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Time Running Out For Medicare Physician Fee Fix

In addition to the 5% fee cut, Medicare will end the "grandfather" protection for certain pathology TC billings by independent labs, unless Congress says otherwise.

Physician lobbies are intensifying their push to get Congress to act during the post-election "lame duck" session to prevent a 5% cut in Medicare physician fees scheduled to begin January 1, 2007. And there's only a short time left to achieve this goal.

Congress has recessed for Thanksgiving, and when it reconvenes in December, lawmakers will have roughly two weeks to wrap up work before closing the second and final session of the 109th Congress prior to the Christmas and New Year holidays.

In addition to lobbying against the physician fee cut, pathology groups are urging Congress to make permanent the "grandfather" protection for pathology technical component billings by independent labs for Medicare services to hospital inpatients and outpatients. The protection expires at the end of this year, and unless Congress intervenes, the Centers for Medicare & Medicaid Services will prohibit separate Part B payment for the pathology TC billings as of January 1.

For more on the outlook for health policy issues as Democrats prepare to assume control of Congress, see the *Focus*, p. 4.

CMS Finalizes Rules For Pricing New Lab Tests

As required by the 2003 Medicare reform law, the Centers for Medicare & Medicaid Services has codified in final regulations a process for obtaining public input on how fees are established for new test codes added to the Part B lab fee schedule each year. The agency announced the codification in the final 2007 Medicare physician fee schedule released November 1.

As proposed earlier this year, CMS has adopted the current process it uses to set fees for new tests, a process in place since 2002, in accord with the 2000 BIPA statute (*NIR, 27, 21/Sep 11 '06, p. 2*). The agency also clarified in the final rules the two methods—"cross-walk" and "gap-fill"—used to set payment levels for new tests. And for the first time, CMS has committed itself to publicize its rationale for final lab fee decisions and its response to comments from affected parties.

Under the finalized process, CMS each year will (as it does now):

- ❑ Make available to the public (via the Internet or other mechanisms) a list of new test codes to be added to the lab fee schedule for the following calendar year (typically, CMS makes the list available in June). ➥ *p. 2*

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- ❑ At the same time, publish a *Federal Register* notice of a public meeting that CMS officials will convene to receive input on how to price the new codes.
- ❑ Hold the public meeting not less than 30 days after the notice (typically in July).
- ❑ Based on comments submitted, release proposed fee decisions for further comment (typically in September).
- ❑ Announce final fee decisions, including the rationale used, related data, and response to comments (typically by early to mid-November).

Several comments requested more time between the date that CMS posts the new codes (and simultaneously publishes notice of the public meeting) and the date that the meeting is held. CMS said this would be difficult because of a tight timetable for finalizing the lab fee schedule and getting it to Medicare contractors with sufficient time to implement the changes by the start of the year. The process is triggered, CMS said, when the CPT Editorial Panel makes available the list of new test codes. This typically occurs in May, and CMS follows up with an Internet posting in June and a *Federal Register* notice of the July public meeting. The final fee schedule is prepared in October and sent to contractors by early to mid-November, giving them only six to eight weeks until required implementation.

Fee-Setting Methods

CMS has stated in the final regulations the two methods it uses to determine fees for new lab tests.

- ❑ *Crosswalk:* Used when a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Payment for the new test is made at the lower of the crosswalk to the local fee schedule amount for the test or the national cap. Most lab fee schedule codes are paid at the national cap.
- ❑ *Gap-fill:* Used when no comparable, existing test is available. Local Medicare contractors set a fee for the first year that the new test is on the lab fee schedule. They base the fee on local pricing patterns, such as charges for the test, routine discounts, the resources needed for the test, and what other payers pay.

To comply with the 2003 Medicare reform law, CMS will eliminate payment of new gap-filled tests at a carrier-specific amount after the first year and subsequently pay for them at their national Medicare fee cap. CMS says this will result in consistent payment in geographic areas for a new test, using the median of the carrier gap-fill amounts. Further, the agency does not propose to allow for formal reconsideration of a fee decision, regardless of method used, but in response to comments, says it may crosswalk a test if it determines that carrier-specific gap-filled amounts will not pay for the test appropriately.

Date Of Service Revised For Stored Specimens

Medicare's general policy on the date of service (DOS) for clinical laboratory tests is the date the specimen was collected—or if collected over two calendar days, the date the collection ended. For lab tests that use a stored ("archived") specimen, the DOS generally is the date the specimen was obtained from storage.

Medicare defines an archived specimen as a specimen stored for more than 30 cal-

The DOS policy modification on archived specimens is finalized in the Medicare 2007 physician fee schedule released earlier this month.

endar days before testing. For lab tests using a specimen stored 30 days or less, the DOS is the date the specimen was collected.

