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Majority Leader Reid Releases Senate Health Care Reform Bill

Despite the threat of procedural landmines that could delay the bill, the Democratic leadership aims to have the Senate complete work on the measure by the December holiday break. The bill would then have to be reconciled with the version passed by the House Nov. 7.

The long-awaited Senate Democratic legislation for health care reform, unveiled Nov. 18 by majority leader Harry Reid (D-Nev.), would expand health care coverage to 94 percent of Americans at a cost of $849 billion in new spending over 10 years.

At press time, the first test of the bill, which has met with staunch Republican opposition, will come Nov. 21 when a vote is scheduled on a motion to proceed with floor debate. Sixty votes are needed to overcome a filibuster.

The Senate bill is similar to the House-passed version. Both include an individual and employer mandate, expanded eligibility for Medicaid and the State Children's Health Insurance Program, a public plan option, a health insurance exchange for comparison shopping among plans, and subsidies to help people buy affordable coverage.

The Senate bill would pay for its changes by Medicare spending cuts, a hike in the Medicare payroll tax, new taxes on health care industries, including $2 billion annually from medical device makers, and on "Cadillac" health plans and wealthy Americans. For provisions that affect clinical labs and pathologists, see the *Focus*, pp. 4-5.

House Passes Medicare Physician Fee Reform

The House on Nov. 19 approved legislation (H.R. 3961) that would cancel a cut in Medicare physician fees due Jan. 1, 2010, and overhaul the annual fee update formula. The vote was 243-183, mostly along party lines. The measure now goes to the Senate where it faces an uphill battle because its cost of nearly $210 billion is not paid for.

Unless Congress steps in, Part B physician fees are due to be slashed by 21.2 percent next year under the current Sustainable Growth Rate (SGR) system used to calculate the annual fee update.

H.R. 3961 would repeal the SGR, cancel the 2010 cut, and base the update for that year on the Medicare Economic Index. This would raise physician fees by 1.2 percent next year, according to Congressional Budget Office (CBO) estimates.

In subsequent years, the update would allow the volume of physician services to grow at the rate of the Gross Domestic Product (GDP) plus 1 percent per year (for primary care and preventive services, the GDP plus 2 percent per year).

Continued on p. 2

INSIDE *NIR*

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Medicare Physician Fee Reform, *from p. 1*

The new update formula would remove items such as physician-administered drugs and diagnostic laboratory services not paid directly to practitioners from the spending targets.

The bill also promotes a shift to coordinated care by allowing accountable care organizations to determine their own spending targets separate from increases or cuts elsewhere in the physician payment system.

H.R. 3961 would increase physician payments by $195 billion, while additional spending on Medicare managed care and the Tricare program for military families would tack on $64 billion more. When offset by $49 billion in Part B premium increases, the bill's total cost is $209.6 billion, according to the Congressional Budget Office.

House Democratic leaders included in the fiscal year 2010 budget resolution a provision that would allow them to consider an unpaid physician payment bill if statutory pay-go was contained in the legislation as well or had been adopted already. H.R. 3961 includes the pay-go language.

The Senate has already rejected a similar bid to repeal the SGR and move to a new physician fee update system because it was not paid for (*NIR 09, 19/Oct. 26, p. 1*). Instead, the Senate reform bill cancels the 2010 cut, grants a 0.5 percent fee increase at an estimated cost of $10.9 billion, but makes no further changes to the SGR.

Kent Conrad (D-N.D.), chairman of the Senate Budget Committee, told reporters Nov. 17 that Medicare physician payment reform must be paid for. He recommended a two–year fix, together with creation of a commission to deal with the deficit in terms of physician payment reform, the alternative minimum tax, and other policies.

With only a few weeks left to avert the 21.2 percent fee cut looming on Jan. 1, Congress may have to consider a short-term fix at least. Senators are under strong pressure from the White House, the American Medical Association, the AARP, and the Military Officers Association of America to approve permanent physician pay reform.

Lab Fee Cut Is Up in the Air

With time running out for Congress to resolve differences in changes to the Medicare lab fee update in 2010, Part B lab fees are scheduled for a cut of 1.9 percent, effective Jan. 1. The current update formula is the full Consumer Price Index update (CPI-U) minus 0.5 percent.

This marks the first time that the update has fallen into negative territory in the 25-year history of the lab fee schedule.

Lab fees got an increase of 4.5 percent this year after being frozen for five years at 2003 payment levels.

The Senate reform bill would allow the 1.9 percent cut in 2010, while the House-passed reform bill would alter the update formula to the CPI-U minus a productivity adjustment for a total cut of 2.7 percent.

Beginning in 2011, the Senate bill would use a new update formula, the CPI-U minus a productivity adjustment (but this could never result in an update below zero). Unlike the House version, it would further cut lab fees by 1.75 percent from 2011 through 2014, and this could force the update below zero.

