WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 26th Year of Publication

Vol. 26, No. 9, February 21, 2005

Lab Groups See Good News In Budget, But Remain Wary

The groups worry that deficit-cutting moves could impact Medicare lab spending. The Congressional Budget Office has just advised Congress that one cost-savings option would be to impose a deductible and 20% co-pay for Part B lab services. Details in the Focus, *pp. 3-6*

Clinical laboratory interests were heartened that the President's budget request for fiscal 2006, which begins Oct. 1 of this year, did not target Medicare Part B lab fees for additional reductions. "We're certainly pleased the budget did not have specific cuts," said Alan Mertz, president of the American Clinical Laboratory Association. "It gives us some more time to educate Congress. With the CPI freeze, we have already given at the office."

Members of the Clinical Laboratory Coalition had been prepared for the worst. "We were poised with press releases and possibly advertisements to press campaigns against whatever we were hit with," said Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science.

Some lab interests did get hit, including lab personnel training and the Laboratory Response Network against bioterrorism. Pathology groups are concerned that there's no budget fix to the Medicare physician fee formula to avert cuts looming for 2006. "It's obviously going to be a challenging year," said attorney Bob Waters, who represents the American Association of Bioanalysts and plays a leading role in the lab coalition. "It remains to be seen whether Medicare will be reopened. If so, we'll be there."

Senate Passes Ban On Genetic Discrimination

The Senate has unanimously approved legislation to prevent health insurers and employers from discriminating against individuals with a genetic predisposition to disease. The bill would bar insurers from excluding these individuals from coverage, charging them higher rates, or requiring them to undergo genetic testing. Employers could not use genetic information to hire or fire workers. The measure—S. 306, introduced February 7 by Sen. Olympia Snowe (R-ME)—passed on February 17.

A similar bill cleared the Senate in 2003, but died in the House. But this time, House backers see brighter prospects. Rep. Louise Slaughter (D-NY), a long-time champion of the ban, plans to introduce a companion bill to Snowe's. The last time around, Slaughter's bill attracted broad bipartisan support (242 co-sponsors). President George W. Bush has said he supports a legislative ban despite opposition from certain business groups and some House GOP conservatives.

INSIDE NIR

OIG Adds New Twist To Hospital-Based Physician Pay

Getting Part A payment has been a problem for hospital-based pathologists and other physicians since the switch to inpatient DRG prospective payment in 1983. Both the OIG and the Medicare agency agree on kickback issues, but each says the other should do more to crack down on abuses

In its latest pronouncement impacting hospital-based pathologists and other physicians, the HHS Office of Inspector General reiterates long-standing policy on Medicare Part A payment, with a new recognition of certain exclusive hospital-physician contracts that would not implicate the federal anti-kickback statute. The policy is contained in supplemental compliance guidance for hospitals, published in the January 31 *Federal Register*.

Pathology and clinical laboratory interests were divided in their reaction. The College of American Pathologists said in *Statline* that the guidance "adopts some of the strongest language to date" in favor of hospital-based pathologists. But laboratory lawyers say other language in the document muddies the impact, rendering it all but useless.

The OIG had earlier proposed language stating that hospitals can "in an appropriate context" require hospital-based physicians to perform "reasonable administrative or clinical duties" free of charge without violating the anti-kickback statute. CAP objected, arguing that the OIG should view the free services as a kickback to the hospital for steering Part B business to the pathologists. CAP even got two members of Congress to write to the OIG in support of its position that hospitals should pay pathologists for Part A services such as serving as lab directors and such *(National Intelligence Report, 26, 5/Dec 16, '04, p. 3*).

CAP now is applauding the final guidance as a sign that the OIG has backpedaled. In the final version, the OIG cautioned that arrangements requiring physicians to provide Part A supervision and management for little or no money would "potentially violate the anti-kickback statute and should be closely scrutinized."

"Unfortunately, There's More"

That's a word of caution from attorney Robert Mazer, a principal in the health law department of Ober/Kaler (Baltimore, MD). The OIG goes on to suggest, he notes, that "in an appropriate context, an exclusive arrangement that requires a hospital-based physician or physician group to perform reasonable administrative or limited clinical duties directly related to the hospital-based professional services at no or a reduced charge would not violate the anti-kickback statute."

The OIG said, for example, that hospital-based pathologists might benefit from exclusive contracts with hospitals (which many have) in ways unrelated to the volume or value of business flowing between the pathologists and the hospital, such as saving on business development costs. "This is a distinction I have never seen before," Mazer told *NIR*. "The reason they don't have business development costs is they have a steady flow of referrals." The bottom line? The OIG's position "continues to be confusing. It seems now there is a slightly different test for evaluating these arrangements than before."

