WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 27th Year of Publication

Vol. 27, No. 9, February 23, 2006

Groups Oppose To Wider Medicare Competitive Bidding

For more on the lab bidding proposal and other controversial provider provisions in the President's HHS healthcare budget plan, see the Focus, pp. 4-6.

Clinical laboratory groups reacted swiftly to oppose the expansion of Medicare competitive bidding for Part B lab services that was proposed in the President's newly released budget request for fiscal 2007. The budget makes two terse references to the proposal, and one says it should build on "successful competition models" tested for durable medical equipment bidding.

The budget plan is premature, to say the least, said the American Clinical Laboratory Association and the American Association of Bioanalysts. They note that the Centers for Medicare & Medicaid is still working to develop a limited bidding demonstration for independent lab services and, at press time, a progress report to Congress, due December 31, 2005, was still pending (*National Intelligence Report, 26, 21/Sep 12 '05, pp. 4-6; 27, 7/Jan 23 '06, p. 1*).

ACLA, AAB, and others in the Clinical Laboratory Coalition oppose lab competitive bidding, saying it would adversely impact patient access, testing quality, and costs. AAB says it would lead to "low-ball" offers from larger labs that could put community and other smaller-sized labs out of business and threaten vulnerable niche markets they serve, such as nursing homes.

INSIDE *NIR*

Physician Claims Now Paid At New Rates

Medicare has begun processing pathology and other physician Part B claims at the 0% update authorized in the Deficit Reduction Act of 2005 and has told local contractors to automatically adjust claims previously paid under the -4.4% update by July 1.

The 0% update is effective January 1 of this year, in accord with the Act, which the President signed into law on February 8. Anticipating enactment of the measure, the Centers for Medicare & Medicaid Services last month sent local carriers corrected data files undoing the -4.4% cut. On February 1, the agency alerted carriers that they would have two business days to start using the new rates (Change Request 4313).

In 2006, the physician fee conversion factor is frozen at the 2005 level of $37.8975. Actual payouts will depend on whether the adjusted work or malpractice expense values for a service have increased or fallen. Practice expense values remain fixed at 2005 levels. CMS decided to halt its previously proposed PE changes pending further review, a move that wiped out technical component increases for flow cytometry codes 88184-88185 and the surgical pathology code, CPT 88305 (*NIR, 27, 3/Nov 14 '05, p. 1*).

CLIAC Briefed On First-Year Cytology PT Results

In 2005, the first year of enforcement of CLIA requirements for gynecologic cytology proficiency testing, 91% of 12,786 individuals enrolled in approved PT programs passed the initial testing event (10 slides in two hours), while only 9% failed, according to preliminary data presented by CLIA officials to the Clinical Laboratory Improvement Advisory Committee at its February 8-9 meeting in Atlanta, GA.

Cytology PT Preliminary Results: Maryland & MIME Programs, 1/31/06

Initial Testing Event (10 slides in 2 hours)

Totals	*Passed*	*Failed*
12,786	11,630 (91%)	1,156 (9%)
(As of 8/26/05)		
5,274	4,624 (88%)	650 (12%)

Totals	*Passed*	*Failed*
CT	6,096 (93%)	439 (7%)
Pri. MD	309 (67%)	152 (33%)
Sec. MD	5,236 (90%)	561 (10%)
LT	16 (80%)	4 (20%)

Second Testing Event (10 slides in 2 hours)

Totals	*Passed*	*Failed*
1, 124	1,015 (90%)	109 (10%)
(As of 8/26/05)		
427	381 (89%)	46 (11%)

Totals	*Passed*	*Failed*
CT	425 (96)	17 (4%)
Pri. MD	87 (66%)	44 (34%)
Sec. MD	501 (92%)	46 (8%)
LT	2 (50%)	2 (50%)

Third Testing Event (20 slides in 4 hours)

Totals	*Passed*	*Failed*
48	(85%)	7 (15%)
(As of 8/26/05)		
10	7 (70%)	3 (30%)

Totals	*Passed*	*Failed*
CT 8	(89%)	1 (11%)
Pri. MD	12 (80%)	3 (20%)
Sec. MD	21 (88%)	3 (13%)
LT	0	0

Fourth Testing Event (20 slides in 4 hours)

Totals	*Passed*	*Failed*
2	1 (50%)	1 (50%)
(As of 8/26/05)		
0	0	0

Totals	*Passed*	*Failed*
CT	0	0
Pri. MD	0	1
Sec. MD	1	0
LT	0	0

Source: CLIA office, CMS

In the second testing event (10 slides in two hours), the "pass" rate was 90% for 1,124 enrollees, while in the third testing event (20 slides in four hours), the rate fell to 85% of 48 enrollees.

