



# NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 09, Iss. 10, May 25, 2009

## President Proposes Physician Fee Hike, Cuts for Other Providers

*For more on the president's budget request for Medicare physicians and other payment policy proposals, see the Focus, pp. 4-6.*

**P**athologists and other physicians would see their Medicare fees increase next year, under the president's budget proposal for fiscal 2010, released this month, but the amount is left to congressional committees to hammer out with White House input. The budget proposes \$311 billion over 10 years for physician payment reform.

But a host of other providers would see major Medicare payment cuts, including hospitals, managed care plans, and home health agencies, with the savings going into a new \$634 billion reserve fund to finance health care reform initiatives.

Of the proposed Medicare savings, the biggest portion would come from requiring managed care plans to bid competitively for Medicare Advantage (MA) contracts to serve beneficiaries. Savings also would come from reducing hospital readmission rates and bundling post-acute care payments into the hospital's inpatient rate. Higher income beneficiaries would pay more in premiums for the Medicare drug benefit, based on a sliding scale. Those earning more than \$85,000 a year (\$170,000 for couples) would pay higher premiums. 🏛️

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## Labs Could See Less in Medicare Fee Update

**T**his year could turn out to "the best of times for clinical labs, in terms of the annual update to their Medicare Part B fees," according to industry analysts. The update for 2010 is shaping up to be significantly less.

Medicare lab fees got a 4.5 percent increase this year, effective Jan. 1. This is the first Consumer Price Index (CPI-U) update to lab fees since 2004. Congress last year approved an update for lab fees in each of the years from 2009 through 2013, but at 0.5 percent less than the full CPI-U update for those years.

Next year's update is likely a much smaller increase. The full CPI-U was 0.9 percent this April, the Bureau of Labor Statistics reported May 15. For 2010, the Congressional Budget Office projects the final CPI-U at around 2.2 percent, translating to a 1.7 percent increase for lab fees. The annual update to lab fees is based on the CPI-U as of June 30 of the previous year.

The good news for labs is that while next year's CPI-U update is likely to be less, there are no signs that Congress is inclined to cancel it. The Senate Finance committee options for health care reform include nothing specifically about any lab fee freeze, Alan Mertz told NIR, "but that doesn't mean it couldn't come later. So far, so good." 🏛️

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## Lawsuit Challenges Patents on Breast, Ovarian Cancer Genes

On May 12, the American Civil Liberties Union and a long list of pathology organizations and other plaintiffs filed a lawsuit charging 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 to a challenge to gene patenting.

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

The patents give Myriad Genetics the exclusive right to perform or license testing for BRCA1 and BRCA2 gene mutations. The company uses its BRCAAnalysis test to assess a woman’s risk of developing breast or ovarian cancer based on detection of BRCA1 and BRCA2 gene mutations. The test is highly profitable, costing around \$3,200, with operating margins of nearly 50 percent. 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 genetic testing have been delayed, limited, or even shut down.

*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 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.”

The lawsuit was filed on behalf of four scientific organizations representing more than 150,000 geneticists, pathologists, and laboratory professionals, as well as individual researchers, breast cancer and women’s health groups, genetic counselors, and individual women. The organizations include the Association for Molecular Pathology (AMP), the American College of Medical Genetics, the American Society for Clinical Pathology (ASCP), and the College of American Pathologists.

AMP president Jan A. Nowak, M.D., Ph.D., said, “This suit is not intended to allege that Myriad Genetics is an unethical company. Rather the intent is to address the larger implications of gene patents. We want to prompt changes to the patent system that will resolve what we see as increasingly narrowing options for manufacturers and laboratories to access gene sequence data to develop the tests needed to make molecular medicine a reality.”



ASCP president Barbara J. McKenna, M.D., FASCP, said the society joined the lawsuit “because its fundamental tenet is that patients come first. Gene patents violate this principle by creating unjustifiable monopolies on human genetic information that is critical in the diagnosis of many diseases. As a result, the market is dominated by a single provider, eliminating competition and scientific diversity, which ultimately drives up costs.”

