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Lab Groups Rally To Thwart Potential Medicare Cuts

Mindful that the best defense is a good offense, the Clinical Lab Coalition, an ad hoc alliance of leading lab/pathology and other interested groups, has staked out an ambitious lobbying agenda for the new Congress. For more on what's in store on Capitol Hill, see the Focus, pp. 4-6

As the first session of the 109th Congress opened earlier this month, the Clinical Laboratory Coalition began mobilizing its member organizations to lobby against potential cuts in Medicare payment and other adverse federal policy changes. Congress is expected to face strong pressure to slash healthcare spending in light of the growing federal budget deficit, the war in Iraq, and the President's bent on tax cuts (*National Intelligence Report*, 26, 6/Jan 10, '05).

The Coalition met January 11 in Washington, DC, and agreed to oppose any legislation that would restore a 20% lab co-pay or reduce the national lab fee caps. The lab co-pay was defeated in final action on the Medicare Modernization Act in the 108th Congress, but lab fee updates were frozen from 2004 through 2008. The Coalition also agreed to:

- ❑ Lobby Congress to end the fee freeze and heed dangers to labs from competitive bidding.
- ❑ Support issues that, while of interest to all, are priorities for some. These include overhauling the lab fee schedule, funding the education and training needed to address the lab personnel shortage, and increasing the specimen collection fee. ▲

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Is It Time To Scrap The Lab Fee Schedule?

Since 1984, Medicare Part B has paid for covered laboratory testing via a fee schedule methodology. In 2000, the Institute of Medicine, at the request of Congress, evaluated the current system and a series of alternatives, a study for which the Clinical Laboratory Management Association successfully lobbied Congress. This month, CLMA and the American Society for Clinical Laboratory Science agreed to develop a proposed alternative payment approach.

ASCLS and CLMA will convene focus groups of their members to explore ideas, then share the results with other members of the Clinical Laboratory Coalition. "If the organizations feel that it's viable, we would convene groups to develop a consensus among the different disciplines," says ASCLS executive vice president Elissa Passiment.

"I'm hoping that if we come up with something really workable and budget-neutral, we could try to get guaranteed updates," similar to hospital market-basket updates, says Kathy Ayres, CLMA's director of legislative and regulatory affairs. She noted that radiologists recently went through a successful revamp of their fee schedule. The ambulance fee schedule also recently went through a negotiated rulemaking. ➔ p. 2



Some lab groups remain leery about jettisoning the lab fee schedule, just as they were when Congress had the Institute of Medicine evaluate alternatives. Among the options evaluated: payments based on relative values and geographic cost differences, competitive bidding and micro-costing

Lab Fee Schedule?, from p. 1

Don Thompson, director of the ambulatory services division at the Centers for Medicare & Medicaid Services, planted the seed during a meeting last month with the lab coalition. He suggested that Congress would frown on unfreezing lab fees early, given that the 20-year-old lab fee schedule “has no basis in reality and hasn’t aged well,” Passiment recalled. CMS has yet to respond to the Institute of Medicine study, Thompson indicated, because of a lack of resources and in-house expertise. An industry proposal would have more credibility with Congress, he suggested.

Passiment said one ASCLS member has come forth with an interesting scheme, which their hospital CFO uses internally to apportion the cost of Part A lab testing per episode of care. Even though hospitals receive no separate payment for Part A tests, this CFO found it useful to estimate actual lab costs per patient per DRG payment. “If you’re going to make better business decisions, you need to know your costs,” Passiment noted.

This CFO tried the micro-costing approach, but it quickly became too complicated. In the end, the hospital developed a new approach. For example, for chemistry tests, take all the CPT codes, rank them from the cheapest and quickest to the most costly and involved, set a value of 1.0 for the median test, and establish a multiplier for the relative resource intensity of the other tests. 🏠

MedPAC Plan On Test Results Reporting Draws Fire

The Medicare Payment Advisory Commission should delay recommending that Congress require clinical laboratories to report all Medicare test results to the Centers for Medicare & Medicaid Services, says the American Clinical Laboratory Association.

MedPAC plans to recommend in March that Congress require labs to report test results with Medicare claims so that CMS can use the data to establish performance incentives for test-ordering physicians, explained ACLA president Alan Mertz. “We have a lot of concerns with this,” he told *NIR*.