The data are derived from the two federally approved PT providers in 2005—the state of Maryland and the Midwest Institute for Medical Education (MIME).

Primary physician readers had the highest failure rates in all the testing events: 33% in the initial round, 34% in the second, and 20% in the third. The failure rate for secondary physician readers ranged from 10% in the initial round, 8% in the second, and 13% in the third. Cytotechnologists had the highest "pass" scores in all the events: 93% in the initial round, 96% in the second, and 89% in the third.

In terms of slide preparation types (conventional, SP, and TP), data from MIME (as of February 3, 2006) show that cytotechnologists scored above 90% in the correct response category on all types out of a total of 62,781 slides reviewed. Primary physician readers had correct responses across all types in the range of 88%-94% of the total 6,224 slides reviewed, but had the highest percentages of incorrect responses, ranging from 6% to 12%. Secondary physician readers did better, with 94% to 97% correct responses across all types of the total 58,072 slides reviewed. Automatic failure rates for interpreting high-grade squamous intraepithelial lesions/carcinoma as normal/benign were highest for cytotechnologists (244/56%), followed by primary MDs (71/36%), and secondary MDs (168/28%).

A CLIAC workgroup is expected to convene in March to begin looking into possible revisions to the current CLIA cytology PT rules, in response to pathology and lab groups that say the 1992 rules need to be updated to reflect changes in cytology science and clinical practice (*NIR, 27, 8/Feb 6 '05, pp. 4-5*).

Also presented at the CLIAC meeting were the latest statistics on laboratories certified under the CLIA program:

- 194,000 total, of which 105,000 are physician office labs.
- Of the total number of certified labs, 113,000 have a certificate of waiver and 39,000 are certified for physician-performed microscopy. For both of these certificate categories, 85,000 are physician office labs.
- Of the total certified labs, 16,000 are accredited by private nonprofit organizations, and some 6,000 of these labs are in physician offices.
- 6,000 labs are in CLIA-exempt states and are regulated by state licensing programs. Washington had 3,000 labs under its regulatory program. New York had 3,000 under its limited CLIA-exempt program (it does not cover physician office labs).

FDA Approves Test For Avian Flu Infections In Humans

The laboratory test was developed by another HHS agency, the Centers for Disease Control & Prevention, and will be distributed to designated labs in the Laboratory Response Network, which domestically includes about 140 labs in 50 states.

The Food & Drug Administration has approved a new laboratory test to diagnose H5 strains of influenza in patients suspected to be infected with the virus. The agency gave expedited approval on February 3 to a product called the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set.

The test provides preliminary results on suspected H5 influenza samples within four hours after a sample arrives at the lab and testing begins. Previous testing technology would require at least two to three days to render results. If the presence of the H5 strain is identified, further testing is conducted to identify the specific H5 subtype (e.g., H5N1, the avian flu virus).

Since December 2003, H5N1 infection has been reported in more than 160 human cases of influenza throughout Thailand, China, Vietnam, Cambodia, Indonesia, Turkey, and Iraq. More than half of those infected have died. Nearly all of these cases are believed to have been caused by exposure to infected poultry. The greatest fear is that H5N1 will evolve into a virus capable of human-to-human transmission that could trigger an influenza pandemic.

The newly approved test will be distributed to designated labs in CDC's Laboratory Response Network to enhance early detection and surveillance as well as increase lab response capacity associated with a potential pandemic. Domestically, the network is a system of about 140 labs in all 50 states with communication links to public health programs across the country. CDC also has shared the test technology with the World Health Organization and its collaborating centers.

Information obtained from the test will be used to track cases of illness with this strain of virus. Testing for H5N1 is indicated when a patient has symptoms of severe respiratory illness and a risk of exposure (for example, direct contact with sick, dead, or infected poultry in a country with outbreaks of the strain among poultry). CDC recommends that testing for influenza A/H5 (Asian lineage) be considered on a case-by-case basis in consultation with local or state health departments. Clinicians who suspect a patient may be infected should contact the state or local health department.

focus on: The HHS Healthcare Budget

President's Plan: Medicare Spending Slowdown, More Competition

Overall, the President's budget request for FY 2007 totals $2.77 trillion, with increases for defense and homeland security well above the inflation rate and flat-funding or cuts in most domestic spending. The projected federal deficit would hover around $355 billion, but could rise to $400 billion when additional funds are sought for the war in Iraq and natural disaster recovery. The HHS portion of the budget would rise $58 billion to $698 billion.

