G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 33rd Year of Publication

Vol. 12, Iss. 2, January 26, 2012

Time Short for Congress to Act on Expiring Physician Fee Fix

Finding the money is a sticking point for enactment of an extensions bill, noted Senate Finance Committee Chairman Max Baucus (D-Mont.) "It just comes down to pay-fors and offsets."

Congress returned this week with little more than a month left to act on two key pathology and clinical laboratory legislative priorities that are set to expire Feb. 29, 2012:

- ❑ The Medicare physician fee fix that blocked a 27.5 percent cut in payments from taking effect Jan. 1 and froze the fee update at 0 percent for two months; and
- ❑ The grandfather protection that allows certain independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of pathology services to hospital inpatients and outpatients.

Both the fix and the protection got a reprieve, until March 1, 2012, as part of payroll tax cut continuation legislation signed Dec. 23 last year (Pub. L. No. 112-78). The rationale for the reprieve was to avoid disruptions at the start of the year and provide time for further negotiations on financing longer-term remedies.

That task has fallen to a 20-member bipartisan House-Senate conference committee charged with finding agreement on extending the payroll tax cut and unemployment benefits and expiring Medicare provisions (*NIR 12, 1/Jan. 12, p. 5*).

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CMS Takes Flak Over Palmetto's New Molecular Diagnostics Program

The Centers for Medicare and Medicaid Services (CMS) is getting heat from a host of medical groups over a molecular diagnostics coverage and payment program that the agency greenlighted for one of its Medicare Administrative Contractors (MACs). The program is set to start March 1, 2012.

The line of attack from these groups is that the program violates the Health Insurance Portability and Accountability Act (HIPAA) and further adds regulatory complexity, cost, and variability in this fast-changing field.

The MAC in this case is Palmetto GBA, which handles the combined Part A and Part B claims processing workload in numerous jurisdictions.

The program under fire is the MolDx program that Palmetto is set to roll out in A/B MAC Jurisdiction 1 (J1), which includes California, Nevada, Hawaii, and the Pacific Territories of Guam, American Samoa, and the Northern Marianas.

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Time Short for Congress to Act, *from p. 1*
At the panel's first meeting on Jan. 24, conferees from both parties agreed that the physician fee fix is one of three top priorities to be tackled before the end of February, along with extension of the payroll tax cut and unemployment benefits.

The divisive issue now, as it was last year leading up to the 11th-hour reprieve, is how and where to compromise on paying for these policy goals, with the GOP generally supporting spending cuts alone with no increase in tax revenue and the Democrats supporting a mix of spending cuts and tax increases.

As conference talks begin, the questions for pathology and lab interests are:

- ❑ Will lawmakers go for another short-term patch to the sustainable growth rate (SGR) formula that triggered the 27.5 percent cut or a permanent SGR overhaul?
- ❑ Likewise, will they extend the grandfather protection or make it permanent? A Senate bill (S. 1680) would extend the protection for another year, through Dec. 31, 2012. A House bill (H.R. 2461) would make it permanent.

Fixing the Physician Fee Update

In a Jan. 20 letter to the committee, the American Medical Group Association said, "We are keenly aware of our country's fiscal condition and existing budget constraints," and while the current short-term patch is helpful, "a longer-term solution would provide medical groups with greater certainty and stability."

In addition, it would "reduce the administrative costs—federal and private—that accumulate from short-term patches."

The American Medical Association (AMA) has advocated replacing the SGR with stable fee increases over the next five years in the transition to a system based on payment and delivery alternatives to traditional fee-for-service.

But the cost of SGR repeal, an estimated $300 billion over 10 years, is a formidable hurdle, and it will multiply the longer a solution is postponed, AMA has warned. It estimates that if the SGR is unchecked, a fix could cost as much as $600 billion in five years.

Democrats on the conference committee have floated a proposal for a permanent fix that could be paid for without touching the Medicare budget. Under this approach, the fix would be financed from the Overseas Contingency Fund (OCO), discretionary money for the wars in Afghanistan and Iraq, which are expected to cost less than budgeted for. However, many Republican lawmakers oppose this move as counting on savings yet to be realized.

The AMA supports applying the OCO surplus to offset the cost of the SGR fix. In a letter to

Change in 2012 Medicare Conversion Factor

In blocking the Medicare physician payment cut that would have taken effect Jan. 1, Congress froze the fee update at 0 percent, effective for claims with dates of service from Jan. 1, 2012, through Feb. 29, 2012.

However, the conversion factor (CF) used to translate the relative value units (RVUs) of a physician's service—work expense, practice expense, and malpractice expense—into a dollar amount will see a slight increase during this period, thanks to a budget-neutral adjustment for changes to the RVUs.

