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House, Senate Split over Medicare Physician Fee Fix

Under the current payment system, Medicare physician fees will be cut by 21 percent in 2010 and cumulatively by 40 percent by 2014, reducing physician participation in the program, the Congressional Budget Office warned in a March 27 letter to the House Budget committee.

In approving budget blueprints for fiscal 2010, the House and the Senate parted ways on overhauling the Medicare Part B physician payment system. Both spending plans approve $330 billion over 10 years for a physician fee fix, but the House would add the costs to the federal deficit while the Senate says it must be paid for, opening the door to potential cuts to other Medicare providers or more short-term fixes.

This is one of several key differences between the two budgets to be worked out by House and Senate lawmakers after Congress returns from its mid-April recess. Another is procedural, but the most contentious: the House wants to use the reconciliation process to pass a final version by a simple majority, making it immune to a Senate filibuster. The Senate Democratic leadership has been wary about acceding to reconciliation, facing a threat from all Republican senators that this could doom bipartisan efforts to enact health care reform.

The Senate passed its budget April 2 by a vote of 55-43, following similar House action earlier that day by a vote of 233-196. All Republicans in both chambers voted against it, joined by some conservative Democrats. The GOP proposed an alternative budget with a freeze on non-defense spending and more tax cuts.

Both the House and the Senate approved a $3.5 trillion budget outline, sticking closely to the president's broad goals for energy, education, and health care reform. Both set aside $634 billion *Continued on p. 2*

AdvaMed Proposal to FDA Reignites Controversy Over Lab-Developed Tests

All tests developed in-house by clinical laboratories, including genetic testing increasingly used in personalized medicine, should be regulated by the Food and Drug Administration, according to a proposal submitted to the agency by a leading medical device industry group.

In a March 27 submission, the Advanced Medical Technology Association (AdvaMed) said the FDA should use a risk-based approach to regulate all in vitro diagnostic tests, whether they are produced by medical device manufacturers or are developed in-house by labs. A risk-based approach would determine the intensity of review required, though low-risk tests should be exempt from premarket review, AdvaMed said. *Continued on p. 7*

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A final congressional budget resolution, while not binding and not requiring the president's signature, is an important indicator of the majority's priorities for legislative action.

Medicare Physician Fee Fix, *from p. 1*

for a reserve fund that the president proposed as a "down payment" on health care reform, including $330 billion for Medicare physician payment reform, but leave it to the committees of jurisdiction to decide how to pay for it.

The president proposed to fund half the reserve by reductions in Medicare and Medicaid spending and half from higher taxes on the wealthiest Americans, including lowering the deduction for charitable contributions for taxpayers earning more than $250,000 from 35 percent to 28 percent. But a GOP amendment to the Senate budget would prohibit changing current tax laws for this deduction to pay for modernizing the health care system.

Physician groups, including the College of American Pathologists, want Congress to repeal the current Sustainable Growth Rate (SGR) payment system, which has triggered fee reductions for most of this decade. Congress has repeatedly stepped in to prevent steep cuts and to grant a modest increase (most recently, the 1.1 percent increase for 2009, expiring at year's end). The administration supports a physician fee fix tied to quality incentives, but instead of advancing its own plan, says it is working with Congress to develop the legislation (*NIR, 09, 5/Mar 16, p. 1*).

Meantime, in the run-up to congressional consideration of specific health care legislation to expand coverage, Senate Finance committee chairman Max Baucus (D-Mont.) has sought to defuse the flareup over the proposed creation of a government-run public plan option that would compete with private insurers, an option favored by the administration and many congressional Democrats but opposed by insurers who say it will put them at a competitive disadvantage and could force them out of the market. In remarks on March 27, Baucus urged all stakeholders "to keep everything on the table," including discussion of the public plan. He said ways could be found to guarantee a "level playing field."

The administration is upbeat about the prospects for enactment of health care reform this year, says Nancy-Ann DeParle, head of the White House Office of Health Reform, which the president established by executive order on April 8. House and Senate Democratic leaders have said they aim to pass reform bills by the August recess, she noted in a recent telephone conference with about 100,000 AARP members, leaving enough time in the fall to reconcile differences. That is an aggressive timetable, note industry analysts, and even Democrats acknowledge that it is optimistic.

But DeParle said, "There's a lot of reason to be optimistic" about enacting a revamping of the nation's health system, pointing to broad public and private support and to rising health care costs and other problems that have created a sense of urgency on Capitol Hill and among stakeholders to act now. Reform can be bipartisan, she said. Both parties want to lower health care costs for individuals, families, business, and the federal and state governments. "The president wants to try to do this in a bipartisan way, and I think we will."