For clinical laboratories, hospitals, and other healthcare providers, there's a lot not to like in the President's budget request for fiscal 2007, which begins October 1 of this year.

The plan, released February 6, asks Congress to make legislative changes to generate $36 billion in Medicare savings over five years, mainly by trimming the annual inflation update for hospitals and other institutional providers and by phasing-out bad debt payments. Part of the savings would also come from "integrating competitive bidding into payment for lab services," according to budget documents. In addition, higher-income beneficiaries would pay a higher Part B premium in 2007, a change that would affect individuals with an income of $80,000 and couples with an income of $160,000.

Even with the proposed savings, Medicare spending would grow 7.7%, compared to 8.1% under current law, noted Health & Human Services Secretary Michael Leavitt. Spending on Medicaid would be curbed by $13.6 billion over five years, principally by limiting the ability of states to shift costs to the federal government.

It's an open question whether lawmakers have the stomach for more entitlement spending reductions in this congressional election year after last year's bitter partisan battle to enact $11 billion in Medicare and Medicaid cuts, which passed by narrow margins in the House and the Senate. Senate Finance Committee chairman Charles Grassley (R-IA) has publicly said it would be difficult to make more program cuts during an election year. But "if Medicare reductions do end up on the table, the Medicare Advantage [managed care] regional stabilization fund [of $10 billion] has to be front and center," he said in a statement.

On other fronts of interest to labs, however, the budget would increase funding for several high-profile initiatives within the U.S. Department of Health & Human Services. These include expanded HIV/AIDS testing and treatment, protection against a potential influenza pandemic, countering bioterrorism, putting development of personalized medicine on a fast track to market, and support for health information technology.

Medicare Provider Updates

In adopting (for political cover, critics say) the recommendations made in January by the Medicare Payment Advisory Commission (MedPAC), the President proposes a mix of update controls for hospitals and other institutional providers over the next three years.

While hospitals in recent years got the full market basket update for their Medicare inpatient and outpatient services, they would get progressively less under the President's plan. Part A inpatient prospective payment would be reduced by 0.45% in FY 2007 and by 0.4% in 2008 and 2009 (for a total savings of $6.61 billion from 2007 to 2011). Part B outpatient PPS would be cut by the same percentages over the same period ($1.47 billion in savings over 2007-2011).

As in past years, the Administration requests no funding for the allied health training account, a small portion of which underwrites training for medical technologists and medical lab technicians.

Skilled nursing facilities, home health agencies, and inpatient rehabilitation hospitals would see a freeze in Medicare payments for FY 2007, followed by 0.4% less than a full inflation update in 2008 and 2009. Curbs on SNF Part A payments would save $5.11 billion over 2007-2011. Hospice payments would be cut by 0.4% over this same period.

The White House argues that the reduced updates won't hurt if hospitals improve productivity and efficiency. But the American Hospital Association counters that hospitals currently get paid well below the cost of caring for Medicare beneficiaries.

New Mechanism To Slow Medicare Growth

The President proposes a new automatic trigger that would require a slowdown of Medicare spending growth when general revenues exceed 45% of Medicare spending in any year. Payments to providers would be automatically cut by four-tenths of 1%. If Congress failed to act, the cuts would go deeper. Payments would be reduced by an additional four-tenths of 1% every year in which the threshold was exceeded.

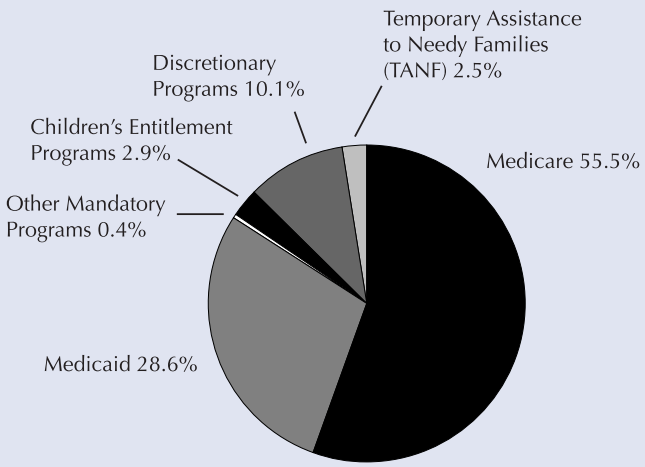
Lab Competitive Bidding

Lab industry analysts can only speculate on what the White House intends by its sparse references to expanding competitive bidding for Part B lab services, for an estimated savings of $1.43 billion over 2007-2011 (all of it in years 2008-2011). Further details are so far unavailable, and at press time, a CMS official declined comment on how the President's proposal meshes with the lab bidding pilot now in the works at CMS.

