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Pathologists, Labs Face Big '07 Medicare Pay Changes

Congress is likely to prevent a physician fee cut in 2007, medical lobbyists say, but it's still unclear to what extent. For 2006, lawmakers opted to freeze physician fees at previous-year levels.

Medicare spending for physician services will be cut by 5.1%, starting January 1, 2007, according to the latest projection by the Centers for Medicare & Medicaid Services. The agency announced the looming cut, plus changes to other physician payment policies, in its proposed 2007 Part B physician fee schedule rule (*Federal Register*, August 22, 2006). The impact will vary by physician specialty and patient mix.

For pathologists, the combined impact of the cut and the revised practice expense and work relative values would result in a 6% reduction in allowed charges. For independent clinical laboratories that bill for pathology and other physician fee schedule services, the result would be a 2% reduction. For diagnostic testing facilities, the cut would be steep—down 25%.

Flow cytometry will see increases, however, despite the projected cut (and even with a zero update), thanks to higher practice expense relative values for the technical component of CPT 88184 and 88185. With the cut, the increases would be about 16% and 27%, respectively; with a zero update, 22% and 33%.

The CMS rule also calls for tighter curbs on "pod" labs and an end to "grandfathered" pathology TC billings. For more on these and other policy proposals, see the *Focus*, pp. 4-6.

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AAB Plans Lobbying Blitz On Bidding Demo

The American Association of Bioanalysts is planning a "Capitol Hill Day" on September 27 to brief members of Congress on continuing concerns with Medicare's planned lab competitive bidding demonstration. AAB is urging members of its National Independent Laboratory Association section and other lab and nursing home interests to participate.

The event will be devoted to "real-life" issues raised by the Part B demo for independent lab services, AAB administrator Mark Birenbaum told *NIR*. The demo's currently scheduled launch date is April 1, 2007 (*NIR, 27, 20/Aug 14 '06, p. 1*). At press time, the site and other specifics had yet to be officially announced.

"More time is needed to look at all the issues," Birenbaum said, "including the wisdom of doing the demo, the impact on beneficiaries, and the problems we've had in communicating with CMS." ➥ *p. 2*

AAB Plans, *from p. 1*

And with CMS yet to disclose key information on the demo site and volume/intensity of services, he added, labs cannot be expected to calculate reasonable bids for over 1,000 test codes in a short time.

CMS has said it intends to identify winning bidding labs in the demo site by January 1. To the American Clinical Laboratory Association, this is an overly ambitious, flawed timetable, given the many unknowns about the demo. ACLA advocates an extension of the demo start date to allow for more consideration of key lab issues, including time needed to prepare complex bids.

For durable medical equipment bidding, CMS gave providers 14 months to prepare between the time the site was announced and the winners were identified, ACLA said in an August 28 statement. In contrast, labs would have only two-three months maximum to get ready.

The lab demo is designed to cover all Part B lab fee schedule codes, except Pap smears and colorectal cancer screening which are excluded by law. CMS also would exempt new test codes added to the fee schedule during the demo's three-year duration. Hospitals and physician office labs doing outreach work will be subject to the demo.

While pressing its concerns about the demo's mechanics, the clinical laboratory industry has a fundamental objection to use of the bidding concept for lab services, saying it treats lab services as a commodity, whereas in practice these services are at the core of a complex medical process that informs some 70% of medical decision-making.

McClellan Resigns Top Spot At CMS

Mark B. McClellan, MD, announced September 5 that he is resigning as administrator of the Centers for Medicare & Medicaid Services. McClellan said he plans to take a break with his family before tackling work in the public policy sector in such likely areas as incentives for healthcare quality and curbs on the growth in healthcare costs.

McClellan took the helm at CMS in 2004, and his tenure was marked by major changes to the Medicare program, including implementation of the Part D benefit for outpatient prescription drugs, financial rewards for providers that reported on quality measures under pay-for-performance models, and public disclosure by providers of their costs and charges.

Before going to CMS, McClellan was commissioner of the Food & Drug Administration and served on the White House Council of Economic Advisors.

His successor at CMS has not been named, but one candidate cited in the media is deputy administrator Leslie V. Norwalk.

CMS Proposes Rules For Pricing New Lab Tests

As required by the 2003 Medicare reform law, the Centers for Medicare & Medicaid Services is proposing to establish a formal regulatory rulemaking process for pricing new CPT codes to be added to the Part B lab fee schedule each year. The agency also is defining the two methods it uses to determine lab test payment levels—"cross-walk" and "gap-fill."

And for the first time, CMS would commit itself to publicize its rationale for final lab fee decisions and its response to comments from affected parties.

Fee-Setting Process

Under the proposed process, CMS each year would (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, this is done in June).
- 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.