The revised CF to be used for physician payment as of Jan. 1, 2012, is $34.0376, the Centers for Medicare and Medicaid Services said in a Jan. 20 emergency update to the physician fee schedule database.

The calculation of the revised CF is illustrated in the following table.

December 2011 CF	$33.9764
2011 "Zero Percent Update"	0.0 percent (1.000)
2012 RVU Budget Neutrality Adjustment	0.2 percent (1.0018)
CY 2012 CF thru 2/29/12	$34.0376

Congress from the AMA and other medical societies, including the College of American Pathologists, AMA wrote, "Using the OCO baseline as an offset for the SGR baseline essentially amounts to 'cleaning up the books' by eliminating bad fiscal policies and allowing for a more accurate accounting of future government expenditures without increasing the deficit."

For now, the odds favor another short-term SGR patch, likely another 10 months through the end of this year or a full 12-month fix (until March 1, 2013), punting the problem to the new 113th Congress to solve.

The search for money to pay for any SGR fix leaves other Medicare providers potentially at risk for reimbursement cuts.

The Medicare Payment Advisory Commission (MedPAC) has urged Congress to act quickly to change the SGR, saying, "It will never be less expensive to repeal the SGR than it is right now." MedPAC, which advises Congress on ways to reform Medicare, voted in October 2011 to recommend financing SGR repeal with cuts to specialists, a freeze on primary care, and cuts to other Medicare providers, of which 9 percent would be squeezed from Part B lab spending, or $21 billion. This option also would cut payments for lab services on the physician fee schedule.

While agreeing that the SGR payment system should be replaced with one that is stable and predictable, the American Clinical Laboratory Association (ACLA) took issue with MedPAC, saying additional lab cuts are "unsustainable." Clinical lab services inform 70 percent of health care decisions but account for only 1.6 percent of Medicare spending, ACLA noted. Yet, payments for these services have been cut by about 40 percent in real (inflation-adjusted) terms over the past 20 years. They are scheduled to decline an additional 19 percent over the next 10 years under changes mandated by the health care reform law, ACLA pointed out.

End of Signature Requirement for Test Requisitions: *Taking a Closer Look at the Aftermath*

Welcome news it was for independent clinical labs and hospital labs serving nonhospital patients when the Centers for Medicare and Medicaid Services (CMS) expunged from the books the requirement for the signature of a physician or nonphysician practitioner (NPP) on paper test requisitions.

These labs in particular would have had great difficulty in obtaining these requisitions from referring doctors and NPPs and would be financially at risk if the test were performed without the signed order.

CMS formally rescinded the controversial signature requirement in the final 2012 Medicare physician fee schedule rule (*NIR 11, 21/Nov. 17, p. 1*). CMS had formalized the requirement in the 2011 fee schedule rule but never implemented it after running into a firestorm of opposition from lab and physician groups and then proposed to scrap it *(NIR 11, 1/Jan. 13, p. 1; 11, 7/April 8, p. 1; 11, 13/July 14, p. 8*).

Bad News and Unknowns

In the wake of the policy reversal, clinical laboratories should consider some bad news and some unknowns, cautions attorney Robert E. Mazer with Ober/Kaler in Baltimore. Take a closer look, he advises, at the expectations CMS set for labs at the same time that it retracted the maligned policy.

CMS does not appear "willing to abandon totally the physician signature requirement," Mazer notes, pointing to CMS's comments in the preamble to the final 2012 rule. The agency restated its position thus: "The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP."

Although the test requisition would not need to be signed, Mazer points out, CMS indicated that it would require generally that there be a signed order for a clinical lab test, such as a signed entry in the medical records.

A laboratory still has the option of requiring a physician or NPP to sign a requisition, CMS said. "Laboratories, however, will have substantial difficulties requiring physicians to sign requisitions after CMS has expressly stated they are not required to do so," Mazer says.

The agency puts the onus on labs "to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP." In fact, Mazer notes, "CMS appears to be requiring a lab to 'ensure' that there is a *signed* test order."

According to CMS, a "laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order." The agency cites several examples of these procedures, but they offer little protection for labs, Mazer observes, offering the following critiques:

- A laboratory cannot determine the extent to which a physician's records include signed test orders based on an audit of its own records.
- Physicians may be unwilling to agree to provide a laboratory with medical records if the laboratory is audited or may refuse to abide by the terms of any such agreement.
- Moreover, even if the physician does provide the requested medical records, these may not include a signed order, as required for the lab to retain payments it may have received (unless it can demonstrate that it is protected by the Medicare statute's "without fault" provisions).

"In fact, 'acceptance of risk' may be the only 'compliance procedure' that is generally available to providers of clinical laboratory services," Mazer says.

