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Medicare Fee Fix Tops Physicians' Legislative Agenda

Pathology and lab groups also place major priority on getting the new Congress to make permanent the "grandfather" protection under which independent labs can bill separately for pathology TC services to hospital patients.

Pathologists and other physicians escaped a 5% cut in their Medicare fees this year and got a zero update instead from the lame-duck session of the GOP-run 109th Congress. Now, they face an even steeper cut in 2008 unless the Democratic-run 110th Congress intervenes.

Medicare physician fees would be cut a whopping -10% in 2008, according to projections from the Congressional Budget Office, under the SGR (sustainable growth rate) formula used to calculate annual fee updates.

"SGR reform will be huge" this year, Gretchen Schaefer, director of communications for advocacy at the College of American Pathologists, told *NIR*. CAP and other physician groups will renew their push to have lawmakers come up with a long-term fix to the Part B physician payment system; otherwise, physicians will be hit by a steady stream of ever deeper fee cuts over the next few years under the current SGR system. Efforts in Congress last year for SGR overhaul generated much discussion, but no action.

For more on the prospects for physician payment reform and other pathology/laboratory priorities, see the *Focus*, pp. 4-6.

Claims Will Be Paid At Correct '07 Rates, CMS Assures Doctors

Pathologists and other physicians can rest assured that their Part B claims for services on and after January 1, 2007, will be paid at the new rates mandated by Congress, the Centers for Medicare & Medicaid Services says. In enacting the Tax Relief & Health Care Act (P.L. 109-432) last month, Congress approved a zero update to physician fees, averting the 5% cut scheduled to take effect under the statutory update formula.

CMS says it expects local Medicare contractors will be able to timely implement the new rates and does not anticipate the need to reprocess any claims as a result of this change to the physician fee update. In early 2006, the agency did have to undertake a large-scale automatic claims reprocessing after Congress allowed a scheduled 4.4% cut to take effect, then reversed it retroactive to the start of the year (*NIR, 27, 8/Feb 6 '06, p. 1*).

CMS also has extended to February 14 the current enrollment period for Medicare participating physicians, which officially ended December 31 of last year.

Continued on p. 2

INSIDE *NIR*

Correct '07 Rates, *from p. 1*
The extension is needed, the agency says, because the change to the physician fee update could affect a physician's participation decision for 2007. If a physician revises his or her participation status during the extended enrollment period, the election is retroactive to January 1. Those who currently participate and wish to continue to do so need take no action.

By signing a participation agreement, providers and suppliers agree to accept assignment for all covered services to Medicare beneficiaries (that is, they accept the Medicare payment as payment in full and agree not to bill others for any balance).

Participating physicians get 5% higher fee schedule amounts. Also, they have "one-stop" billing for beneficiaries who assign both their Medicare and Medigap payments to participants.

Providers enrolled with Medicare but choosing not to accept assignment for every covered service do not have to sign a participation agreement in order to bill Medicare and receive payment.

FDA Okays New Blood Screening Test For Chagas Disease

The Food & Drug Administration has approved a new test to screen blood donors for a blood-borne parasite that causes Chagas disease, a serious and potentially fatal parasitic infection. The test, called the Ortho T. cruzi ELISA Test System, detects antibodies to the *Trypanosoma cruzi* parasite and is the first such test approved by the FDA.

The test is manufactured by Ortho-Clinical Diagnostics Inc. (Raritan, NJ), a Johnson & Johnson subsidiary. In addition to screening people who donate whole blood, the test is intended for use in screening plasma and serum samples from organ, cell, and tissue donors. The test is not approved, at this time, to diagnose the disease.

According to the FDA, as many as 11 million people are currently infected by *T. cruzi*, most commonly in parts of Mexico, Central and South America. Most have no symptoms or signs of the disease. The infection is usually acquired from the bite of an infected insect, but also can be transmitted through blood transfusion or organ transplants.

Early infection is usually mild and unrecognized, but persists lifelong and may lead to organ damage, particularly of the heart and esophagus, causing an estimated 50,000 deaths annually throughout the world. Infection can also be severe in people whose immune systems are suppressed, such as organ transplant recipients. Chagas disease can be treated successfully if detected soon after infection, but there is no cure once the disease has entered the chronic stage.

