WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 29th Year of Publication

Vol. 29, No. 8, February 11, 2008

President's Budget Spares Lab Fees, Is Silent on Physician Fee Fix

But labs and pathologists face the threat of the 45% trigger provision. The budget would cut all provider payments when general revenues exceed 45% of Medicare financing. For details on the FY 2009 budget, see the Focus, *pp. 3-6.*

While hospitals and other institutional providers face deep cuts in their Medicare payments under the President's budget request for fiscal 2009, unveiled February 4, clinical labs have escaped further proposed reductions in the Part B lab fee schedule. But lab competitive bidding is still a priority for savings in the budget.

The budget does not address a Medicare physician fee fix. Congress prevented a 10.1% cut scheduled for January 1 of this year under the SGR update formula and approved a 0.5% increase through June 30. As of July 1, the 10.1% cut is due to take effect unless lawmakers block it again.

Though major cuts are proposed for virtually all providers in traditional Medicare, Medicare managed care would get only a slight trim. The White House has already indicated it opposes any further reductions in Medicare Advantage.

The budget got a frigid reception on Capitol Hill, with Senate and House health leaders calling it "dead on arrival." The Senate Finance Committee has already said it will craft its own Medicare spending legislation later this year.

San Diego Labs Ask Court for Immediate Halt to Medicare Competitive Bidding Demo

Following up on a lawsuit filed recently, three San Diego area clinical laboratories and health systems asked a federal court on February 4 for a temporary restraining order to put an immediate stop to Medicare's lab competitive bidding demonstration project, including solicitation of bids due February 15. At press time, the court is expected to rule quickly, after giving the government a chance to respond.

Under the timeline for the demo announced by the Centers for Medicare & Medicaid Services, bids are due February 15, winning labs are to be selected by April 11, and Medicare is to begin paying for demo tests under a competitively bid fee schedule on July 1.

Internist Laboratory of Oceanside, Sharp Healthcare of San Diego, and Scripps Healthcare of San Diego filed suit January 29 to block the demo, citing immediate irreparable harm to thousands of Medicare fee-for-service beneficiaries and requiring the government to follow public notice and comment on the demo in accord with the Administrative Procedures Act.

Continued on p. 2

INSIDE *NIR*

Lab bidding demo: Key design requirements..... 2

Focus on the FY 2009 Medicare budget 3-6
— Provider payment cuts loom large
— 45% trigger poses additional cutback threat
— Call for national lab competitive bidding repeated
— Market reforms to expand healthcare coverage

HHS cannot stop Medicare lab payments to hospital in CLIA lab dispute, court rules 7

FDA approves new test identifying four common respiratory viruses..... 8

Don't miss our upcoming Molecular Diagnostics conference, April 30-May 2 8

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Bidding Demo, *from p. 1*

The San Diego-Carlsbad-San Marcos metro area is the first of two sites to be selected by CMS for the lab demo. In 2006, the area included 223,000 fee-for-service beneficiaries, and Part B spending for the 303 lab tests in the demo totaled $21.1 million, according to CMS project officer Linda Lebovic.

The aim of the demo, required by Congress in the Medicare Modernization Act of 2003, is to see if competitive bidding can be used to pay for Part B independent lab services at rates below the current lab fee schedule while maintaining quality and access to care.

Lawsuit Against the Demo

The lawsuit to stop the demo was filed against Health & Human Services Secretary Michael Leavitt in the U.S. District Court for the Southern District of California. The lab plaintiffs argue, in part, that HHS:

- ❑ Failed to follow a legally required rulemaking process by not holding appropriate public hearings and failing to allow Medicare recipients, physicians, and others to provide input into the process.
- ❑ Failed to incorporate protections for small businesses, as required by law. The demo requires all labs to perform all 303 demo tests or obtain the financial and bidding cooperation of reference labs, which are now considered competitors.
- ❑ Has established a program that threatens severe and irreparable injury to the plaintiffs as well as their employees and patients.

Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles, filed the suit on behalf of the plaintiffs. "HHS has overstepped its bounds, and by doing so, threatens to cause havoc to the clinical laboratory landscape of San Diego, Carlsbad, and San Marcos," he said in a statement. "We are respectfully asking the court to stop the project in its tracks and allow the public a chance to weigh in on this ill-conceived government mandate."

