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## FY 2005 HHS Budget Highlights Biodefense, Disease Screening

*As promised in the State of the Union address, the President's budget seeks refundable tax credits to help low-income seniors buy health insurance coverage, association health plans to help small businesses buy coverage for workers and new health savings accounts*

President Bush's budget request for the U.S. Department of Health & Human Services in fiscal 2005, which begins this Oct. 1, emphasizes increased spending on public health readiness to counter bioterror-related threats as well as initiatives targeted to disease prevention and screening. The plan proposes outlays of $580 billion for HHS (6% above the current fiscal year), most of which goes to federal entitlements such as Medicare. Discretionary budget authority, which is subject to appropriations by the Congress, would rise only 1.2%, an increase of $819 million to a total $67 billion.

The HHS spending request is part of the $2.4 trillion FY 2005 budget plan the President recently sent to Capitol Hill, where it has already come under sharp criticism for spiraling deficits for years to come and a virtual freeze on everything except national defense, homeland security and federal benefits. The plan envisions cutting this year's $521 billion deficit in half over five years, mainly by discretionary spending cuts and enhanced revenue from an economic recovery.

But in an election year, the initial reaction on the Hill ranged from skeptical to hostile. GOP fiscal hawks were quick to note that while they back limits on government growth, they don't think the deficit can be tamed by eliminating or reducing popular programs. ➟ *p. 2*

## Big Pay Boost For Managed Care

Starting Mar. 1, private health plans in the federal Medicare+Choice program will get a 10.6% increase in payments to serve beneficiaries. The upswing results from changes in how the payment rate is set under the Medicare reform law (Public Law 108-173). The higher payments aim to keep plans in the program and attract new ones. Medicare+Choice has been plagued with mass defections in the past few years as plans say that annual payment increases, capped at around 2%, are outstripped by annual cost hikes of 10-12%.

Plans may use the boost in payments to reduce beneficiary premiums or co-pays, enhance benefits, stabilize or expand their network of physicians, hospitals and other providers, establish a reserve fund to accommodate market fluctuations or any combination of these approaches. ➟ *p. 6*

INSIDE *NIR*

**FY 2005 HHS Budget Highlights,** *from p. 1*

Democrats charged that the President's proposal to make permanent the tax cuts due to expire by decade's end will only exacerbate the deficit as outlays increase when the baby boomers begin to retire.

Despite keeping the lid on overall discretionary spending, the President's plan does call for several new initiatives among the various agencies that make up HHS. Here are the highlights:

### Centers for Disease Control & Prevention

A total of $6.9 billion, a net drop of $58 million from FY 2004. Priorities are:

- ❑ $130 million for CDC's role in the Bio-Surveillance Initiative, including $100 million for "BioSense," which uses automated analysis of electronic health data to highlight potential public health problems, plus $20 million more to improve lab reporting capacity and linkages between public health and commercial labs.
- ❑ $10 million more, for a total $220 million, for breast and cervical cancer screening of low-income women and those with no health insurance.
- ❑ $10 million to expand diabetes detection, including diagnostic testing.
- ❑ $790 million for domestic HIV/AIDS prevention and research, including capitalizing on rapid testing technologies.

### Centers for Medicare & Medicaid Services

- ❑ Begin implementation of the Medicare prescription drug and modernization law (DIMA, P.L. 108-173). By June of this year, beneficiaries are to be offered privately run, government-endorsed drug discount cards; enrollment is expected to start by May. Medicare outlays for the program, which includes subsidies for the low income, are projected at $2.3 billion in 2004 and $3.25 billion in 2005. A comprehensive Part D drug benefit is to debut in 2006.
- ❑ In accord with DIMA, Part B is to begin covering, as of Jan. 1, 2005, screening tests for cardiovascular disease and diabetes. These tests, along with various cancer screenings, will also be covered as part of a beneficiary's initial physical exam by a physician. The budget puts no price tag on this expanded screening.

### Food & Drug Administration

- ❑ A net hike of $149 billion for a total of $1.8 billion. Increases are targeted to protect the food supply and to speed-up the availability of new drugs and medical technologies, including biodefense medical countermeasures.
- ❑ $26 million more for the medical device program to expedit premarket reviews. Total program funding would be $252 million, including $35 million from industry-specific user fees.
- ❑ $77 million for patient safety, including bar code labeling requirements for prescription drugs to help hospitals and pharmacies avoid drug-related medical errors.