*The agency essentially would codify in regulations the current public process it has had in place since 2002 to receive pricing input from affected parties, in accord with the BIPA 2000 statute. The pricing procedures are detailed in Medicare's proposed physician fee schedule rule for 2007 (*Federal Register*, August 22, 2006).*

- Hold the public meeting 30 days after the notice (typically in July).
- Based on comments submitted, release its proposed fee decisions for further comment (typically in September).
- Announce final fee decisions, including the rationale used, related data, and response to comments (typically, fees are finalized in late October).

Fee-Setting Methods

CMS is proposing to state in regulations the two methods it now 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 proposes to eliminate payment of new gap-filled tests at a carrier-specific amount after the first year and subsequently pay for them at the national cap. CMS says this "would result in consistent payment in geographic areas for a new test using the median of the carrier gap-fill amounts."

Bush Orders Price Transparency In Federal Programs

The move is part of the Administration's overall strategy to empower consumers, stimulate price competition, and reduce rising growth in healthcare spending.

President George W. Bush on August 22 signed an executive order that requires four federally funded healthcare programs to make information available to the public on the costs and the quality of care that they reimburse. The government pays for about 40% of the healthcare provided in the U.S.

In effect, the President said, the order tells healthcare providers that to do business with the government, "you've got to show us your prices."

The order applies to the Departments of Health & Human Services, Defense, and Veterans Affairs and to the Office of Personnel Management, which oversees health insurance plans for federal workers. The Administration hopes private employers and state and local governments will follow suit, and response from these sectors has been supportive.

The four federal agencies also are to promote interoperability of health information technology and adoption of e-health records.

HHS Secretary Michael Leavitt said his Department is working with private payer and provider groups that have been developing quality measures for diverse healthcare settings. In Medicare, early measures of quality have been established for hospitals, nursing homes, and other institutions for several years and are being expanded, Leavitt said. Also, Medicare last June 1 began posting information on the Web about the prices it pays for hospital care. Pay rates to physicians are planned to be posted this fall.

Critics say the President's initiative does not address more critical issues like affordable healthcare or the rising number of uninsured Americans.

focus on: Pathology, Lab Payment Policy

Medicare's Proposed 2007 Physician Fee Schedule Rule: *Impact On Pathology, Lab Service Providers*

The proposal, which appeared in the August 22 Federal Register, *is the second issued by CMS for the 2007 Part B physician fee schedule. The first, proposed June 29, revised work and practice expense relative values (NIR, 27, 17/Jun 29 '06, p. 1).*

Highlighted below are major policy changes affecting pathology and independent laboratories that the Centers for Medicare & Medicaid Services has proposed, starting January 1, 2007. CMS projects that it will pay approximately $61.5 billion to 875,000 physicians and other healthcare professionals next year.

Scheduled Physician Fee Cut

Unless Congress intervenes, Medicare spending for Part B physician services is currently projected to be cut by 5.1% in 2007. This figure will be updated in the final physician fee schedule rule, CMS says, but the agency does not foresee a substantial change. Earlier this year, the estimated cut was 4.5%.

Impact of '07 Fee Cut, RVU Changes

Pathology	-10%
Independent laboratory	-2%
Diagnostic testing facility	-25%
Physician component of CPT 88305	-8%

Source: CMS

What's behind the negative update? CMS says the statutory fee update formula requires reductions when actual spending exceeds a target rate. Spending for physician services and other Part B services has been growing much faster than the target rate, CMS notes. In 2005, spending for physician services rose 10% above the previous year, mainly due to increased volume and intensity of services to beneficiaries, including office visits, imaging, laboratory services, and physician-administered drugs. For 2006, the projected spending growth is 10.6%.

Flow Cytometry Gains

While most physician fee schedule payments are slated for cuts in 2007, the technical component of flow cytometry codes CPT 88184 and 88185 would increase significantly, now that CMS has accepted higher practice expense relative value units, in line with data submitted by pathology and laboratory organizations. Even with a 5.1% cut, the TC of 88184 and 88185 would rise 16% and 27%, respectively. With a zero update, the increases would be 22% and 33%.

The TC increases are the same that CMS proposed last year, then cancelled as part of a broader problem the agency said it found with its PE methodology, prompting it to scuttle all PE RVU changes and value all physician services at 2005 levels (*NIR, 26, 21/Sep 12, '05, p. 1; 27, 3/Nov 14 '05, p. 1*). PE RVUs account for $30 billion in physician fee schedule payments or about 45% of overall payments under the fee schedule.

Though CMS proposes lower PE RVUs for the physician interpretation of flow cytometry services, the TC increases should help restore some of the pay cuts that pathologists and labs experienced this year, note lab industry sources.

