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Lab Groups Lobby Congress Against Medicare Budget Threats

The lab organizations oppose expansion of lab competitive bidding, elimination of lab personnel training funds, and any further cuts in lab fees, which remain frozen at 2003 levels through 2008.

Members of leading national clinical laboratory and pathology associations converged on Congress late last month for a two-day lobbying blitz to oppose major lab-related proposals in the President's fiscal 2007 budget request and to continue to educate lawmakers about the clinical value of lab testing and the savings it generates via preventive screening, early detection, and management of disease.

Approximately 150 representatives from the American Society for Clinical Laboratory Science, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association took part in the lobbying sessions held March 27-28. This marks the first time the three have come together like this, Don Lavanty, legislative counsel to ASCLS, told the *National Intelligence Report*, and the aim was to deliver a clear, unified message, he said.

One major part of the message that the lab advocates delivered to members of Senate and House health committees and to members from their states and districts was strong opposition to the President's proposed nationwide rollout of Medicare lab competitive ➥ *p. 2*

Medicare Expected To Reduce Trip Fee

The Medicare travel allowance to collect specimens from homebound and nursing home beneficiaries is expected to be reduced in line with a decrease in the federal standard mileage rate, *NIR* has learned from the Centers for Medicare & Medicaid Services.

CMS sources told *NIR* the agency "is developing a correction Change Request to the payment amounts" for trip fee codes P9603 (per mile) and P9604 (flat-rate basis), though the release date is uncertain. But most important to labs, no payback will be required: "The instruction will not require Medicare contractors to retract payment for claims already paid."

The mileage rate, set by the Treasury Department, was reduced to $0.445 per mile effective January 1, 2006, down from the $0.485 per mile in place since September 5, 2005. This change would decrease the trip fee codes by four cents to 89.5 cents per mile or $8.95 on a flat-rate basis. The personnel portion of the trip fee remains frozen by law at $0.45, in accord with the five-year lab fee freeze (through 2008). ➥ *p. 5*

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Many lab personnel training programs are going out of business without federal support, warns lobbyist Don Lavanty, and this only exacerbates the growing shortage of lab professionals, which already has resulted in tight markets for recruitment and retention across the country.

Lab Groups Lobby Congress Against Medicare Budget Threats, *from p. 1*

bidding (*NIR, 27, 9/Feb 23 '06, pp. 4-6*). Before such an expansion, lawmakers should at least wait, lab advocates said, for results of the bidding demonstration for independent lab services that Congress required in the 2003 Medicare reform law. That project is still in the design phase at the Centers for Medicare & Medicare Services, and a progress report, due to Congress last December 31, was still in clearance at press time.

While ASCLS, ASCP, and CLMA have provided input to CMS on the draft bidding design, the groups like others in the Clinical Laboratory Coalition still do not believe that a model can be developed to meet the objective of providing lab testing at fees below current Medicare rates, while simultaneously maintaining quality and access in diverse healthcare settings, such as nursing homes and in rural areas.

The lobbying blitz also sought to "get lawmakers more energized," Lavanty said, to support funding of Title VII and Title VIII health professions education programs, including the allied health account that devotes a portion of its dollars to train medical lab technologists and technicians. The President's budget would eliminate this funding. The Senate, in approving its version of the 2007 budget on March 16, rejected this proposal and approved a bipartisan amendment offered by Sens. Arlen Specter (R-PA) and Tom Harkin (D-IA) to restore health professions training funds, including $11 million for allied health, the same level as in FY 2006.

House GOP Leaders Halt Floor Action On FY '07 Budget

Facing sharp dissension in their ranks and unified opposition from Democrats, the House Republican leadership on April 6 stopped floor debate on a fiscal 2007 budget blueprint until after the two-week Easter break, but hopes to resume work on a revised version when members return. Floor action collapsed over a host of issues, including tax cuts, domestic spending, and disaster aid.

The House had been working on the plan (H. Con. Res. 371) that its Budget Committee approved March 29 by a party-line vote of 22-17. Like the Senate-passed budget, the measure does not include the President's request for $36 billion in Medicare spending cuts over five years (*NIR, 27, 11/Mar 27 '06, p. 2*). But the measure did leave the door ajar for a return to Medicare if needed by the Ways & Means Committee to achieve $4 billion in savings over five years. Staff on the budget panel said Medicare was not a target at this point. The panel also rejected $13 billion in Medicaid spending cuts that the President sought.

The GOP majority on the House Budget Committee defeated an amendment by Democrats that would have lifted the ban on Medicare negotiating directly with drug makers for outpatient prescription drugs purchased under the new Part D benefit. The Senate-passed budget lifted the ban, enacted in the 2003 Medicare reform law. The House Budget Committee also beat back Democratic moves to repeal the $10 billion stabilization fund for Medicare managed care plans and to increase Medicare payment for physicians in rural areas by $354 million in 2007 and $241 million in 2008.