In a January 6 letter to MedPAC chair Glenn Hackbarth, JD, ACLA listed a number of issues that labs would have to resolve before they could routinely report test results to Medicare:

- Labs would have to retool their billing and results reporting systems at considerable cost.
- Medicare should consider lab values in the full context of medical records.
- Labs must first work to finish standardizing their data.
- Labs must comply with HIPAA and state privacy and security laws.
- Many tests yield narrative rather than numerical results.
- Many labs contract out claims submission.

Meanwhile, the College of American Pathologists joined other physician groups in opposing MedPAC’s proposal to set aside at least 1% to 2% of physician payments to redistribute on the basis of performance. 🏠



CDC Calls For Expanded TB Testing Of Lab Workers

In the draft guidelines, CDC expands the potential places where TB infection control standards would apply by adopting the term “healthcare-associated settings.” The old guidelines were aimed mainly at hospital-based facilities

All clinical laboratory workers should undergo baseline screening for tuberculosis upon hire, and annual re-testing should be conducted for those who work in labs where clinical specimens that might contain *M. tuberculosis* are manipulated, advises the Centers for Disease Control & Prevention in draft revised guidelines to prevent TB transmission in the workplace. Comments on the draft are being accepted through February 4, and the agency expects to finalize the document this year.

The draft expands CDC-recommended protections to all “healthcare-associated settings,” a term that encompasses hospital-based and freestanding laboratories and additional outpatient and non-traditional facility-based settings (such as emergency medical services, skilled nursing facilities, and home healthcare). The protections apply to “healthcare workers,” a term that includes all paid and unpaid persons working in these settings who have potential exposure to the bacterium through air space shared with persons with infectious TB.

The draft uses the term “tuberculin skin test” (TST) instead of “purified protein derivative” (PPD) and allows use of the FDA-approved whole-blood interferon assay, QuantiFERON-TB, as an option in place of the TST in TB screening programs for workers. If a lab’s risk assessment indicates that it is “low risk,” annual re-testing is not recommended.

CDC also has revised recommendations for annual respirator training and periodic user seal-checking, previously called “fit testing.” The agency wants lab personnel who use respiratory protections to get the same training on their use and care and the same fit-testing as other healthcare workers. The federal Occupational Safety & Health Administration has established annual fit-testing for healthcare workers, but Congress last year barred OSHA from using funds to administer or enforce this requirement.

The CDC guidelines won’t be directly enforceable like OSHA requirements, Sheila Dunn, head of Quality America (Asheville, NC), tells *NIR*. But the Joint Commission on Accreditation of Healthcare Organizations can cite facilities for failure to follow CDC guidelines, she adds, as can OSHA under its rarely used general-duty clause.

The 1994 CDC guidance was issued to counter a resurgence of TB in the U.S. in the mid-1980s and the early 1990s, including TB and HIV co-infection and the rise of multi-drug resistant TB strains. While that guidance has resulted in diminished risk of healthcare-associated transmission, CDC says the update is needed to reflect shifts in the epidemiology of TB, advances in scientific understanding, and changes in the healthcare system over the past decade. In this context, the agency says, the revised guidelines emphasize maintaining momentum to avert another TB resurgence and to eliminate any lingering threat to healthcare workers. 🏠

Controls Recommended For Clinical Labs

ADMINISTRATIVE

- Annual infection-control plan
- Lab-specific risk assessment
- Biosafety Level 2 for non-aerosol generating specimen manipulations
- Biosafety Level 3 for certain high-risk specimen manipulations

ENVIRONMENTAL

- Meet biosafety requirements for clinical microbiologic labs
- For clinical specimens that could aerosolize, manipulate them only in a certified class I or II biosafety cabinet

RESPIRATORY PROTECTION

- Lab workers who manipulate clinical specimens outside a biosafety cabinet should at least wear N95 disposable respirators



focuson: *Inside The 109th Congress*

Healthcare Groups Anxious To Dodge The Spending Ax

For lab groups, the 20% co-pay for Medicare Part B testing is a specter not to be ignored. The idea is likely to be aired in Congress again as lawmakers look for savings. Imposing the co-pay is tempting because of the dollars at stake. When the co-pay was last debated in the 108th Congress, the savings to Medicare was estimated at more than \$18 billion over 10 years

With President George W. Bush sworn in for a second term and the 109th Congress firmly in Republican control, healthcare provider groups, including clinical laboratory and pathology interests, are anxious to head off any moves in the Nation's Capital to squeeze more savings from their Medicare and Medicaid revenues. In the buzz around Washington, healthcare spending is in serious jeopardy.