Top Slots at HHS Still to be Filled

A Senate vote on the president's choice of Kansas Democratic Governor Kathleen Sebelius as secretary of Health and Human Services has been delayed until after the mid-April recess. She received a warm reception at her confirmation hearing before the Senate Finance committee, but Republicans later objected to a quick vote without a chance for debate.

Also awaiting confirmation is the president's pick of Margaret Hamburg as commissioner of the Food and Drug Administration (*NIR, 09, 6/Mar 30, p. 7*). Joshua Sharfstein, M.D., the president's pick as the FDA's principal deputy commissioner, became acting FDA commissioner on March 30.

Federal Infrastructure for Health IT Taking Shape

The government is moving quickly to erect the federal infrastructure to spur nationwide adoption of electronic medical records (EMRs), as required by the American Recovery and Reinvestment Act of 2009 (ARRA), signed into law Feb. 17. The goal is to have a national system of EMRs for all Americans by 2014 to improve the quality of care, reduce medical errors, and lower health care costs.

Massachusetts physician David Blumenthal has been named to head the Office of the National Coordinator for Health Information Technology (HIT) that ARRA formally established within the U.S. Department of Health and Human Services (HHS) (*NIR, 09, 6/Mar 30, p. 7*).

HHS is in the process of forming two key committees created by ARRA to address issues in electronic exchange and use of health information. It has already solicited nominations of individuals to serve on the panels.

The HIT Policy Committee is charged with making recommendations to the national coordinator on implementation of a nationwide HIT infrastructure, including areas where standards, implementation specifications, and certification criteria are needed, including the privacy and security of an individual's protected health information. The panel will have at least 20 members who are required to be representative of a broad spectrum of stakeholders.

The clinical lab industry should have its own representatives on the new health IT committees, says the American Clinical Laboratory Association, noting that lab test results account for 60 percent of the electronic medical record and that labs, in particular independent labs, have extensive experience in establishing e-links to thousands of physician offices.

The HIT Standards Committee is charged with advising the national coordinator on standards, implementation specifications, and certification criteria. It shall, as appropriate, provide for the testing of standards and specifications by the National Institute for Standards and Technology.

Within 90 days of receiving the committee's recommendations from the national coordinator, the HHS secretary is to consult with other relevant federal agencies on whether to propose their adoption. The secretary is required to adopt, through rulemaking, an initial set of standards by Dec. 31, 2009.

The American Clinical Laboratory Association (ACLA) has nominated its president Alan Mertz to the policy committee and Ken McCaslin, senior health care standards architect at Quest Diagnostics, to the standards committee.

At Quest, McCaslin, who has more than 25 years of experience in the lab industry, is responsible for relationships with standards organizations and government initiatives such as the Health Information Technology Standards Panel (HITSP), ACLA noted. He also has actively participated in the development of specifications for the EHR-Lab Interoperability and Connectivity Standards project (ELINCS) and chairs ACLA's HIT data standards committee.

Bill Aims to Modernize Medicare Lab Fee Schedule

With the Obama administration and the Congress poised to tackle physician payment reform as part of broader health care change, the time is right to put lab fee schedule reform on the legislative agenda as well, say backers of the bill.

Legislation has been introduced in the House (H.R. 1452) to overhaul Medicare's fee schedule payment methodology for Part B clinical laboratory services and to increase the Medicare fee for collecting lab test specimens.

The bill, championed by the Clinical Laboratory Management Association (CLMA) and the American Society for Clinical Laboratory Science (ASCLS), would establish a negotiated rulemaking process to develop a single Medicare national lab fee schedule that would align reimbursement with actual testing costs. Similar legislation was introduced last year, but no further action was taken.

CLMA and ASCLS note that the current local Part B lab fee schedules have not undergone a fundamental review and updating since they were adopted in 1984, based on 1983 local prevailing charge data. Since then, the groups point out, the costs of clinical lab tests, including new genetic and genomic tests, equipment, supplies, and medical professional staff have increased exponentially.

As a result, clinical labs have suffered real reductions in reimbursement, not just reductions in the rate of increase that other providers have experienced, said CLMA president JoAnne Milbourn.

The bill also would raise the fee for collecting lab test specimens from nursing home and homebound beneficiaries to $6.04 in 2010 and adjust it thereafter by the annual Consumer Price Index (CPI) update. The current fee, unchanged for 25 years, is $3.

H.R. 1452 was introduced by Rep. Bart Stupak (D-Mich.), chairman of the House Energy and Commerce subcommittee on oversight and investigations, along with Republican cosponsors Michael Burgess (Texas) and C.W. Bill Young (Fla.) and Democratic cosponsors Sanford Bishop Jr. (Ga.) and Rick Boucher (Va.). It has been referred to the Energy and Commerce and the Ways and Means committees.

