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It's Down To The Wire Again For Medicare Physician Fee Fix

The wild card for the healthcare agenda in the "lame-duck" session is the outcome of the November elections, with current polls showing the GOP in danger of losing control of one or both Houses. To capture the House, the Democrats need a net gain of 15 seats; in the Senate, a net gain of six seats.

With the "lame-duck" session of Congress slated to open November 9 after the midterm elections, physician lobbies are gearing up for a blitz to get Congress to prevent a 5.1% cut in Medicare fees in 2007. Unless lawmakers act, the cut is to begin January 1, in accord with the formula set by law to calculate fee updates.

When the looming physician pay cut is combined with reduced payment for work and practice expense, the impact on pathology services would be a 10% reduction in total Medicare allowed charges next year. Even without the cut, pathology services would be reduced 5% due to relative value unit (RVU) changes that hit the hardest at the professional component.

For independent lab services payable under the physician fee schedule, the combined impact would be a 2% decline ➥ *p. 2*

Call To Arms: Industry Must Make Its Case To Congress & Regulators

The clinical laboratory industry's top priorities on Capitol Hill should be to stop Medicare competitive bidding and get fair payment for lab testing—including a thaw in the Part B fee freeze and higher fees to match the higher costs of novel genetic testing technologies. That was the message that Thomas Mac Mahon, LabCorp's top executive, emphasized in keynote remarks at the recent Lab Institute 2006, sponsored by Washington G-2 Reports/IOMA.

Mac Mahon urged the industry to send a clear, consistent message to Congress—lab testing "offers impressive value." It influences as much as 80% of medical decisions on treatment and therapy for patients, helps clinicians diagnose disease early and initiate care when therapy is most effective, and saves on more costly care for long-term disease complications.

The industry also needs to keep an eye on the Food & Drug Administration, Mac Mahon said, noting its recent proposal to require premarket review for certain lab-developed genetic tests. But Scott Gottlieb, a senior advisor to the FDA acting commissioner, assured the Institute audience that the guidance targeted a narrow category of "home-brew" tests, adding "We want to remain flexible enough not to impede innovation." For more on key policy issues, see the *Focus*, pp. 3-6.

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Medicare Physician Fee Fix, *from p. 1*

in total allowed charges; without the cut, this category would see a 4% increase, according to projections by the Centers for Medicare & Medicaid Services.

Reimbursement for flow cytometry technical component services would increase in 2007, however, thanks to higher practice expense RVUs that CMS proposes to adopt, based on supplemental data from the American Clinical Laboratory Association. For CPT 88184, the increase would be 22% (assuming a zero update in physician fees); for 88185, it would 33% (assuming no update). The PE RVU increases are the same that CMS proposed last year, then cancelled when it said it found a broader problem with its PE methodology. As a result, the agency scuttled all PE RVU changes and valued all physician services in 2006 at 2005 levels (*NIR, 26, 21/Sep 12, '05, p. 1; 27, 3/Nov 14 '05, p. 1*).

Finding, Funding A Fee Fix

Senate and House health committee leaders have pledged to enact legislation to prevent the 5.1% cut and fix the update problem. They agree with physician groups that an alternative must be found to the current SGR (Sustainable Growth Rate) formula, which would trigger even steeper cuts in coming years—approximately 37% by 2015, while physician practice costs increase by 20%, noted the American Society for Clinical Pathology in its comments on Medicare's 2007 physician fee schedule proposal.

But instead of a long-term SGR fix, the committee leaders are looking at a short-term remedy, most likely a multi-year fix with a zero update or a modest increase tied to physician quality reporting measures.

Lawmakers are sensitive to what any fix would cost and how to pay for it. A one-year fix would cost $13 billion over five years, the Congressional Budget Office has estimated, while replacing the SGR system would cost $218 billion over 10 years. Nonetheless, said the CBO, unless Congress acts soon, beneficiary access to care could be threatened as physicians increasingly decide they cannot afford to accept Medicare patients.