The lawsuit, *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*, was filed in the United States District Court for the Southern District of New York in Manhattan. Attorneys for the plaintiffs include Chris Hansen and Aden Fine of the ACLU First Amendment Working Group; Lenora Lapidus and Sandra Park of the ACLU Women’s Rights Project; and David Ravicher of the Public Patent Foundation, a nonprofit organization affiliated with Benjamin N. Cardozo School of Law. 🏛️

## Senate Bill Would Make Pathology TC Billing Protection Permanent

Legislation has been introduced in the Senate that would make permanent the “grandfather” provision that allows independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. This protection is set to expire at the end of this year.

The legislation, S. 947, the Physician Pathology Services Continuity Act of 2009, was introduced April 30 by Sen. Blanche Lincoln (D-Ark.) and cosponsored by Sen. Pat Roberts (R-Kan.). It has been referred to the Finance committee.

The “grandfather” protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed to end the pathology TC billings. CMS said the TC is reimbursed as part of Medicare’s Part A inpatient payment, and labs should seek TC payment from the hospital, not Part B.

### Other Lab-Related Legislation Introduced This Year

- ❑ **H.R. 1452, *Modernizing the Lab Fee Schedule.***  
Bipartisan bill would require negotiated rulemaking to develop a single national lab fee schedule, adjusted for geographic and other practice cost variations. Referred to the Energy and Commerce and the Ways and Means committees.
- ❑ **H.R. 1699, *Revising the Date of Service.***  
Bipartisan bill would change Medicare regulations to allow an independent laboratory to be paid directly by the program for molecular and other complex diagnostic tests performed after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected. Current policy requires the hospital to bill for the service, not the lab. Referred to the Energy and Commerce and the Ways and Means committees.

Since CMS proposed the policy change, Congress has stepped in repeatedly to block it and has granted numerous extensions of the protection, most recently in the Medicare Improvements for Patients and Providers Act that became law July 15, 2008.

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. 🏛️



# focuson: *The President's Medicare Budget*

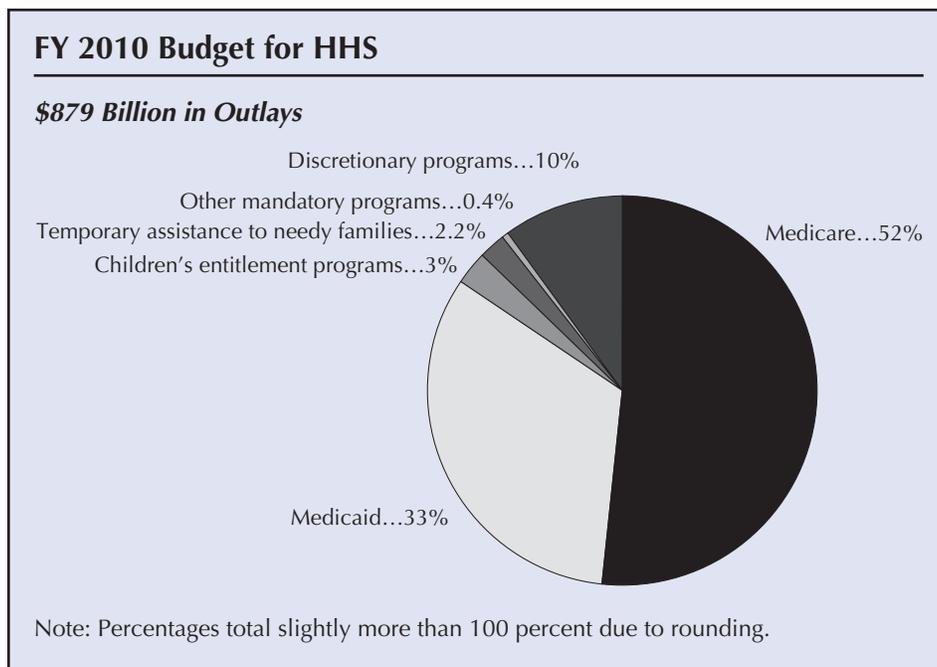
## Quick Guide to Provider Payments and Other Policy Proposals

**P**resident Barack Obama this month sent Congress his administration's budget request for fiscal year 2010, which calls for Medicare and Medicaid spending cuts totaling \$309 billion over 10 years, with the savings earmarked for a \$634 billion reserve fund to finance reform of the nation's health care system.

The administration's legislative proposals for Medicare spending cuts would contribute \$520 million to the reserve fund in 2010 and \$287.4 billion over 10 years. The lion's share of the savings would come from introducing competitive bidding for Medicare managed care plans, bundling inpatient and post-acute care payments, and curbing home health payments.

