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Senate Set to Consider Medicare Physician Fee Increases

At press time it was unclear whether Senate debate on the jobs bill, which includes Medicare physician fee increases, could stretch into the week of June 14. Once the bill clears the Senate, it must again be considered by the House.

On June 8 Senate Finance Committee Chairman Max Baucus (D-Mont.) offered an amendment to a jobs and tax extenders bill (H.R. 4213) that would cancel the 21 percent cut in Medicare physician payments that took effect June 1 and replace it with reimbursement increases through 2011.

This short-term fix would hike physician fees by 2.2 percent for the rest of this year and by 1 percent in 2011 at an estimated cost of $23 billion. In 2012, however, payment policy would revert to current law, or a cut of 33 percent.

Majority leader Harry Reid (D-Nev.) also noted on June 8 that a longer fix, perhaps through 2013, could be offered when H.R. 4213 comes to the floor.

If Congress does not act soon on a fee fix, pathologists and other physicians could see a cut in their Part B payments by the middle of the month. Anticipating congressional action, the Centers for Medicare and Medicaid Services has told contractors to hold claims for physician services on and after June 1 for 10 business days.

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New Push to Preserve Pathology 'Grandfather' Protection

Congress needs to act this year to extend beyond its current expiration on Dec. 31, 2010, the "grandfather" provision that allows independent clinical laboratories to bill Medicare directly for the technical component (TC) of pathology services for hospital inpatients and outpatients.

In a May 20 letter to Senate and House majority and minority leaders, the American Clinical Laboratory Association (ACLA) and the College of American Pathologists joined 12 other provider, health care professional, and patient groups to urge passage this year of legislation that would extend the grandfather protection and eight other Medicare policies set to expire at the end of this year, including reasonable cost payments for lab tests furnished by small rural hospitals.

Abolition of the pathology grandfather protection has been repeatedly proposed by the Centers for Medicare and Medicaid Services (CMS), contending that the TC is reimbursed as part of the hospital's Part A inpatient prospective payment, and thus labs should seek TC reimbursement from the hospital, not Part B.

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Pathology 'Grandfather' Protection, *from p. 1*

Since 1999, Congress has repeatedly blocked CMS from eliminating the protection, enacting temporary extensions, most recently in the health care reform law. The protection lapsed at the end of 2009 but was restored for one year retroactive to Jan. 1, 2010, when the president signed the reform bill into law on March 23 (*NIR, 10, 7/April 8, p. 1*).

Who Benefits From the Pathology 'Grandfather' Provision?

The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to eliminate independent lab billings for the technical component (TC) of pathology services to hospital patients.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

"Failure to extend these various Medicare policies will prompt limited access to services for beneficiaries in rural and other underserved areas, payment cuts to health care professionals, as well as the creation of an unsustainable health care environment," the groups said in the May 20 letter to congressional leaders.

"The combination of these policies impact a wide spectrum of the health care delivery process, including access to care through ambulance services, performance of diagnostic laboratory tests, and extensive rehabilitation services needed to return Medicare beneficiaries to their homes and communities. The policies impact patients and health care providers including solo practitioners, post-acute care facilities, and community hospitals that serve patients with various diagnoses and impairments." The letter is posted on the ACLA Web site at *www.clinical-labs.org*

Health Plans Get a Break on Preventive Service Mandates

A provision in the health care reform law requires that for plan years (policy years in the individual market) on and after Sept. 23, 2010, private insurers must cover, at a minimum, without cost sharing, a range of preventive services.

But the law—the Patient Protection and Affordable Care Act (PPACA, Public Law No. 111-148)—also provides an exemption from this mandate for health plans that qualify for "grandfather" protection.

A grandfathered plan is a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of the law (March 23, 2010). Renewal of the plan after such date does not alter the grandfather status of the plan.

"New employer plans will not be able to have copays and deductibles after Sept. 23, but some existing plans will be grandfathered and thus not required to drop their cost-sharing policies," attorney Peter Kazon with Alston & Bird in Washington, D.C., told *NIR*.

"But when the health exchanges become effective in 2014, they will not be able to have cost sharing for the preventive services specified in the law," he noted. Private plans participating in state-based exchanges will be required to comply with full coverage of the mandated preventive services.

Regulatory Interpretation Key

Congress included this protection and other grandfather provisions in PPACA to give employers and insurers time to transition to the new law. But the law is vague

on what constitutes a grandfathered plan and when, if ever, the protection will end. Plans that do not qualify must abide by all the consumer protections in the new law, including mandated preventive service reforms.