Common Kickback Arrangements

Illegal kickbacks between hospitals and hospital-based physicians may take a variety of forms, the OIG notes, including, without limitation:

- A hospital requiring physicians to pay more than the fair market value for services provided to the hospital-based physicians by the hospital.
- A hospital compensating physicians less than the fair market value for goods or services provided to the hospital by the physicians.

Source: HHS OIG. See also the Management Advisory Report titled "Financial Arrangements Between Hospitals and Hospital-Based Physicians," *oig.hhs.gov/oei/reports/oei-09-89-00330.pdf.*

focus on: The Federal Healthcare Budget

FY '06 Budget Plan Straddles The Fence On Medicare

By not saying anything for or against, the Administration has tossed into Congress' lap the big issue of whether to cut Medicare provider payments to help rein in the budget deficit, along with where to cut and by how much

For clinical laboratories, pathologists, and hospitals, what's most striking in the fiscal 2006 budget request by President George W. Bush is its silence on Medicare payment updates—in effect, leaving it up to Congress to decide, amid mounting concern over the historic federal deficit, whether these providers should be targeted for cutbacks.

Pathologists and other physicians, for example, face a scheduled Part B fee cut unless Congress steps in to mandate a short-term fee hike (as it did for 2004 and 2005) or moves to fix the fee update formula, a long-term solution that physician groups advocate. The last physician fee cut (-5.4%) occurred in 2002. The American Medical Association is pushing hard for a permanent fix, saying that the current formula, left unchanged, is poised to slash physician fees by 31% over the next eight years. The House Ways & Means Committee held a February 10 hearing to explore alternatives to the formula.

Tax Cuts, National Security Get Top Priority

The budget request of $2.57 trillion continues to shift priorities from domestic programs to tax cuts and national security, with large increases sought for the Departments of Defense and of Homeland Security. Adding to deficit worries is the President's intent to make his tax cuts permanent and to overhaul Social Security by letting workers divert some of their payroll taxes into private savings accounts, a change that would require trillions of dollars in additional borrowing.

To address the growing ranks of the uninsured, the budget reiterates proposals for tax-based initiatives that the President has sought in the past, but Congress has rejected. These include tax credits to help individuals purchase private health plan coverage, association pools to help small businesses negotiate coverage with group plans, and greater Medicaid flexibility to expand coverage to low-income working families, but without increasing federal contributions to the program.

How Key HHS Agencies Fared *($$ in millions)*

Agency	FY 2004	FY 2005	FY 2006	Chg Proposed (2005-06)	% Chg (2005-06)
CMS net outlays	$450,062	$489,247	$543,946	$54,699	11.18
—Medicare	269,176	295,432	345,551	50,119	16.96
—Medicaid	176,231	188,272	192,562	4,290	2.28
CDC	7,213	8,034	7,543	-491	-6.11
FDA	1,695	1,801	1,881	80	4.44
NIH	28,040	28,649	28,845	196	0.68
Total HHS outlays	542,006	583,957	642,188	58,231	9.97

Source: FY 2006 budget documents.

Tough Medicare Choices For Congress

In looking for savings in the Medicare arena, lawmakers already have on their table an array of cost-cutting options from the Congressional Budget Office and recommendations from the Medicare Payment Advisory Commission (MedPAC, which reports independently to Congress). MedPAC has called for a freeze on skilled nursing and home health payments, a reduction in the hospital update to 0.04% below the market basket rate (while the CBO says a 1% cut is an option), and making the physician fee update equal to changes in input prices minus an adjustment for productivity (while the CBO cites a physician fee freeze as another option for 2006).

Laboratories are still vulnerable too. The CBO's just-released Medicare savings options book includes imposition of a deductible and a 20% co-pay for Part B lab services in 2006, for a savings of $800 million that year and $5.9 billion over five years. The Clinical Laboratory Coalition says it will be especially vigilant against any restoration of a 20% lab co-pay, as well as further reimbursement cuts. The co-pay was dropped in 1984 in the switch to the lab fee schedule. A legislative attempt to restore it was beaten back in 2003, but under a last-minute change in the Medicare Modernization Act, labs had to accept a five-year freeze on their fee updates, from 2004 through 2008. The President's FY 2006 spending plan leaves the fee freeze intact.