Medicare physician payments would increase, however. The budget provides \$311 billion over 10 years for this purpose. But the administration cautions, "This reflects our best estimate of what Congress has done in recent years for physician payments but does not suggest it should be a future policy. The administration believes the current Medicare physician payment system needs to be reformed to give physicians incentives to improve quality and efficiency."

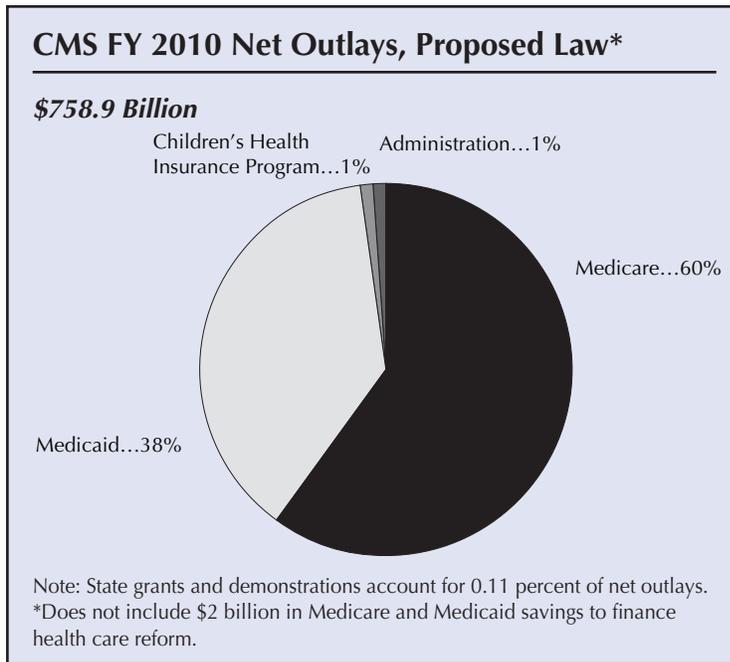
The administration offers no specifics on how to fix the Medicare physician payment system, but says it will work with Congress on the issue. Congress last month signaled that a fundamental overhaul of the system could be put off for at least two more years. The final budget resolution calls for blocking the physician fee cut of 21 percent scheduled for 2010, granting a two-year payment increase, and letting the committees of jurisdiction decide how to fashion the increase.



The budget also signals the administration's support for ways to reward physician groups that coordinate care for Medicare beneficiaries. These voluntary groups, known as physician bonus eligible organizations (BEOs), should receive incentive payments if they improve the quality of care and produce savings.

### MEDICARE LEGISLATIVE PROPOSALS

- Competitive Bidding Under Medicare Advantage**



Private health plans in the Medicare Advantage (MA) program would be required to bid competitively for contracts to serve beneficiaries, saving an estimated \$177 billion over 10 years. Payments to plans would no longer be tied to fee-for-service rates but would be based on an average of plans' bids as well as enrollment in the prior year. The purpose is to drive down overpayments to MA plans and let the market set the upper payment level.

**□ Hospital Quality Incentive Programs**  
Hospitals would be paid an incentive amount based on the quality of care provided, reducing program spending by about \$12.1 billion over 10 years. The incentive would link a portion of base operating payments to performance on

specified quality measures. The portion linked to performance would be 5 percent in 2011 and 15 percent by 2015.

**□ Reducing Hospital Readmissions**

Nearly 18 percent of the hospitalization of Medicare beneficiaries resulted in the readmission of patients who had been discharged from the hospital within the last 30 days, the administration notes. Sometimes the readmission could not be prevented, but many of these readmissions are avoidable, the budget says.

The administration proposes to adjust payments for targeted conditions and procedures by 30 percent for hospitals whose readmission rates exceed the 75th percentile, if the patient is readmitted within 30 days of discharge due to complications or related diagnoses. The estimated savings: \$8.4 billion over 10 years. The pay adjustment would begin in 2010. Public reporting of readmission rates would begin in 2013.

**□ Bundled Medicare Payments**

To promote efficient and coordinated care, the administration proposes that hospitals receive bundled payments that cover not just the hospitalization, but also the post-acute care provided 30 days after the hospitalization. Hospitals with high rates of readmission would be paid less if patients were readmitted within that 30-day period. The bundling policy would save an estimated \$16.1 billion over 10 years. It would begin in 2013.