End To "Grandfathered" Pathology TC Billings

CMS is proposing to end, after December 31, 2006, the "grandfather" protection that allows independent clinical labs to bill and be paid by Medicare for the technical component of pathology services for hospital inpatients and outpatients. This protection, approved by Congress, expires on that date.

Bipartisan legislation to block the termination and make the protection permanent as of January 1, 2007, was introduced in the Senate (S. 3609) on June 29 (*NIR, 27, 18/Jul 17 '06, p. 1*). An identical provision is included in a bipartisan rural healthcare bill introduced September 7 by the House Rural Health Care Coalition by lead sponsors Reps. Greg Walden (R-OR) and Earl Pomeroy (D-ND). The College of American Pathologists is spearheading the lobbying push to preserve the protection. Ending it would hurt small and rural hospitals, CAP argues, because they cannot afford to maintain pathology services in-house and rely heavily on independent labs (*NIR, 27, 18/Jul 17 '06, p. 1*).

In 2001, 4,773 PPS hospitals and critical access hospitals, or approximately 95% of all such facilities, outsourced some TC pathology services to labs that got direct payment for those services, said the Government Accountability Office in a report to Congress. Eliminating direct payment would have saved Medicare $42 million that year, while beneficiary cost-sharing would have been reduced by $2 million (NIR, 24, 21/Sep 12 '03, p. 1).

The "grandfather" protection applies to hospital/lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end separate Part B payment for the pathology TC services and require labs to seek reimbursement from the hospital instead. CMS said the TC is included in the hospital's Part A payment (*NIR, 25, 4/Nov. 25 '03, p. 2*). Congress has stepped in repeatedly—most recently in the 2003 Medicare reform law—to stop CMS from ending the protection.

S. 3609 also would stipulate that a change in ownership on or after July 22, 1999, would not affect a hospital's "covered" status under the protection. Currently, a hospital loses the protection when it gets new owners, because it is considered a "new" hospital and thus cannot be "grandfathered" (*NIR, 25, 16/Jun 7 '04, p. 7*).

Under existing policy, the "grandfather" protection applies to the hospital, not the lab. So, hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. Medicare also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology (CMS Transmittal AB-01-47).

Summary Of Key Payment Changes

- ❑ Implement a 5.1% cut in Medicare spending for physician services in accord with the statutory fee update formula.
- ❑ Replace the current "top-down" approach to calculating practice expense with a "bottom-up" approach to be phased-in over four years. CMS would calculate direct expenses using procedure-level data for clinical staff time, supplies, and equipment.
- ❑ Terminate "grandfather" protection that allows independent labs to bill for the TC of pathology services for hospital patients.
- ❑ Clamp tighter regulatory controls on "pod" labs.

Crackdown On 'Pod' Labs

Medicare's policy on "pod" or "condo" labs has been to monitor their billings, in response to anti-kickback concerns raised by the HHS Office of Inspector General, though the agency did not rule out further controls if needed (*NIR, 26, 4/Nov 22 '04, p. 4*). Now, CMS is proposing to tighten the rules on benefits reassignment and Stark self-referral exceptions.

'Pod' Labs & Pathologists: Typical Arrangements

An entity leases space in a medical building and divides the space into separate areas equipped with microscopes and a minimal amount of other lab equipment. The entity subleases each space to a physician group practice, even though the space may be located many miles away from the practice's medical office and even in a different state. The entity hires a histologist to perform the TC of the anatomic pathology service and makes arrangements with a pathologist to perform the PC and supervise the pod lab.

In one business model, the pathologist and histologist perform their services for different group practices by moving from cubicle to cubicle. Each group practice pays the pathologist a fee for every slide reviewed and pays the entity a management fee, which covers space rental and the histologist's salary. The group practice then bills Medicare for the global service, typically at a mark-up from what the practice paid the pathologist and the entity.

In another common model, the histologist performs the TC of the pathology service for the entity and the entity bills for that service, while the group practice bills for the PC performed by an independent contractor pathologist who has reassigned to the practice his or her right to receive Medicare payment.

"We are concerned that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to overutilization of services and higher program costs," CMS said.

Reassignment Rules: CMS would amend the benefits reassignment rules as follows:

- If the technical component of a diagnostic test (other than a clinical lab test payable under the lab fee schedule) is billed by a physician or medical group under a contractual arrangement, the amount billed is subject to anti-markup rules. It must be the lowest of the net charge to the group, the physician's actual charge, or the fee schedule amount.
- To bill for the TC, the billing entity must have performed the professional component (the PC or physician's interpretation).

The agency is considering whether there should be an anti-markup provision on the PC of testing and invites comments on this issue.

CMS further proposes to modify the reassignment rules to require a group practice to agree to give employed physicians access to the claims information the entity has submitted for their services. This requirement already applies to independent contractor physicians.