One financing source that members of Congress have mentioned is the $10 billion stabilization fund created by the 2003 Medicare reform law. It is designed to encourage regional PPO plans to enter and stay in the Medicare managed care market, a major priority of the Bush administration, which has repeatedly threatened to veto any attempt to use this fund or any other Medicare Advantage financial incentives for other purposes.

In the search for a longer-term physician fee fix, Congress is looking to the Medicare Payment Advisory Commission for suggested alternatives to the SGR formula. MedPAC staffers have devised some options they say would be "less aggressive" in cutting physician fees, though all would increase spending in the range of 4.2% to 7.3%. Congress asked MedPAC for a report in last year's Deficit Reduction Act. Unlike now, when the update is adjusted by total cumulative spending since the start of the SGR system to a target amount, the options floated by Commission staff are non-cumulative and adjust the update by comparing only previous-year spending to the target. This would produce updates ranging from a negative 4% to a positive 3%.

focus on: *Lab Institute 2006*

Taking The Temperature Of The Clinical Laboratory Industry

Opportunities in the clinical laboratory testing market far outweigh the big challenges, said LabCorp chairman and CEO Thomas Mac Mahon at the opening session of Lab Institute 2006, held September 27-30 by Washington G-2 Reports/IOMA in Arlington, VA.

Scientific advances in molecular diagnostics are revolutionizing the clinical care of patients and are energizing the industry, so it's vital that lab-developed test innovations not be stifled by federal regulation, he told the Institute participants.

The U.S. lab industry—an estimated $45 billion market—is getting a lot of attention from legislators, regulators, and investors, but for very different reasons, observed Mac Mahon, who is retiring at the end of this year after 25 years in the lab business. Wall Street sees us as a solid, innovative growth industry, he said, while legislators and regulators see us through the prism of rising healthcare costs, quality and safety concerns, and initiatives that tie payment to performance outcomes.

On hand at Lab Institute to shed new light on key legislative and regulatory challenges facing clinical labs were Congressman Pete Stark (D-CA), top officials from the Medicare program and the Food & Drug Administration, as well as leading industry executives, researchers, and lobbyists.

Mac Mahon urged the industry to intensify lobbying in Washington to protect its share of Medicare dollars. "If our voice is not as loud and clear as others, we will not get our share of the pie … We need to better communicate the value of what we do in economic and quality terms." We spend less than four cents on the dollar for lab testing, he noted, yet the results shape up to 80% of medical decisions on individual treatment and therapy.

Election Uncertainty

The dominant political mood in the nation's capital is uncertainty over how the November elections and the prospect of a Democratic upset in one or both Houses will impact unfinished healthcare business, said Alan Mertz, president of the American Clinical Laboratory Association. No major Medicare legislation is likely to pass other than a fix to prevent a 5.1% cut in 2007 physician fees and a bill to promote wider adoption of health information technology and electronic health records, he told the Institute. But next year and beyond, Congress will come under increasing pressure to cut Medicare expenditures, he cautioned, and labs could resurface as a target. "If you think it's bad now, it will only get worse, if only because of demographic trends [in the Medicare population]."

Pending health IT legislation has a good chance of passing, Mertz said, though differing House and Senate versions, including provisions significant for the lab industry, have yet to be reconciled. The House-passed bill includes e-health safe harbors for donation of HIT to physician referral sources and a transition for Medicare billing and payment purposes from the ICD-9 diagnosis and procedure coding system to ICD-10 by the year 2010. The Senate-passed bill contains no such

provisions. ACLA is lobbying to ensure that labs are included as providers covered by the e-health safe harbors and that no switch is made to ICD-10 earlier than 2012 to account for cost and complexity concerns (*NIR, 28, 1/Oct 9 '06, p. 4*).

Lab Test Payments

Mac Mahon said the industry must "push back" against any legislative proposal to revive a 20% lab co-pay or make any further cuts in Part B lab fees. Legislative action has already caused lab fee caps to fall from 115% to 74% of the national median, and over the last 15 years, according to an issue brief for Congress prepared by the Clinical Laboratory Coalition, the lab fee schedule has received the full Consumer Price Index update only twice. Aggravating the problem is the current fee freeze through 2008, though there's virtually no chance of a thaw while Congress grapples with curbs on Medicare spending growth.