The budget blueprints are not binding on House and Senate committees with jurisdiction over specific programs like Medicare; they set spending targets and priorities for increases/decreases for the committees to consider.

With the GOP and the Democrats set to wrestle for control of Congress in the November elections, lab lobbyist Don Lavanty told *NIR* he doesn't think lawmakers will want to do anything on Medicare before then. It's especially unlikely in the House where 35 seats are in play, he said, either through a member's retirement or in closely fought districts. Should Congress return after the elections for a lame-duck session, it could be a different story, he cautioned.

MedPAC Briefed On New Part B Lab Spending Study

Five leading lab industry groups commissioned the study to help policymakers identify Medicare spending trends and factors contributing to rising utilization.

Medicare spending for carrier-paid Part B laboratory claims is growing at a slower rate than other healthcare sectors, while a key driver of rising lab service utilization is greater physician compliance with clinical practice guidelines when ordering lab tests, according to a report recently released by five major lab industry associations.

Representatives of the groups shared the findings at a March 22 meeting with Dr. Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC), and staff Ariel Winter and Dana Kelley who are assigned to study lab payment issues. MedPAC is an independent federal panel established by law to advise Congress and the U.S. Department of Health & Human Services on issues and trends affecting the Medicare program.

The key findings presented at the briefing included:

- Spending for carrier-paid lab claims is growing slower than other health sectors—10.4% per year over 2000-2004 (the period studied by MedPAC). Clinical lab testing comprised 45% of spending in the "lab and other tests" category. Outlays for "other tests" (including EKGs, pacemaker analyses, and pulmonary function tests) grew 13.3% per year.
- Ten tests accounted for 58% of clinical lab spending growth over 2000-2004, all consistent with clinical practice guidelines (*see box, p. 4*).
- Primary care physicians accounted for 78% of the growth in the number of lab tests over 2001-2004, and three common conditions they manage—diabetes, high cholesterol, and high blood pressure—accounted for nearly 40% of lab test spending growth over this period.

Impetus For The Study

The report, *Trends in Medicare Carrier-Paid Laboratory Testing Services*, was sponsored by the American Clinical Laboratory Association, the American Association of Bioanalysts, AdvaMed, the American Society for Clinical Laboratory Sciences, and the Clinical Laboratory Management Association.

It was written by Christopher Hogan, PhD, president of Direct Research LLC (Vienna, VA) and previously a staff member of the Physician Payment Review Commission and MedPAC.

The idea for the study, ACLA president Alan Mertz told *NIR*, originated in response to a March 3, 2005 letter from CMS official Herb Kuhn to MedPAC, stating that laboratory and other tests accounted for 11% of overall spending. The total was not broken down for clinical lab test spending, Mertz said.

As MedPAC then began to look in earnest at Part B lab spending growth and increased utilization of lab services, the lab groups decided they needed a definitive independent study of spending trends and use of the most common and fastest-growing tests, he said.

Mertz emphasized that the study shows "we're not growing as fast as other sectors of healthcare. Where use of lab testing is growing, it's for major chronic diseases in areas where clinical practice guidelines recommend that doctors order tests, with tremendous value to patients." In addition, the most cost-effective sector of the physician community—primary care—is managing more of the clinical care, he noted.

MedPAC director Miller told the groups that no recommendations on lab services would be presented to the Commission before March 2007, and he agreed with the study's findings that growth in lab services is consistent with physician compliance with clinical guidelines. But MedPAC remains concerned about the regional variation it has found in use of lab tests and wants to correlate this variation to patient outcomes.

The lab-sponsored report is posted on the ACLA Web site, *www.clinical-labs.org*.

Clinical Laboratory Testing—A $40 Billion Market

- Medicare spending for carrier-paid Part B lab spending totals $3.5 billion, or 2% to 3% of all healthcare spending, yet lab testing influences or directs approximately 80% of such spending.*
- Medicare spending for carrier-paid lab services from 2000 increased at 10.4% per year, less than other healthcare sectors
- Key drivers in lab spending growth include physician compliance with clinical practice guidelines, newly developed technology, emphasis on preventive medicine, and the aging of the population.
- Market share among lab sectors remains virtually unchanged over the past 10 years. The pattern of growth for outpatient department services is the same as for carrier-processed claims.

Source: MedPAC briefing presentation on lab service spending trends, March 22, 2006.

**Editor's Note:* Does not include hospital outpatient and outreach lab spending. The 2005 Medicare Trustees Report found that the total for all lab spending rose by 9.4% to $6 billion in 2004. Carrier-paid labs accounted for $3.3 billion, or 55% of the total, while intermediary-paid labs accounted for $2.705 billion, or 45% of the total.

