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Physician Fee Fix Caught in House-Senate Committee Deadlock

Clinical laboratories, hospitals, home health agencies, and other providers are on alert to block cuts in their Medicare payments to pay for a physician fee fix.

In only a few weeks, a cut of nearly 28 percent in Medicare physician fees is scheduled to kick in. Congress blocked the cut from taking effect Jan. 1 of this year, but only for two months, until March 1.

Congress is again expected to intervene, but the details of a physician fee fix remain unclear at press time, caught in the deadlock between House and Senate negotiators over extending the payroll tax cut and unemployment benefits.

Also on the negotiating table is the pathology grandfather protection, which expires Feb. 29. This allows certain independent clinical laboratories to bill Medicare separately for the technical component of pathology services to hospital inpatients and outpatients. CMS plans to eliminate such billings as of that date unless Congress decrees otherwise. The protection is part of a series of Medicare extenders that House Republicans have eyed for maximum savings.

The sticking point for the House-Senate conference committee is how to pay for these provisions, with Republicans generally supporting spending cuts alone and Democrats insisting on a balance of cuts and tax revenue increases.

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IRS Issues Proposed Rule on Medical Device Tax

The Internal Revenue Service (IRS) has published in the Feb. 7 *Federal Register* a proposed rule offering guidance on the 2.3 percent excise tax on the sale of certain medical devices to be imposed after Dec. 31, 2012.

The tax applies to the device's manufacturer, producer, or importer and is expected to generate $20 billion over 10 years. It was enacted under the Patient Protection and Affordable Care Act and is intended to help pay for the cost of health care reform.

The proposal triggered renewed calls to the House and Senate leadership for repeal of the excise tax from the Medical Device Manufacturers Association (MDMA), the Advanced Medical Technology Association (AdvaMed), and other groups.

MDMA President and CEO Mark Leahey said that the "complexities and unanswered questions in the IRS's proposed regulations show just how important it is to repeal the onerous medical device tax. It is a tax on innovation that is already eliminating jobs in this vibrant industry and will thwart efforts to improve patient care when we can least afford it."

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Physician Fee Fix, *from p. 1*

Committee members on both sides have signaled interest in going for more than another short-term physician fee fix, but time is short to act before the Feb. 29 deadline so they may have no other choice but to extend the fix, likely through this year or for a full 12 months or more and punt the issue of a permanent fix to next year's Congress to resolve.

A permanent fix that would repeal the sustainable growth rate (SGR) fee update formula is not considered likely at this point, given its cost. Maintaining the 2011 reimbursement rates for physicians would cost $316 billion over 10 years (2013-2022), according to a Congressional Budget Office report released Jan. 31.

One option to finance SGR repeal, advocated by the American Medical Association, the College of American Pathologists, and other physician groups, would tap unspent savings from other programs, such as the Oversees Contingency Operations fund, which has nearly $900 billion in discretionary funds previously allocated for the wars in Afghanistan and Iraq. Democrats on the committee have floated the option but Republicans have rejected it.

Another option floated by Democrats would repeal the SGR and pay for it by closing corporate tax loopholes, cutting tax breaks for oil companies, increasing taxes on those with annual income of more than $1 million, and tapping unspent war funds. House Republicans have proposed to pay for the physician fee update and other extensions by raising Medicare premiums for the wealthy, cutting spending for the health reform law, and freezing pay for federal workers. But that has gotten the cold shoulder from Democrats.

Looking beyond the current deadlock to the horizon, under current law, federal spending cuts of at least $1.2 trillion are set to kick in automatically in January 2013. The pain is to be spread between defense and nondefense spending, with each bearing half of the cuts. Medicare spending would be cut by 2 percent.

The automatic triggers are part of the deal reached last July to raise the debt ceiling. Under that accord, a joint select committee of the House and the Senate was charged with devising spending cuts of up to $1.5 trillion or at least $1.2 trillion that Congress could approve by Christmas. That effort collapsed in December, however, when committee members were unable to bridge partisan differences over reducing the deficit.

AMA to Congress: 'Stop Switch to ICD-10'

The American Medical Association (AMA) is calling on Congress to halt the implementation of ICD-10 diagnosis and procedural code sets, set to begin Oct. 1, 2013, and to work with stakeholders to craft an alternative.

The Centers for Medicare and Medicaid Services (CMS) meanwhile is eyeing that deadline as a firm date and has been preparing providers via implementation handbooks and teleconference updates. The agency already moved the start date once, from 2011 to 2013, in response to industry concerns that more time was needed for the changeover.