In situations where a specimen is taken while the patient is being treated in the hospital, but then later used for a lab test after the patient has been discharged, the DOS may affect payment because if it falls during an inpatient stay or outpatient procedure, payment for the test is bundled with the hospital service and is not paid separately under the Part B lab fee schedule.

Starting in 2007, the Centers for Medicare & Medicaid Services is modifying the stored specimen requirements, including for use in chemotherapy sensitivity testing. The DOS is the date the specimen is obtained from storage, even when obtained less than 31 days from the date it was collected, without violating the unbundling rules as long as the following conditions are met:

- ❑ The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- ❑ The specimen was collected while the patient was undergoing a hospital surgical procedure.
- ❑ It would have been medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted.
- ❑ The results of the test do not guide treatment provided during the hospital stay.
- ❑ The test was reasonable and medically necessary.

In setting the 14-day standard, CMS said it wanted to distinguish post-discharge tests legitimately performed on stored specimens from the care the beneficiary received in the hospital. Tests for cancer recurrence and therapeutic interventions can be so distinguished, CMS said. Specimens typically are live cancer cells collected at the time of the procedure, cultured at the lab, and ultimately tested.

Senate Bill Introduced To Replace CLIA Cytology PT

Sen. Johnny Isakson (R-GA) on November 15 introduced legislation that would replace the existing cytology proficiency testing program under CLIA (the Clinical Laboratory Improvement Amendments). Isakson is a member of the Health, Education, Labor & Pensions Committee. His bill, S. 4056, mirrors House legislation (H.R. 6133) introduced in September by Rep. Tom Price (R-GA).

Both measures would do away with annual PT of pathologists and laboratory professionals who do Pap smear screening and diagnosis, and as an alternative, require annual continuing medical education that provides opportunities for improving screening and interpretation skills. The College of American Pathologists, which is spearheading the lobbying campaign for the legislation, says this approach is modeled on that used by the Food & Drug Administration to assure mammography quality. CAP is opposed to the existing CLIA cytology PT program, saying it is based on outdated science and clinical practice and needs a fundamental overhaul.

Meantime, the Centers for Medicare & Medicaid Services has said its work on a proposal to revise CLIA cytology PT rules will not be completed until at least February 2007. As a result, PT testing next year will continue under the current rules (*NIR, 28, 1/Oct 9 '06, p. 3*).

focus on: Healthcare Policy

Outlook For Health Priorities In Congressional Power Shift

While weighing final action on key spending and tax credit bills, Democrats and Republicans are busy with essential housekeeping, including organizing their leadership teams to drive the party's priorities in the next Congress (see table, p. 5).

Flush from their victory in this month's midterm elections, Democratic health leaders have been airing a host of healthcare policy changes they want to make when they take control of the 110th Congress in January. But the GOP will still have a major say in what legislation gets enacted, given the Democrats' narrow majority and the President's veto power.

For the moment, however, Democrats and Republicans alike must decide how they want to proceed on major unfinished business during the "lame duck" session, where the GOP remains in the driver's seat. A "must pass" item is legislation to keep funds flowing to federal agencies. Health & Human Service programs now operate under a continuing resolution at current-year spending levels, since Congress has yet to enact an HHS spending bill or opt to keep HHS going via a further continuing resolution. Beyond that, the outlook depends on how much the parties can and want to do before closing shop in December.

Physician Fee Fix

An appropriations measure or an omnibus bill could be the vehicle for preventing Medicare from instituting a 5% cut in physician payments as of January 1, 2007. The cut is required under the statutory fee update formula. When actual physician spending exceeds a target rate, the update is negative. Physician groups are unanimous in urging lawmakers to scrap the SGR (sustainable growth rate) factor in setting fee updates. Without an alternative, these groups say, even steeper cuts are projected in coming years—about 37% by 2015, while physician practice costs increase by 20%, the American Society for Clinical Pathology has told the Centers for Medicare & Medicaid Services. The ever deeper cuts will result, the American Medical Association has warned, in more physicians pulling out of the program and threatening beneficiary access to care.

There is bipartisan agreement that the SGR system must be overhauled, but Capitol Hill analysts expect Congress to hold off on this until next year. In the short term, lawmakers have a number of options—prevent the cut and grant a zero update (in effect, freezing physician fees at 2005 levels) or adopt a multi-year fix with modest increases, possibly tied to some quality reporting rewards.

The big hook in any fee fix is how to pay for it, Jason DuBois, vice president of government relations for the American Clinical Laboratory Association, tells *NIR*. Any fix, even a zero update like that in place this year or a modest multi-year increase tied to quality reporting, would prove 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.