The proposed 'pod' lab curbs are likely to make 'insourcing' of anatomic pathology—bringing all or part of the work in-house—more attractive to physician specialties as a less legally risky way to capture more pathology revenue (NIR, 27, 20/Aug. 14 '06, pp. 4-5).

Stark "Centralized Building" Requirement: To meet this standard under Stark self-referral exceptions, CMS would require a minimum 350 square footage. This would apply to:

- Exceptions for in-office ancillary services and physician services.
- Independent contractor physicians and employed physicians.
- Only to space where four or more group practices owned or leased space in the building and shared the same physician in the group.

Substantially all equipment would have to be in the centralized building and could not routinely be moved as needed from one group's space to another.

CMS invites comments on other changes, including:

- Should the group practice be required to employ, in the centralized building space, a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week?
- Should the centralized building space be able to be located in another state?

♦ MEDICARE COVERAGE A·D·V·I·S·O·R·Y

The new policies on screening benefits and blood glucose testing were announced in the proposed 2007 Medicare physician fee schedule rule, published in the August 22 Federal Register.

New Screening Benefit

Starting January 1, 2007, Medicare will add abdominal aortic aneurysm (AAA) screening to the list of covered Part B preventive services, as required by the Deficit Reduction Act of 2005. Coverage is limited to a one-time-only ultrasound screening upon referral from the physician who provided the beneficiary's initial "Welcome to Medicare" physical exam (this exam must be performed within the first six months after the individual's Part B coverage begins).

Who is eligible? Individuals at risk for AAA, including anyone with a family history of AAA; a man aged 65 to 75 who has smoked at least 100 cigarettes in his lifetime; and any other individual who manifests risk factors for which screening is recommended by the U.S. Preventive Services Task Force. The Part B deductible is waived. The Centers for Medicare & Medicaid Services also proposes to use its national coverage decision (NCD) process to modify AAA coverage in the future to account more quickly for other risk factors and alternative screening technologies.

CMS would pay for the AAA benefit using the yet-to-be-finalized HCPCS code GXXX1, *Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm screening*. Payment would be at the same rate as CPT 76755.

Blood Glucose Testing In Nursing Homes

CMS reiterates existing policy that the test-ordering physician must be the one who treats the beneficiary and uses the test results in care of that patient. The agency would add a requirement that for each blood glucose test provided to a beneficiary residing in a skilled nursing facility, the treating physician must certify that the test is medically necessary. A standing order is not sufficient for a series of blood glucose tests.

Changes To Osteoporosis Screening Benefit

Currently, beneficiaries at risk for osteoporosis are eligible for bone mass measurements (BMM) once every two years. Coverage may be more frequent when medically necessary, for example, to monitor a beneficiary on long-term glucocorticoid therapy of more than three months, or to perform a confirmatory baseline measurement for future monitoring if the initial test was done with a technique different from the proposed monitoring method.

CMS would drop coverage of the single-photon absorptiometry (SPA) procedure, saying newer techniques are superior in accuracy and precision, and would revise "bone mass measurement" to read: "Is performed with either a bone densitometer (other than a single-photon or dual-photon absorptiometry) or with a bone sonometer system cleared for this use by the FDA."

For a medically necessary BMM to be covered for an individual being monitored during FDA-approved osteoporosis drug therapy, the monitoring would have to be performed using a dual energy x-ray absorptiometry system (axial system).

CMS would expand the number of beneficiaries who qualify for BMM due to long-time steroid therapy by reducing the dosage equivalent required for eligibility from an average of 7.5 milligrams per day of prednisone for at least three months to 5.0 mg/day.

CMS Eyeing Development Of Lab Quality Measures

Lab providers, take notice. In a "sleeper" provision in Medicare's proposed 2007 physician fee schedule rule, the Centers for Medicare & Medicaid Services says it is exploring development of quality measures for labs, including requiring them to submit test values using LOINC as the standard coding vocabulary.

A similar idea was recommended in the Medicare Payment Advisory Commission's report to Congress in connection with devising pay-for-performance programs for various providers (*NIR, 26, 10/Mar 7 '05, p. 1*). MedPAC said Medicare should require clinical labs to report patients' test results with the claims they submit. The results, which are central to physician treatment decisions, would be used to assess the quality of their care, the panel noted.

CMS has already proposed LOINC as the standard for HIPAA claims attachments. The LOINC database—which stands for Logical Observations: Identifiers, Names, Codes—currently contains about 41,000 observational terms, of which nearly 31,000 are related to lab testing. The government has adopted LOINC in various programs, and many clinical labs use it too. But CMS acknowledges that major operational challenges must be met before Medicare could use test values appropriately to evaluate medical care. The agency says it will work with the lab community in these efforts.

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