One plaintiff, Internist Laboratory, is a family-owned business with eight employees and gets roughly 65% of its business from Medicare beneficiary lab tests. If Internist is not chosen as a "winning" lab, it is only a matter of time before it will close, Hooper said. "This is devastating for the hundreds of elderly and special-needs patients who depend on it." Sharp HealthCare will most likely have to close some local drawing stations if it is not a "winning" lab, he noted. "This includes the likelihood of sending out its lab tests for urgent care patients, potentially causing a significant and dangerous delay in critical testing results. Like Sharp, Scripps Health may be forced to discontinue completely, or significantly decrease, furnishing lab services to non-hospital patients."

The National Independent Laboratory Association fully supports the lawsuit filed in part by its Oceanside member, Internist Laboratory. "Rather than creating competition, *Continued on p. 7*

Demo Design: Key Elements

- ❑ Required bidders: Labs that expect to bill Medicare for at least $100,000 annually for demo tests for fee-for-service beneficiaries during any year of the three-year project. Labs below the threshold are "passive" labs, that is, not required to bid, but they will be paid at the competitively set rates for demo tests.
- ❑ Services covered: Part B lab services furnished by independent labs and by hospitals and physician practices when their labs are functioning in effect as independent labs. Tests excluded: Pap smears, colorectal cancer screening, and new lab tests added to the fee schedule during the three-year run of the project.
- ❑ Labs must submit bids for all demo tests whether done in-house or referred out.
- ❑ Non-winners cannot bill Medicare for any demo tests during the project's run, nor can they legally refuse to serve beneficiaries, based on payment.

focus on: The Medicare Budget

President Calls for Steep Medicare Provider Pay Cuts, Lab Fees Spared, But Physician Fee Fix Not Addressed

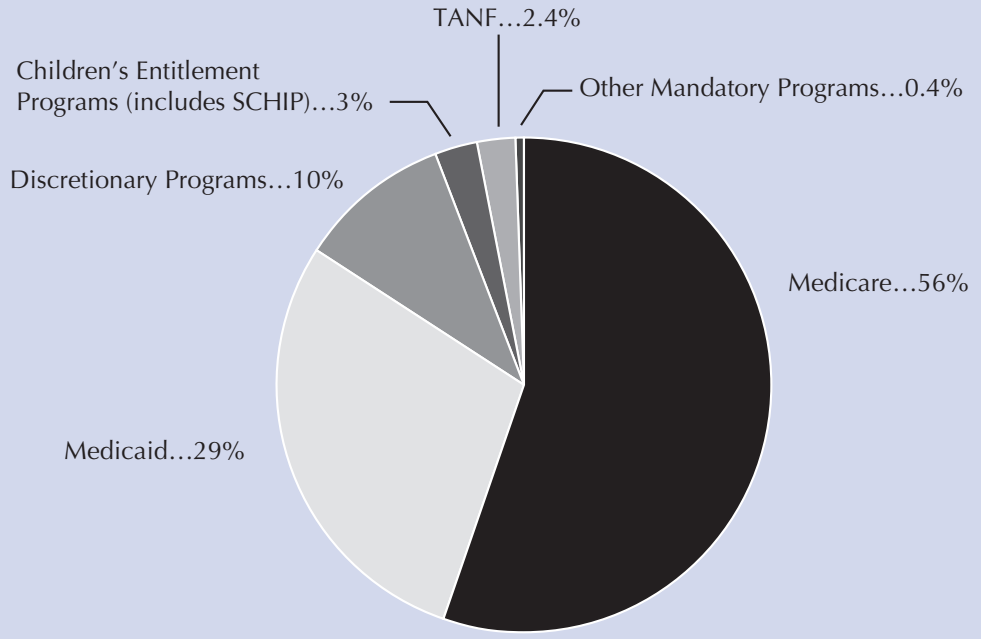
Clinical lab fees payable under Medicare Part B are not included on the hit list for provider payment cutbacks in the President's budget request for federal fiscal year 2009, released February 4 and sent to Congress. Lab fees, frozen since 2004 at 2003 levels, are scheduled to emerge from the freeze at the end of this year and are in line for an automatic Consumer Price Index update in calendar 2009 unless Congress says otherwise.

But the Bush Administration continues to be wedded to a policy of switching to competitive bidding nationwide to reimburse Part B laboratory services. Like last year, the FY 2009 budget proposes a national rollout of lab bidding, saving an estimated $110 million in FY 2009 and $2.3 billion over 2009-2013.