The International Classification of Diseases, 10th Revision (ICD-10), would replace the current ICD-9 codes required in all transactions covered under the Health Insur-

ance Portability and Accountability Act (HIPAA), including claims for Medicare payment.

In a Jan. 17 letter to House Speaker John Boehner (R-Ohio), AMA's executive vice president and CEO, James Madara, M.D., said, "The implementation of ICD-10 will create significant burdens on the practice of medicine with no direct benefit to individual patient care and will compete with other costly transitions associated with quality and health IT reporting programs."

AMA's main arguments against ICD-10 implementation are:

• It is complex and costly. Physician practices will have to master 68,000 codes versus the current 13,000 codes, "a massive administrative and financial undertaking, requiring education, software, coder training, and testing with payers," posing a significant risk of disruptions in claims processing and payment. Moreover, the cost ranges from $83,290 to more than $2.7 million, depending on the size of the medical practice.

• It is a major disruption to physician time and resources as practices are working to adopt electronic health records (EHR), while at the same time struggling to avoid financial penalties for not meeting the requirements of other Medicare quality IT programs, including e-prescribing, EHR meaningful use, and the Physician Quality Reporting System.

"More needs to be done to synchronize federal health IT programs," AMA concludes, calling for a "reasonable, sequenced timeline" for the above penalty programs. The AMA also objects to CMS backdating reporting requirements under these programs, "causing physicians to face a penalty based on activity in a year prior to the year of the penalty prescribed by law." For example, CMS is basing the 2012 e-prescribing penalty on a physician's e-prescribing activity in 2011.

A Word of Caution

Don't wait to see what Congress will do—that's the advice of the American Health Information Management Association (AHIMA). Providers should continue efforts to make the switch to ICD-10 by the October 2013 compliance deadline.

Stopping work would lead to large financial losses for health care organizations that have spent several years preparing for ICD-10 and would also cause organizations to miss the deadline, Dan Rode, vice president for advocacy and policy at AHIMA, said in a Jan. 30 statement.

"Without ICD-10 data, there will be serious gaps in our ability to extract important patient health information that will give physicians and the health care industry measures for quality of care, provide important public health surveillance, support modern-day research, and move to a payment system based on quality and outcomes," he said.

Preparing for ICD-10

Clinical laboratories and pathologists should be aware that there is no grace period for adopting the ICD-10 coding system.

Key tasks:

- Coders and pathologists who assign diagnostic codes will need to be trained on the new system.
- Medicare's national coverage determinations (NCDs) for 23 of the most frequently ordered clinical lab tests and local coverage determinations will need to be converted to the new codes. CMS says it will publish the NCDs with ICD-10 codes well before the changeover date.
- Labs and pathologists will need to reprogram medical necessity software programs and redo any forms or requisitions that currently have an ICD-9 code on them.

Updates on the transition, including implementation guides, are posted at *cms.gov/ICD10*.

focus on: Medicare Payment Policy

The CMS Innovation Center: A Year in Review

Providing high-quality care at lower cost is a goal the Center for Medicare and Medicaid Innovation is aggressively pursuing under its authority and funding from the health care reform law (the Patient Protection and Affordable Care Act).

In a report on its first-year progress released Jan. 26 at a summit on innovation, the center said that "since opening our doors we have introduced 16 initiatives involving over 50,000 health care providers that will touch the lives of Medicare and Medicaid beneficiaries in all 50 states and will continue to expand its partnerships and reach in the years to come."

Housed in the Centers for Medicare and Medicaid Services (CMS), the center's mission is "to move quickly to identify, test, and spread delivery and payment models to help providers improve care while cutting costs." Along with meeting the complex needs of Medicare-Medicaid dual eligibles, the center's initial efforts are concentrated in the following areas.

Patient Safety in Hospitals

The Partnership for Patients initiative is working with hospitals, physicians, nurses, other clinicians, consumer groups, and employers to reduce hospital-acquired conditions and preventable hospital readmissions.

The prime incentive for providers to participate in the Innovation Center's wide-ranging demonstration projects is a chance to share in the savings they achieve for Medicare.

The program is a public-private collaboration with over 7,100 organizations participating as of January 2012—including more than 3,200 hospitals. These organizations have pledged to meet the program's two goals: reduce preventable harm in hospitals by 40 percent and reduce readmissions to hospitals within 30 days of discharge by 20 percent in the next three years.