In dealing with curbs on domestic spending, Congress is expected to invoke the budget reconciliation process, whereby tax and spending targets are set to guide deliberations by House and Senate appropriations committees. House Budget Committee chair Jim Nussle (R-IA) told a February 8 hearing that he aims to instruct committees to give special attention to entitlement spending growth—"to dip the growth curve slightly—not cut—just try to slow it down."

The final outcome this year, Hill observers speculate, will be driven less by ideology and more by fiscal discipline, with an eye toward next year's congressional elections. This opens the door for deficit-cutting measures by GOP fiscal conservatives and Democrats, leaving the White House less sure that it can line up the GOP ranks like it has done thus far.

Shock Over Drug Benefit Costs

The latest deficit news raising hackles on the Hill came soon after the budget was released, with disclosure that the Medicare Part D prescription drug benefit would cost an estimated $720 billion over 10 years, well above the $400-billion figure Congress relied on in establishing the benefit (a higher projection by the Medicare chief actuary, $534 billion, was withheld from lawmakers during debate over the drug coverage). In explaining the new, higher estimate, Administration officials say it accounts for 10 years of full program costs, from 2006-2015, while the $400-billion estimate includes years 2004 and 2005 when the government was ramping up to implement the full benefit.

Medicaid Takes Biggest HHS Hit

Prior to the official release of the President's FY 2006 budget, there was a lot of Washington buzz about the White House proposing a cap on federal Medicaid spending, but that didn't materialize.

Rather, the budget calls for a net $45 billion in reductions over 10 years, with $15 billion more for home disabled community-based care and $60 billion in savings by closing "loopholes" that the Administration says allows states to inflate their costs, and by restructuring pharmacy payments for prescription drugs. The cuts would hold projected 2006 Medicaid outlays to $192.6 billion, up $4.3 billion or 2.3%.

HHS Secretary Michael Leavitt and White House press chief Scott McClellan told reporters that the Administration would propose broader legislative reforms to enable Medicaid to cover 12-14 million more people at no extra cost.

Nonetheless, the $720-billion estimate has spurred legislative moves to amend the benefit in ways that supporters say would reduce costs. One way is to allow Medicare to negotiate bulk discounts with drug companies; another is to lift the ban on importing less expensive drugs from Canada and other nations (as the reintroduced bipartisan Dorgan-Snowe bill would do). The White House is opposed to these changes. But Senate Budget Committee chair Judd Gregg (R-NH) has suggested that given the soaring costs, adjustments might be needed to make the benefit "affordable."

Mr. Bush has vowed to protect the benefit, which he considers one of his major achievements. In remarks at the February 11 swearing-in of the new HHS Secretary, Michael Leavitt, the President said he would veto any legislation that diminished or repealed drug coverage. He did acknowledge previously that the issue could arise later. "Once we modernize and save Social Security for a young generation of Americans, then it will be time to deal with the unfunded liabilities in Medicare," he told White House reporters on February 8.

Lab Personnel Training Hit

Despite alarms sounded by lab groups and lab employers over the growing shortage of qualified lab personnel, the budget plan wants to slash funding for allied health training run by the HHS Health Resources & Services Administration and including programs for medical technologists and medical technicians. The White House proposes a 96% reduction in allied health training dollars. Most of the current funds go to educate dentists, nurses, and other allied health professionals, with some $1 million per year for clinical laboratory education.

"The fact that there's no Title VII or VIII funding doesn't please us," said Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science. But Congress is likely to restore the money, she said. In what has become a standing ritual in recent years, the White House has sought next to no funding for these programs, but Congress has approved close to prior-year funding levels for them.

Under the budget plan, the Health Resources & Services Administration also would get:

- Zero funding for health professions training. This year it got $252 million.
- $10 million for scholarships for disadvantaged students, down from $47 million this year.
- $1 million for workforce information and analysis, the same as this year.

Lab Response To Bioterror

Scott Becker, executive director of the Association of Public Health Laboratories, took a dim view of how the budget plan would impact the Laboratory Response Network, designed to counter bioterrorism and other disease outbreaks. The plan, he notes, would cut state and local terrorism pre-

At FDA, Food Defense Gets Biggest Boost

The Bush Administration's budget priorities for the Food & Drug Administration emphasize protecting the food supply against contamination, including terrorist activities and diseases such as "mad cow." The biggest increase would be in the foods program for a total of $522 million, with $30.1 million for food defense.

Overall, the FDA budget would total $1.9 billion, including $1.5 billion in budget authority and $382 million in industry user fees. This is double the appropriations in FY 2001 and nearly 4.5% above the FY 2005 level.