The bottom line is this, he concludes: "Although the final rule changed specific requirements related to physician signatures, laboratories should be aware they remain vulnerable financially if physicians do not sign test orders. CMS has left them at risk for physician behavior they cannot control and cannot monitor effectively.

"The extent of this risk will depend on the frequency of Medicare audits of labs for this purpose and the extent to which medical record documentation fails to include signed orders. Increased use of electronic health records by physicians should reduce the occurrence of inadequate documentation but will not eliminate it."

The full text of Mazer's comments can be found in Ober/Kaler's *Payment Matters Newsletter* (Nov. 29, 2011).

New Report Touts Gains, Benefits of Genetic Testing Sector

A new report released this month and sponsored by the American Clinical Laboratory Association (ACLA) shows that genetic and genomic testing is not only a "game changer" in medical practice, but also has a major impact on the economy, creating 116,000 jobs and $16.5 billion in annual economic output.

"Job creation is critical to improving the state of the union—and this industry is doing just that," said Alan Mertz, ACLA president. "Genetic and genomic testing, like the Internet in the early days, also offers vast opportunity for the future."

According to the report prepared by Battelle Technology Partnership Practice (Cleveland), genetic and genomic testing generates $6 billion in personal income annually for U.S. workers. It also generated $657 million in estimated state and local tax revenue and nearly $1.2 billion in federal taxes in 2009.

Various industry sources estimate that the total U.S. clinical laboratory testing market is $62 billion. The Battelle survey of clinical labs determined that genetic and genomic testing constitutes about 9.5 percent of the market, or $5.9 billion.

"This industry is one of America's true economic success stories," said Mertz. "It is not only helping us beat cancer and other diseases, it is also building strong economic growth in a field of innovation where the U.S. is, and always has been, the leader."

Innovative genetic tests are transforming medical care, the study says, helping physicians to better target treatment to the exact cause so that patients get the right treatment early, saving lives and saving money. Significant improvements are being seen in such conditions as childhood leukemia, HIV, heart disease, cervical cancer, blood clotting, melanoma, and colorectal cancer. "In the 1960s, the cure rate for childhood leukemia was only 4 percent," Mertz said. "Today, that exceeds 80 percent."

Looking ahead, Mertz said, "Legislation that provides a pathway for continued innovation in this sector is essential to maintaining America's competitive edge globally."

Key Applications of Genetic and Genomic Testing

- ❑ *Disease diagnosis*: Screening a patient with a suspected disease, usually a hereditary genetic disease
- ❑ *Predictive medicine*: Presymptomatic testing of individuals to ascertain the risk of developing adult-onset diseases and disorders (such as Huntington's disease or breast cancer)
- ❑ *Genotyping of a specific disease*: For example, genotyping a patient's specific HIV strain or cancer tumor to guide therapeutic approaches
- ❑ *Pharmacogenomics*: Testing to optimize drug therapies, based on the patient's genotype and known genetic linkages to drug efficacy or toxicity
- ❑ *Identity testing*: Assists in providing individual genetic identification profiles that can be used to establish biological relatedness
- ❑ *Forensic testing*: Used to establish the identity of an individual based on a specimen of blood, urine, or other tissue
- ❑ *Carrier screening*: Testing unaffected individuals who carry one copy of a gene for a disease that requires two copies for the disease to be expressed
- ❑ *Newborn screening*: Testing newborns shortly after birth for disorders that are treatable but difficult to otherwise detect clinically

The Battelle report is posted at *www.acla.com* or *www.labresultsforlife.org*.

CMS Takes Flak, *from p. 1*
It will require labs to register a molecular test, have supporting information vetted by experts chosen by Palmetto, and be assigned a proprietary McKesson Z-Code™ in order to get paid for the test at a rate to be established by Palmetto.

The program will affect all hospital, private, and reference labs that perform molecular diagnostic testing and bill Medicare in J1. Labs that bill J1 services performed by a lab not in J1 will have to register their molecular tests.

AMA, CAP Urge Halt to MolDx

The American Medical Association (AMA) has threatened to file a HIPAA complaint if Palmetto does not suspend MolDx implementation. In a Dec. 19, 2011, letter to acting CMS administrator Marilyn Tavenner, AMA's executive vice president and CEO James Madara, M.D., said the program "is contrary to the agency's obligation to comply with standard code use as mandated by HIPAA and adds regulatory complexity, cost, and variability while also committing the agency to a path that may very well increase health care costs dramatically. Use of Z-Codes by HIPAA-covered entities will place these entities out of compliance with HIPAA and subject them to complaints and penalties under the law."

Representatives of the College of American Pathologists (CAP) have met with CMS officials to convey their concerns and asked the agency to delay or revoke the program. Palmetto's adoption of the Z-Codes amounts to the creation of a local coding system, which violates HIPAA, they told officials during the meeting, reports CAP's *Statline*. "By statute, local codes are not permitted." Also, "Palmetto's creation and use of its Z-Codes would circumvent the process of stakeholder input into changes prior to implementation," they said.