Partnership for Patients is investing up to $500 million in public-private engagement networks that will help hospitals adopt proven strategies to reduce hospital-acquired conditions in their own facilities and systems.

Another component, the Community-Based Transitions Program, is a $500 million initiative to reward hospitals, physicians, and others who partner together to keep patients out of the hospital after discharge.

Taken together, these components have the potential to save 60,000 lives, reduce millions of preventable injuries and complications in patient care, and, by meeting its goals, save our health care system as much as $50 billion over 10 years, according to the CMS Office of the Actuary.

Encouraging Care Coordination

The Pioneer Accountable Care Organization (ACO) Model tests the rapid transition to a new payment model where experienced organizations are paid according to their ability to improve the health of their patient population, rather than for each specific service they provide.

Starting Jan. 1, 2012, 32 organizations are participating in this demonstration to see what can be achieved through highly coordinated care for more than 860,000 Medicare fee-for-service beneficiaries. The initiative is scheduled to run for three years (with an optional two-year extension). Total funding is set at $77 million.

Participating organizations must create similar arrangements with private-sector payers so that more patients have access to this highly coordinated care. According to the CMS Office of the Actuary, this model is projected to save Medicare up to $1.1 billion over five years.

The Advanced Payment ACO Model will test whether prepayment of a portion of future shared savings to support ACO infrastructure and care coordination will allow more physician-based and rural ACOs to participate in the Medicare Shared Savings Program where they can share in savings they generate for Medicare if they meet certain quality-improvement metrics. This model is slated to start in April and July of this year with payments to end in June 2014. Total funding is set at $175 million, with an estimated 650,000 Medicare beneficiaries affected.

Bundled Payments for Care Improvement

Patients experience care in episodes, often visiting multiple doctors' offices, hospitals, and laboratories as they seek treatment and recovery. But today's system of paying separately for each service often leads to disjointed care, poor outcomes, and a confusing and frustrating experience for many patients.

If a demonstration shows success in delivering high-quality care while lowering costs to Medicare, the secretary of Health and Human Services has the authority to implement it nationwide.

The Bundled Payments for Care Improvement initiative builds on episode-based payment models pioneered in the private sector by redesigning payment to match the patient's experience. It is slated to start this year and run for three years, with funding set at $118 million.

The program offers providers four patient-centered episode-of-care models to choose from, allowing them flexibility to choose the conditions they believe make sense to bundle, decide how best to work together to deliver high-quality, coordinated episodes of care, and determine participating providers' share of payment. Health care organizations will give Medicare a discount off the current cost of care for the episodes covered under the initiative, thereby ensuring Medicare Trust Fund savings.

Transforming Primary Care

The Comprehensive Primary Care Initiative, set to start this year and to run for four years at a cost of $322 million, is a collaboration between public and private payers and primary care practices to support patient-centered primary care in communities across the country. Primary care practices will receive new public and private funding for primary care functions not currently supported by fee-for-service payments, including a chance to share net savings generated through this program. In return, participating practices will agree to give patients 24-hour access to care, create personalized care plans for their patients, and coordinate with other providers to ensure patients are getting healthy and staying well. It is expected to affect 315,000 Medicare beneficiaries.

The Federally Qualified Health Center Advanced Primary Care Practice Demonstration tests whether primary care at community health centers can improve care and

patients' health, and reduce costs. In October 2011, 500 community health centers in 44 states were selected to receive approximately $42 million over three years to reorganize as Patient Centered Medical Homes and improve the coordination and quality of care they give to people with Medicare and other patients.

And slated to start this summer is the Independence at Home demonstration, providing home-based care for patients with multiple chronic conditions. It will run for three years, with funding of $15 million. An estimated 10,000 Medicare beneficiaries will be affected.

The hope fueling the Innovation Center's programs is that health care organizations that participate successfully will be energized to spread their best practices, lessons learned, and improved care strategies to others, so their efforts are not limited to a demonstration site or a particular community.

Engaging Local Innovators

The Health Care Innovation Challenge, announced in November 2011, will award up to $1 billion in grants to applicants who "put into practice the most compelling new ideas for rapidly delivering better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and the state Children's Health Insurance Program, particularly those with the highest health care needs." The initiative is also looking for new models of workforce development and deployment to support the transition to high-value care. Awards will range from $1 million to $30 million for a three-year period. Providers, payers, local government, public-private partnerships, and multipayer collaboratives may apply.