The FDA noted that concerns about the potential for Chagas disease in the United States related to blood transfusion and organ transplants have intensified because of the increase of U.S. residents who previously lived in countries where the infection is endemic.

"The availability of this test offers an important new safety measure to protect recipients of blood, organs, and tissues against a potentially very serious, though

uncommon infection," said Jay Epstein, MD, director of the Office of Blood Research & Review in FDA's Center for Biologics Evaluation & Research.

In studies reviewed by the FDA, the test was accurate 99% or more of the time. In field trials of over 70,000 donor samples, the number of individuals falsely identified as positive was very small, the FDA noted, only 2-3 per 100,000 test results.

Pathology RVU Changes = Lower PC Rates, Some TC Gains

Though Congress intervened to block a 5% across-the-board cut in Medicare spending for physician services in 2007, pathologists will still see a steep cut this year. The Centers for Medicare & Medicaid Services projects a 6% cut in total pathology allowed charges, due mainly to changes in practice expense relative value units (RVUs) in the Part B physician fee schedule.

The 6% cut generally means lower reimbursement for the professional component (PC) of the pathology service (the physician's interpretation). The average PC-only payment for the most commonly billed anatomic pathology services will drop by 9% to 10%, according to an analysis by Pathology Service Associates. On the technical component (TC) side, however, codes for flow cytometry and in situ hybridization will increase significantly (*see table*).

CMS cautions physicians that while the 5% across-the-board cut was canceled, this does not "reinstate the payment rates for individual physicians' services at 2006 levels." These rates rise or fall depending on other factors, including revised practice expense RVUs, the five-year review of work RVUs, and a budget-neutrality adjustment that shifts more dollars to primary care. The 6% cut in pathology spending is an average, CMS notes. The actual impact will vary by procedure, specialty, and work mix.

Meantime, pathology and lab groups say the TC increases for flow cytometry are welcome gains after a steep reduction in 2005, when CMS first priced the new CPT system of flow cytometry codes that were introduced that year. Fees for both the TC and the PC fell by as much as 50%. The new CPT system replaced the old per-marker code 88180 with two new codes for the TC (88184-85) and three for the physician's interpretation (88187-89), but not until after CMS had published its proposed rule for the 2005 fee schedule.

Selected Pathology Codes:
Final Non-Facility RVUs, Fees for 2007

CPT Code	*Work RVUs*	*PE RVUs (06/07)*	*Malpractice RVUs*	*Total RVUs (06/07)*	*Fee (06/07)**	*% Chg ***
FLOW CYTOMETRY						
88184, 1st marker	0.00	1.32/1.60	0.02	1.34/1.62	$50.78/$61.39	21%
88185, add'l marker	0.00	0.64/0.85	0.02	0.66/0.87	$25.01/$32.97	32%
88187, read 2-8 markers	1.36	0.45/0.44	0.01	1.81/1.81	$60.59/$60.59	0%
88188, read 9-15	1.69	0.57/0.54	0.01	2.27/2.24	$86.03/$84.89	-1.3%
88189, read 16 & more	2.23	0.75/0.68	0.01	2.98/2.92	$112.93/$110.66	-2%
IN SITU HYBRIDIZATION						
88365-TC	0.00	1.62/1.88	0.02	1.64/1.90	$62.15/$72	16%
88367-TC	0.00	3.50/3.85	0.06	3.56/3.91	$134.91/$148.18	10%
88368-TC	0.00	1.80/2.46	0.06	1.86/2.52	$70.49/$95.50	35%

Source: Final rules, Medicare physician fee schedule, 2006 and 2007. CPT codes © American Medical Assn. *"Pure" fee, rounded up, not adjusted for geographic cost differences, using conversion factor of $37.8975. **Rounded up.

focuson: Healthcare Policy

Key Laboratory, Pathology Priorities For The New Congress

Even before officially taking control of the 110th Congress, Democratic leaders promised to give priority to a broad range of healthcare issues, including coverage of an estimated 47 million uninsured Americans, expanded stem cell research, and changes to the Medicare prescription drug benefit and Medicare managed care program.