Gene Patent Lawsuit Set to Move Forward

The lawsuit, Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al., *was filed in the U.S. District Court for the Southern District of New York in Manhattan.*

A federal district judge has scheduled a Dec. 11 hearing for arguments in a landmark legal challenge to the patenting of human genes. The lawsuit was filed in May 2009 by the American Civil Liberties Union on behalf of plaintiffs representing researchers, physicians, laboratory professionals, genetic counselors, and individual women (*NIR 09, 10/May 25, p. 2*).

The defendants are BRCA1 and BRCA2 patent holders Myriad Genetics and the University of Utah Research Foundation, along with the U.S. Patent and Trademark Office. BRCA1 and BRCA2 are indicators for hereditary predisposition to breast and ovarian cancer. The judge earlier this month rebuffed the defendants' motions to dismiss the case on technical grounds and ruled that the plaintiffs had legal standing to pursue their case.

The suit alleges that the patents are illegal and restrict both scientific research and patients' access to medical care and that patents on human genes violate the First Amendment and patent law because genes are products of nature.

In allowing the case to go forward, New York district court judge Robert W. Sweet acknowledged the long-term influence this case could have on the widespread use of gene sequence information in biomedical and clinical research and patient care.

Because the lawsuit attacks the whole idea of patenting human genes, it could have far-reaching repercussions beyond the Myriad Genetics case. Approximately 20 percent of all human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses, says the American Civil Liberties Union.

The patents give Myriad Genetics the exclusive right to perform or license testing for BRCA1 and BRCA2 gene mutations. The company uses its BRCAnalysis test to assess a woman's risk of developing breast or ovarian cancer based on detection of these mutations. The test is highly profitable, and most insurance providers reimburse it.

According to the lawsuit, such monopolistic control over these genes is a disincentive for medical research because Myriad Genetics not only has the right to enforce its patents against other entities (and has previously threatened to do so), but also has the rights to future mutations discovered on the BRCA2 gene. Without the company's permission, "researchers are prevented from even looking at these genes." As a result, scientific research and use of genetic testing in molecular medicine have been delayed, limited, or even shut down.

The plaintiffs further argue that the patents "make it impossible for women to access other tests or get a second opinion about their results or seek additional testing elsewhere when their tests come back with inconclusive results."

Meantime, a top federal advisory panel has recommended new statutory protections for researchers and clinicians that would allow independent study of more genes and expanded use of patent-protected genes in clinical practice without the fear of patent infringement liability.

The recommendation is one of six concerning gene patenting and licensing that the HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) approved at its October meeting (*NIR 09, 19/Oct. 26, p. 3*).

focuson: Health Care Reform

Quick Guide to Lab, Pathology Provisions in New Senate Bill

Like the House-passed version, the Senate reform bill would emphasize a shift in Medicare toward rewarding quality and efficiencies, rather than volume alone. It provides incentives for prevention and wellness programs and encourages providers to improve patient outcomes and lower costs through coordinated care and medical home models by letting them share in the savings they achieve for Medicare.

The health care reform legislation released by the Senate Democratic leadership is a blending of bills passed by two committees of jurisdiction: Finance and HELP (Health, Education, Labor, and Pensions). Below are Medicare provisions that specifically target clinical laboratories and pathologists.

Physician Fee Update

Cancels the 21.2 percent cut scheduled for Jan. 1, 2010. Grants a 0.5 percent increase instead, at an estimated cost of $10.9 billion. No further changes to the current update formula based on the Sustainable Growth Rate (*related story, p. 1*).

Lab Fee Update

Continues the current annual update formula for 2010, which calls for a cut of 1.9 percent (the Consumer Price Index Update [CPI-U] minus 0.5 percent). Beginning in 2011, the 0.5 percent reduction would be replaced with a productivity adjustment (currently an estimated minus 1.3 percent); however, the adjustment could never cause the update to fall below zero. On top of this, the lab fee update would be reduced by 1.75 percent in each year from 2011 through 2014. This could result in a negative update.

Complex Molecular Tests: Date of Service Policy

Authorizes a two-year Medicare demonstration project, beginning July 1, 2011, to pay clinical laboratories directly for certain complex molecular diagnostic tests performed within 14 days of a beneficiary's discharge. The Health and Human Services (HHS) Secretary is to set the payment rates for these tests. The cost is not to exceed $100 million, to be drawn from the Medicare budget.

Under current Medicare rules, if a lab performs testing on blood or tissue samples collected by a hospital for inpatients and outpatients within the 14-day period, it must be paid by the hospital through its inpatient DRG payment, rather than a direct payment from Part B. The change would allow hospital-based and independent labs to get direct payment.

