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# NATIONAL INTELLIGENCE REPORT®

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## Cuts in Medicare Lab Fees: How Much and How Long?

*Reform bills in the House and Senate agree on applying a productivity adjustment to the update for Medicare lab fees, but differ over additional update reductions.*

The annual update to the Medicare clinical laboratory fee schedule is being hammered out to produce savings in health care reform legislation approved by House and Senate committees and now being readied for floor action and a vote. For labs, the question is how much of a hit will they take in a final version and for how many years.

Currently, the lab fee update is the Consumer Price Index (CPI-U) minus 0.5 percent, as required under the Medicare Improvements for Patients and Providers Act of 2008. For 2010, the formula is projected to result in a 1.9 percent cut in fees for Part B covered clinical lab services.

Under the reform bill approved by the Senate Finance Committee Oct. 13, lab fees in 2010 would be updated under the current formula, but beginning in 2011 and in subsequent years, labs would get the full CPI-U update minus a productivity adjustment (currently pegged at a negative 1.3 percent), with a guarantee that the adjustment would never cause the update to fall below zero. The productivity adjustment is estimated to save $5 billion over 10 years. *Continued on p. 2*

## Medicare Physician Fees: Senate Rejects Bid for Quick, Costly Long-Term Fix

The Senate on Oct. 21 voted down a bill, introduced by Debbie Stabenow (D-Mich.) and backed by the American Medical Association and the AARP, that would cancel the 21 percent cut in Medicare physician fees due in 2010 and repeal the Sustainable Growth Rate (SGR) system used to calculate the update, which has triggered cuts over the past seven years.

The bill, which would cost $247 billion over 10 years, failed to win the 60 votes needed to begin floor debate. While it had support from 47 Democrats, it was opposed by all Republicans, 12 Democrats, and one independent, Joseph Lieberman (Conn.), who objected that the fix was not paid for and would add to the deficit. House Democratic leaders previously said they would not support a fee fix unless it met "pay for" rules.

Senate majority leader Harry Reid (D-Nev.) said after the vote that he is "hopeful we can pass a multiyear fix after health insurance reform." *Continued on p. 8*

### INSIDE *NIR*



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**Medicare Lab Fees,** *from p. 1*

On top of this, the Finance bill would impose an additional cut of 1.75 percent in the update for each of the years from 2011 through 2014, rising to 1.95 percent in 2015 (these cuts may include a reduction below zero). Finally, $100 million would be diverted to pay for a change in Medicare's date of service (DOS) policy for labs furnishing complex molecular tests.

### Beating Back Threats to Medicare Lab Payment

Despite the prospect of cuts ahead in the lab fee schedule to help pay for health care reform, clinical laboratories this year have fended off other big threats:

- *Lab copay:* Senate Finance option to impose a 20 percent copayment on Part B covered clinical laboratory services. Estimated cost to seniors: $24 billion. Plus, added costs to labs to collect the copay, even when, as in most cases, the amount collected would be less than the cost of collecting it.
- *Lab tax:* Finance chairman's proposal to impose a levy of $750 million over 10 years, or $7.5 billion total, on clinical laboratory services as part of new fees on medical device makers, insurers, and other industry sectors.

The House tricommittee reform legislation would cancel the current 0.5 percent reduction and grant the full CPI-U update minus a productivity adjustment, beginning in 2010. The result would be a projected CPI-U cut of 1.4 percent plus a reduction of 1.3 percent for productivity, for a total cut of 2.7 percent.

While none in the industry welcome further cuts in Medicare lab fees, the continuing downward pressure on payments threatens small laboratories that serve vulnerable populations avoided by the larger labs, such as nursing home and homebound patients. For the small labs, Medicare comprises a substantial part of their revenue and they are not in a position to absorb fee cuts like the larger labs whose Medicare business is a much smaller portion of total testing revenue.

How the lab fee cuts will be allocated is of special concern to the National Independent Laboratory Association and the American Association of Bioanalysts. Mark Birenbaum, Ph.D., who heads these groups, noted, "If not done properly, it will put many community labs out of business and give large corporate labs that have a small percentage of Medicare Part B work a huge competitive advantage. These large corporate labs are the same labs that stand to gain from increased enrollment due to health care reform."

