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Obama Proposes More Medicare Cuts, Lab Groups Wary

The provider cost-cutting drive raises a potential threat to lab fees as lawmakers come under the gun to find savings to finance health care reform.

President Barack Obama has proposed $313 billion more in reduced Medicare and Medicaid spending over 10 years to help pay for his health care reform agenda. The bulk of the savings would come from hospitals, drug companies, and physician imaging services.

"But labs are far from out of the woods," an industry source told *NIR*. "Lobbying by these influential groups to get some of that money back would pressure lawmakers to find savings elsewhere in Medicare, leaving less protected providers like labs vulnerable to raids on their reimbursement."

The $313 billion savings package is on top of the Medicare and Medicaid cuts the president called for in his budget request to Congress in February. Those cuts, combined with higher taxes on wealthier Americans, would go into a $635 billion reserve fund to finance health care system changes. In all, the president said, "Nearly $950 billion would be set aside to offset the cost of reform over the next 10 years." Reform should be fully funded and budget neutral, he noted. The cost over that time period is estimated by the administration and other sources to be at least $1 trillion. *Continued on p. 2*

Medicare Physician Fee Fix: Permanent or Short-Term?

Repeal of the system used to update Medicare physician fees each year—long a legislative priority of pathology and other medical groups—could come sooner rather than later under a proposal by House committees preparing health care reform legislation.

In a June 15 joint memo, the Ways and Means and Energy and Commerce committees said physicians would get a fee hike in 2010 (though the amount was not specified), and starting in 2011, physicians would be paid under a new system that pegs increases for most services to growth in the gross domestic product (GDP) plus 1 percentage point per year, with an extra growth allowance for primary care and preventive services.

Under the current Sustainable Growth Rate (SGR) update formula, Medicare physician fees are due to be cut by 21 percent in 2010 and even more after that unless Congress intervenes, as expected. The SGR ties the annual update to a physician spending target. When spending exceeds the target, the update is negative; when it falls below the target, the update is positive. *Continued on p. 6*

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More Medicare Cuts, *from p. 1*

The president's latest proposal for Medicare cuts does not mention laboratories, but "labs are not off the hook," warn industry analysts. The administration has proposed a series of Medicare payment reforms but is letting Congress take the lead in hammering out the legislative details. One industry source told *NIR*, "The White House is under pressure to cut the federal deficit and deliver on its health care reform pledge. At this point, it appears to care more about getting the savings to support reform than where the money comes from."

Money will be tight, agreed Jason DuBois, vice president of government relations for the American Clinical Laboratory Association (ACLA). "We are very vigilant against Medicare cuts in lab spending and protecting the annual update to the Part B lab fee schedule," he told *NIR*. Congress has approved a lab fee update of 0.5 percent less than the full Consumer Price Index update from 2009 through 2013.

"At the same time, we are working to advance lab priorities in the debate over health system overhaul," he said, emphasizing the vital role that the lab plays in achieving reform goals for promotion of prevention and wellness programs and for personalized medicine. The Clinical Laboratory Coalition, of which ACLA is a member, advocates no patient copay for preventive services and seeks new reimbursement incentives for genetic and molecular diagnostics to advance personalized medicine (*NIR, 09, 11/June 8, pp. 4-6*).

The president's latest Medicare and Medicaid savings proposals include:

- ❑ $110 billion by adjusting Medicare provider payments to reflect productivity improvements in the economy as a whole.
- ❑ $106 billion in cuts to the disproportionate share hospital (DSH) program for Medicare and Medicaid.
- ❑ $75 billion in reductions in Medicare prescription drug spending.
- ❑ $14.4 billion in cuts to nursing homes, long-term care hospitals, and inpatient rehabilitation hospitals.
- ❑ $6 billion in cuts to physician imaging services.
- ❑ $1 billion in savings from reducing program fraud and abuse.

The $313 billion in reduced Medicare and Medicaid spending, the White House said, would lengthen the solvency of the Part A hospital trust fund by seven years and reduce beneficiaries' Part B premiums, based in part on program spending, by $43 billion over 10 years.

In a June 12 briefing, Peter Orszag, director of the White House Office of Management and Budget, said providers would ultimately benefit because overall reform will result in nearly universal insurance coverage. For example, DSH payments now made to hospitals to offset the cost of care for the uninsured would no longer be needed. Further, hospitals should be able to handle productivity payment adjustments, he said, by improving the efficiency of care, for example, through use of health information technology.