Quick action on two of these issues came soon after Congress opened January 4. As part of her "first 100 hours" must-do agenda, House Speaker Nancy Pelosi (D-CA) scheduled votes on bills to expand stem cell research and to allow Medicare to negotiate directly with drug companies for discounts under the Part D benefit. Medicare was barred from direct negotiations when the GOP-run Congress enacted the benefit in 2003. At press time, both measures were expected to easily pass the House, where the Democrats hold a comfortable majority.

Different political dynamics come into play in the Senate. Democrats have a majority of one, and this, combined with the threat of a filibuster or presidential veto, will give the GOP a major say in what legislation gets enacted. Also, with Democrats pledged to reduce federal spending, new Medicare and other health initiatives could be constrained by pay-as-you-go rules, which require that new spending be offset by reductions elsewhere in the budget.

Physician Fee Fix

Replacing the current Medicare physician fee update system is the top priority for pathology and other physician groups, and, as in the last Congress, bipartisan agreement is expected. Physicians staved off a 5% cut in 2007 fees, but under the statutory SGR (sustainable growth rate) formula, a 10% cut is projected for 2008.

The SGR formula has triggered cuts since 2000, though Congress has blocked them. But because the targets have not changed, the action has only delayed the negative updates. "As a result, the cumulative SGR formula calculates even larger payment cuts and a longer period of negative updates," said Dana Kelley, an analyst with the Medicare Payment Advisory Commission (MedPAC) during a January 9 briefing of the panel.

Absent an alternative to the SGR, even steeper cuts are ahead, physician groups warn—about 37% by 2015, while physician practice costs increase by 20%, the American Society for Clinical Pathology says. The ever-deeper cuts will result in more physicians pulling out of Medicare and threatening beneficiary access to care, says the American Medical Association.

The SGR formula is based on a target rate of growth for Medicare spending for physicians' services. It ties reimbursement to a number of factors, including growth in the volume of services relative to growth in the national economy. The SGR compares actual spending to target spending and adjusts the update. When actual physician spending exceeds a target rate, the update is negative.

One overriding concern in enacting a new physician payment system is how to pay for it. Any fix, even a zero update or a modest multi-year increase tied to quality reporting, would be costly. 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.

Democratic health leaders have indicated they prefer to wait to consider an SGR overhaul until Congress receives a report on SGR alternatives it requested from MedPAC. The report is due March 1. MedPAC staff have floated several 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%. MedPAC is not likely to recommend one course of action, chairman Glenn Hackbarth has publicly cautioned. Instead, the report will present a series of changes that could be phased-in over several years, including the advantages and disadvantages of different options, he said.

In advance of the report, MedPAC commissioners aired disagreements at their January 9 meeting about the value of holding down growth in physician services through expenditure targets. While the goal of the SGR was to control the volume of services through targets, it had the opposite effect, as physicians found other ways to maintain or increase their service volume and income—for example, through financial investments in imaging equipment or ambulatory surgical centers.

MedPAC analyst Kevin Hayes noted that the report to Congress will include several options to consider. One would be to repeal the SGR, not replace it with targets, and develop new approaches such as linking payment to quality. Another option would be to use targets but reconfigure the SGR to apply to all of Medicare, be adjusted by region, and give providers an array of options for sharing in gains that result from their improved efficiency.

Bonus Payments & Pay-For-Performance Plans

Any reform of Medicare physician payments is expected to be tied to expanded quality reporting requirements. Congress already has required that a pay-for-performance (P4P) system be implemented to reward doctors who voluntarily report certain quality measures to Medicare. As a first step, Medicare is to begin making bonus payments of 1.5% to reporting physicians, starting July 1 of this year and running through December 31.

Physicians who report quality data will receive about $300 million in bonus payments, according to the CBO. Doctors who account for about two-thirds of Medicare physician spending will qualify. At this point, pathologists are not included, according to the College of American Pathologists.