## DOS Policy Change

The Finance committee bill also provides that for a two-year period beginning July 1, 2011, in cases when a specimen is collected from an inpatient beneficiary and a lab test is ordered within 14 days of the beneficiary's discharge from the hospital, the lab furnishing the test may bill Medicare Part B for the test if:

- The test is an analysis of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies, or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, gene expression or similar method, or is a cancer chemotherapy sensitivity assay or similar method, but does not include methods principally comprising routine chemistry or routine immunology.
- The test is performed only by the lab offering the test.
- The test is not furnished by the hospital where the sample was collected from the patient directly or under arrangements.

# SACGHS Backs Protections From Gene Patent Liability Lawsuits

A top federal advisory panel is recommending new protections for researchers and clinicians that would allow independent study of more genes and expanded diagnostic use of patent-protected genes in patient care without the fear of patent infringement liability.

The recommendation is one of six in the controversial area of gene patenting and licensing that the HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) approved at its Oct. 8-9 meeting in Washington, D.C.

***Approximately 20 percent of all human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, breast and colon cancer, asthma, and many other illnesses, says the American Civil Liberties Union.***

In endorsing the new protections, a broad majority of members said, "The secretary of HHS should support and work with the secretary of commerce to promote the following statutory changes … that would create an exemption from liability for infringement of patent claims on genes for:

- "Anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes.
- "Those who use patent-protected genes in the pursuit of research."

In other recommendations, SACGHS urged the HHS secretary to:

- Promote "more than voluntary adherence to current guidelines that encourage nonexclusivity in licensing of diagnostic genetic/genomic technologies." The secretary also should "convene stakeholders—for example, industry, academic institutions, researchers, and patients—to develop a code of conduct that will further encourage broad access to such technologies."
- Enhance transparency in licensing.
- Establish an advisory body on the health impact of gene patenting and licensing practices.
- Work with the secretary of commerce to ensure that the U.S. Patent and Trademark Office is kept apprised of scientific and technological developments related to genetic testing.
- Ensure equal access to clinically useful genetic tests.

SACGHS is the latest to weigh in on the controversy over gene patenting and licensing practices and the effect they have on advances in molecular medicine. A major legal challenge to gene patents was filed earlier this year by the American Civil Liberties Union and a long list of pathology organizations, patients, and other plaintiffs. The lawsuit asserts that patents on two human genes associated with breast and ovarian cancer, BRCA1 and BRCA2, are unconstitutional and should be invalidated because genes are "products of nature." The suit is the first to apply the First Amendment in challenging gene patenting (*NIR 09, 10/May 25, p. 2*).

The defendants are the U.S. Patent and Trademark Office, which granted the patents, Myriad Genetics, and the University of Utah Research Foundation (Salt Lake City), which hold the patents.

The patents give Myriad 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 *Continued on p. 6*

focus on: Health Care Reform

# New Momentum Behind Legislative Drive for Fundamental Change

Despite staunch Republican opposition and pushback from the health insurance industry, the drive to enact the most sweeping reform of the nation's health care system in generations has new traction on Capitol Hill.

Senate and House committees of jurisdiction have passed their versions of reform, and the Democratic leadership in each chamber is working to meld its committee bills into a single version for floor action, followed by approval of a compromise measure by year's end. And with the endgame in sight, the president has dispatched his health care team to confer regularly with congressional negotiators.

The goals behind the reform effort are to expand coverage of the uninsured, provide affordable choices and competition, and reduce costs by rewarding quality and efficiency, not just volume.

There is broad agreement on some basic mechanisms to achieve these goals, including expansion of Medicaid and the State Children's Health Insurance Program, incentives for coordinated care, and promotion of preventive services and wellness programs. But on other mechanisms—such as the individual and employer mandate, premium subsidies to help people buy coverage, and the government health insurance option to compete with private insurers—there are differences over structures, requirements, and costs. All bills would rely on some combination of taxes and cuts in Medicare and Medicaid spending to pay for the changes.

The Senate Finance Committee was the fifth and final congressional committee to approve a health care reform bill. Chairman Max Baucus (D-Mont.) crafted it as a "centrist" bill to attract support from conservative Democrats and the GOP. It got one Republican vote from Olympia Snowe of Maine, and holding her support is seen as key in securing the 60 votes needed to block a filibuster.

The Baucus bill in general would require individuals to get health insurance coverage, establish a health care exchange, reform the private insurance system, expand Medicaid to those earning up to 133 percent of the federal poverty level, and establish state-based cooperatives to compete with private health plans.

To promote prevention, the bill would provide an annual "wellness" visit for Medicare beneficiaries and their physicians to focus on prevention, eliminate out-of-pocket costs for Medicare screening and prevention services, and create incentives in Medicare and Medicaid for completing healthy lifestyle programs.