Of the proposed Medicare savings in the president's fiscal 2010 budget, released earlier this year, the biggest portion—$177 billion over 10 years—would come from requiring managed care plans to bid competitively for Medicare Advantage contracts. Home health agencies see their reimbursement cut about $34 billion over 10 years.

Savings also would come from hospital quality incentive payments ($12 billion over 10 years), reducing hospital readmission rates ($8.4 billion), and bundling post-acute care payments into the hospital's inpatient rate ($16.1 billion). 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.

Senate Bill Revises 'Date of Service' Policy in Labs' Favor

Recently introduced Senate legislation would change Medicare policy to allow independent laboratories offering complex, advanced diagnostic tests to bill Medicare directly for the tests when ordered less than 14 days after a patient's hospital discharge.

Under current Medicare rules, the date of service (DOS) for a lab test ordered within that time frame is the date the specimen was collected. As a result, the test is treated as having been performed when the patient was in or at the hospital, and the hospital must bill for it, even though the hospital no longer has a direct connection with the patient or the test ordered.

The Senate bill to change this DOS policy—S. 1220, the Patient Access to Critical Lab Tests Act—is sponsored by Sen. Arlen Specter (D-Pa.) and Sen. Ron Wyden (D-Ore.). It was referred to the Finance committee with a request by Specter that it be considered in the panel's markup of health care reform legislation. Similar legislation (H.R. 1699) has been introduced in the House by Pennsylvania Reps. Jason Altmire (D) and Tim Murphy (R) (*NIR, 09, 7/Apr. 13, p.* 5).

"Advances in lab medicine enable providers to be far more effective in targeting treatment for patients or in determining a patient's predisposition to a disease or condition. This bill corrects an antiquated Medicare rule so that patients can receive cutting-edge genetic and molecular diagnostic tests in time to make a difference"
—Alan Mertz, ACLA president

The bill, like its House counterpart, is strongly supported by the American Clinical Laboratory Association (ACLA) and the Coalition for 21st Century Medicine, which includes ACLA members among the parties representing diagnostic technology companies, clinical labs, researchers, physician groups, venture capitalists, and patient advocacy groups.

The groups said the legislation will remove regulatory hurdles that deny patients access to life-saving genetic and molecular diagnostics "because Medicare requires billing to be routed through a hospital that is no longer caring for the patient (and, in the case of outpatients, may have only seen the patient for a few minutes).

In a statement of support, the groups noted, "A physician will frequently order tests on a blood or tissue sample after a patient has gone home from the hospital, but before 14 days. These tests are performed by specialty labs that could be hundreds of miles away from the hospital. So, when the lab, following Medicare rules, attempts to bill the hospital for the test, there are a number of understandable reactions:

- ❑ The hospital is reluctant to pay the lab, and subsequently bill Medicare, for a test it did not order and did not perform.
- ❑ The hospital may not be familiar with the test, or why it was ordered, or know how to bill Medicare for it.
- ❑ For inpatient care, hospitals are paid a set amount for the patient's care and will be reluctant to pay a lab (again, for a test it did not order) and reduce its own revenues.

The coalition further noted that "the development of new innovative technologies is undermined if the companies developing them have no assurance payment will be made for medically necessary testing."

focus on: Health Care Reform

Congressional Committees Chafing at the Starting Gate

The Obama administration and congressional allies want to complete work on health system overhaul this year before the midterm elections in 2010 dominate the legislative agenda.

Senate and House committees have begun the contentious task of writing health care reform legislation in an ambitious timeframe, amid concerns on all sides about its cost and Republican criticism that the process is too important to rush. But the Democratic chairmen are confident they can have bills ready for floor action before the August recess so that the measures can be reconciled in September and a final version can get to the president in October.

The cost of overhauling health care is a big issue the committees face as they sift through a slough of proposals. According to preliminary estimates by the Congressional Budget Office, the Senate Finance draft bill would cost $1.5 trillion over 10 years, while the draft before the Health, Education, Labor, and Pensions (HELP) committee would cost $1 trillion over 10 years.

The HELP committee began markup of a 615-page draft on June 17. Markup by the Finance committee, set to begin by the end of this month, could be delayed a few more weeks as members seek to scale back their draft's costs. Chairman Max Baucus (Mont.) said any delay would not affect the August deadline, noting that more time for deliberations improves the prospects for a bipartisan outcome and fully funded reform.

In the House, the Ways and Means committee continues to weigh revenue-raising options to pay for health care reform. Earlier this month, the panel joined with Energy and Commerce and Education and Labor to announce a tricommittee framework for reform legislation.