Replacing The SGR System

Incoming 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 the Medicare Payment Advisory Commission (MedPAC). The report is due in spring 2007. But MedPAC is not likely to recommend one course of action, said chairman Glenn Hackbarth at a Commission meeting earlier this month. Instead, the report most likely will present a series of changes that could be phased-in over several years, including the advantages and disadvantages of different options, he noted.

"Grandfather" Protection For Pathology TC Billings

Pending legislation (H.R. 6030, S. 3609) would make permanent this protection—due to expire at the end of this year—and, if enacted, a likely vehicle is a spending bill or resolution. Securing the protection is vital to a wide number of affected groups, DuBois said, which have been lobbying for the protection, including the Rural Healthcare Coalition, the American Hospital Association, the College of American Pathologists, the American Society for Clinical Pathology, and ACLA. Unless Congress steps in, CMS plans to eliminate the protection.

Democratic Win = Leadership Changes On Key Health Committees

Committee	*In Line To Become Chair*	*Current Chair*
HOUSE **Energy & Commerce** —Health Subcommittee	John Dingell (MI) In position to vie for the chair: Edolphus Towns (NY), Frank Pallone Jr, (NJ), Anna Eschoo (CA)	Joe Barton (TX) Nathan Deal (GA)
Ways & Means —Health Subcommittee	Charles Rangel (NY) Pete Stark (CA)	Bill Thomas (CA), retiring Nancy Johnson (CT), lost bid for re-election
Appropriations — Subcommittee on Education, HHS & Labor	David Obey (WI) David Obey (WI)	Jerry Lewis (CA) Ralph Regula (OH)
SENATE **Health, Education, Labor & Pensions**	Edward Kennedy (MA)	Mike Enzi (WY)
Finance	Max Baucus (MT)	Charles Grassley (IA)
Appropriations —Subcommittee on Labor, HHS & Education	Robert Byrd (WV) Tom Harkin (IA)	Thad Cochran (MS) Arlen Specter (PA)

The "grandfather" protection allows independent 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 contends that the TC is reimbursed under the hospital's DRG payment, and labs should seek payment from the hospital, not Medicare Part B. Ending the protection would be particularly devastating to small and rural hospitals, CAP has warned, because they cannot afford to do the work in-house and must contract it out.

HIT & E-Health Legislation

Expect no further action here until next year, say industry sources. The House and the Senate approved separate bills to promote wider use of health information technology and e-health records, but have been unable to resolve differences. This has helped clinical labs "dodge the bullet" on the ICD-10 transition, at least legislatively, DuBois noted, though CMS has indicated it could require the switch administratively. The House bill called for a nationwide transition from the current ICD-9 diagnosis and procedure coding system by October 1, 2010. The Senate-passed version contained no ICD-10 provision.

Changing Leadership Lineup

The Democrats poised to assume leadership of key health committees are well briefed on lab industry issues, says veteran lobbyist Don Lavanty. For example,

Enactment of the Democrats' healthcare priorities faces formidable odds, notes an election-year analysis by the law firm of Patton Boggs, LLP (Washington, DC). Progress will hinge on "a narrow majority, presidential veto power, industry resistance, and significant fiscal constraints."

both Reps. Charles Rangel (NY), in line to head the House Ways & Means Committee, and Pete Stark (CA), in line to head the health subcommittee, have said they think competitive bidding for laboratory services is a bad idea. What this might mean for the current CMS demo 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. CMS has announced an April 2007 start date for the rollout and said it would identify winning labs by January 2007. Lab groups protest that the timeline is not practical since many technical issues must be resolved. At press time, the Clinical Laboratory Coalition was to meet with CMS project officials for further discussions.

The incoming head of the House Energy & Commerce Committee, John Dingell (MI), is known, Lavanty said, for advocating greater oversight of the Food & Drug Administration and the CMS-run CLIA lab regulatory program vs. the GOP reliance on corrective marketplace mechanisms. Also, he said, the incoming Democratic majorities on the appropriations side include members supportive of lab workforce issues, including addressing the growing shortage of qualified personnel and new support for lab personnel education and training.

Outlook For 2007

The day after the voters gave them control of Congress, Democratic leaders outlined some broad healthcare priorities they want to bring to the fore next year, including expanding coverage to uninsured Americans (an estimated 47 million), stem cell research, and changes to the Medicare drug and managed care programs.

Prescription Drug Benefit: Currently, Medicare is barred from directly negotiating prices for Part D prescription drugs with pharmaceutical makers or interfering in price negotiations between drug makers and Part D drug plans. Democrats favor lifting the prohibition. This would likely accompany creation of a standard federal benefit to compete with private plans.