The President has vowed to cut the burgeoning federal budget deficit (now pegged at more than \$400 billion) in half by 2009, while making tax cuts permanent, pushing major reforms in Social Security, implementing a pricey new Medicare drug benefit, and footing the costs of military operations in Iraq and Afghanistan. That puts strong pressure on Congress to cut federal spending, and healthcare is a perennial target.

The opening salvo in the battle will come in early February when the President unveils his fiscal 2006 budget request. Congress in turn will fashion a budget resolution setting forth the broad outlines of tax and spending targets, leaving it to individual committees to hammer out the details. The budget reconciliation process is a favorite tool for Congress because it requires only a majority to pass and thus escapes the threat of a filibuster in the Senate.

Possible Cutbacks No Secret

Spending reductions in Medicare and Medicaid have already been aired on Capitol Hill. Mark Hayes, a GOP aide for the Senate Finance Committee, has noted that cutbacks could total \$107 billion over five years. This includes \$55 billion from Medicare and \$27 billion from Medicaid, along with \$25 billion to fix the formula for calculating physician fees under Medicare Part B. But due to the high cost of fixing the formula, attorney Colin Roskey, who is with the Washington, DC office of Alston & Bird, thinks Congress is likely to back another one to two-year increase in physician fees to avoid any projected fee reductions. Lawmakers took this approach in 2003 by authorizing not less than a 1.5% increase in physician fees in 2004 and 2005.

Sources expect a big fight this year over federal Medicaid spending. The White House has been talking about setting limits by switching to a block grant approach, riling congressional Democrats and governors in both parties. Finance Committee member Jeff Bingaman (NM) led Senate Democrats last month in circulating a letter urging the President not to propose capping federal Medicaid spending in his FY 2006 budget request.

And late last month, the National Governors Association wrote to congressional leaders of both parties, saying its members look forward to reforming Medicaid in ways that can save both state and federal dollars, but oppose any reform that is part of the budget reconciliation process, particularly if it involves shifting costs to states.

Provider groups generally focus more on Medicare issues because of the program's precedent-setting nature in the healthcare marketplace. But Medicaid has grown to

Incoming HHS chief Michael Leavitt is expected to play a pivotal role in Medicaid reform. He advocated major changes in this area when he was Utah's governor during the 1990s.

rival Medicare in dollar value. Last month, 26 medical specialty groups and others wrote to the President, urging him not to include in his FY 2006 budget request any caps on Medicaid spending and likewise for Medicare. Lab interests also worry that certain Medicaid cost-cutting ideas could spread, such as Florida Medicaid's effort to mount a winner-take-all competition for independent laboratory services.

Medicare reimbursement cuts already loom for many providers. The Medicare Payment Advisory Commission (MedPAC) agreed this month to propose that Congress cut payments to hospitals for inpatient and outpatient services in 2006 by 0.4 percentage points below the market basket, while freezing prospective payments for home health agencies and skilled nursing facilities. MedPAC did back a 2.9% boost for physician fees, but also proposed establishing, for the first time, pay-for-performance incentives for physicians and other providers.

Lab/Pathology Concerns

Laboratory and pathology interests are warily eyeing their legislative prospects. The Clinical Laboratory Coalition—an alliance of leading lab, pathology, professional/trade groups and companies working on federal issues—has already agreed on particular threats they must counter, including moves to restore a 20% lab co-pay, reduce lab fee caps, extend the fee freeze, or impose competitive bidding on a

wider scale without waiting for the Centers for Medicare & Medicaid Services to complete its lab bidding demo report. Congress required CMS to submit this report by December 31, 2005.

"I'm still hopeful the laboratory industry won't be a target," says Jeff Jacobs, vice president of public policy at the American Society for Clinical Pathology. "But we're worried, given some of the rumors we're hearing about possible cuts."

In other policy areas, lab and pathology groups have a host of priorities for Congress. These include, at a glance:

- Remedying lab personnel shortages is a key issue for the American Society for Clinical Laboratory Science, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association. This year, the Title VII allied health professions training program is up for a five-year

reauthorization. ASCLS, ASCP, and CLMA want lab training to get more money than it has been getting through the annual appropriations process, and they support allied health and lab-specific legislation in the works that would do just that.