### National Institutes of Health

- ❑ An increase of $764 million to a total $28.8 billion, or 2.7% above FY 2004, to support research priorities in biodefense, obesity, nuclear and radiological threat countermeasures and diseases such as cancer, HIV/AIDS, diabetes, Parkinson's and Alzheimer's, plus new avenues of post-genomics research. $150 million is earmarked to construct an additional 20 Biosafety Level 3 labs in metropolitan areas nationwide.

# Lab Coalition Sets Legislative Priorities For 2004

The Clinical Laboratory Coalition agreed in a Jan. 27 meeting on Medicare priorities for the 2004 legislative session, attorney Bob Waters with Arent Fox (Washington, DC) tells the *National Intelligence Report*. Waters chairs the group and represents the American Association of Bioanalysts. Topping the list is an effort to ensure that members of Congress and their staff, in particular new players on the House Ways & Means, Energy & Commerce and Senate Finance committees, understand the laboratory sectors key issues. Among them are:

- ❑ Ending the five-year freeze on lab fee updates that began Jan. 1 and runs through 2008.
- ❑ Forestalling any revival of attempts to levy a lab co-pay.
- ❑ Preventing the spread of lab competitive bidding.
- ❑ Raising the specimen collection fee.
- ❑ Improving reimbursement rates for new tests.

# Part B Lab Spending Up Nearly 14.4% In 2002

Despite a congressionally mandated freeze that restricted Medicare Part B lab fees to their 1997 levels, Part B spending for lab services in calendar 2002 increased 14.36% to $5.01 billion, according to data from the Centers for Medicare & Medicaid Services' Office of the Actuary. For Part B overall, spending rose 9.12% to $112.127 billion.

Calendar Year 2002 was the final year of the five-year lab fee freeze imposed under the 1997 Balanced Budget Act (BBA). Nonetheless, it marked the fourth consecutive year of growth in Part B lab spending. Compared to 1998, the first year of the BBA freeze, Part B lab spending was 38% higher in 2002.

According to CMS data, independent and physician office labs maintained a 55% share of total Part B lab spending, the same portion they have held since 1999. Their share has declined from a high of 74% in 1991, as hospital labs grew their outreach programs.

## Healthcare Spending Keeps Accelerating

Overall U.S. healthcare spending increased 9.3% to $1.6 trillion in 2002, marking the sixth straight year of accelerated growth for this sector of the economy, CMS reported. Prescription drug spending grew the fastest, 15.3%. Hospital spending rose 9.5%; physician spending, 7.7%; and home health spending, 7.2%.

Healthcare accounted for 14.9% of the gross domestic product (the total value of all goods and services produced in the U.S.). That's up from 14.1% in 2001 and 13.1%-13.5% during the previous decade.

Medicare accounted for 17% of healthcare spending, Medicaid 16% and other public programs 13%. Private payers covered 35% of healthcare spending. The amount paid out-of-pocket declined to 14%.

### Labs Get Bigger Piece Of The Pie

After declining every year since 1992, the lab share of total Part B spending rose in 2002. Growth was 4.47%; in 2001, it was 4.26%. The main reason for the rise in share, said a CMS official, was the 5.4% reduction in physician fees in 2002. This curbed Part B spending growth for physicians' services that year to 6.55% and caused their share of total Part B spending to drop to 39.97% from 40.92% the previous year. The American Medical Association, along with pathology and other medical specialties, has since persuaded Congress to halt fee update reductions slated through 2005 under the current statutory formula. These groups continue to lobby for changing the formula to prevent any further reductions.

# FY 2004 Allied Health Training Funds Approved

*For health professions training overall, Congress approved $294 million for FY 2004. The President's budget for 2005 would slash this spending to $11 million*

As expected, Congress has approved $11.852 million in fiscal 2004 spending for training allied health professionals, including medical technologists and technicians. This is a drop of 0.59% from the previous year's level. The Senate initially sought a 93% cut for allied health and other Title VII training programs (*related stories: NIR, 24, 22/Sept. 29, '03, p. 3; 25, 6/Jan. 12, '04, p. 4*).

The money is part of the $820 billion omnibus FY 2004 appropriations bill signed into law by President Bush on Jan. 23 (H.R. 2673, P.L. 108-199). The measure contains funding for the U.S. Department of Health & Human Services, 10 other departments and numerous federal agencies. It was the first order of business when the second session of the 108th Congress convened on Jan. 20.