Starting Points

As Congress considers health care reform, Democrats and Republicans agree at the start on three broad goals that will shape their decisions: expand health care coverage, improve the quality of care, and lower health care costs. But they differ sharply on philosophy and financing. The GOP advocates reliance on tax and market reforms to achieve these goals, rather than more government intervention.

Both parties agree, however, that in any reform:

- ❑ People should be able to keep the insurance coverage and the doctor they like.
- ❑ Affordable, accessible coverage options should be available to all, regardless of pre-existing conditions. Premium subsidies should be available to help low-income individuals and families purchase the coverage they need.
- ❑ The job-based system through which a majority of Americans are covered should be strengthened.

There also is bipartisan agreement that reform should include incentives for prevention and wellness programs, personalized medicine, and coordinated care, especially for chronic conditions that consume the most Medicare dollars.

Key Points of Controversy

Public Plan Option: Democrats and the Obama administration support creation of a new public plan that would compete with private insurers for enrollees, saying

this would expand consumer choices. Republicans oppose a government-sponsored plan that it fears could morph into a single-payer system. The GOP also sides with the health insurance industry in arguing that the proposal puts private plans at a competitive disadvantage in the market and could force them to cut back on benefits or close their offerings.

The latest to dispute the GOP assertions is Health and Human Services Secretary Kathleen Sebelius, who noted in July 17 remarks to a private forum, "In 30 states across the country, state employees can choose between a public health insurance option and private insurance companies. The side-by-side competition has not destroyed the private market, nor has it become a single-payer system."

The American Medical Association has signaled it would support a public plan alternative, but not one based on already low Medicare reimbursement rates and coverage variations.

Some compromises have been floated in the Senate on this politically charged issue. Kent Conrad (D-N.D.) has proposed introducing health insurance "consumer cooperatives" to compete with private plans. This initiative could include a federal charter to license and regulate nonprofit cooperatives, permitting them to provide health insurance around the country. The cooperatives could also be operated by the states either within states or as regional entities, according to the draft Conrad proposal.

The tax break individuals get on job-provided health care benefits is not expected to be eliminated, but lawmakers are looking at reducing or capping it as one way to help pay the reform tab. Obama also has proposed paying for reform in part by "means-testing" the Medicare drug benefit and reducing the tax benefits of itemized deductions such as charitable contributions, home mortgage interest, and state and local taxes.

Another compromise, aired by Sen. Olympia Snowe (R-Me.), would hold off for now on a public plan, giving private insurers time to demonstrate that they can provide affordable quality coverage options. If they cannot deliver, then the government could institute a public plan option.

Employer Mandate: Democrats generally support the "play or pay" approach. Employers would be required to offer their employees health care coverage or pay into a pool to cover the uninsured. The Obama administration backs an employer mandate, but with an exemption for small businesses. Large employers say the mandate would drive up their already fast rising health care costs and could force them to trim or drop employee coverage. The GOP opposes increases in levies on business to fund reform. In the House, its Health Care Solutions Group called for strengthening job-based coverage by moving to opt-out, rather than opt-in rules, granting a new small business tax credit, and allowing dependents to remain on their parents' health policies up to age 25.

Individual Mandate: Democrats and the Obama administration support requiring all Americans to obtain health care coverage as affordable options become available, though the president has said waivers should be given to those who cannot afford coverage. It is not clear how the mandate would be enforced. One option would be to use the tax code to penalize people who do not comply.

National Health Insurance Exchange: There is agreement that the exchange would be valuable as a "one-stop shopping" center to help people find the health care coverage they need and can afford. But opinion is split as to who should run it—the federal government, states, or a third-party administrator.

Expansion of Medicaid: To cover more of the uninsured, Democrats favor expanding the federal-state Medicaid program by lowering the eligibility level. The HELP draft bill would open the program to those with incomes at 150 percent of the federal poverty level, but GOP critics say this would strain already stressed state budgets and raise federal matching costs. They favor grants or subsidies instead to help those with low incomes buy insurance coverage.

Medicare Physician Fee Fix, *from p. 1*
For most of this decade, the SGR has triggered negative updates, and Congress has repeatedly blocked them with temporary fixes.

It is not yet clear if the Senate Finance committee will go as far as its House counterparts to repeal the SGR. Other options before it prior to markup envision a short-term fix. One option would be "to update the Part B fee schedule by 1 percentage point in 2010 and 2011 and freeze it in 2012. Calculations under the SGR formula would then revert to the current law for 2013."

Another option would "have the same schedule of updates for 2010-2012 as above; however, once the update calculation reverted to current law SGR for 2012, a floor of minus 3 percent would be in effect. Beginning in 2014, the update for localities with two-year average fee-for-service growth rates at or greater than 110 percent of the national average would have a minus 6 percent floor."