A lot is riding, legal analysts say, on whether the Department of Health and Human Services (HHS) takes a narrow or broad interpretation of the statute.

With health plans preparing their offerings for next year, they are particularly anxious to learn how any changes, including changes to benefits and cost sharing, would affect their grandfather status. Some speculate that any change would trigger loss of this status. That was included in the House version of health care reform but not in the final bill that became law. Other analysts speculate that it may take substantial changes to coverage to lose the status.

Plans Not Exempt, However, From Some Consumer Protections

While exempt from mandated preventive services and other consumer requirements, grandfathered plans must under insurance reforms that take effect Sept. 23, 2010:

- ❑ Provide dependent coverage for children until age 26
- ❑ Not use pre-existing condition exclusions for children this year (and everyone in 2014)
- ❑ Impose no lifetime insurance limits (but not annual limits)
- ❑ Not retroactively cancel coverage after a policyholder gets sick (called rescissions)

Small-group plans must spend at least 80 percent of premiums on medical expenses or improving the quality of care.

Source: National Association of Insurance Commissioners

Mandated Preventive Services

Under PPACA, the services that must be covered with no cost sharing include:

- ❑ Preventive services with an A or B rating from the U.S. Preventive Services Task Force,
- ❑ Recommended immunizations from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and
- ❑ With respect to infants, children, and adolescents, evidence-informed preventive care and screenings stipulated in comprehensive guidelines supported by the Health Resources and Services Administration.

Cost sharing is defined as:

- ❑ Deductibles, coinsurance, copayments, or similar charges, and
- ❑ Any other expenditure required of an insured individual which is a qualified medical expense with respect to essential health benefits covered under the plan.

There are certain exceptions: premiums, balance billing amounts for non-network providers, and spending for noncovered services.

An interval of one year is allowed from the time a preventive service recommendation or guideline is issued and the plan or policy year for which it takes effect.

The requirement to provide the mandated services is one of numerous provisions in the law aimed at accelerating the shift to prevention and wellness to help reduce and manage disease complications and avoid costly hospitalizations while rewarding quality and cost-saving outcomes (*NIR, 10, 9/May 5, pp. 3-6*).

On the immediate horizon, Medicare is authorized to add an annual wellness visit with health risk assessment in 2011 and to waive most beneficiary cost sharing, as of Jan. 1, 2011.

New Boost for Research by Small Life Sciences Companies

Up to $1 billion in tax credits and grants are available this year for therapeutic research by small and midsize life sciences companies, including drug, therapeutic, and diagnostic companies. The money is provided under the health care reform law, the Patient Protection and Affordable Care Act.

What Applicants Can Do Now

- ❑ Check IRS Notice 2010-45 which contains detailed information on eligibility and application procedures for certification.
- ❑ Determine that your company and project are eligible and whether to apply for a tax credit or a grant option. The latter is intended to help startups compete with established companies.
- ❑ Draft in a layperson's terms a summary of the health care and economic benefits your project can contribute to the research goals in the statute.
- ❑ Identify which costs related to your project are eligible for the credit or grant. Generate cost reports for your project covering 2009 and 2010 (projected through the end of the year), such as salary, lab costs, contractor costs, and other qualified investments.
- ❑ Separate out ineligible costs, such as certain executive compensation, interest, and facility maintenance expenses (such as a mortgage or rent, insurance, utilities, and maintenance personnel), and costs relating to support functions such as human resources, accounting, data processing, etc.

Source: Health Care Reform Advisory by Jonathan T. Cain and Travis L. Blavis with the law offices of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

The application period will be open for one month, starting June 21, the Internal Revenue Service announced in new rules on how to compete for the money available under the new, temporary Qualifying Therapeutic Discovery Project (IRS Notice 2010-45). Applications must be postmarked no later than July 21, 2010. Electronic filing is not authorized under the IRS guidance.

The IRS will conduct a preliminary review of all timely filed applications by Sept. 30, 2010, to eliminate applications that are incomplete or from unqualified taxpayers. Finally, the IRS will issue certification notices to recipients by Oct. 29, 2010.

The program offers a choice between an income tax credit and a cash grant (not to exceed $5 million per company) for up to 50 percent of a company's costs paid or incurred in 2009 and 2010 and directly related to a "qualifying therapeutic discovery project" (QTDP).