# CMS To Clarify "Off-Label" Provision In CLIA Surveyor Guidelines

*The recently released guidelines are used by state surveyors to gauge a lab's compliance with rules under the Clinical Laboratory Improvement Amendments (NIR, 25, 7/Jan. 26, 04, p. 1)*

Addressing concerns from clinical laboratories, the Centers for Medicare & Medicaid Services will clarify, an official said, a provision in revised CLIA surveyor guidelines that appears to suggest labs could be in trouble with the Food & Drug Administration if they participated in any "off-label" use of tests.

The provision at issue states: "CAUTION: 'Off-label' use is not supported by the manufacturer's clinical data and, when identified, must be reported to the FDA." It appears in that section of the guidelines which explains how to establish and verify performance specifications as required in Subpart K of the CLIA Quality Assurance/Quality Control final rule. The provision goes on to say that off-label uses include changes in intended use, such as when a lab uses a different sample matrix, such as plasma instead of urine; uses a test for a different purpose, such as screening instead of diagnosis; or changes the type of analysis, such as reporting qualitative results as quantitative.

"These are modifications that are not unusual," a concerned lab official told *NIR*. Labs often run tests on different matrices than the ones specified in the manufacturer's FDA-approved label, this official said. For example, a lab may take plasma it had already drawn for other tests and use it in a test labeled for serum. Or a lab may use serum instead of urine simply because the sample is easier to collect. There should be no problem, as long as the lab properly validates the off-label use, as required by CLIA.

"This is something that caught us by surprise," commented David Sundwall, MD, senior medical and scientific officer of the American Clinical Laboratory Association and head of the federal Clinical Laboratory Improvement Advisory Committee. He said the issue may come up at CLIAC's Feb. 11-12 meeting.

"This is not a new policy," Judy Yost, who heads the CLIA program at CMS, told *NIR*. "Only in extreme circumstances would we report these to the FDA." Over the past 12 years, CMS has reported very few instances, less than 10, she added. In some cases, surveyors identified tests that did not appear to be clinically relevant. Others were done with "very unusual" bodily fluids or specimen types.

Yost said she intends to clarify the provision when CMS next revises the CLIA

surveyor guidelines. Also, she intends to verbally clarify it at the next bimonthly meeting with regional CMS officials who oversee the state surveyors. Further, she said, "if someone wants to write us, we'll give them a written response."

# Is The Day Of Reckoning Closer On CLIA Waiver Dispute?

*The solution lies, say observers tracking the dispute, in striking an acceptable balance between FDA's market focus on the safety and effectiveness of a lab test with CDC and CMS concerns over the quality processes that assure accuracy in diagnosing and treating patients*

On the eve of the Feb. 11-12 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC), there are signs that the controversy over CLIA waived criteria could be approaching a turning point, various sources tell *NIR*. The dispute triggered a power struggle among HHS agencies that share CLIA responsibilities, fueled by rival aims of medical device makers, on the one hand, and lab professional groups on the other.

One government official, speaking on background, says that with disagreements now minimized, the parties involved are closer to consensus than ever before. And CLIAC chairman David Sundwall, MD, says a waiver workgroup representing lab professionals, test manufacturers and other interests has made good progress and will report to the full committee at the upcoming meeting in Atlanta, GA. Both declined to comment on specifics prior to the meeting.

The controversy in its broadest terms centers on how flexible the Food & Drug Administration should be when waiving tests, a point that has become even more delicate in the wake of a successful power grab by FDA for complete authority over CLIA test categorization. Last Nov. 13, Health & Human Services Secretary Tommy Thompson re-delegated this authority to FDA, overriding objections from the Centers for Disease Control & Prevention and the Centers for Medicare & Medicaid Services. According to outside sources familiar with the issue, CDC and CMS officials as well as lab professional groups were concerned that FDA, after taking responsibility for CLIA test classification in 2000, had rapidly expanded the number and type of tests going to market as waived.

What's at the heart of the dispute? Basically, FDA favored waiving a test if, after statutory requirements are met, lay users could duplicate the results of professional users, an approach welcomed by test manufacturers. Getting their products waived makes it easier to access the lucrative physician office and alternate testing site markets. The main requirement is that the user follow the manufacturer's instructions. Personnel qualifications are negligible; high school graduates can perform waived testing. The approach favored by CDC and CMS stresses that a waived test must be highly accurate to prevent misinterpretation of results that could be detrimental to patient care, a stance backed by lab professional groups.

## Follow The Bouncing Ball

Authority over CLIA waived testing has bounced back and forth from agency to agency since the federal lab regulatory program got underway in 1992.