**□ Physician-Owned Hospital Conflict of Interest**

New physician-owned hospitals would be prohibited from seeking reimbursement for services to beneficiaries referred to the hospital by a physician with a financial interest in the hospital. Existing physician-owned hospitals would be "grandfathered" if they meet certain criteria but would be barred from expanding.

**□ Cuts in Home Health**

Payments to home health agencies would be cut by about \$34 billion over 10 years. There would be no inflation update for 2010, saving an estimated \$460 million.



**□ Anti-Fraud and Abuse Efforts**

The administration would boost Medicare and Medicaid anti-fraud and abuse funding at CMS by \$311 million for fiscal 2010 and \$1.7 billion over five years for greater oversight of the Medicare Advantage and prescription drug programs.

**MEDICARE INSOLVENCY WARNING**

Less than a week after the White House released its budget request, the Medicare Trustees weighed in with a warning that the Medicare hospital trust fund is expected

to be insolvent in 2017, two years earlier than expected. The earlier date reflects lower projected payroll tax income as a result of the recession, though rapidly rising health care costs are central to Medicare's solvency problems, the trustees note in their 2009 annual report.

At a briefing on the report, administration officials, who also serve as trustees, said the rising

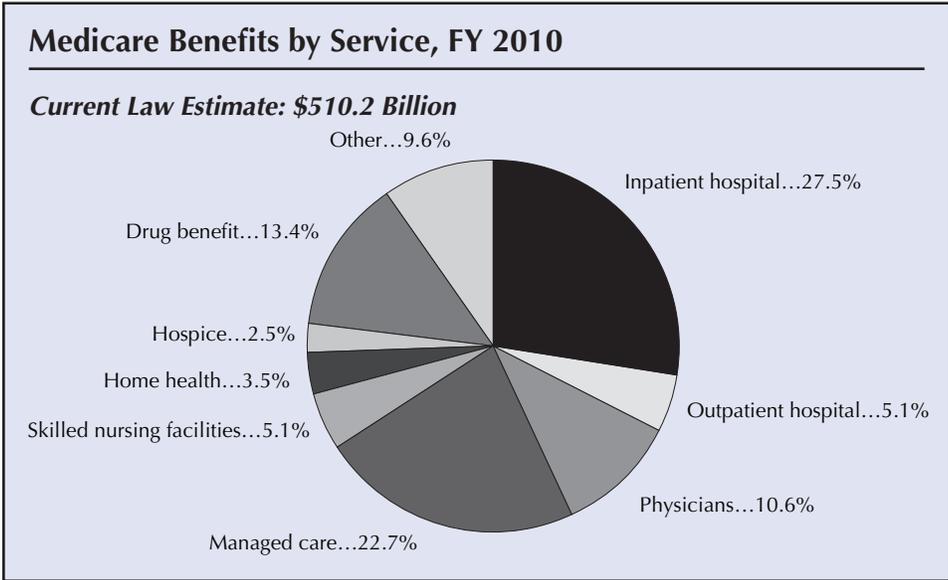
costs underscore the need for comprehensive health care reform legislation.

Total Medicare expenditures were \$468 billion in 2008, according to the report, and are projected to rise faster than workers' pay or the economy overall. As a percent of the gross domestic product, Medicare expenditures are projected to increase from 3.2 percent in 2008 to 11.4 percent by 2083. For Medicare to be brought into

actuarial balance over the next 75 years, a 134 percent increase in the payroll tax, a 53 percent reduction in program spending, or some combination is needed.

The report said, "These projections demonstrate the need for timely and effective action to address Medicare's financial challenges. Consideration of reforms should occur in the relatively near future. The sooner the solutions are enacted, the more flexible and gradual they can be."

The trustees found that Medicare Part B fee-for-service for physician, laboratory, and other services, and Part D, which pays for prescription drug coverage, are expected to remain adequately funded indefinitely because current law requires financing to meet projected costs. 🏛️



costs underscore the need for comprehensive health care reform legislation.

**Lab Spending Up 3.3 Percent in 2008**

Medicare spending for Part B clinical laboratory services grew 3.3 percent in calendar year 2008, to a total of \$7.343 billion, according to the 2009 Medicare Trustees report issued May 12.