An IRS fact sheet provides examples of how the tax credit or grant would work. In one case, a 150-employee pharmaceutical firm developing a treatment for Alzheimer's disease and investing $6 million for 2009 and 2010 can get a tax credit of up to $3 million for those years. In another example, a 35-employee biotechnology firm developing cancer cures and investing $3 million for 2009 and 2010 has no tax liability for those years. It qualifies for a total tax credit grant of up to $1.5 million.

Qualified Projects

A QTDP must be designed to achieve any of the following objectives:

- ❑ Treat or prevent diseases or conditions by conducting preclinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product by the Food and Drug Administration or the Public Health Service,
- ❑ Diagnose diseases or conditions or determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or
- ❑ Develop a product, process, or technology to further the delivery or administration of therapeutics.

A project also must show a reasonable potential to meet one or more of the following goals:

- ❑ Develop new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions,
- ❑ Reduce long-term health care costs in the United States with potential to create and sustain high-quality, high-paying jobs and advance competitiveness in the life, biological, and medical sciences.
- ❑ Significantly advance the goal of curing cancer within the next 30 years.

Benefit of Therapeutic Discovery Tax Credit: Two Cases

Example 1: Pharmaceutical firm developing Alzheimer's treatment

Francine's Pharmaceuticals

- ❑ Employees: 150
- ❑ Qualifying project: Developing drug to meet unmet need for treatments for Alzheimer's disease, which could also reduce health care costs and increase U.S. competitiveness.
- ❑ 2009 investment in project: $3 million
- ❑ 2010 investment in project: $3 million

Tax credit for 2009: Up to $1.5 million
Tax credit for 2010: Up to $1.5 million
Total therapeutic discovery tax credit:
Up to $3 million

Example 2: Biotechnology firm developing cancer cures

Bob's Biotech

- ❑ Employees: 35
- ❑ Qualifying project: Performing research that could contribute to curing cancer as well as potentially create high-quality U.S. jobs
- ❑ 2009 investment in project: $1 million
- ❑ 2010 investment in project: $2 million
- ❑ No tax liability in 2009 or 2010

Grant for 2009: Up to $500,000
Grant for 2010: Up to $1 million
Total therapeutic discovery tax credit grant:
Up to $1.5 million

Source: IRS Fact Sheet on Notice 2010-45.

"Today, the biotechnology industry employers 1.3 million workers, and the industry continues to be a key growth engine for our economy," the IRS said. The program is looking for projects that have the potential to produce a new or significantly improved technology as compared to existing commercial technologies and lead to the construction or use of a production facility in the United States within five years.

Companies must submit a separate application for each QTDP for which they seek a credit or grant. If you are conducting more than one QTDP, multiple applications are permitted. A complete application will consist of three components:

- ❑ A Project Information Memorandum.
- ❑ IRS Form 8942 (to be available by June 21) requiring information about the company's ownership, number of employees working on the QTDP, basic information on the status of the QTDP, and the company's qualified investments for 2009 and 2010.
- ❑ Consent to disclose certain information to permit publication of information concerning program awards.

The Department of Health and Human Services (HHS) will review the application to determine whether a project shows reasonable potential to meet one or more of the statutory goals. If HHS determines favorably and the IRS determines that, compared to the submissions of other taxpayers, it is more likely to create and sustain high-quality, high-paying jobs and advance competitiveness in the life, biological, and medical sciences, then a certification will be awarded.

There is no right to appeal a denial of or the amount of a credit or grant. Applicants must meet all qualifying requirements and demonstrate the merits of their QTDP in their initial submissions.

CMS Announces New Waived Tests, Billing Codes

The list of CLIA-waived tests and billing codes is updated quarterly. For the July 1 update, which includes a complete list of all currently waived tests, see CMS Transmittal 1968, Change Request 6906 at www.cms.hhs.gov/transmittals.

The July 1, 2010, update by the Centers for Medicare and Medicaid Services (CMS) to the list of test devices waived under the Clinical Laboratory Improvement Amendments (CLIA) includes the latest approved by the Food and Drug Administration for this category. New waived tests are approved on a flow basis and are valid as soon as approved. Waived testing is the least regulated under CLIA, requiring only that the user follow the manufacturer's instructions and subject only to random inspection.

When billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as CLIA-waived. Your claims are edited to check whether you are certified for waived testing prior to approval for payment.