Under the original CLIA statute, FDA was to categorize tests as waived, moderate or high complexity (CDC did this for tests commercially available prior to 1992). The idea was to give test makers a "one-stop shop" for market and CLIA clearance. But due to FDA budget and staffing constraints, CDC continued to categorize tests from 1992 through the rest of the decade. For waived tests, it relied, since 1995, on draft criteria it proposed but never finalized.

In January 2000, FDA finally assumed responsibility for test categorization, substituting its own waiver guidance and paving the way for a proliferation of waived devices to hit the market, including a rapid HIV-1 screening test about which lab professionals in and out of government had voiced concerns. FDA subsequently withdrew its waiver guidance and said it would rely on CDC's draft criteria.

Top HHS echelons then intervened, affirming CMS as the lead HHS agency on CLIA matters, including resolution of the waiver criteria issue. Last November, HHS gave FDA the upper hand on CLIA test rankings. CMS still handles disbursement of funds to FDA and CDC to underwrite their CLIA work.

*The increased higher rates could vary by county anywhere from 6.3% to 57%, due mainly to risk adjustment, CMS notes. Leading HMOs in southern California and the New York metropolitan area say they'll use the new money to cut premiums and co-pay*

**Big Pay Boost For Managed Care,** *from p. 1*

A member survey by AAHP-HIAA, the main trade association representing health insurance companies, found that 34 companies representing 75% of Medicare managed care enrollees intend to use at least some of the windfall to encourage greater provider participation. Many had lost providers after benefits were cut in response to payment levels set under the 1997 Balanced Budget Act, notes the association's president and CEO, Karen Ignani. "Some of our companies are now trying to shore up their provider networks to expand their participating physicians list."

Clinical labs that have signed contracts with M+C plans might seek better terms when they renegotiate, knowing that this extra pool of funding is available to the plans. Similarly, they could benefit in negotiations with providers that serve plans offering Medicare managed care.

Labs also need to be ready for growth projected for Medicare managed care. Since peaking in 1999 at 6.3 million beneficiaries, the M+C program has dwindled to 4.6 million, or about 11% of the Medicare population. The Congressional Budget Office has estimated that, despite changes made under Medicare reform, only 9% of beneficiaries will participate in plans that offer coverage under the Medicare Advantage program, which will officially replace M+C at the start of 2006. The Bush Administration is more optimistic, estimating that participation will increase to 32% by 2009.

If the Administration is correct, in just five years one of every three Medicare beneficiaries would be outside the traditional fee-for-service program. Importantly for labs, the Part B lab fee schedule and other lab policy requirements would not apply to serving this population. Large labs, like Quest Diagnostics and LabCorp, are well positioned, analysts say, to lock up a major portion of this market.

# Colorectal Cancer Screening Gets More Cost-Benefit Scrutiny

*Medical device makers are leery about government use of cost-benefit analyses in deciding whether to reimburse their products, especially costly new genetic tests. The IOM last year advised Congress against Medicare coverage of thyroid screening, saying the benefits didn't justify the added costs*

With medical device manufacturers on the threshold of marketing many expensive new tests based on molecular diagnostics, economic modeling software is starting to play a role in helping Medicare decide whether to cover them. But given early indications that the models vary widely in their output, the Institute of Medicine has begun the work of verifying their accuracy and applicability.

Colorectal cancer screening is one of the first in line for scrutiny. Last year, Medicare approved coverage of the Insure immunoassay-based fecal occult blood test developed by Enterix Inc. (Falmouth, ME). In reaching this decision, officials used the Miscan computer model to compare its cost-effectiveness with the traditional guaiac-based test. This year, Medicare reimburses the Enterix test at a maximum allowable of $18.09 (HCPCS codes G0328, G0328QW). The traditional alternative (CPT 82270) has a maximum allowable of $4.54.

The IOM convened a workshop on Jan. 26-27 to see if the five leading computer models could agree on the relative cost-effectiveness of colorectal cancer screening alternatives, from the guaiac-based test to the "gold standard," colonoscopy, and a variety of recommended screening protocols. The workshop compared the Miscan model, which CMS had used, with four others—the Vijan, Harvard, Vanderbilt

and Ladabaum models—using standard assumptions about adherence to screening protocol, test performance, unit cost of test procedures, follow-up and surveillance protocols, an IOM official said.

The Institute found that it could achieve agreement by enforcing a rigid set of arbitrary assumptions. Further study will be required to determine the range of assumptions over which such agreement can be maintained, said IOM staff officer Judith Wagner. Perhaps the most significant initial finding, she noted, is that "all the models show that any colorectal cancer screening is cost-effective" in terms of delivering at least an extra year of life for under $30,000. A workshop summary will be published, most likely in June or July, she added. Ordering details will be posed on the IOM Website, *www.iom.edu*.