In remarks at Lab Institute, Congressman Pete Stark (CA), the ranking Democrat on the House Ways & Means health subcommittee, took issue with the notion that labs don't have enough clout to negotiate with Medicare. "Your ability is better than you think. There is at least one lab in every congressional district. Representatives respond to their districts. We're politicians, after all. It's taxpayers' money we are spending, and you should have a say in it."

Lab reimbursement is squeezed on the private side as well, said Greg Richard, president of Accumim Diagnostics, Inc., because health insurers are "applying increased rigor" in their coverage of new technologies, comparable to that now applied to pharmaceuticals. This means increased reliance on peer-reviewed journals, published guidelines, and data on long-term quality and cost outcomes.

For labs, the variation in the coverage criteria that health plans use is a big challenge to surmount, Richard said. While the national Blue Cross/BlueShield Association has a technology assessment center that sets coverage guidelines, the local Blues don't have to go along. Moreover, some health plans have their own technology assessment teams. For labs, the key to success, he concluded, is to work closely with test manufacturers on coverage and reimbursement strategies and involve health plan medical directors and technology assessment teams early in the process.

Lab Competitive Bidding

Despite unanimous opposition from the lab industry, Medicare competitive bidding "is upon us," Mertz noted. The Centers for Medicare & Medicaid Services is moving ahead with the demonstration called for in the 2003 Medicare reform law and has announced a tentative launch for April 2007. Nonetheless, said Mac Mahon, the industry should continue to voice opposition to lab bidding, saying quality and patient access would suffer. In his view, "the best system is the current one where all labs compete side by side for business. We don't want a two-tiered system."

In an update on the bidding project, CMS official Linda Lebovic told Institute participants that the demo design is awaiting final clearance at the Office of Management & Budget. The project is planned to run in two sites for three years each. Upon approval, CMS will announce the sites, issue a bidders' package, and hold a bidders, conference to explain what is required of labs in the demo areas.

The bidding demo is limited to independent lab services (including hospital and physician lab outreach) and will cover all tests on the lab fee schedule, except Pap smears and colorectal cancer screening which are excluded by law. Medicare will pay nothing for fee schedule tests to labs that are required to bid but fail to qualify as winners.

CMS has said it expects to announce winning bidders by January 1. Lab industry groups question whether it's practical to meet this or the April target date, since many technical issues need to be resolved before labs can even begin to compute a bid, Mertz observed, such as the demo site characteristics and guaranteed volume. The industry is urging Congress and CMS not to rush into the demo before major lab concerns are addressed, he said.

FDA & Lab-Developed Tests

On the regulatory front, Mac Mahon said, "We must recognize that the role of the FDA over home-brew tests is evolving." The agency has consistently maintained that it has the authority to regulate home-brews, but has exercised enforcement discretion. But in early September the FDA issued draft guidance signaling that it will require premarket review for certain types of lab-developed tests previously subject only to CLIA high-complexity requirements.

The guidance will have a profound impact on the industry, Mac Mahon emphasized. "We need a practical solution to regulation that does not chill scientific innovation or delay the introduction of new tests of proven clinical value." Can you imagine where we would be, he asked, if we had had to get FDA approval before introducing HIV genotyping, viral load testing for HIV and hepatitis C as well as tests for human papillomavirus and cystic fibrosis?

Inside the FDA there is clear recognition of the great value of genetic testing developments, Scott Gottlieb, MD, deputy commissioner for medical and scientific affairs at the agency, told Institute participants. In his post, he serves as a senior advisor to the acting FDA commissioner, Dr. Andrew von Eschenbach.

"We want to be flexible enough not to impede innovation," Gottlieb stressed. Under the "least burdensome approach," the agency has limited its regulation of lab-developed tests to their commercially available analyte-specific reagents. But as home-brews become more complex, the agency has taken another look at them, he said, and decided to require premarket review for a narrow category called In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), which are used to diagnose breast and other cancers, cardiovascular disease, and Alzheimer's disease, among others.