Top Ten Lab Tests

- Ten tests accounted for 58% of spending growth from 2000 to 2004, including:
  - Tests of thyroid and parathyroid function (CPT 84443, 83970)
  - Blood lipids (presumably for patients with high cholesterol)
  - Glycated hemoglobin (presumably for patients with diabetes)
  - Prothrombin time (presumably for patients on blood thinners)
  - Blood ferritin (presumably for patients with anemia)
  - Natriuretic peptide, a new clinical lab test to identify congestive heart failure
- For the 10 fastest-growing clinical lab tests, most of the growth was due to more persons being tested (for example, for blood lipids or glucose levels), not more tests per person.

AAB Forms New National Independent Lab Association

NILA is intended to focus on one of the biggest issues for community clinical labs—how to stay in business and compete, and how to get their viewpoints heard, said AAB chief Mark Birenbaum.

The American Association of Bioanalysts has formed a new trade association for independent community clinical laboratories, AAB administrator Mark Birenbaum, PhD, noted in a recent interview with *NIR*.

The new National Independent Laboratory Association (NILA) is intended to function as a platform enabling laboratory executives and senior-level management to exchange technical and business expertise and to focus on legislative and regulatory issues facing their industry.

The formation of NILA "makes it clear to those in clinical laboratory management that AAB membership is open to them," even if they are not scientifically trained, Birenbaum noted. In a sense, NILA represents a "return to AAB's roots in the 1950s" as a trade group for community lab owners and executives, he said.

NILA officially began accepting members early this year. Membership is limited to laboratories with gross annual revenues of up to $500 million. Member labs can each name two executive-level representatives who will be entitled to vote on group matters. Annual NILA dues are $1,000 per lab, which includes two individual AAB director or owner memberships.

NILA will hold a special meeting during the 50th anniversary celebration of the AAB Educational Conference, June 8-10, 2006, in Las Vegas, NV. For more on NILA, contact the AAB, 906 Olive St., Suite 1200, St. Louis, MO 63101-1434. Tel: 314-241-1445.

Briefly Noted

New Release Date For CLIA Lab Inspection Report: May 31 is the new tentative release date for a report by the congressional watchdog agency—the General Accountability Office—on how well federal, state, and private accrediting bodies are handling CLIA laboratory inspections, following up on deficiencies uncovered, and sharing information regularly, a GAO spokesperson told *NIR*. The previous target date was March 17 (*NIR, 27, 8/Feb 6 '06, p. 8*).

The study was requested by Rep. Elijah Cummings (D-MD) in the wake of media reports of quality testing failures at Baltimore's Maryland General Hospital, which went undetected by surveyors at all levels and surfaced only when a whistle-blower filed suit. The report also is to look at changes in CLIA certification and accreditation programs as a consequence.

Medicare Expected To Reduce Trip Fee, *from p. 1*

CMS adopted the $0.485 per mile rate in a program memo last November announcing the 2006 lab fee schedule and made the rate retroactive to September 5. The Treasury then said the $0.485 per-mile rate was a one-time increase through December to account for higher fuel prices, and on January 1 of this year pared the rate to $0.445 per mile.

Under current Medicare policy, the trip fee is $0.935 per mile or $9.35 on a flat-rate basis. Previously, it was $0.855 (P9603) or $8.55 (P9604).

CMS To Allow Continued Use Of Surrogate UPIN

The CMS decision is especially welcome news to independent labs and to pathologists in teaching medical centers, among others, who worried that without the surrogate UPIN, they would be performing services for which payment would be rejected.

In a recent policy reversal, the Centers for Medicare & Medicaid Services has decided not to eliminate, effective April 1, 2006, the use of the surrogate UPIN OTH000 on Medicare claims from physicians, clinical laboratories, and other healthcare providers.

CMS announced the change on March 31 (Change Request 5019). Under the now-defunct policy eliminating use of the "dummy" Unique Physician Identification Number (Change Request 4177), Medicare would have required labs and other providers to submit the referring/ordering physician's actual UPIN or the claims would be returned as "unprocessable" (*NIR 27, 5/Dec 19 '05, p. 7*).

The surrogate UPIN was intended for interim use when a UPIN had been requested but not yet received. A Medicare audit in 2004 found that an excessive number of claims used the surrogate when UPINs had been assigned in many cases. In addition, the audit found that more than 10 million claims were submitted with the surrogate UPIN during the period studied.

In lobbying for the policy reversal, the billing committee of the American Clinical Laboratory Association argued that because clinical lab testing is time-sensitive, member labs typically perform the service and provide test results whether or not they have a UPIN for the ordering physician or practitioner. Not all providers have UPINs or must have one, ACLA noted, adding that without the surrogate, labs will be providing services for which they won't be paid.