For pathologists and other physicians, the budget is silent on what happens July 1, when a 10.1% cut in their Medicare fees is slated to kick in—in effect, punting the issue to legislators to fix and decide how to pay for it with cuts elsewhere under congressional pay-as-you-go rules. The President simply notes that Congress blocked the cut from taking effect January 1 of this year, as required under the update formula, and approved at 0.5% increase only through June 30.

Composition of the FY 2009 HHS Budget

$737 Billion



Source: HHS Budget in Brief. Percentages total slightly more than 100% due to rounding.

For hospitals and other institutional providers, the budget news is bad. The President is proposing to freeze their updates and, once the freeze is lifted, reduce their market basket/CPI updates by $7.24 billion in FY 2009 and $117 billion over 2009-2013. Hospitals also would absorb most of $4.8 billion in other Medicare reductions, including capital and disproportionate share payments.

The Medicare Advantage managed care program would get only a slight trim: a cut of $1 billion by eliminating duplicate hospital indirect medical education payments for MA beneficiaries. The President has already signaled that he will oppose any congressional cuts in Medicare managed care this year. Last year, he used a veto threat to block a major cut in Medicare Advantage payments, in part to help pay for a physician fee increase. In a compromise, MA cuts were limited to $1.4 billion from the Regional PPO stabilization fund.

FY 2009 Medicare Outlays, Benefits

For the Centers for Medicare & Medicaid Services, the President's FY 2009 budget requests $711.2 billion in mandatory and discretionary outlays, a net increase of $32.7 billion over the FY 2008 level.

It includes a combination of Medicare legislative and administrative proposals to save $12.8 billion in FY 2009 and $182.7 billion over five years, slowing the program's average annual growth rate over five years from 7.2% to 5%.

The net savings from the legislative proposals alone total approximately $12.2 billion in FY 2009 and $178 billion over five years.

Net proposed law spending on Medicare benefits will total $413.3 billion, covering 45.5 million individuals who are either 65 and older, disabled, or suffer from end-stage renal disease.

Deep Freeze for Hospitals, Other Part A Providers

The major lobbying organizations for hospitals, skilled nursing facilities, and other providers under Medicare prospective payment were quick to express alarm to Congress over the magnitude of the cuts, noting that the Medicare Payment Advisory Commission has recommended an increase for 2009.

The President's budget would:

- ❑ Freeze the market basket/CPI update in 2009 through 2011 for inpatient hospitals, long-term care hospitals, skilled nursing facilities, hospices, outpatient hospitals and ambulance services, followed by a full update less 0.65% annually thereafter.
- ❑ Freeze the market basket/CPI update for inpatient rehabilitation facilities and ambulatory surgical centers in 2010 and 2011, followed by a full CPI update less 0.65% annually thereafter.
- ❑ Freeze the market basket update for home health agencies in 2009 through 2013, followed by a full market basket update less 0.65% annually thereafter.

The budget request also seeks to eliminate bad debt reimbursement for unpaid beneficiary cost-sharing over four years for all providers. Medicare now pays 70% of unpaid co-pays and deductibles to hospitals and skilled nursing facilities.

45% Trigger: Sequester Warning

The budget contains another provision that leaves Medicare providers open for further reductions. The provision, mandated by the 2003 Medicare Modernization Act, requires the President to propose, and the Congress to quickly consider, ways to rein in Medicare spending when general revenue funding exceeds 45% of program financing. The FY 2009 budget proposes to sequester -0.4% of all provider payments

when general fund revenues exceed 45%. The sequester order would increase each year by -0.4% until general revenue funding is brought back to 45%.

Last year, for the second year in a row, the Medicare trustees noted in their annual report that general revenue funding is projected to exceed 45% of Medicare financing within the next seven years, thus prompting the "funding warning" mandated by the MMA. The trustees issued their first warning in 2006, estimating that the 45% threshold would be reached in 2012. In the 2007 report, they projected it would be reached in 2013.

Now that the second consecutive warning has been sounded, the law requires the President to propose legislation to bring Medicare funding below the 45% threshold. Congress then must "fast-track" consideration of the plan, but is not required to enact any specific proposal. House Democratic health leaders Charles Rangel (D-NY), who chairs the Ways & Means Committee, and Pete Stark (D-NY), who chairs its health subcommittee, have been openly skeptical of the 45% trigger, calling it "arbitrary" and noting that no other federal program is subject to such a warning.