The congressional budget resolution for fiscal 2010 envisions a short-term fix. The resolution, though not binding, blocks the physician fee cut of 21 percent scheduled for 2010, grants a two-year payment increase, and lets the committees of jurisdiction decide how to fashion the increase.

President Obama noted his concerns about the SGR payment formula in recent remarks to the American Medical Association. "With reform, we will ensure that you are being reimbursed in a thoughtful way that's tied to patient outcomes, instead of relying on yearly negotiations about the SGR that's based on politics and the immediate state of the federal budget in any given year," he said.

House Bill Makes Pathology TC Billing Protection Permanent

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

The bill—H.R. 2534, the Physician Pathology Services Continuity Act of 2009—was introduced by Rep. John Tanner (D-Tenn.) and cosponsored by Rep. Geoff Davis (R-Ky.). It has been referred to the Energy and Commerce and Ways and Means committees.

A companion bipartisan bill in the Senate (S. 947), introduced by Blanche Lincoln (D-Ark.) and cosponsored by Pat Roberts (R-Kans.), has been referred to the Finance committee (NIR, 09, 10/May 25, p. 3).

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.

Since CMS proposed the payment policy change, Congress has stepped in repeatedly to block it by granting temporary 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.

♦ CLIA *Advisory*

New Waived Tests and Billing Codes

The July 1 update to the list of CLIA waived tests includes the latest tests approved by the Food and Drug Administration for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

When billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived in accord with CLIA (the Clinical Laboratory Improvement Amendments).

CPT Code	*Effective Date*	*Description*
87880QW	Sept. 25, 2008	Quidel QuickVue In-Line Strep A {direct from throat swab} (K934484/A013)
80069QW	Dec. 4, 2008	Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel) {Whole Blood}
80069QW	Dec. 4, 2008	Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel) {Whole Blood}
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	Dec. 4, 2008	Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	Dec. 4, 2008	Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}
81003QW	Jan. 5, 2009	Jant Pharmacal Corporation Accustrip URS Reader
80101QW	Jan. 5, 2009	Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}
80101QW	Jan. 5, 2009	Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version}

The list of CLIA waived tests and billing codes is typically updated quarterly. For the July 1 update, which includes a complete list of all currently waived tests, see CMS Change Request 6459 at www.cms.hhs.gov/transmittals.

The new waived CPT code 80069QW has been assigned for the albumin, total calcium, carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium, and urea nitrogen tests performed using the Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel) {Whole Blood} and the Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel) {Whole Blood}.

The new waived CPT code 82550QW has been assigned for the creatine kinase test performed using the Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood} and the Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}.

For 2009, the description for CPT code 82040 was modified from "albumin; serum" to "albumin; serum, plasma or whole blood." Thus, the CPT code assigned to whole blood albumin tests performed on the following test systems has been changed from 82042QW (albumin; urine or other source quantitative, each specimen) to 82040QW with an effective date of Jan. 1, 2009 for certain Abaxis tests.

Appeals Court Upholds Revocation of Lab's CLIA Certificate

A federal appeals court has upheld the government's one-year revocation of a laboratory's CLIA certificate for referring proficiency testing (PT) samples to another lab for analysis before submitting its own results. The court denied a petition for review filed by Wade Pediatrics in Muskogee, Okla.

The lab said it was only checking the accuracy of its work, but the appeals court for the 10th Circuit found that "while consultation between labs may be permissible in other circumstances before and after a proficiency test, asking an outsider for help during a test corrupts the process and defeats its purpose. In fact, this is what Congress intended to prevent in enacting CLIA."

In the case before the court, Wade failed parts of two PT rounds in 2005 and on the advice of a field investigator for the Centers for Medicare and Medicaid Services (CMS), turned to another certified lab, at Muskogee Regional Medical Center, for training and comparison testing. In PT rounds during 2006, a technician from Wade tested PT samples on the center's equipment, ostensibly to double-check results. When CMS found out, it revoked Wade's CLIA certificate for one year, the penalty required by law.

The case is Wade Pediatrics v. HHS, *10th Cir., No. 08-9529 (6/2/09).*

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Crystal Gateway Marriott Hotel, Arlington, Va.

Oct. 19-21
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How to Leverage the Convergence of the Lab, Pathology, Imaging, and IT
Crystal Gateway Marriott Hotel, Arlington, Va.

Nov. 12
Lab Leaders Summit
Driving Growth in Your Business
The Princeton Hotel, New York City

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