The "HHS Budget in Brief" merely notes that the plan continues the Administration's priority to foster more competition among Medicare providers: "CMS successfully tested a competitive bidding model for durable medical equipment in Polk County, Florida, and San Antonio, Texas. Based on that success, the Medicare Modernization Act of 2003 expanded DME competitive bidding nationwide and required a similar competitive process for outpatient drugs. The budget proposes to build on these successful competition models by extending competitive bidding to Medicare lab services."

If Congress were to rule out competitive bidding, but wanted to find lab savings elsewhere, this could open the door, lab groups fear, for consideration of a 20% lab co-pay or additional cuts in lab fees and fee caps already frozen through 2008. Cuts in Part B lab spending are tempting targets in a pinch. Latest Medicare data show that the rise in such spending has steadily outpaced other program expenditure growth over the past several years (*related story, p. 8*).

HHS Budget by Operating Division



Source: HHS Budget in Brief, February 2006

Protection Against Influenza Pandemic

In November 2005, the President made a $7.1 billion emergency supplemental request to fund a three-year strategic plan to improve preparedness for a potential influenza pandemic. For the first phase, Congress provided $3.3 billion. To fund the next phase, the FY 2007 request calls for $2.3 billion. In addition, the budget requests:

- ❑ $352 million in 2007 to fund activities within the Centers for Disease Control & Prevention, the Food & Drug Administration, and the National Institutes of Health to expand surveillance and detection of influenza.

The budget request is silent on a fix to avoid future cuts in Medicare physician fees, but accompanying documents signal support for higher payments for top-performing doctors. Tackling the physician fee update problem is something Congress will likely have to do this year, Senate Finance chairman Charles Grassley (R-IA) has indicated.

- ❑ $79 million for international activities, risk communication, and development of rapid laboratory tests.

CDC will work with the FDA to rapidly conduct genetic analysis and establish a reference library of currently circulating influenza viruses. CDC also will establish lab facilities with proper biocontainment specifications, space and special equipment, animal resources, and trained personnel to conduct these investigations.

Protection Against Bioterrorism

Since 2001, more than $7 billion has been provided to increase state, local, and hospital preparedness in the event of another terrorist attack in the United States. In 2007, the President proposes to spend an additional $1.3 billion, with $25 million set aside for a competitive bidding pilot to establish "cutting-edge emergency care capacity" in one or more metropolitan areas.

HIV/AIDS

The budget requests $188 million for a new domestic HIV / AIDS initiative, of which $93 million would go to CDC to expand rapid testing to an additional three million people in at-risk populations, including low income and minority communities. The remainder would go to the Ryan White AIDS program to provide treatment for people on state waiting lists for medications.

Critical Path Initiative: Personalized Medicine

The budget requests $6 million to launch this FDA initiative designed to stimulate a new generation of scientific tools to improve measurements for drug effectiveness, including laboratory tests, and thus avoid adverse side effects. This would enable the FDA to approve prescription drugs for individual groups of people, rather than drugs to treat whole populations. The initial funding would go to the agency's medical imaging projects, which include collaboration with other agencies to develop, for example, new cancer drugs and improve their effectiveness using a PET scan.

Health IT & E-Health Records

In 2004, the President set a national goal to have electronic health records for most Americans within 10 years. The FY 2007 budget includes $169 million toward that goal, an increase of $59 million over 2006. The bulk of the funds ($116 million) would go to the Office of the National Coordinator for Health Information Technology within HHS to support strategic planning, coordination, and analysis of major health IT technical, economic, and operational issues. The HHS Agency for Healthcare Research & Quality would get $50 million for health IT advances in patient safety and quality of care. The agency would continue its health IT work in hospital settings in 2007, but would use $29 million for its five-year program to improve health IT efforts in ambulatory care.

Expanding Healthcare Coverage

The White House remains bullish on market solutions to make healthcare coverage more affordable and accessible. The FY 2007 budget advocates a series of health insurance reforms:

- ❑ Expansion of tax-free health savings accounts (HSAs) for routine medical expenses, linked to a high-deductible private insurance policy to cover catastrophic costs. New incentives proposed include tax credits for purchasing HSAs, increasing the amount an individual can contribute to an HSA, and making HSA premiums tax-deductible.
- ❑ Creation of association health plans to allow small businesses and community groups to consolidate purchasing power to obtain healthcare coverage.
- ❑ Permitting the purchase of health insurance across state lines.
- ❑ Reforming medical liability law to reduce frivolous lawsuits against healthcare providers.
- ❑ Expanding tax deductions on out-of-pocket medical expenses.