Summing up the FDA's approach to CLIA-waived testing, top agency official Scott Gottlieb said in answer to a question at Lab Institute, "If a test can be waived, it's good to waive it." While acknowledging that sample surveys have found quality problems in labs that perform waived testing, he said the FDA thinks it safe and important enough to get more testing into more hands and expand patient access.

These tests require special attention, Gottlieb noted, because they combine an assay and an algorithm to compute a binary answer about appropriate treatment and therapy for a particular patient. A large number of data bits generate information about patterns and the algorithm analyzes the patterns. The problem, he said, is that the algorithms are proprietary and complicated, so it is hard for physicians to see how the test results were arrived at and to validate them independently. Tests that look at a single gene or biomarker are not likely to come under the same scrutiny as IVDMIAs, Gottlieb said, because they give a straightforward diagnosis using processes that are transparent to physicians and that can be independently validated.

In issuing the draft guidance rather than relying on warning letters to labs, Gottlieb pointed out, the FDA was concerned that it not create the perception that "we need to bite off more … that is not our intent … we trust labs." The agency also wants to

avoid undue burdens on test makers. "We recognize HIV and other testing areas where labs were able to move quickly to modify and improve tests without clearing new regulatory hurdles."

Contractor Reform

Starting next year, the lab industry will see a big change in who processes and pays their Medicare claims, CMS official Whitney May alerted the Institute audience. In accord with the 2003 Medicare reform law, the current system of Part A intermediaries and Part B carriers is being replaced with a new national system of 15 Medicare Administrative Contractors (MACs) that will combine Part A/B work for their geographic regions.

Consolidation in the lab market will continue to reshape the industry, noted LabCorp chairman and CEO Thomas Mac Mahon at Lab Institute. And not long in afterward, on October 3, his company announced that it has won an exclusive 10-year contract with United HealthCare, the nation's largest payer after Medicare, to serve as United's exclusive national lab, effective January 1, 2007. LabCorp also will develop and manage lab networks in selected areas nationwide and be liable to United for up to $200 million if it cannot contain leakage to outside labs in these areas. Despite the LabCorp contract, United is expected to sign agreements with regional labs, especially where LabCorp does not have a large service presence.

The transition is being handled in stages, said May, who is director of the division of MAC strategy and development at the CMS Center for Medicare Management. The first MAC contract was awarded earlier this year, and a Request for Proposal for three more was released September 29. The law gives CMS six years (until 2011) to competitively bid and transition all Medicare fee-for-service workloads to the MAC system, but CMS aims to complete the job by the end of 2008. The law also requires that MAC contracts be reopened for competitive bidding every five years.

The new A/B MAC structure will not consolidate local lab fee schedules, May pointed out. The local fee schedule that now applies to a lab will remain the same. But MACs will have to consolidate local coverage decisions of the entities they supplant, she noted. These decisions should be consistent across the regions under the MAC, with minimal, if any, variation, she added.

In the latest RFP, CMS is seeking bids for the following MAC jurisdictions:

- ❑ Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas
- ❑ Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska
- ❑ Jurisdiction 12: Delaware, the District of Columbia, Maryland, New Jersey, and Pennsylvania

CMS expects to award these contracts in July 2007. The first A/B MAC contract, announced July 31 of this year, covered Jurisdiction 3—Arizona, Montana, North and South Dakota, Utah, and Wyoming—and was awarded to Noridian Administrative Services in Fargo, ND (*NIR, 27, 20/Aug 14 '06, p. 7*).

Outlook For The Industry

To Mac Mahon, the value of lab testing and the industry will be enhanced by the next generation of advances in proteomics and biomarkers as researchers continue to drill even deeper into the biological and chemical causes of disease and disabilities. "We also face increased consumer expectations due to well-publicized breakthroughs in molecular diagnostics and related therapies. And the power of molecular biology, of genetics, of proteomics, of biomarkers," he concluded, "will revolutionize the way people are treated. We have already seen the first stages for HIV, HCV, HPV, and cervical cancer. We need to move the bar forward and not be stopped by regulation."