The increased spending under this and other Medicare changes will be offset in part by cutting back the Medicare managed care stabilization fund included in the 2003 Medicare reform law, saving $6.5 billion, said the CBO.

Cytology PT

The College of American Pathologists will continue to pursue a legislative solution to the "flawed" CLIA cytology proficiency testing program currently enforced by the Centers for Medicare & Medicaid Services. CAP says the program, which operates under 1992 rules, is outdated and out of touch with changes in cytology practice. Late last year, bills championed by CAP to overhaul the program were introduced in the House and the Senate (H.R. 6133, S. 4056). In 2005, CAP also backed a House-passed bill that called on CMS to suspend the current program and implement specific changes.

Meantime, CMS has announced that a proposed revision of the cytology PT rules won't be available until July. A federal advisory panel, CLIAC, last June recommended revisions, including scoring and frequency of testing.

For 2007, pathologists and cytotechnologists continue to be subject to testing requirements under the current rules.

Competitive Bidding

The Clinical Laboratory Coalition has been lobbying legislators and regulators on the controversial Medicare competitive bidding demonstration for independent lab services. Coalition members unanimously oppose the idea of applying competitive bidding to lab services, saying it treats the services as a commodity rather than a complex service. ACLA, which is part of the coalition, would like to see legislation to stop CMS from going ahead with the lab bidding demo, its president Alan Mertz told *NIR*.

At press time, the last official word from CMS was that the demo design was still awaiting final clearance from the Office of Management & Budget. The proposed sites had yet to be announced. The demo is still set for an April 2007 launch, as CMS noted in instructions to contractors, but this timeframe could be pushed forward if more time is needed to solicit bids and choose winning labs.

Lab groups expect a sympathetic ear on Capitol Hill to their concerns about Medicare competitive bidding. Both Reps. Charles Rangel (NY), head of the House Ways & Means Committee, and Pete Stark (CA), head of its health subcommittee, have said they think competitive bidding for lab services is a bad idea. What this might mean for the current CMS project is unclear. The leaders could use their oversight authority to revisit the issue or at least extend the rollout of the lab bidding demo while lab industry concerns are addressed.

Expanded Controls On 'Home Brew' Tests

In this area, laboratory and pathology groups are keeping an eye on two fronts—the Food & Drug Administration and the office of Sen. Edward Kennedy (D-MA), who chairs the Health, Education, Pensions & Benefits (HELP) Committee.

The FDA announced last September that it was tightening the rules for in-house developed (home brew) lab tests and will require premarket review for new types of DNA tests that combine assays and algorithms to produce results tailored to a specific patient. In draft industry guidance, the FDA said it will regulate tests known as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), and most will be subject to class II and III special controls. Examples include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease, among others.

The FDA requested public comment on the guidance and recently extended the deadline to March 5, 2007. The agency also has scheduled a public meeting on February 8 to solicit more input.

Meanwhile, Kennedy's office continues to work on a draft bill to regulate home brew tests. A draft that surfaced last year would have defined virtually all home brews as class II devices, requiring labs to submit a 501(k) application for each test developed in-house. In other provisions, FDA review would proceed on a volume basis, rather than a risk basis, and tests in the lowest 20% of volume would be exempt from FDA review (molecular diagnostics would fall in this category).

Pathology TC 'Grandfather' Protection

Making this protection permanent is a legislative goal for the College of American Pathologists, the American Clinical Laboratory Association, and other provider groups. Last year, Congress approved a one-year extension, through 2007.

The "grandfather" protection allows qualified clinical labs to be paid by Medicare for the technical component of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999. CMS recently notified local Medicare contractors that it was canceling its plan to eliminate the protection as of January 1, 2007 (*related story, p. 7*).

States Get Financial Incentive To Beef Up False Claim Laws

The clinical laboratory industry knows all too well the legal hazards posed by the federal False Claims Act (FCA). Throughout the 1990s in particular, the government wielded the Act to wring multimillion-dollar settlements from large labs nationwide to resolve allegations of fraudulently billing Medicare and Medicaid for medically unnecessary testing.