Specifics of the Bill

The secretary of Health and Human Services (HHS) would appoint a negotiated rulemaking committee, representative of all stakeholders, whose purpose is to achieve consensus on a single national Medicare lab fee schedule, with no beneficiary cost sharing. It must have mechanisms for an automatic annual CPI update and for other periodic revisions "to reflect the evolution of costs, value, and utilization of lab tests," the legislation states.

Moreover, it should be able "to incorporate new clinical lab tests and technology in a timely manner and provide appropriate reimbursement." In the transition to the new payment method, labs would be paid a blended rate based on the old fee schedules and the new one.

H.R. 1452 gives the committee 24 months to report to Congress on its work. If consensus is reached, the HHS secretary has 36 months to propose and finalize regulations establishing a Medicare modernized clinical lab fee schedule. If consensus is not reached, the bill stipulates that "authority remains with the Congress to establish such a fee schedule, taking into account the purpose and key elements of H.R. 1452."

Bill Would Revise 'Date of Service' Rule in Labs' Favor

Legislation has been introduced in the House that would change Medicare regulations to allow an independent laboratory to be paid directly by the program for complex diagnostic tests performed after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected.

The bill, H.R. 1699, defines these tests as "DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, chromosomal changes, biochemical changes, cell response, gene expression, or a cancer chemotherapy sensitivity assay but do not include methods principally comprising immunohistochemistry, flow cytometry, enzyme assay, or immunoassay."

H.R. 1699 is sponsored by Rep. Jason Altmire (D-Pa.) and cosponsored by Reps. Anna Eshoo (D-Calif.) and Tim Murphy (R-Pa.). It has been referred to the Energy and Commerce and the Ways and Means committees.

Altmire said the current rules impede use of personalized medicine advances in patient care, noting that his bill "will cut through the red tape to ensure that doctors can utilize all the tools at their disposal to provide patients with the best possible care." Eshoo said the current policy requiring the hospital to bill for the service—rather than have the lab submit the bill—creates obstacles for beneficiaries and extra work for hospitals.

The American Clinical Laboratory Association (ACLA) strongly supports the bill, saying it will resolve "date of service" issues that are obstructing access to genetic and molecular tests, delaying patients' diagnosis and treatment, and discouraging investment in developing new tests.

Under current Medicare regulations, the date of service for a lab test ordered less than 14 days after a patient's discharge from a hospital is the date on which the specimen was collected. The effect is that the test is treated as having been performed when the patient was in or at the hospital. "Today, when a lab test is ordered within 14 days of discharge, the hospital, not the lab, must bill Medicare for the service," ACLA said, "creating access problems for this category of tests that are ordered after the patient's hospital stay."

Panel on Effectiveness Research Up and Running

The newly formed Federal Coordinating Council on Comparative Effectiveness Research will hold a public listening session in Washington, D.C., on April 14 to discuss its activities and to get input on priorities that it should address. The panel will accept oral and written comments, and the public may also listen live via audio conference or watch the session online at *www.hhs.gov/recovery*.

The council is authorized by the American Recovery and Reinvestment Act of 2009 (ARRA) to help coordinate this research and guide funding allocations to support it. Comparative effectiveness research (CER), a priority of the Obama administration, got a $1.1 billion boost under ARRA.

The council is an advisory board comprised of representatives of federal agencies charged with coordinating federal research on CER. Names of the 15 members were announced March 19 by the Department of Health and Human Services. They are

drawn from the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, the Food and Drug Administration, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, the Office of the National Coordinator for Health Information Technology, and the Departments of Defense and Veterans Affairs.

"The Obama administration is committed to openness and transparency," said HHS spokeswoman Jenny Backus. "Comparative effectiveness research will expand choices for patients, not limit them, and the council looks forward to hearing from all parties as it moves ahead."

The aim of CER is to evaluate available health care tests and treatments to determine their significant advantages or disadvantages. The findings would help patients make better decisions about the health care they need or want and help physicians focus on the best tests and treatments for individual patients. While there is broad agreement on the concept, there are widely different interpretations of its appropriate use.

The Obama administration promotes CER as a way to inject more quality into federal programs. But the priority being given to such research has drawn fire from some members of Congress who fear it could lead to federal interference in medical decisions by enforcing clinical treatment and protocols. To calm the air, the administration has said CER would not be used to mandate coverage, reimbursement, or other policies of public or private payers and will not include national clinical guidelines or coverage determinations.

Of the $1.1 billion approved for CER, $300 million goes to the Agency for Healthcare Research and Quality, $400 million to the National Institutes of Health, and $400 million for discretionary use by the HHS secretary to "fast track" development and dissemination of CER for health care treatments and strategies. The council will provide input on priorities for the $400 million fund allotted to the secretary, but will not make final decisions about the kind of projects that will be funded, HHS said.