FDA Clears First RNA Test To Help Diagnose HIV

A test that detects the RNA (the nucleic acid or genetic material) of the HIV-1 virus has been approved by the Food & Drug Administration to help diagnose primary infection with HIV-1, the main virus that causes AIDS. The test also is approved to confirm HIV-1 infection when antibody screening tests are positive.

The test—the Aptima HIV-1 RNA Qualitative Assay—is manufactured by Gen-Probe in San Diego, CA. "This product offers medical labs the ability to perform a gene-based test for HIV-1 that, until now, was only available as part of a larger kit used to screen blood and plasma donors," said FDA official Jay Epstein, MD, in an October 5 statement. Epstein is director of the Office of Blood Research & Review in FDA's Center for Biologics Evaluation & Research.

The test could be a potential alternative, the FDA said, to the Western blot now used to confirm HIV-1 infection when HIV-1 antibody screening results are positive. The Western blot can be hard to interpret and may not always provide a conclusive result, the agency noted. In such cases, the FDA said, the Aptima test may help in HIV-1 diagnosis. It also can be used in clinical labs and public health facilities to detect HIV-1 infection before the appearance of antibodies.

OIG Wades Into Physician Pay-For-Performance Issues

In a new advisory opinion, the HHS Office of Inspector General said it would not impose administrative sanctions on a managed care company over its agreement with a state Medicaid agency to disburse financial rewards to physicians under the agency's pay-for-performance (P4P) program. The OIG concluded that the company was acting solely as payment administrator for the state.

Washington is enthusiastic for P4P initiatives. The congressional health leadership has signaled that it is anxious to get P4P going for physicians in the Medicare program sooner rather than later and is looking at requiring it as part of legislation to avert a physician fee cut in 2007. Medicare already has P4P for hospital inpatient services, has proposed extending it to outpatient payment updates, and is looking at ways to introduce it for physician services.

The party requesting the opinion sells managed care products and services and won a competitively bid contract with the state Medicaid agency to develop and implement a disease management program for chronically ill beneficiaries with asthma, diabetes, chronic pulmonary disease, coronary artery disease, and congestive heart failure. The program includes financial incentives for doctors who order or recommend certain services to improve patient outcomes and reduce overall medical costs. The company disburses the P4P payments from its own bank account. State law bars the Medicaid agency from paying directly from a state bank account.

The OIG said the anti-kickback statute is not implicated for several reasons:

- The P4P payments are funded by the state.
- The company has no control or discretion over the payments. Further, the payments do not reflect the use of the company's products or services, so there is no nexus between them. "In these circumstances, the company is not using another party's funds to disguise payments for referrals," the OIG concluded.
- The company and the state agency have taken "meaningful steps to minimize any misimpression by physicians that the company is paying them for referrals of Medicaid business."

Virtually All Hospitals Report Quality Data, Says Medicare

In 2007, 11 more measures will be added to the 10-measure starter set of quality data that hospitals report for heart attack, heart failure, pneumonia, and improved surgical care. For more on the data, go to www.cms.hhs.gov/HospitalQualityInits.

Of the nation's 3,490 eligible acute care hospitals, 99% voluntarily reported quality data and thus will receive the full market basket update to their Medicare inpatient payments in fiscal 2007, the Centers for Medicare & Medicaid Services announced September 29.

Hospitals that opted not to report will get 2% less, a much greater impact than last year's 0.4 percentage point reduction, the agency noted. Of those eligible for financial rewards for voluntary reporting, 171 failed to meet the FY 2007 reporting requirements, 143 failed the submission requirements, and 28 chose not to participate. The payment differential for reporting or choosing not to is authorized in the 2003 Medicare reform law and the 2005 Deficit Reduction Act.

Meantime, CMS has run into stiff opposition to its proposal to tie inpatient quality reporting to the 2007 Medicare outpatient payment update. Hospitals that don't voluntarily report the quality data required to get the full market basket update for inpatient payments would also get 2% less in their outpatient update. The American Hospital Association and AdvaMed have told CMS that this linkage exceeds the agency's statutory authority.

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