Now, under terms of the Deficit Reduction Act of 2005, states have a new financial incentive to align their false claims statutes with the FCA requirements. If a state false claims statute meets certain requirements, the state is entitled to an increase of 10 percentage points in its share of any amounts recovered under a state action brought under such a law. Effective January 1, 2007, the state must, in order to qualify, have in effect a law that:

- ❑ Establishes liability to the state for false or fraudulent claims described in the FCA with respect to any expenditures related to state Medicaid programs.
- ❑ Contains provisions that are at least as effective in rewarding and facilitating *qui tam* (whistle-blower) actions.
- ❑ Contains a requirement for filing an action under seal for 60 days with review by the state Attorney General.
- ❑ Contains a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.

The HHS Office of Inspector General has set forth guidelines for how it will review state false claims statutes in line with these requirements (*Federal Register*, August 21, 2006). According to the latest posting on the OIG's Web site, ten states had requested such a review. Three meet the requirements—Illinois, Massachusetts, and Tennessee. Seven did not—California, Florida, Texas, Nevada, Indiana, Louisiana, and Michigan—but pending certain changes could get another review. Details are posted at *www.oig.hhs.gov/fraud/falseclaimsact.html*.

♦ MEDICARE CLAIMS A·D·V·I·S·O·R·Y

CMS Rescinds Notice Ending Pathology TC Protection

In a January 5, 2007 transmittal, the Centers for Medicare & Medicaid Services made it official—the agency told its local contractors to disregard previous instructions and continue to make Part B payments to qualified independent laboratories for the technical component of pathology services to hospital inpatients and outpatients for another year (CMS Change Request 5468).

The "grandfather" protection for such billings expired at the end of 2006, and CMS had told contractors last September to be ready to eliminate it as of January 1, 2007. But under the Tax Relief & Health Care Act (P.L. 109-432), Congress extended the protection for an additional year, through December 31, 2007.

The "grandfather" provision applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed ending such billings on grounds that Medicare pays for the TC as part of the hospital's DRG payment. The "grandfather" protection applies to the hospital, not the lab, CMS has noted. Hospitals may switch labs without losing the protection; independent labs cannot switch hospitals and still be protected.

Down Syndrome Screening Urged For All Pregnancies

The syndrome is caused by the presence of an extra copy of chromosome 21 and is characterized by congenital heart defects and mental retardation. The risk is about one case for every 1,300 births in young women, but increases sharply beyond age 35.

The American College of Obstetricians & Gynecologists (ACOG) is recommending that all pregnant women, regardless of age, be offered screening for Down syndrome and other fetal chromosomal abnormalities in the first trimester of pregnancy, according to revised clinical management guidelines published in this month's issue of *Obstetrics & Gynecology*.

ACOG's recommendations are based on new markers and strategies for Down syndrome screening, including nuchal translucency (ultrasound) testing. The guidelines call for a combination of a blood test to screen for biochemical markers of Down syndrome and a nuchal translucency test to be offered to all pregnant women during the first trimester.

Historically, maternal age (35 or older at the time of delivery) has been used to identify women at highest risk of having a child with Down syndrome, and these women have been offered genetic counseling and amniocentesis or chorionic villus sampling (CVS). In the mid-1980s, biochemical serum screening for women under 35 was introduced based on how levels of maternal serum alpha-fetoprotein (AFP) and/or human chorionic gonadotropin (hCG) are affected by Down syndrome pregnancies. This testing was previously performed in the second trimester.

washington WATCH

On a Personal Note

Here, we typically shine the spotlight on what's doing with politicians, administration officials, and industry lobbies. This time, we'd like the light to shine on a dedicated public servant we've known for a long time.

Judy Holtz has retired, effective January 3, from the HHS Office of Inspector General, where she began her career in 1977. Most recently, she was acting director for external affairs, responsible for managing all OIG activities with Congress, including hearings, requests, and inquiries and oversight of preparation of OIG rules and *Federal Register* notices.

For us, she was for so many years, as chief public affairs officer, the first face we encountered at the OIG and always amiable. She took her job seriously, and we always got prompt answers to our requests for accurate and reliable information.

Thanks, Judy, for your collaboration over the years. We wish you all the best in retirement.

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