CPT Code	Effective Date	Description
82465QW, 83718QW, 84478QW, 80061QW, 82947QW, 82950QW, 82951QW, 82952QW	Dec. 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system
82465QW, 83718QW, 84478QW, 80061QW	Dec. 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)
G0430QW	Jan. 1, 2010	American Screening Corp. One Screen Drug Test Cards
G0430QW	Jan. 1, 2010	American Screening Corp. One Screen Drug Test Cups
G0430QW	Jan. 1, 2010	Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards
G0430QW	Jan. 1, 2010	UCP Biosciences Inc. UCP Home Drug Screening Test Cards
G0431QW	Jan. 1, 2010	Phamatech QuickScreen One Step Amphetamine Test
G0431QW	Jan. 1, 2010	Phamatech QuickScreen One Step THC Screening Test
86308QW	Jan. 4, 2010	Acceava Mono Cassette [for whole blood]
81003QW, 82044QW, 82570QW, 84703QW	Jan. 4, 2010	Siemens, Clinitek Status+ Analyzer
81003QW, 82044QW, 82570QW, 84703QW	Jan. 4, 2010	Siemens, Clinitek Status Connect System
82274QW, G0328QW	Jan. 26, 2010	Care Diagnostics Clarity IFOB Test

Drug Screening Codes

In the July 1 update transmittal, CMS reiterated its previous instructions on proper use of new drug screening codes by CLIA-waived labs, as of April 1, 2010:

- If you perform a qualitative drug screening test for multiple drug classes using a nonchromatographic method, bill G0430QW.
- If you perform a qualitative drug screen, single drug class method (e.g., immunoassay and enzyme assay), each drug class, use G0431QW. This code is a direct replacement for CPT 80101 and 80101QW, which Medicare will no longer cover as of July 1, 2010.

Tighter Deadline to Report and Return Overpayments

You have 60 days to report and return identified overpayments under a provision in the recently enacted health care reform law as part of the government's tightening of health care program safeguards.

An overpayment is defined in the Patient Protection and Affordable Care Act (PPACA) as "funds that an individual receives from Medicare and Medicaid to which they are not entitled."

The identified overpayment must be returned to, as appropriate, the Department of Health and Human Services, the state, an intermediary, a carrier, or a government contractor by the later of 60 days from when the overpayment is identified or the date any corresponding cost report is due.

Failure to meet the deadline may result in liability under the federal False Claims Act that subjects offenders to treble damages and penalty provisions.

The reporting and return obligation applies to a "person," defined to include providers, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, and prescription drug plan sponsors.

The obligation appears to be effective immediately, based on the statutory language, noted Joshua J. Freemire, an associate with the health law group at Ober/Kaler in Baltimore, in a recent advisory.

The 60-day time limit is not exactly new, he said. "CMS has tried twice before to require the return of identified overpayments within 60 days (once in a 1998 proposed rules and again in 2002), but it abandoned both efforts in the face of broad industry criticism. That criticism was well-founded then and is even more so now."

PPACA, however, does not define "identified," he pointed out, so it is unclear when the 60-day period actually starts. "Is it when the potential overpayment is discovered? When an overpayment is confirmed? When it is both confirmed and quantified?"

The Centers for Medicare and Medicaid Services is likely to issue additional implementing guidance, Freemire said. Until then, he advised providers and suppliers to:

- ❑ Assume the 60-day time limit is effective as of the date of enactment of PPACA (March 23, 2010).
- ❑ Investigate immediately and vigorously suspected overpayment situations (which include suspected Stark or anti-kickback violations) and repay as quickly as possible.
- ❑ In preparation, get familiar with the repayment policies and procedures for your local Medicare contractor so that repayment, when necessary, can be made as quickly as possible. Not all contractors accept paper checks or electronic fund transfers and they may lack the ability to offset an overpayment within the 60-day time limit.

"In essence, the new provision offers providers more questions than answers and threatens significant penalties for those who guess incorrectly," Freemire concluded.

Senate Set to Consider, *from p. 1*

The Baucus amendment reflects the physician fee fix that the House approved May 28 before Congress left for the weeklong Memorial Day recess. The 19-month fee increase is a scaled-back version of an earlier House proposal to grant physician fee increases through 2014 at an estimated cost of $65 billion (*NIR 10, 10/May 25, p. 1*).

June 1 marked the third time this year that Congress has failed to avert the 21 percent cut required under the Sustainable Growth Rate (SGR) update formula while lawmakers grapple with whether to go with a permanent or temporary fix, the related costs, and how to pay for it.

The freeze on fees at their 2009 levels, in place since Jan. 1, expired May 31, and the Senate left for the Memorial Day recess before blocking the SGR cut.

Pathology and other physician groups favor scrapping the SGR formula but acknowledge that only a temporary fix may be politically possible. Even so, it would bring short-term stability and predictability to Medicare payment updates, they say.

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