Medical device review would get $12 million more, for a total of $289 million, to ensure that devices are safe and effective.

With FDA under fire for drug safety lapses involving popular, approved pain medicines like Vioxx, the budget would allot $6.5 million more to the Office of Drug Safety for a total of $33 million.

paredness programs, which include the network, by $130 million below the FY 2005 level. The network now consists of 134 reference labs in all states, up from 91 in 2001, and more than 8,800 clinical lab personnel have been trained for a role in detecting and reporting public health emergencies.

The cut in preparedness programs would be limited to capital expenses like laboratory equipment. But once purchased, the equipment still requires annual spending for maintenance contracts and reagents, Becker said. "There's no line item for the reagents CDC produces for the Laboratory Response Network. That's a big, big concern for us. If there's an event, there may not be enough reagent for all the testing required."

Becker also took a dim view of the big cut proposed for allied health training, despite the lab personnel shortage, but elsewhere saw one bright spot—a recognition of the need for global disease detection, especially important in lights of SARS, avian flu, and other emerging diseases. For this initiative, the budget seeks $34 million, a $12 million increase. But overall, he concluded, "this budget is a really difficult pill to swallow."

Budget Beefs Up NIH Research Priorities

In FY 2006, the White House proposes $28.8 billion total for the National Institutes of Health, up $196 million from 2005.

Research priorities include biodefense (up $56 million from this year to $1.8 billion), the "roadmap" for medical research (up $98 million, to $333 million), acceleration of neuroscience research ($26 million more for areas that include "core" centers to focus on DNA sequencing, molecular biology, proteomics, or drug screening).

In 2006, the budget says, nearly 84% of NIH funds will go to the extramural community, supporting work by 200,000 research personnel affiliated with some 3,000 university, hospital, and other research facilities.

For CDC, the budget plan requests a total of $7.5 billion, down $491 million from the 2005 level. Funding for buildings and facilities would fall 89%, from $240 million to $30 million. Support for the Strategic National Stockpile would increase $203 million to $600 million, in large part to establish portable hospital units that CDC could deploy to treat mass casualties. Improving biosurveillance remains a high priority, with $79 million to continue this interagency initiative, whose centerpiece is BioSense, which automatically analyzes electronic health data to highlight potential public health problems. Chronic disease prevention and health promotion programs would be held to $840 million, down $59 million from 2005. Block grants to states for preventive health services, funded at $131 million this year, would be zeroed out, and HIV/AIDS and TB prevention programs would be cut by $4 million, to $956 million.

Medicare Administrative Cuts Proposed

Though the budget plan punts to Congress on the issue of Medicare provider payment updates, it does propose administrative measures to cut $15 billion in non-lab provider payments over the next five years, according to Administration officials and provider representatives. Among the savings:

- ❑ $10.1 billion over five years by revising resource utilization groups under skilled nursing facility prospective payment.
- ❑ $4.6 billion by expanding to all 500 diagnosis-related groups a requirement, which now applies only to 29 DRGs, for post-acute-care services to be paid as transfers rather than discharges.
- ❑ $810 million over five years by implementing the "75% rule" for inpatient rehabilitation hospital reimbursement.
- ❑ $320 million by changing bad debt policy.

Update On Frequency Limits for New Diabetes Screening

The Centers for Medicare & Medicaid Services has instructed its local carriers to revise their billing systems to correctly incorporate the two-tier frequency limits for the new diabetes screening coverage that the Medicare Modernization Act of 2003 established. The revisions are to be implemented April 4, and apply to dates of service back to January 1.

Section 613 of the MMA mandates coverage of diabetes screening tests twice a year for individuals diagnosed with pre-diabetes, and once a year for at-risk individuals who were previously tested but not diagnosed with pre-diabetes or who have never been tested. CMS defines pre-diabetes as abnormal glucose metabolism diagnosed on the basis of a fasting glucose level of 100 to 125 mg/dL or a two-hour post-glucose challenge of 140 to 199 mg/dL.

To show that they are ordering a diabetes test for screening purposes, providers must use ICD-9 diagnosis code V77.1 in the header diagnosis section of the claim. To show that the beneficiary has been diagnosed as pre-diabetic, providers must use the modifier "TS" (follow-up service required).

The CMS directives appear in Publication 100-4, Transmittal 446, Change Request 3637 (January 21, 2005) and Publication 100-4, Transmittal 457, Change Request 3677 (January 28). The CMS contact is Betty Shaw, 410-786-9502.

Covered CPT Codes

CMS regulations (November 15, 2004) define covered diabetes screening tests as fasting blood glucose or post-glucose challenge tests involving any of three CPT codes below.