Innovation Advisors Program

In December 2011, the Innovation Center selected 73 individuals out of 920 applications through a competitive process to participate in the Innovation Advisors initiative. It is designed as a network of experts whose aim is to diffuse new ideas or innovations for possible testing throughout local health care organizations and local communities. The first group started its six-month orientation and applied research period in January 2012.

IRS Issues Proposed Rule, *from p. 1*

AdvaMed President and CEO Stephen J. Ubl assailed the tax as anti-competitive and job-killing. It "will cost jobs—as many as 43,000 are at risk—at a time when the American economy is struggling and U.S. medical technology leadership in the world market is threatened by competitor nations who have grown their industries through more favorable tax and regulatory policies." The job loss estimate is based on a report from the Manhattan Institute in 2011.

Sen. Orrin G. Hatch (R-Utah), ranking member of the Senate Finance Committee, also weighed in, saying the tax "will ultimately stifle the development of lifesaving medical devices with costs that will be passed on to consumers."

Comments on the proposal are due May 7. The IRS plans a May 16 public hearing to obtain industry and consumer input into a final version.

Definition of 'Taxable Medical Device'

The health care reform law defines "taxable medical device" as any device, as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for humans.

The term generally means an instrument, apparatus, implement, machine, contrivance, implant, *in vitro reagent (italics added)*, or other similar or related article, including any component, part, or accessory, that is:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or
- Intended to affect the structure or any function of the body and that does not achieve its primary intended purposes through chemical action within or on the body and that is not dependent upon being metabolized for the achievement of its primary intended purposes.

Retail Exemption

Not included in the above definition are eyeglasses, contact lenses, hearing aids, and any other medical device determined by the secretary of Health and Human Services to be of a type that is generally purchased by the general public at retail for individual use.

"To provide greater certainty," the IRS said in the proposed rule, "we propose a safe harbor for categories of medical devices that fall within the retail exemption," including in vitro diagnostic home-use kits or over-the-counter test kits approved by the Food and Drug Administration; for example, kits to determine pregnancy or monitor blood glucose levels.

In addition, the tax imposed by the law does not apply to the sale of taxable medical devices that are:

- For use by the purchaser for further manufacture or for resale by the purchaser to a second purchaser for use in further manufacture; and
- For export or for resale by the purchaser to a second purchaser for export.

Lab's Loss of CLIA Certificate Upheld

An administrative law judge has ruled that the Centers for Medicare and Medicaid Services (CMS) acted correctly when it revoked a southern California laboratory's certificate under the Clinical Laboratory Improvement Amendments (CLIA), cancelled the lab's approval to bill Medicare, and barred its owner and operator from owning or operating another lab for two years from the date of revocation.

Carol Cozad Hughes with the Departmental Appeals Board of the U.S. Department of Health and Human Services issued the decision in a Jan. 17 ruling in the case, *Huntington Beach Clinical Laboratory Inc. v. CMS.*

In upholding CMS's action, Hughes found that the lab:

- Misrepresented its annual testing volume. Its Jan. 11, 2010, CLIA application, signed by the lab's director, Howard Pfupajena, M.D., said the annual volume would be 8,500. Based on this number, CMS imposed a CLIA fee of $1,174 for a compliance survey and $150 for the certificate. Because fees are based on annual testing volume, the amounts would have been higher had the lab more accurately

Lab's Loss of CLIA Certificate, *from p. 7*

reported its volume. Medicare billing data show that from February through at least June 2010 the lab billed the program for 120,782 tests, more than 14 times the reported volume.

- ❑ Performed testing beyond that authorized by its CLIA certificate. The lab was only certified to perform urinalysis, endocrinology, and toxicology, but 92 percent of the 120,782 tests billed to Medicare from February through June 2010 were beyond the scope of its certificate. Supposedly, just two individuals performed all the tests.
- ❑ Neither the lab nor its owner appealed the revocation, but in a submission that CMS accepted as an appeal, Pfupajena argued that he should not be sanctioned because he resigned from his position as director before the lab lost its certification on Sept. 28, 2010. The state survey agency, however, said it never received such a notice.
- ❑ Hughes disagreed, finding the billing documents for the unauthorized testing showed that it occurred between February and June 2010, when Pfupajena admitted he was the director. "The fact that he managed to tender a resignation letter a few weeks before CMS sent its first notice, on Sept. 3, 2010, does not make him less accountable for the rule violations that occurred on his watch," she said.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

March 7
CLIA Compliance, PT, and Quality Control: What's New for 2012?
Featured speaker: Judy Yost, top CLIA official at CMS

Conferences

April 17-19
MDx *Next*
Molecular Diagnostics 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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