and Medicaid Services cautions that when billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived under CLIA (Change Request 7566). Prior to payment approval, claims are checked for waived testing certification.

Below are the latest tests approved by the FDA as waived under CLIA.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
81003QW	Feb. 14, 2011	Germaine Laboratories Inc. AimStrip Urine Analyzer
G0434QW	April 22, 2011	UCP Biosciences Inc. UCP Drug Screening Test Cups
G0434QW	April 22, 2011	Diagnostic Test Group Clarity Multiple Drug Screen Cups
81003QW	March 24, 2011	Mediwatch urinewatch Urine Analyzer
G0434QW	June 17, 2011	Insight Medical Drug of Abuse Urine Cassette Test
G0434QW	June 17, 2011	Insight Medical Drug of Abuse Urine Cup Test
G0434QW	June 17, 2011	Instant Technologies Inc. iScreen Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Instant Technologies Inc. iScreen Drug of Abuse Urine (Cup) Test
G0434QW	June 17, 2011	Jant Pharmacal Accutest Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Jant Pharmacal Accutest Drug of Abuse Urine (Cup) Test
G0434QW	June 17, 2011	Total Diagnostic Solutions Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Total Diagnostic Solutions Drug of Abuse Urine (Cup) Test
G0434QW	June 30, 2011	Diagnostic Test Group Clarity Simple Drug Screening Cups
G0434QW	June 30, 2011	Diagnostic Test Group Clarity Multi-Drug Test Cards
81003QW	July 14, 2011	Stanbio Uri-Trak 120 Urine Analyzer
G0434QW	July 21, 2011	UCP Biosciences Inc. U-Checker Drug Screening Test Cups
Source: CPT codes © American Medical Association.		

Note: Contractors are not required to search their files to either retract payment or retroactively pay claims; however, they should adjust claims brought to their attention.

Health Care Spending Hit by Weak Economy

National health care spending rose 3.9 percent in 2010 to $2.6 trillion or $8,402 per person, according to a Jan. 9 report from the Centers for Medicare and Medicaid Services. But its share of the gross domestic product was unchanged from 2009, remaining steady at 17.9 percent.

Traditionally, annual health care spending has risen at much higher rates, for example, 7.6 percent in 2007 and 11 percent in 1990, the report noted.

The struggling economy contributed to the slower growth in 2010, as it also did in 2009, as consumers cut back on health care services, affecting hospital and physician care and prescription drugs. This was felt across the health care sector, including Medicare and Medicaid expenditures.

Medicare spending totaled about $525 billion in 2010, or 20 percent of national health care spending, according to the report. It grew by 5 percent in 2010, compared with 7 percent in 2009. The slower growth rate resulted from less spending on the Medicare Advantage program. Fee-for-service enrollment rose 1.5 percent in 2010, the biggest increase since 2004, while enrollment in Medicare Advantage grew rose 5.6 percent in 2010, down from 10.5 percent in 2009.

Medicare to End Hold on Physician Claims for 2012

The Centers for Medicare and Medicaid Services (CMS) has instructed its local contractors to put a hold for the first 10 business days of January 2012 (through Jan. 17) on Medicare physician claims with a date of service on or after Jan. 1.

The hold affects claims with a date of service on or after Jan. 1. It does not affect claims for services rendered on or before Dec. 31, 2011. These will be processed and paid under normal procedures and time frames, CMS noted.

"We expect these claims to be released into processing no later than Jan. 18," CMS said in a Jan. 4 mailing to providers. Medicare contractors also will be posting the new payment rates on their Web sites no later than Jan. 11.

The hold should have minimal impact on cash flow, the agency said in a Dec. 19, 2011, alert to providers, because under current law, clean electronic claims are not paid sooner than 14 calendar days (29 days for paper claims) after the date of receipt.

CMS imposed the hold only a few business days before the end of last year when Congress had yet to block a 27.5 percent cut in physician fees as of Jan. 1, 2012. Soon after, on Dec. 23, 2011, Congress passed and President Obama signed the payroll tax cut extension bill cancelling the cut and freezing the fee update until March 1, 2012.

Conference Calendar

Feb. 9-10
Pathology Institute 2012
Pathology Under Attack: Practice Models and Business Strategies for a New Era
Program partner: Laboratory Economics
Westin Beach Resort and Spa
Fort Lauderdale, Fla.
www.g2path.com

April 17-19
Molecular Diagnostics Spring 2012: *Gaining the MDxEdge in Your Lab*
Fairmont Copley Plaza
Boston
www.mdxconference.com/Home

June 6-8
Lab Outreach 2012
Paris Las Vegas
Las Vegas
www.G2Outreach.com

Oct. 10-12
30th Anniversary Lab Institute
Crystal Gateway Marriott
Arlington, Va.
www.labinstitute.com/Home

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