- Increasing the Medicare specimen collection fee remains a priority for the American Association of Bioanalysts. The fee, set at \$3, has remained unchanged since the Part B lab fee schedule debuted in 1984. AAB also wants the Food & Drug Administration to close certain waived test loopholes under CLIA. FDA is expected to issue its reworking of CLIA waived test criteria this year.
- ACLA will work to prevent the "substantially in excess" rule, proposed by the HHS Office of Inspector General, from going final and to fight MedPAC's initiative to require reporting of laboratory data to help Medicare pay physicians for

Major Healthcare Issues Likely To Return

- **Medical Liability:** The President has been on the stump this year, promoting caps on malpractice awards, but Senate Democrats who stalled the legislation before have opposed such caps. The betting is that compromise will be needed for the White House to get its way.
- **The Uninsured:** Congress will dismiss any grand schemes from Democrats to cover more uninsured, both on ideology and cost grounds. The more affordable, market-oriented alternatives the President has previously proposed—alternative tax credits, association health plans, and state high-risk pools—may advance further this session.
- **Patient Safety:** This legislation, which would establish a voluntary system for reporting medical errors, passed the House, but got stalled last year in the Senate. The White House has previously endorsed the House-passed version.



performance (*related story, p. 2*). The OIG’s proposed rule would give it the power to exclude from Medicare and Medicaid any provider that charges these programs more than 120% of its usual charges. Many in the lab industry fear this could limit their ability to discount services to physicians and managed care plans.

- The American Association for Clinical Chemistry plans to push for legislation to prevent medical errors, expand newborn screening, and support healthcare information technology.

New Political Dynamics On The Hill

The November elections further strengthened the Republican grip on Congress. In the Senate, the GOP gained four seats to achieve a 55-45 majority (assuming that the lone independent, Jim Jeffords (VT), continues to vote with the Democrats). But Republicans are still five votes short of the supermajority needed to overcome a filibuster on major bills as well as judicial nominations.

At the Senate committee level, one important change is the move by Judd Gregg (R-NH) to chair the Budget Committee. As the former head of the Health, Education, Labor & Pensions (HELP) Committee, he showed an interest in issues such as patient safety and healthcare information technology. In his new post, he could help make sure those initiatives get funded. But he is also known as a “budget hawk,” sources say, suggesting he would be more likely to use his knowledge of Medicare to cut funding. The new HELP chair, Mike Enzi of Wyoming, has said he intends to work closely with ranking Democrat Edward Kennedy (MA), as he has before on issues such as the Needlestick Safety & Prevention Act.

In the House, the GOP enjoys a 232-202 majority. House Republicans will continue to dictate policy, as long as they can avoid divisive internal fractures like the one that almost derailed the Medicare Modernization Act in 2003, when some fiscal conservatives broke ranks to vote against the measure despite strong support for it from the White House and the Hill GOP leadership.

Bill Thomas (CA) remains chair of the Ways & Means Committee, and Joe Barton (TX) becomes the new chair of Energy & Commerce. It appears that Michael Bilirakis (FL)

could lose his seat as chair of the E&C health panel, a prospect that one lab lobbyist rued. He “has always had his door open,” the lobbyist said, noting that last fall Bilirakis killed a proposal for a \$5 Medicare claims processing fee that could have harmed clinical labs. His most likely successor is Nathan Deal (GA) or possibly Charlie Norwood (GA), who was a dentist before he went into politics.

Eyeball To Eyeball On Competitive Bidding

Members of the Clinical Laboratory Coalition raised concerns about competitive bidding in a January 12 meeting with Mark McClellan, MD, PhD, administrator of the Centers for Medicare & Medicaid Services. CMS is at work on a Part B lab bidding demonstration, as required by the Medicare Modernization Act of 2003.

McClellan assured them that he understood the importance of quality and access as competitive criteria and reassured them about plans to keep them informed and involved during the development of the bidding pilot.

He also listened to concerns about the lack of representation of community labs on the Technical Expert Panel advising the contractor selected to design the demo—RTI International (Research Triangle Park, NC). He appeared responsive to the issue of protecting community labs, which typically serve difficult niche markets such as skilled nursing facilities and lack the economies of scale to survive in a bidding war.

For provider groups, the fight in this new Congress could be more of an up-hill struggle than in the previous Congress. Then, most providers had key advantages in warding off the worst as the White House and Congress focused on the elections. Now, there’s a different political landscape, with the President entering his final term and the GOP safe in its Hill majorities for two more years. If deficit-cutting remains a dominant theme, healthcare spending is very much front and center on the chopping block. 🏛️



ACLA, CAP Challenge Reductions In Flow Cytometry Fees

As it now stands, CMS has cut payment by as much as 70% for the professional component and by more than 40% for the technical component, says the College of American Pathologists

Medicare fees for new flow cytometry codes in 2005 are set too low and need to be increased, the American Clinical Laboratory Association and the College of American Pathologists assert in comments to the Centers for Medicare & Medicaid Services on the Part B physician fee schedule (see *NIR*, 26, 5/Dec. 16, '04, p. 8).