Labs Urged to Stay Vigilant

The budget news on the Medicare lab fee schedule is welcome, but some general provisions in the budget are problematic and labs need to keep a sharp eye on these areas, Mark Birenbaum, administrator for the American Association of Bioanalysts and the National Independent Laboratory Association, told *NIR*.

One area deals with the 45% trigger for Medicare spending reductions. The budget envisions cuts in provider payments across-the-board, and labs could be swept up in it, he said. Another area to watch is the plan for steep cuts in payments to hospitals and other Part A providers. "This is not a good environment for labs," Birenbaum said, noting that these providers will lobby against the cuts. But blocking the cuts and even granting a modest increase would have to be paid for by reductions elsewhere under pay-

Initiatives on E-Health Records

In support of the President's goal for most Americans to have electronic health records by 2014, the FY 2009 budget includes $66 million for the Office of the National Coordinator for Health IT. Among the top priorities:

— Support establishment of an independent and sustainable public-private partnership as a successor to the American Health Information Community (AHIC).
— Continue the development of health data standards.
— Find remedies against privacy and security breaches.

To promote physician adoption of e-health records, the budget would provide $3.8 million for the second year of a demonstration project that provides financial incentives for up to 1,200 physician practices to adopt certified EHR systems.

To support health IT investments in patient safety, $45 million would be allocated to the HHS Agency for Healthcare Research & Quality, with $29 million targeted to the Ambulatory Patient Safety Program, including $7 million in new health IT grants.

Meantime, HHS Secretary Michael Leavitt announced January 22 that two nonprofit organizations will lead the transition of AHIC from a federal advisory group to a public-private partnership based in the private sector. LMI, a government consulting firm in McLean, VA, will join with the Brookings Institution, a Washington, DC think tank, to design and complete the transition, expected by December 2008. HHS will pony up $5 million for the project.

as-you-go rules. Physicians too will join hospitals and other providers in lobbying against cuts and for a payment increase. In the battle over offsets, labs could again become an easy target.

The savings projected for competitive bidding are not related to anything real, based on what is going on now, Birenbaum said. The numbers assume a nationwide rollout of lab competitive bidding, but the CMS bidding project has yet to get off the ground in the initial site (*related story, p. 1*).

"The figures in the budget will start looking much different when Congress gets down to action on Medicare spending legislation later this year, as expected," he told *NIR*.

Senate Finance Committee chairman Max Baucus (D-MT) expressed a similar assessment. "The proposed reductions are 'dead on arrival' with me and with most of the Congress."

At a February 6 hearing he told HHS Secretary Michael Leavitt, "You've asked for huge, Draconian cuts, which this Congress is not going to make. We're not going to solve the problem by just whacking the bejeebies out of Medicare." The budget's call for Medicare spending reductions "smacks of a meat-ax," he said, based "more on ideology than trying to find a meeting of the minds between the Congress and the Administration."

Republican Sen. Pat Roberts (KS) told Leavitt, "You're sure going to reduce [Medicare] costs, but we're not going to have a program." The hospital cuts in the budget would amount to $653 million in lower reimbursement over five years for Kansas hospitals, he said, noting, "We can't do that and stay in business."

Leavitt responded that the Medicare growth reductions were needed to help the program survive financially, to keep beneficiaries' premiums affordable, and to help balance the federal budget by 2012.

Expanding Healthcare Coverage

On the healthcare reform front, the President is again proposing, as he has over the past few years, a series of tax code and market-based changes that he says will make healthcare coverage options in the private insurance market more affordable and accessible.

This is the way to go to cover more Americans, he said: "Consumer choice, not government control." In the budget plan for FY 2009, the Bush Administration would:

- Replace the existing and unlimited tax exclusion for employer-sponsored insurance with a standard deduction for those with at least catastrophic health insurance. As long as a family has at least a catastrophic coverage policy, it will be able to deduct $15,000 from its income ($7,500 for an individual).
- Expand health savings accounts.
- Establish association health plans for small employers, civic groups, and community organizations to create a competitive marketplace across state lines.
- Reform medical liability law to reduce "frivolous" legal proceedings.