Critics of MolDx have also questioned the lack of transparency in the program's operation, including use of experts whom Palmetto chooses to determine coverage and payment and Palmetto's say over payment rates. Some fear eliminating currently used stacking codes opens the door for the contractor to also reprice common assays as well as new tests.

In contrast, the AMA process to handle molecular pathology codes is more inclusive and transparent than Palmetto's, critics note, though Medicare has yet to recognize these new codes that AMA introduced in the 2012 update to the *Current Procedural Terminology* (CPT). Unlike the Z-Codes, developed privately without input from stakeholders, CPT's molecular pathology codes were devised over a two and one-half year process that included CMS, other payers, providers, and several organizations, including CAP. The 101 codes cover 90 percent of existing molecular tests. However, CMS has delayed implementation of these codes for Medicare use until it decides where to place—and thus price—them: on the lab fee schedule, which requires no cost sharing by beneficiaries, or on the physician fee schedule, which requires a 20 percent copay from beneficiaries. CAP continues to advocate that there is professional work involved in molecular pathology and the codes should be placed on the physician fee schedule.

MolDx Highlights

Laboratory service providers will register their molecular diagnostic tests with Palmetto and submit test information and supporting evidence for a coverage and reimbursement determination by subject matter experts in academia and industry

who will provide technical assessments, will sign confidentiality agreements, and can only assess the data that Palmetto gives them.

Each test will be assigned a unique McKesson Z-Code™ and Palmetto will set a specific value for each test using enhanced gap-filled, value-based, and market-based methodologies. Once a Z-Code is assigned, the provider will not have to submit documentation with every claim for the test.

The burden is on the lab to make the best case using any and all evidence to support clinical utility. Labs and manufacturers that get a determination of noncoverage may ask for a new technical assessment six months after the noncoverage notice was issued.

Starting March 5, 2012, claims without a Z-Code will be rejected. Claims will not be considered for adjudication unless the test has been submitted to the registry for review and a Z-Code has been assigned. Providers will use existing CPT codes in the formal claim lines and Z-Codes in the "comment" box.

Which types of molecular assays are subject to MolDx?
Gene tests, infectious disease probes, tumor markers, pharmacogenomic assays, predictive and risk assessment assays, and other molecular tests, with or without an existing CPT or Healthcare Common Procedure Coding System (HCPCS) code that does not specify one test per unique CPT/HCPCS code. Multivariant molecular testing (predictive and prognostic) is a subset of molecular diagnostic testing.

Which diagnostic tests will be affected?
Tests that are coded as follows:

- ❑ Require or use more than one CPT code to identify the service.
- ❑ Use the methodology-based stacking CPT codes (83890-83914), microarray CPT codes (88384-88386), and cytogenetic CPT codes (88230-88291).
- ❑ All pathology and laboratory codes listed as Not Otherwise Classified (NOC).

Aiming for Greater Code Specificity
Medicare and other payers have grown increasingly uneasy over use of CPT stacking codes to bill for molecular diagnostics, saying the lack of specificity makes it hard to identify what test is being billed, what exactly they are paying for, and why. One problem when using "stacked" codes to bill Medicare for a test's component procedures is that not all labs use the same components, so Medicare potentially could pay different amounts for essentially the same test.

Palmetto says the Z-Codes will solve this problem by helping to identify the billed test, determine reasonable and necessary services, and apply appropriate reimbursement.

The American Medical Association sought to address the issue of specificity in the new molecular pathology codes introduced in *CPT 2012*. They include 92 analyte-specific codes and nine resource-based codes. While CMS is retaining the current code stacking scheme, it has asked labs to report the new CPT molecular code for the test along with the stacked codes and to indicate what they would charge under the single coding system.

Medicare *Claims Advisory*

Interest Rate Dips for Medicare Overpayments, Underpayments

Effective Jan. 19, 2012, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, will drop to 10.50 percent, the Centers for Medicare and Medicaid Services announced in the latest quarterly rate update (Transmittal 203, Change Request 7570).

This is down from 10.875 percent in effect since Oct. 20, 2011.

Medicare Regulation 42 CFR §405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2012) or the private consumer rate as fixed by the Department of the Treasury.

The Treasury has notified the U.S. Department of Health and Human Services that the private consumer rate has been changed to 10.50 percent.

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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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
MDx *NEXT* Spring 2012
Gaining the MDxEdge
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
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 G2 Compliance Report (ISSN 1524-0304) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3 , Peterborough, NH 03458-1467 USA. Tel: 800-401-5937 or 973-718-4700. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

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