ACLA wants fees for two of the codes, CPT 88184 and 88185, to be revised upward retroactive to January 1. The association says that CMS set the payment levels without the benefit of public comment because the CPT Editorial Panel approved the codes after CMS had published its proposed 2005 physician fee schedule. Plus, the low payment levels will cut reimbursement to half the 2004 rate, ACLA notes: "This ... will make it extremely difficult for labs to continue to offer these valuable diagnostic services, which are vital to physicians treating patients with leukemia and lymphoma."

Based on views of eight member companies, ACLA wants CMS to change the practice expense cost inputs used in setting fees by factoring in additional instruments, higher reagent antibody costs, and higher staff costs reflecting the need for lab technologists, not technicians, to handle the technical work.

CAP urges CMS to carefully monitor beneficiary access to flow cytometry services. The College agreed with CMS that professional interpretation is not normally required when flow cytometry is used for immunocompetency and transplant assessment. That's why, in response to concerns CMS raised about rising costs, CAP proposed codes for such interpretation-free assessments, which were later adopted by CPT. 🏠

◆ QUESTION of the M·O·N·T·H

Why is the HHS Office of Inspector General planning this year to investigate Medicare billings for hospital inpatient laboratory services? I see it's in the 2005 work plan.

We asked the OIG what lab services it had in mind, given that inpatient lab testing is generally considered part of a hospital's DRG prospective payment. The OIG said the problem is not on the Part A side, but rather that Medicare Part B is paying for lab tests that are already reimbursed via DRGs (diagnosis-related groups). In 2001, the OIG noted, there was a sharp increase of \$73 million in improper billings.

Where a hospital refers testing for an inpatient to an outside lab, Medicare still pays for it as part of the DRG payment; the outside lab may not bill or seek payment directly from Medicare, but must bill "under arrangements," meaning that it must bill and get paid by the hospital.

Another caution applies to diagnostic services performed three days prior to a hospital admission. If a hospital is paid under prospective payment, those services, including lab testing, that are furnished to a beneficiary by the admitting hospital or an entity it wholly owns or operates (or by another entity under arrangements with the hospital) are considered inpatient services. 🏠



New Efforts Aim To Increase Lab Testing Among Minorities

Blacks, for example, were three times more likely to be hospitalized than whites for diabetes complications and were twice as likely to have limbs amputated, signs that their diabetes was not as closely monitored and controlled, noted the Agency for Healthcare Research & Quality

Two federal initiatives were announced last month to improve healthcare among racial and ethnic minorities, in part by boosting utilization of clinical tests for screening and disease management.

One initiative is a public-private partnership, the National Health Plan Learning Collaborative to Reduce Disparities and Improve Quality. The three-year collaboration—which involves the HHS Agency for Healthcare Research & Quality and nine large health insurers—was fueled in part by AHRQ’s findings last year on the delivery of healthcare services to diabetics. Nationally, only 20% get recommended hemoglobin A1c tests, cardiovascular tests, and other services. “Blacks, Hispanics, and people who live in poor neighborhoods are even less likely to receive these services and consequently are hospitalized more often for complications of diabetes,” the agency said.

In a related development, the Centers for Medicare & Medicaid Services has solicited applications for projects demonstrating cancer prevention and treatment for blacks, Hispanics, Asian Americans and Pacific Islanders, and American Indians and Alaska Natives. The initiative, required by the Benefits Improvement & Protection Act of 2000, partly involves developing strategies for enhancing utilization

of screening services for cancers of the breast, cervix, colon, rectum, and prostate. For details, see www.grants.gov. The contact is Diane Merriman, 410-786-7237. 🏛️

washington WATCH

A prominent figure on the national lab scene and a former top federal and hospital trade executive is leaving for a new top public health job. Utah Gov. Jon Huntsman, Jr., has named **David Sundwall**, MD, to head the state’s health department. Sundwall, who hails from Utah, served from 1994 to 2003 as president of the American Clinical Laboratory Association, where “he did a lot in turning around the reputation of the industry and building this organization,” says current head Alan Mertz. Sundwall stayed on as ACLA’s Senior Medical and Scientific Officer, overseeing CPT issues, while also chairing the Clinical Laboratory Improvement Advisory Committee. He was chief of the HHS Health Resources & Services Administration in 1986-1988 and later headed the Federation of American Health Systems.

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