82947 – Glucose, quantitative, blood (except reagent strip)
82950 – post-glucose dose (includes glucose)
82951 – tolerance test (GTT), three specimens (includes glucose)

To order these codes for screening purposes, use ICD-9 code V77.1. To show that the patient has been diagnosed as pre-diabetic, use the modifier "TS" with these codes.

The MMA allows other tests, as the HHS Secretary deems appropriate after consulting with appropriate organizations.

Purchased Diagnostic Test Fix Delayed For Physicians

Medicare officials have delayed until further notice a change affecting pathologists and other physicians who purchase diagnostic tests/interpretations from suppliers outside their carrier jurisdiction. As of April 1, physicians filing claims for these services were to bill their carrier and be paid under the Part B physician fee schedule for the purchased services at the rate applicable to the zip code where the services were performed. Instead, they will continue to be paid for these services at the rate set by their local carrier (*NIR, 26, 3/Nov 8, '04, p. 3*).

The Centers for Medicare & Medicaid Services says it needs to address locality reporting issues in the edits that contractors use to process these claims (Pub. 100-04, Transmittal 464, Change Request 3694, February 4, 2005). The agency is providing contractors with a national abstract file containing all local fee schedules for services subject to the rules on purchased diagnostic testing.

The delay does not affect clinical laboratories and independent diagnostic testing facilities that purchase diagnostic tests/interpretations from out-of-jurisdiction suppliers. As of April 1, they will be paid for these services at the rate in effect for the zip code where the service was performed.

CLIAC Urges FDA Action On CLIA Waived Testing

The federal panel that advises the government on scientific and technical issues under CLIA (Clinical Laboratory Improvement Amendments) has called on the Food & Drug Administration to expedite release of its long-promised guidance on criteria for waived testing. The guidance has become a critical issue as the number of FDA-approved waived devices has proliferated, while government studies and lab professionals have raised concerns over problems with the quality of waived testing (*NIR, 25, 14/May 10, '04, p. 1; 26, 2/Oct 25, '04, p. 4*).

At its February 16-17 meeting in Atlanta, GA, the Clinical Laboratory Improvement Advisory Committee also agreed to address quality control problems in CLIA-waived labs in an article for the *Morbidity & Mortality Weekly Report*, published by the Centers for Disease Control & Prevention. The article is to be based on findings by the Centers for Medicare & Medicaid Services and a CLIAC workgroup on good lab practices (*NIR, 26, 1/Oct 11, '04, p. 4*). CLIAC also asked CMS to update CLIA cytology proficiency testing requirements. Enforcement of these rules begins nationwide this year, now that CMS has approved a PT provider, Midwest Institute for Medical Education (*NIR, 26, 6/Jan 10, '05, p. 6*).

Correction: Karen Nickel, chief of laboratory field services for the California Department of Health Services, said her office is going to "get out of the examination business permanently." The state has no plans to stop licensing clinical laboratory professionals. An article on page 5 of the February 7 issue incorrectly quoted her.

Handing Over The Reins

Lou Turner, DrPH, HCLD, is the new CLIAC chair, succeeding David Sundwall, MD, who resigned to become executive director of Utah's state health department (*NIR, 26, 7/Jan 24, '05, p. 8*).

Turner, appointed to CLIAC last year, is director of North Carolina's state public health laboratory. She is the panel's fourth chair since it was formed following enactment of CLIA in 1988.

washington WATCH

Bush's Pick For FDA Chief

The President has tapped **Lester Crawford**, a career government official who's been FDA deputy chief for almost three years, to permanently run the "hot-button" agency, recently buffeted by a series of drug safety controversies. Industry interests mostly endorse the choice, citing his experience and steady hand, but some public interest groups and legislators argue that he has not been aggressive enough on drug safety problems, discourages internal dissent, and caves in too readily to political pressure.

Independent observers see the selection as a fairly safe one for an Administration that almost certainly doesn't want broad changes at FDA. Though Crawford undoubtedly will be grilled in upcoming Senate hearings, he's expected to be confirmed.

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December which are one-issue months) by Washington G-2 Reports (a division of the Institute of Management and Administration), 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (202) 564-0465. Website: www.g2reports.com. **Order Line: (212) 629-3679.**

Bowman Cox, *Managing Editor*; Jim Curren, *Editor*; Dennis Weissman, *Executive Editor*; Janice Prescott, *Sr. Production Editor*; Perry Patterson, *Vice President* and *Group Publisher*.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.