The budget also would provide $500 million in grants to states to fund innovative ways to promote affordable health insurance for the chronically ill, $100 million annually for outreach campaigns to enroll eligible children in Medicaid and the State Children's Health Insurance Program, and an increase of $181 million to fund over 300 new or expanded community health centers to serve an additional 1.2 million people in medically underserved areas, including 80 new sites in poor rural and urban counties.

Regulatory Beat

Second Medicare Enrollment Period: Since enactment of the 2005 Deficit Reduction Act changed the rates for the Medicare physician fee schedule, the Centers for Medicare & Medicaid Services has created a second Medicare Participation Enrollment period for 2006. It will run for 45 days, beginning on February 15 and ending on March 31. Among the key details:

- The effective date for changes in participation status will be retroactive to January 1.
- Contractors are to get the word out through provider education channels. There will not be a mass-mailing of Participation Agreements to providers associated with the second enrollment period.
- Physicians and practitioners who submit their participation choice (or withdrawal request) for the second enrollment period must begin to bill claims in accord with their decision after the election is submitted to the local carrier.
- Providers who do not wish to change their current Participation or non-Participation status will not need to do anything.

Change In Medicare Payment Floor: The payment waiting period for Medicare contractors to pay paper claims (the payment floor date) has been extended from 26 to 28 days, effective for claims received on or after January 1, 2006. The implementation date for this change is March 13, CMS has announced (Change Request 4284, February 10, 2006).

Under the new payment floor date, required as a result of an amendment to the Social Security Act, payment for clean claims can be issued on the 29th day following receipt of the clean claim. Contractors are not required to reopen or otherwise reprocess any claims received after January 1 and prior to March 31.

♦ QUESTION *of the* M·O·N·T·H

Whatever happened to a proposed rule being developed for a genetic testing specialty under CLIA, with specific test performance, quality control, and personnel requirements? Also, what has the FDA done lately to encourage development of genetic testing devices for clinical use in tailoring therapeutics and dosages to individual patients?

According to Judy Yost, the top CLIA official at the Centers for Medicare & Medicaid Services, the CLIA genetic testing rule is still in development, with contributions from the CLIA advisory committee and the HHS Secretary's Advisory Committee on Genetics, Health & Society. In a briefing at the CLIAC meeting this month, Yost said she was hopeful a proposal could be issued this year, and called for comments on unresolved issues.

Meantime, the Food & Drug Administration this month issued new draft guidance to speed up development of pharmacogenomics and genetic tests for heritable markers and get them to the clinical laboratory. The guidance applies whether testing is for single markers or multiple markers, and it also covers microarrays. Tests of gene expression and tests for non-heritable (somatic) mutations are not specifically addressed, though many of the same principles may apply, says the FDA. The guidance also considers nucleic acid-based analysis only, but the principles may be applied to other matrices (such as protein) when the purpose is to provide genetic information. The draft guidance, issued in the *Federal Register* (February 9, 2006) and posted at *www.fda.gov/cdrh,* replaces a draft published in 2003.

Part B Lab Spending Up 9.4% To $6 Billion

In 2004, Medicare covered a total of 41.7 million enrollees. Over the past six years, annual Part B lab spending per enrollee has increased by 7.6% per year to reach $144.

Latest data from the 2005 Medicare Trustee Report show that Part B laboratory spending for services furnished by independent, hospital outpatient/outreach, and physician office labs was up 9.4% to $6.018 billion in calendar 2004, according to an analysis by our sister publication, *Laboratory Industry Report*.

After declining through most of the 1990s, Part B lab spending has rebounded strongly over the past six years, rising at an average rate of 8.8% per year. Over the same time period, total Part B spending rose 8.5% per year to reach $134.9 billion, and total Medicare expenditures rose 6.1% per year to reach $304.3 billion. In 2004, hospital labs had a 45% share of the Medicare lab market, while independent labs and physician office labs had 55%.

A separate analysis in our *2006 Medicare Reimbursement Manual* found that in 2004 the top 100 lab and pathology services, ranked by the number of total Medicare-allowed services, included 89 lab codes and 11 pathology codes. For these services, allowed charges totaled $4.051 billion or an average allowed charge of $14.47 per procedure. The fastest-growing lab tests in terms of allowed services between 2003 and 2004 were CDC and automated different WBC count (85025), the comprehensive metabolic panel (80053), and the lipid panel (80061). For more on the top 100, order the Manual through our Website, *www.g2reports.com* or call 800-401-5937, ext. 2.

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

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