Washington pundits do not think the proposals will go anywhere this year, but speculate that some of the President's ideas, such as tax code reform, could become part of a comprehensive healthcare reform debate in the next Congress and Administration, along with such issues as a mandate to have insurance coverage, tax credits to buy insurance, and subsidies for low-income individuals to obtain coverage.

Court Blocks Medicare Pay Cutoffs in CLIA Lab Dispute

A federal district court January 10 waived the "usual remedy exhaustion" requirement, preventing the Health & Human Services Secretary from canceling a California hospital's approval to receive Medicare and Medicaid payment for clinical laboratory services (*Victor Valley Community Hospital v. Leavitt*).

More than 60% of the patients at Victor Valley, one of four hospitals in the High Desert region of California with a population of about 500,000, receive Medicare or Medicaid (Medi-Cal) services.

Representing the hospital in the case are Jordan Brian Keville and Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles. Hooper also is representing plaintiffs in the lawsuit to halt the Medicare lab bidding demo (related story, p. 1).

In July 2007, the Centers for Medicare & Medicaid Services determined that Victor Valley was not in compliance with the CLIA proficiency testing condition because it improperly referred proficiency testing samples to an outside laboratory. CMS informed the hospital it would postpone the proposed revocation of CLIA certification if Victor Valley requested an administrative hearing. However, CMS warned, cancellation of all Medicare and Medi-Cal payments would go into effect, regardless of whether a hearing was requested.

The district court found that if Victor Valley lost Medicare and Medi-Cal payment for laboratory services, it would have to struggle to provide basic services and maintain necessary equipment and would likely have to trim its operations or shut down. If the hospital ceased operating, the court found, it would be difficult or impossible for the other three hospitals in the area to meet the community need for birthing and emergency services.

The court's decision effectively stops the federal government from cutting off payments while the issue is resolved. The case is now at the administrative hearing level to determine whether the revocation of the CLIA certificate was justified.

Bidding Demo, *from p. 2*

the CMS plan will result in fewer labs, less competition, and the government picking winners and losers," said Mark Birenbaum, administrator for NILA and the American Association of Bioanalysts. "Internist is fighting for its life and for the health and well-being of the San Diego community." Internist was one of the few clinical labs that stayed open during the wildfires in San Diego last year, he noted. Many other area patient service centers were closed, leaving physicians and patients with few options for critical lab services, he said.

The Clinical Laboratory Coalition, whose 10 member organizations include the leading lab and pathology groups, also fully supports the lawsuit, while continuing to lobby Congress to enact legislation pending in the House and the Senate to repeal the demo.

Nonetheless, CMS is planning to go ahead with the project in San Diego, starting July 1, and has notified local contractors about implementation details for claims processing (Change Request 5772, February 1, 2008). The memo also notes that a later CR will be issued to launch the demo in a second site, with a tentative start date of July 1, 2009.

FOR THE RECORD:

The fee associated with the crosswalk of new CPT 80047 to 80048 on the Part B lab fee schedule should be $11.83. This rate is paid by most carriers and Medicare Administrative Contractors, though on some local fee schedules it is lower. In our January 28 issue, the rate was incorrectly cited as $11.42.

FDA Okays New Test for Four Common Respiratory Viruses

The ProFlu+ test is more accurate when used with patient data, bacterial or viral cultures, and X-rays in diagnosing a patient. Positive results do not rule out other infection or co-infection, and the virus detected may not be the specific cause of the disease or patient symptoms, the FDA cautioned.

The Food & Drug Administration has cleared for marketing a test that simultaneously detects four common respiratory viruses, including the flu, in a patient's respiratory secretions. The ProFlu+ molecular biology device, manufactured by Prodesse Inc. of Milwaukee, WI, provides results in as few as three hours. Other diagnostic tests for respiratory viruses are fast but not as accurate, or are accurate but not as rapid, the FDA said.

The real-time test employs a multiplex platform that allows several tests to be processed using the same sample to detect influenza A virus, influenza B virus, and respiratory syncytial virus A and B (RSV). These viruses can cause influenza, an infection of the airways called bronchiolitis, and pneumonia. All are among the leading causes of lower respiratory tract infections.

Antiviral drugs are most effective when initiated within the first two days of symptoms, the FDA noted. The new test, part of the new era of molecular medicine, can help the medical community quickly determine whether a respiratory illness is caused by one of these four viruses and initiate the appropriate treatment, the agency said.

 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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