The affected tests are defined as:

- ❑ An analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay.
- ❑ Determined by the HHS secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics.
- ❑ Billed using a Health Care Procedure Coding System (HCPCS) code other than a not otherwise classified code under this system.
- ❑ Approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act.

Not later than two years after the completion of the demonstration project, the HHS Secretary is to send Congress a report on the results, including their impact on access to care, quality of care, health outcomes, and expenditures.

Pathology 'Grandfather' Protection for TC Billings

Authorizes a two-year extension of the pathology "grandfather" provision, which expires at the end of this year. The protection allows an independent clinical laboratory to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients.

It applies to hospital-lab arrangements in effect as of July 22, 1999, when the Medicare program first proposed to end such billings. The Centers for Medicare and Medicaid Services (CMS) argued that the TC is reimbursed via Part A inpatient payment, and labs should seek TC payment from the hospital, not Part B. Since CMS proposed the payment policy change, Congress has repeatedly blocked it by granting temporary extensions of the protection.

The "grandfather" protection applies to the hospital, not the lab, CMS says. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology.

Comparison of Major Features in Health Care Reform Bills

	Senate bill	*House-passed bill*
Individual mandate	Penalty for not obtaining health insurance coverage of as much as $750 per adult; to be phased in over time.	Penalty of up to 2.5 percent of adjusted gross income or the average cost of premiums on the health care exchange, whichever is lower. Exemptions for low-income individuals and families.
Employer mandate	Businesses with more than 50 employees would pay a flat fee for each employee who receives a subsidy to purchase insurance in the exchange. Employers must make premiums affordable for workers.	Businesses with annual payrolls above $500,000 must provide coverage to their employees or pay a penalty of as much as 8 percent of payroll. Employers must pay 72.5 percent of premiums for individuals, 65 percent for families.
Health insurance exchange	Markets where small businesses and individuals not covered at work can shop to find affordable health insurance choices, with standard set of minimum benefits.	Similar
Public plan option	Creates a government health plan to compete with private insurers in the exchange, starting in 2014. States may opt out. Also, helps states and cooperatives provide coverage.	Creates a similar government health plan, but with no state opt-out.
Insurance market reforms	Bars insurers from discriminating based on health status, denying coverage due to preexisting conditions, or dropping coverage when a person gets sick. Eliminates yearly and lifetime limits on coverage.	Similar
Independent entity on Medicare payments	Creates a new entity, the Independent Medicare Advisory Board, to make Medicare reimbursement decisions.	No provision.

CMS Announces $92M Payout for Physician Quality Reporting

Medicare paid more than $92 million in incentive payments to over 85,000 eligible physicians and other health care professionals who successfully reported quality-related data under the 2008 Physician Quality Reporting Initiative (PQRI), the Centers for Medicare and Medicaid Services (CMS) announced this month.

This was well above the $36 million paid in 2007 when 56,700 qualified professionals earned an incentive payment, the agency noted. For that year, these professionals could only participate in the program during a six-month reporting period. In 2008, the program expanded to allow reporting for either a six-month or a 12-month period.

"We are very pleased with the results for 2008," said Charlene Frizerra, acting CMS administrator. "More health professionals have successfully reported data, and the substantial growth in the national total for PQRI incentive payments demonstrates that Medicare can align payment with quality incentives."

The average incentive amount for individual professionals in 2008 was over $1,000, with the largest payment to an eligible professional totaling over $98,000.

Eligible professionals from all states and territories participated in the 2008 PQRI. Health practices with participating eligible professionals in Florida and Illinois received the highest incentive payments for that year. In Florida, eligible professionals received a total of over $7.5 million, and in Illinois, they received over $6 million.

The PQRI is a voluntary program established in late 2006 by the Tax Relief and Health Care Act. In the initial years, eligible professionals who satisfactorily submitted quality data for covered professional services furnished in the applicable reporting period were able to receive incentive payments of 1.5 percent of total estimated allowed charges under Medicare Part B for these services.

In 2008, Congress extended the PQRI under the Medicare Improvements for Patients and Providers Act (MIPPA) and authorized incentive payments through 2010. Beginning in 2009, Congress increased the incentive payment to 2 percent of estimated allowed charges for all covered professional services furnished during the applicable reporting period for 2009 and 2010.

CMS added 52 new quality measures for the 2009 PQRI year, raising the total number of measures to 153. These new measures cover all types of healthcare professionals who provide services to Medicare beneficiaries and address areas such as osteoarthritis, back pain, coronary artery disease, and HIV/AIDS, as well as 18 measures that must be reported exclusively through PQRI-qualified registries.

Approved Pathology PQRI Measures

The following were developed by the College of American Pathologists (CAP), approved by the American Medical Association, and introduced to the Physician Quality Reporting Initiative at the start of 2008.