Doughnut Hole: Democrats aim to shrink this gap in Part D coverage. The standard drug plan has a $250 deductible and 25% coinsurance for the first $2,250 in drug costs. For the next $2,850, no benefits are paid. Enrollees continue to pay premiums, but shoulder 100% of the costs. After this coverage gap, the drug plan covers catastrophic costs, with the beneficiary liable for 5%. Part D plans offer various coverage and cost options, including doughnut hole coverage.

Reducing Managed Care Payments: Democrats want to see if Medicare is overpaying Medicare Advantage plans, compared with what traditional Medicare fee-for-service spends for comparable beneficiary care. They also have called for elimination of the managed care stabilization fund.

The White House already has warned that the President would veto bills that allow Medicare to negotiate drug prices directly, cut funding for Medicare managed care plans, and promote stem cell research.

Much of next year's congressional debate on healthcare will be to set the stage for the 2008 elections. In remarks at the recent Lab Institute 2006, Congressman Stark said he does not foresee anything beyond minor healthcare initiatives next year despite the Democratic gains, though the party can use its oversight power to frame the legislative calendar, hold committee hearings, and request studies.

♦MEDICARE COVERAGE A·D·V·I·S·O·R·Y

ICD-9 Changes To National Policies For Lab Tests

Effective January 1, 2007, Medicare will cover additional ICD-9 diagnosis codes under its National Coverage Determinations (NCDs) for 23 of the most frequently ordered clinical laboratory tests. For lab tests covered under the NCDs to be payable, active valid ICD-9 codes must be used on Part B lab claims to document that the testing is medically necessary. Lab billing systems should implement the 2007 update as of January 1. There is no grace period to shift to new codes.

ICD-9 codes have been added to the NCDs below, as follow (CMS Change Request 5384):

- ❑ Prothrombin Time ..... V58.83 (Encounter for therapeutic drug monitoring)
- ❑ Partial Thromboplastin Time V58.83
- ❑ Thyroid Testing ..... 783.0 (Anorexia); 793.99 (Other nonspecific abnormal findings on radiological and other exams of body structure)
- ❑ Fecal Occult Blood Test ..... 995.20 (Unspecified adverse effect of unspecified drug, medicinal and biological substance)

The latest update makes few changes, unlike the October 2006 update which made additions and deletions to all lab NCDs (*NIR, 27, 22/Sep 25 '06, p. 7*).

Wealthier Seniors To Pay More In '07 Premiums

Starting January 1, 2007, the Medicare Part B monthly premium will be subject to means-testing for the first time, as required by the 2003 Medicare reform law. The higher a beneficiary's annual income, the more he or she will pay in premiums for the standard healthcare benefit. An estimated four to five million beneficiaries will pay more than the base amount next year, says the Centers for Medicare & Medicaid Services.

In 2007, the Part B premiums will range from a base of $93.50 per month for individuals with income of $80,000 or less to a high of $161.40 per month for individuals with income of $200,000 or more. On top of this, beneficiaries will see higher out-of-pocket expenses next year for Part A and Part B deductibles.

The Social Security Administration has ruled that means-testing of the Part B premium is linked to work income—where a decrease or increase is regarded by the agency as a major "life-changing event"—but not to income from investments that fluctuate, such as dividends, which the agency says are not events with a potentially permanent effect on income (*Federal Register*, October 27, 2006). The taxable year to be used for the premium sliding scale is "that beginning in the second year preceding the year involved." For 2007, for example, taxable year 2005 will be used to calculate the premium.

2007 Part B Deductible, Coinsurance & Premium Amounts

Deductible $131/yr
Coinsurance ..... 20% (not applicable to lab testing)

Premium Table

Premium/month	*Individual Income*	*Combined Income (Married)*
$ 93.50	$80,000 or less	$160,000 or less
$105.80	$80,000.01 - $100,000	$160,000.01 - $200,000
$124.40	$100,000.01 - $150,000	$200,000.01 - $300,000
$142.90	$150,000.01 - $200,000	$300,000.01 - $400,000
$161.40	$200,000.01 or more	$400,000.01 or more

Source: CMS Change Request 5345.

Medicare Opens Enrollment Period For 2007

November 15 is the start date for eligible physicians, practitioners, and suppliers to enroll in, or terminate their enrollment in, the Medicare participation program for 2007. The decision must be made by December 31 of this year. 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 provided 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.

The majority of physicians and other providers have chosen to participate in Medicare. During 2006, 93% of all physicians, practitioners, and suppliers billed under Medicare participation agreements.

Those 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.

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