Use of UPINs on claims will be phased out completely by May 23, 2007, in Medicare's transition to the National Provider Identifier (NPI), as required under HIPAA rules to facilitate electronic data exchange. Since January 3, 2006, Medicare systems will accept claims with an NPI, but an existing legacy Medicare number must also be on the claim.

Medicare Implements Revised 'Date Of Service' Policy

Effective April 1, the Medicare program began implementing revised requirements for the "date of service" (DOS) on reimbursement claims for Part B clinical laboratory tests (Centers for Medicare & Medicaid Services, Change Request 4156).

As a general rule, the DOS of the test is the date the specimen was collected. An exception is made for archived specimens. But it was unclear how long a specimen must be in storage to be considered "archived."

CMS has now clarified that the time frame is more than 30 calendar days. For these specimens, the DOS is the date the specimen was retrieved from storage. For specimens stored 30 days or less, the DOS is the date the specimen was collected.

National Medicare Coverage Approved For Cardiac Test

Previously, coverage of the MTWA procedure was at the discretion of the local Medicare contractor.

The Medicare program began national coverage of a non-invasive diagnostic test for cardiac patients—the Microvolt T-wave Alternans (MTWA)—as of March 21, the Centers for Medicare & Medicaid Services has announced.

CMS made the decision based on studies showing that the test is useful in identifying patients at risk for sudden cardiac death from ventricular arrhythmias who would best benefit from an implantable cardiac defibrillator. Sudden cardiac death accounts for half of cardiovascular deaths. Of the 350,000 annual cases, only 20% survive long enough to be discharged from the hospital.

The MTWA is performed by placing high-resolution electrodes on the chest prior to an exercise. The electrodes detect beat changes in the EKG T-wave. "Spectral analysis," a mathematical model of measuring and comparing time and EKG signals, is used to calculate the minute voltage changes. The technology is produced by Cambridge Heart Inc., an R&D company in Bedford, MA. Roderick de Greef, chief financial officer for Cambridge, said Medicare will reimburse physicians $322 per test, which would include $75 for a disposable sensor and the technician's time.

In another cardiac-related decision, CMS rejected expanded Medicare coverage for external counterpulsation therapy. This outpatient procedure currently is covered for beneficiaries with disabling angina who are not surgical candidates.

Celebrating National Medical Laboratory Week ❖ April 23-29

We at Washington G-2 Reports/IOMA are proud to join in this nationwide salute to the 300,000 medical laboratory professionals and board-certified pathologists in the United States. This year's theme: Laboratory Professionals: Providing Answers, Guiding Cures.

This annual event, now in its 31st year, is a special occasion to educate the public about the key role that these individuals play in healthcare, to promote the health professions, and recruit students for these professions. Many participating members hold displays, open houses, and other public activities in their institution or local area. For details, visit the ASCLS Web site, *www.ascls.org*.

National Medical Laboratory Professionals Week is sponsored and coordinated by a committee representing the following 11 national clinical laboratory organizations:

★ American Society for Clinical Laboratory Science
★ American Society for Clinical Pathology
★ American Association for Clinical Chemistry
★ American Association of Blood Banks
★ American Medical Technologists
★ American Society of Cytopathology
★ American Society for Microbiology
★ Association of Public Health Laboratories
★ Clinical Laboratory Management Association
★ College of American Pathologists
★ National Society for Histotechnology

OIG Repeats Call For Lab Co-Pay, Wider DRG Window

The OIG also urges state Medicaid agencies to use Medicare's Correct Coding Initiative (CCI) edits on provider claims: "Most don't use the edits. Only seven use all or some of [them]. In 2001, 39 Medicaid agencies paid $54 million for services that would have been denied under CCI edits."

For the latest sign that many Medicare lab cost-cutting options never completely get off the chopping block, despite universal opposition from clinical laboratory and pathology interests, see the latest Red Book issued by the HHS Office of Inspector General. In it, the OIG again proposes that Congress:

- ❑ Adopt beneficiary co-insurance and deductible for Part B laboratory services. This would save an estimated $1.13 billion in the first fiscal year and up to $2.13 billion in the fifth year, the OIG said.
- ❑ Expand the DRG payment window for preadmission services, including lab testing, from the current three days to seven days, for an estimated annual savings of $83.5 million. Non-physician preadmission services are not separately billable to Part B; they are considered part of the hospital's Part A payment.

The OIG also advises the Centers for Medicare & Medicaid Services to review Part B fee levels: "Although prices on individual tests are being reduced by legislation, we continue to believe that payments for lab services need to be evaluated." The Red Book, officially known as the *2005 Cost-Saver Handbook*, is a compendium of the OIG's recommendations on ways to reduce expenditures throughout the U.S. Department of Health & Human Services. It is posted at *www.oig.hhs.gov*.

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