In Memoriam

Ronald H. Laessig, Ph.D., a well-known industry public health leader in Wisconsin who also played a leading role on the national industry stage for decades, passed away March 29. He was emeritus director of the Wisconsin State Laboratory of Hygiene and emeritus professor of population health sciences and pathology at the University of Wisconsin Medical School in Madison. He retired about a year ago after 40 years of service to the university and the state.

Dr. Laessig died unexpectedly but peacefully in his sleep, said friend and colleague James O. Westgard, Ph.D, who hailed him as a "quality builder" in all aspects of clinical laboratory medicine. In his long career, Dr. Laessig served as chairman of the FDA's Advisory Committee on In Vitro Diagnostic Products, a member of the board of the American Association for Clinical Chemistry, and president of the National Committee for Clinical Laboratory Standards.

Dr. Laessig received his B.S. degree from the University of Wisconsin-Stevens Point and his Ph.D. in analytical chemistry from the University of Wisconsin-Madison. He did his post doctoral work at Princeton University and the Centers for Disease Control in Atlanta.

AdvaMed Proposal to FDA, *from p. 1*

AdvaMed urged the FDA to align its "safe and effective" requirements for in vitro diagnostic tests with CLIA quality control rules for lab testing. It also urged the Centers for Medicare and Medicaid Services to support "timely and adequate Medicare reimbursement for all new diagnostics."

The AdvaMed submission comes on the heels of a petition filed with the FDA last December by Genentech, a developer of cancer drugs (*NIR, 09, 1/Jan 12, p. 1*). The company asked the FDA to subject lab-developed tests (LDTs) to the same scientific and regulatory standards, including premarket review and post-market surveillance, that it applies to in vitro diagnostic tests developed and sold by device makers as test kits.

In a quick response, the American Clinical Laboratory Association (ACLA) asked the FDA to deny Genentech's petition (*NIR, 09, 4/Feb 23, p. 3*). The petition, if accepted, ACLA said, would impose a "new, unnecessary regulatory framework on all LDTs," hindering the ability of clinical labs "to incorporate medical innovations quickly and effectively into patient care, provide rapid response to disease outbreaks, and provide treatment guidance for patients with rare diseases or in other situations where no FDA-cleared test exists."

Reacting to AdvaMed's petition, representatives of lab industry groups said they could agree with some proposals, such as a risk-based regulatory approach and better reimbursement for new diagnostic tests. But they object to the argument that labs providing LDTs are medical device makers and thus these tests are subject to premarket review. A lab performing an LDT is not selling a test kit, they say, but is selling a service performed only in that lab and subject to the most stringent level of CLIA regulation.

LDTs include commonly used tests for breast and colon cancer, AIDS, and other diseases that have a history of being safe and effective, notes ACLA. The association and the College of American Pathologists oppose further expansion of FDA regulation over LDTs, contending that CLIA standards assure the analytical and clinical validity of these tests. "All health care-related lab tests are already either cleared by the FDA or performed in a lab regulated by CLIA, or both. Also labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight, often are also regulated by states, and most have further oversight via lab accrediting bodies," ACLA has pointed out.

The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as IVDMIAs (in vitro diagnostic multivariate index assays) that use a proprietary algorithm to produce a patient-specific result.

Changes at Key FDA Unit With Lab Oversight

The FDA Office of In Vitro Diagnostics (OIVD) announced it has received approval to increase staffing and to create a personalized medicine program. Personnel have also been reorganized in light of new agency leadership and the new administration's priorities. Among the changes:

- Don St. Pierre is the acting director of OIVD. The long-time former director, Dr. Steve Gutman, retired in December and is now at the University of Central Florida.
- Francis Kalush has moved to the office of the director of the Center for Devices and Radiological Health to operate as network leader for diagnostics and personalized medicine.
- Elizabeth Mansfield is on detail as the FDA's senior director of genomics and personalized medicine, reporting directly to the commissioner.
- Alberto Gutierrez is deputy office director for new device evaluation.

OIG Changes Course on Provider Self-Disclosure Protocol

The protocol enables a provider to voluntarily disclose self-discovered evidence of potential fraud in a bid to avoid the costs and disruptions of a government investigation and civil or administrative litigation.

The HHS Office of Inspector General (OIG) will use the health care provider self-disclosure protocol (SDP) only for kickbacks intended to induce or reward physicians for referrals. It will no longer accept disclosure of a liability under the physician self-referral law.

Inspector General Daniel R. Levinson announced the change in a March 24 open letter to the health care industry. "The OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law."

He also announced establishment of a $50,000 minimum settlement amount for kickback-related disclosures accepted into the SDP after March 24, adding that "we will continue to analyze the facts and circumstances of each disclosure to determine the appropriate amount consistent with our practice of generally resolving the matter near the lower end of the damages continuum, *i.e.*, a multiplier of the value of the financial benefit conferred."

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