- Breast cancer resection pathology reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.
- Colorectal cancer resection pathology reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.

CAP has continued to develop additional measures and is urging Congress and CMS to streamline the measures approval process. Nine measures cleared by CAP and the AMA in 2007 remain stuck in the review pipeline.

♦ Medicare Claims *Advisory*

Lab National Coverage Policies: Coding Changes in January 2010

The Centers for Medicare and Medicaid Services announced the changes in a Nov. 6 transmittal to Medicare contractors (Change Request 6717).

The Jan. 1, 2010 update to ICD-9-CM diagnosis codes covered under Medicare's clinical laboratory national coverage decisions (NCDs) includes changes affecting testing for serum iron and gamma glutamyl transferase (GGT), plus corrections to previously issued effective dates for prothrombin time, serum iron studies, and GGT.

The changes are:

• **Serum Iron Studies**

Delete ICD-9-CM codes 453.50-453.52 from the list of ICD-9-CM codes that are covered by Medicare for this NCD (190.18).

• **Gamma Glutamyl Transferase**

Add ICD-9-CM codes 453.50-453.52 to the list of ICD-9-CM codes that are covered by Medicare for this NCD (190.32).

• **Corrections to Effective Dates**

The effective dates for a series of codes for prothrombin time, serum iron studies, and GGT ranging from 200.30 to 202.78 were inadvertently changed to July 1, 2009, with the July 1, 2009 quarterly lab NCD release. The correct dates are Oct. 1, 2007, and will be reinstated with the January 2010 NCD update. Medicare contractors will adjust affected claims in these three categories if brought to their attention.

Lab NCDs

Alpha-fetoprotein
Blood Counts
Blood Glucose Testing
Carcinoembryonic Antigen (CEA)
Collagen Crosslinks
Culture, Bacterial, Urine
Digoxin Therapeutic Drug Assay
Fecal Occult Blood
Gamma Glutamyl Transferase (GGT)
Glycated Hemoglobin/Glycated Protein
Hepatitis Panel
HIV Testing (Diagnosis)
HIV Testing (Prognosis including monitoring)
Human Chorionic Gonadotropin (hCG)
Lipids
Partial Thromboplastin Time
Prostate-Specific Antigen (PSA)
Prothrombin Time
Serum Iron Studies
Thyroid Testing
Tumor Antigen by Immunoassay CA 125
Tumor Antigen by Immunoassay CA 15-3/CA 27.29
Tumor Antigen by Immunoassay CA 19-9

Posted at www.cms.hhs.gov/CoverageGenInfo.

Medicare has NCDs for 23 frequently ordered clinical laboratory procedures, along with related provisions for uniform coverage, claims processing, and medical necessity documentation (*box*). The NCDs were established via a negotiated rulemaking process required by the 1997 Balanced Budget Act. They specify the circumstances under which Medicare will pay for a test, the appropriate CPT and ICD-9-CM codes to use, coverage limitations (such as frequency limits), and other guidelines.

All the NCDs except Blood Counts set forth the ICD-9-CM diagnosis codes covered and presumed to demonstrate medical necessity. The NCD for Blood Counts uses an exclusionary approach. Because so many diagnosis codes could support their medical necessity, the lab negotiated rulemaking committee decided it was easier to list the codes that would not support medical necessity.

Medicare Error Rate Doubles in 2009 Due to Calculation Changes

The percent of Medicare fee-for-service payment errors more than doubled in fiscal year 2009 compared with 2008, ending several years of downward trends in error rates, the Centers for Medicare and Medicaid Services announced Nov. 17.

Medicare incorrectly paid 7.8 percent of fee-for-service claims in 2009, translating into $24.1 billion in inappropriate payments. That compares to a 3.6 percent rate in 2008.

CMS said the sharp increase was due to changes in how the error rate was calculated in 2009, saying the new methodology gives a "more complete accounting of Medicare's improper payments than in past years." The error rate, the agency added, was not necessarily or even likely due to fraudulent activity, but most likely resulted from inadequate documentation.

Among the changes in how the rate is determined are requirements that providers' past claims histories not be allowed to stand in for missing documentation and that medical information be included with durable medical equipment claims as supporting documentation.

Upcoming G-2 Events

Webinars

Nov. 24
Practical Planning and Preparation for 2010: Lab and Pathology Coding, Billing, and Reimbursement

Dec. 9
Certification Update: What the Unification of the ASCP and NCA Means for the Industry

Dec. 17
To Give or Not to Give: Labs, Pathologists, Docs, and Freebies

Times: 2:00 p.m. – 3:30 p.m. (Eastern)

Conferences

Dec. 7-9
2nd Annual LabCompete: Laboratory Sales and Marketing Conference
Scaling New Heights in a Volatile Market

Sheraton Wild Horse Pass Resort and Spa, Chandler, Ariz.

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