The legislation would be paid for through nearly $410 billion in Medicare and Medicaid spending reductions over 10 years, a tax on insurers offering high-end "Cadillac" insurance plans, and new fees on the health insurance industry and certain providers, including $4 billion a year from medical device makers for 10 years.

The bill also would create a 15-member independent Medicare commission to present Congress with proposals to reduce excess cost growth and improve quality of

care for Medicare beneficiaries. In years when Medicare costs are projected to be unsustainable, the proposals will take effect unless Congress passes an alternative that achieves the same level of savings. That measure could be considered on a fast track. The commission would be prohibited from making proposals that ration care, raise taxes or Part B premiums, or change Medicare benefit, eligibility, or cost-sharing standards.

Like its House counterparts, the Baucus bill would achieve savings from Medicare managed care by changing Medicare Advantage (MA) payments from statutory benchmarks to payments based on competitive bids from insurers. Under this provision, plans would be eligible for bonuses based on quality measures and evidence-based care management programs. Currently, MA plans get approximately 14 percent more in payments than traditional Part B fee-for-service for comparable services. Plans argue they need higher payments to offer benefits not covered by Part B and reduce enrollee cost-sharing.

## Comparison of Key Provisions in Reform Bills

| | *Senate Finance bill* | *Senate HELP bill* | *House bills** |
|---|---|---|---|
| **Individual mandate** | Penalty for not obtaining health insurance, starting at $200 per adult in 2014, rising to $750 per adult, $1,500 per family in 2017; thereafter, indexed to inflation rate. Exemption for those who cannot find a policy costing less than 8 percent of adjusted gross income | Penalty up to $750 | Penalty up to 2.5 percent of income |
| **Employer mandate** | Businesses with 50+ employees to provide coverage or pay a fee based on number of employees who get a federal subsidy to buy coverage. Fee capped at $400 per employee. No requirement for sharing in premium costs | Businesses with 25+ employees to provide coverage for workers or pay penalty of $750 for every employee over age 25. Employers to pay 60 percent of premiums for workers | Businesses with annual payroll of more than $500,000 to provide employee coverage or pay penalty of up to 8 percent of payroll. Employers to pay 72.5 percent of premiums for individuals, 65 percent for families |
| **Health insurance exchange** | One-stop shop for small businesses and people not covered at work to find affordable health insurance choices, with standard set of minimum benefits. May be Web portal, by mail, or at walk-in locations | Similar | Similar |
| **Public plan option** | Creates state-based nonprofit cooperatives to compete with private insurers in the exchange. Also allows states to negotiate with insurers to cover low-income individuals | Creates a government health insurance plan to compete in the exchange | Same as Senate HELP provision |
| **Insurance market reforms** | Bar insurers from discriminating based on health status, denying coverage due to pre-existing conditions, or dropping coverage. Eliminate yearly and lifetime limits on coverage | Similar | Similar |
| **Independent body on medicare payments** | Establish Medicare commission whose proposals for spending reductions would take effect unless Congress intervenes | No provision | No provision |

*Three committees: Ways and Means, Energy and Commerce, and Education and Labor.

**Gene Patent Liability Lawsuits,** *from p. 3*
detection of BRCA1 and BRCA2 gene mutations. The test is highly profitable, and most insurers reimburse for it.

The plaintiffs charge that such monopolistic control over these genes is a disincentive for medical research because Myriad 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 genetic testing 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."

Meanwhile, Myriad is still in the gene patent news. It has announced plans to use newly acquired gene patent rights to develop a test that can help predict an individual's hereditary risk of pancreatic cancer. The test would expand Myriad's portfolio of predictive genetic tests, including those for hereditary breast and ovarian cancer, colorectal and uterine cancer, colon cancer, and melanoma.

In a deal with Johns Hopkins University (JHU), the company obtained an exclusive global license to patents covering mutations in PALB2, a tumor suppressor gene that was recently identified by JHU researchers as a susceptibility gene for familial pancreatic cancer. These mutations have been shown to substantially increase an individual's risk for developing pancreatic cancer later in life.

# New Rules Curb Insurers Use of Genetic Information

An individual's genetic information will have greater protection under new rules issued Oct. 1 by the Departments of Health and Human Services (HHS), Labor, and the Treasury.

*A majority of states have laws to protect the public from genetic discrimination, and they vary widely in approach, application, and level of protection. While GINA establishes uniform national safeguards, it does not preempt state requirements.*

The rules are designed, the agencies said, to help ensure that genetic information is not used adversely in determining health care coverage and to encourage more individuals to participate in genetic testing, which can help better identify and prevent certain diseases.