## ♦REGULATORY W·A·T·C·H

**Stark Self-Referral Rules:** The Centers for Medicare & Medicaid Services has delayed—to July 7 of this year—the effective date of the percentage compensation provision in the Phase I rulemaking under the Stark statute that restricts physician self-referrals under Medicare/Medicaid. The agency says it expects to address the "set in advance" issue in Stark Phase II final rules. Many percentage compensation arrangements, used primarily by academic medical centers and medical foundations, are based on factors such as percentage of revenue and don't fit the requirement under various Stark exceptions that compensation be "set in advance."

**Electronic Comments:** CMS on Jan. 30 began accepting comments on proposed or final rules electronically. You can file comments at *www.regulations.gov* or *cms.hhs.gov/regulations/comments*, a CMS Website that uses a copy of the Food & Drug Administration's electronic docket system. Future CMS proposed rules will include links to the CMS site. After a comment period closes, CMS will post all electronic comments, including any personally identifiable or confidential business information. The CMS system also will accept comments on notices that request public input, including requests for advisory committee nominations.

## ♦CODING A·D·V·I·S·O·R·Y

*Our lab is having difficulty getting Medicare payment for certain tests for patients with chronic end-stage renal disease. The tests, which are ordered by physicians at independent dialysis facilities, are ESRD-related, but don't fall within the ESRD composite rate, so we should be able to bill Medicare directly for them. But our carrier denies these claims. We were told to use a CB modifier, but only after validating that the claims were for skilled nursing facility (SNF) patients in Part A stays. We have no way of doing so. What should we do?*

Re-submit the claims using the CB modifier after Feb. 23. Your problem stems from a Medicare transmittal (AB-02-175, Dec. 13, 2002), that permitted bypassing the SNF consolidated billing edit by using the CB modifier, but only for SNF Part A stays. On Jan. 23 of this year, CMS issued a new transmittal (No. 69), which drops the requirement to determine whether the patient is in a SNF Part A stay. Contractors are to implement the change this Feb. 23, but it is effective for dates of service on or after Apr. 1, 2001, the same as the original memo. Transmittal 69 can be found at *cms.hhs.gov/manuals*. The CMS contact is Joan Proctor-Young, 410-786-0949.

# Changes Coming & Proposed In Drug Abuse Testing

*Allowing alternatives to urine testing would be a boon for the employee drug testing market. Oral- and saliva-based tests are priced much higher than urine tests, which account for over 90% of all employee drug tests in the U.S.*

As President Bush asks Congress for new money for student drug testing, the government plans to expand the types of specimens acceptable for testing under federal workplace drug testing rules.

The Administration's fiscal 2005 budget for the U.S. Department of Education seeks a $23 million increase for school-based drug testing programs for students involved in school athletics or extracurricular activities, a practice upheld by the U.S. Supreme Court. The money would significantly pump up the current $2 million program that provides drug testing grants to eight school districts, a spokesman tells *NIR*.

Meantime, the HHS Substance Abuse & Mental Health Services Administration intends to issue revised rules that set specifications for alternatives to traditional lab-based urine tests, including lab testing of hair, saliva and sweat. The agency also would set standards for point-of-care methods for urine samples. The changes, in the works for years, are aimed at improving precision in drug screening and making it harder for workers to cheat on urine tests.

SAMSHA rules apply to 1.6 million federal workers and are followed by regulatory bodies that conduct drug testing in industries they oversee, such as the airline and transportation sectors. Thousands of other public and private employers adhere to the rules as well. In all, an estimated 33 million workplace drug tests are done each year for U.S. employers; SAMHSA is responsible for about 6.5 million.

## washington WATCH

### Feeding Off The Medicare Trough

The importance and complexity of the Medicare reform law has caused a hiring frenzy by drug companies and other interests eager to land key architects of the bill. Among them: former Medicare chief **Tom Scully**, who's started a healthcare practice at Alston & Bird LLP (Washington, DC) … senior CMS official **Tom Grissom** now lobbying for medical device maker Boston Scientific Corp. … **Rep. Billy Tauzin** (R-LA), who's resigned as Energy & Commerce Committee chair and, after 12 terms, won't seek reelection. He's a strong contender, say Washington circles, to head the pharmaceutical industry's lobbying arm. Beating him out the door: a half dozen Hill senior health staffers enroute to the private sector.





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