The growth was tempered by an increase in the number of beneficiaries enrolling in Medicare managed care plans, from 8.7 million in 2007 to 10 million in 2008, the trustees noted.

Of the \$7.343 billion spent in 2008, independent labs and physician office labs accounted for \$4.309 billion, an increase of 3.9 percent from \$4.146 billion in 2007. Hospital lab outpatient and outreach services accounted for \$3.034 billion, up 2.5 percent from \$2.961 billion in 2007.

In 2008, Part B lab services constituted 1.6 percent of overall Medicare program spending. Over the past five years, Part B lab spending has risen an average 6.1 percent per year, compared with the 10.8 percent average growth rate for total Medicare expenditures.



## Obama Fills the Top Posts at FDA and CDC

President Barack Obama this month filled the top positions at two of three federal agencies within the U.S. Department of Health and Human Services (HHS) that directly influence clinical laboratories.

He named Thomas Frieden to head the Centers for Disease Control and Prevention (CDC), and his nomination of Margaret Hamburg to become commissioner of the Food and Drug Administration (FDA) was confirmed by the Senate May 18. Both have previously served as health commissioner for New York City.

The president had not announced, at press time, his nomination for administrator of the third key agency, the Centers for Medicare and Medicaid Services (CMS). The current acting administrator is Kerry Weems, a veteran with decades of service within HHS. Weems was nominated by President Bush in January 2007 to head CMS. While confirmation hearings were held, no further action was taken.

### New FDA Commissioner

Margaret Hamburg, M.D., is a bioterrorism expert. Since 2001, she has served as vice president for biological programs at the Nuclear Threat Initiative. During the Clinton administration, she was an assistant secretary for planning and evaluation at HHS. Hamburg also has served as the assistant director of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

Lab industry groups will be closely watching how Hamburg executes the Obama administration's priority to improve the safety of medical products and the degree to which regulatory oversight of lab-developed tests (LDTs) would be expanded. Pending on her desk are petitions filed by Genentech and AdvaMed asking the agency to require premarket review of LDTs. The president's fiscal 2010 budget requests an increase of \$166 million for medical product safety activities over the previous-year level. The FDA Center for Devices and Radiological Health would get an increase of \$47.78 million, the budget notes, allowing "additional resources to increase capacity to regulate the diagnostic technology used to develop drugs and dosing based on a person's genetic makeup (personalized medicine) and to advance guidance on nanotechnology issues involving medical devices."

### New CDC Director

Thomas Frieden, M.D., M.P.H., who has been New York City health commissioner since January 2002, is an advocate of preventive medicine, a major priority for the president's proposed overhaul of the nation's health care system. He is expected to take office in June. The post does not require Senate confirmation. The president hailed Frieden as "an expert in preparedness and response to health emergencies and has been at the forefront of the fight against heart disease, cancer, and obesity, infectious diseases such as tuberculosis and AIDS, and in the establishment of electronic health records."

Frieden helped ban smoking and trans fat from restaurants in New York City and also helped develop a network of electronic health records in primary care physician offices that the city helps pay for. He previously spent five years in India on national tuberculosis control efforts. He began his career at the New York City health department in 1990 as a CDC Epidemiologic Intelligence Service Officer. 



# Modest Growth Seen in POLs Doing CLIA Waived, PPM Tests

A total of 210,367 labs are currently registered with the CLIA program, notes the president's CLIA budget. POLs account for the majority—approximately 109,093, or 51.9 percent.

The number of physician office laboratories (POLs) that perform testing classified as waived or provider-performed microscopy under CLIA is projected to grow 3.5 percent in the fiscal year 2009-2010 survey cycle, according to the president's budget proposal for the Centers for Medicare and Medicaid Services released this month.

Currently, approximately 90,064, or 82.6 percent, of CLIA-certified POLs perform waived or microscopy testing. These labs are not required to undergo routine on-site inspections every two years, as are labs that perform tests of moderate and high complexity under CLIA.

The budget request for the CLIA program for FY 2010 is \$56.4 million, all of it financed by user fees, as required under the CLIA statute (the Clinical Laboratory Improvement Amendments of 1988). It includes funding for state survey workloads (excluding waived labs, PPM labs, state-exempt labs, and accredited labs). Workloads projected for the FY 2009-2010 cycle include 19,336 nonaccredited labs; state validation surveys of 809 accredited labs; and approximately 1,409 follow-up surveys and complaint investigations. 

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