The rules implement Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) and are effective for group and individual insurers Dec. 7. Title II relates to employment and takes effect Nov. 21. It bars employers from using genetic information when making decisions on hiring, firing, job placement, or promotion.

### Curbs on Insurance Markets

Under GINA, group health plans and issuers in the group market cannot:

- ❑ Increase premiums for the group based on the results of an enrollee's genetic information.
- ❑ Deny enrollment.
- ❑ Impose exclusions for pre-existing conditions.

- ❑ Use other forms of underwriting based on genetic information.

In the individual health insurance market, GINA prohibits insurers from using genetic information to:

- ❑ Deny coverage.
- ❑ Raise premiums.
- ❑ Impose exclusions for pre-existing conditions.

Plans and insurers generally are barred from asking an individual or family member to undergo genetic testing. But if an individual seeks a plan benefit, the plan or issuer may request family medical history or other genetic information to determine whether the benefit is medically appropriate and payable, but the amount of information sought must be kept to the minimum necessary for payment.

### Ban on Collection of Genetic Information

The rules clarify GINA's prohibitions against plans or insurers collecting genetic information, either for underwriting purposes or prior to or in connection with enrollment.

- ❑ The term "collect" means to "request, require, or purchase genetic information."
- ❑ The ban on "underwriting purposes" encompasses more than rating and pricing a group policy. It also includes changing deductibles or other cost-sharing methods or providing discounts, rebates, payment in kind, or other premium differential mechanisms in return for completing a health risk assessment or wellness program.

HHS also has issued a notice of proposed rulemaking that would modify the Health Insurance Portability and Accountability Act (HIPAA) privacy rule to align with GINA on prohibiting health plans from using or disclosing genetic information for underwriting purposes.

The HIPAA modification bans "the use and disclosure of genetic information by covered health plans for eligibility determinations, premium computations, applications of any pre-existing condition exclusions, and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits."

In combination with the new penalties for violations of the HIPAA privacy rule, as authorized in the American Recovery and Reinvestment Act of 2009, a use or disclosure of genetic information in violation of this rule could result in a fine of $100 to $50,000 or more for each violation.

#### Key Definitions in the GINA Rules

***Genetic Test***

An analysis of human DNA, RNA, chromosomes, proteins, or metabolites if the test detects genotypes, mutations, or chromosomal changes.

***Manifestation or Manifested***

A disease, disorder, or pathological condition is manifested when an individual has been or could reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved.

A disease, disorder, or pathological condition is *not* manifested if a diagnosis is based principally on genetic information.

Plans and insurers may increase premiums or contribution rates based on the manifestation, as long as it is not used as genetic information to raise premiums or contribution rates.

**Medicare Physician Fee Fix,** *from p. 1*

Despite the Stabenow bill's defeat, it has prompted consideration of an alternative to the one-year fix approved by the Finance Committee. The Finance bill would block the 21 percent cut and grant physicians an increase of 0.5 percent in 2010 at a cost of $10.9 billion. One option being aired would be a two-year fix that would cost $25 billion.

In the House, the tricommittee reform legislation includes a provision to cancel all SGR cuts and base the fee update in 2010 on the Medicare Economic Index. Starting in 2011, the update would allow for growth based on the gross domestic product (GDP) plus 1 percent (2 percent for evaluation, management, and preventive services). Pathology interests are concerned that the payment differential be budget-neutral and not be at the expense of other physicians.

## Pathology 'Grandfather' Protection for TC Billings

Both House and Senate versions of reform legislation include a two-year extension of the pathology "grandfather" provision, which expires at the end of this year. The protection allows independent clinical labs 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.

## Upcoming G-2 Events

### *Webinars*

**Oct. 29**
**Bringing Social Media Into the Lab: Integrating Facebook, Twitter, and YouTube Into Your Growth Strategy**
2:00 p.m. (Eastern)

**Nov. 24**
**Practical Planning and Preparation for 2010: Lab and Pathology Coding, Billing, and Reimbursement**
2:00 p.m. (Eastern)

### *Virtual Symposium*

**Oct. 27**
**The Future of Health Care: Capitalizing on Emerging EMR Opportunities**
**Online 10:30 a.m. – 6:00 p.m. (Eastern)**

### *Conferences*

**Nov. 12**
**Lab Leaders Summit**
**Driving Growth in Your Business**
**The Princeton Club of New York**

**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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