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Final Medicare Rule Cuts Physician Fees, Punts On Pod Labs

Despite the overall fee cut, primary care physicians will see major payment increases for office visits, resulting from the latest review of work RVUs that the law requires every five years.

Unless Congress intervenes, Medicare payments for physician services will be cut 5%, starting January 1, under the final 2007 physician fee schedule rule released November 1. The cut, lower than the 5.1% cut projected earlier this year, is being made in accord with the statutory fee update formula, said the Centers for Medicare & Medicaid Services.

For pathology, there is good news and bad in other payment policy changes. The good news is that Medicare will increase reimbursement for flow cytometry technical component services (CPT 88184 and 88185) between 14% and 25% despite the negative update. Pathology and lab organizations have long lobbied for an increase after the TC and the professional component were cut by as much as 50% in 2005.

The bad news is that on top of the 5% cut, pathology will take a hit from changes to the physician work and practice expense relative value units (RVUs). The combined impact of these ➥ *p. 2*

INSIDE *NIR*

Hopes Dim For Lab Workforce Legislation

Despite lobbying by clinical laboratory and pathology societies in support of legislation addressing lab workforce issues, it is unlikely that the post-election "lame-duck" Congress will authorize new spending targeted to lab personnel training or restore funds cut this year from the Title VII allied health training account, a small portion of which goes to programs for medical technologists and medical lab technicians.

A series of authorization bills to boost allied health dollars—including H.R. 1175, which would authorize $11.2 million in new money for scholarship and loan programs for medical lab personnel—have languished inside Congress since being introduced in the House and referred to committee.

Allied health appropriations for fiscal 2007 are held to the 2006 level of $4 million in pending House and Senate HHS spending bills, down significantly from the $11.8 million approved for 2005. The President's FY 2007 budget proposed elimination of allied health spending. Currently, allied health is funded at $4 million under a government-wide continuing resolution that keeps federal agencies running at 2006 levels through November 18.

Medicare will pay approximately $61.5 billion to over 900,000 physicians and other healthcare professionals in calendar year 2007 as a result of the payment rates and policies adopted in the final fee schedule rule.

Final Medicare Rule, *from p. 1*

changes on total allowed pathology charges, estimates CMS, is a 6% cut in 2007 (the first year of the four-year PE RVU transition) and a 7% cut in 2010. For independent labs, the impact is a gain of 2% in 2007 and 17% in 2010; for diagnostic testing facilities, a cut of 2% in 2007 and 6% in 2010.

Also to the dismay of pathology and lab groups, CMS decided not to pursue restrictions on "condo" or "pod" labs, arrangements by which certain physician specialty groups seek to increase revenue from pathology referrals. The agency had proposed tightening the Medicare benefits reassignment rule and the Stark safe harbor for in-office ancillary services, but opted to delay final regulations to allow further consideration of the issues. Said acting agency head Leslie Norwalk, "We want to be careful not to interfere with legitimate group practice arrangements that enable beneficiaries to get medical services at one location."

CMS also will eliminate the "grandfather" protection that allows independent labs to bill Part B for pathology TC services to hospital inpatients and outpatients. The protection, granted by Congress, expires at the end of this year, and CMS does not seek to extend it. The agency contends that the TC services are reimbursed under the hospital's prospective payment and that labs should turn to the hospital to get reimbursed.

Outpatient Pay Rates Rise

Hospital outpatient services will get a 3.4% market basket update, starting January 1, 2007, under a final rule issued November 1 by CMS. After taking into account other changes in the rule, the agency estimates, hospitals will see an overall average boost of 3%.

Beginning in 2009, pay rate increases will be tied to the reporting of quality measures. CMS plans to develop measures appropriate to outpatient care. The agency also is expanding the reporting of additional quality measures for inpatient services, starting in fiscal year 2008. And for the first time, hospitals would report risk-adjusted outcome measures to get the full payment update, including 30-day mortality measures for patients with an acute myocardial infarction or heart failure.

CMS also has adopted a policy that all providers and suppliers generally be assigned to a Medicare Administrative Contractor based on geographic location, but a large qualified provider chain would be permitted to file all claims with the MAC that has jurisdiction over the chain's home office. MACs are new entities that combine Part A/B work now split between carriers and intermediaries.

In other provisions, the final physician fee schedule rule:

- ❑ Expands the preventive services benefit to include ultrasound screening for abdominal aortic aneurysms for at-risk beneficiaries as part of the initial "Welcome to Medicare" physical exam by a physician.
- ❑ Qualifies more beneficiaries for bone mass measurement due to long-term steroid therapy. The dosage equivalent required for eligibility is reduced from an average of 7.5 milligrams per day of prednisone for at least three months to 5.0 milligrams.
- ❑ Waives the deductible for colorectal cancer screening.
- ❑ Requires that for blood glucose monitoring in skilled nursing facilities, the physician must certify that each test is medically necessary. A standing order is not sufficient.
- ❑ Codifies in regulations the public process that CMS now uses to solicit comments on establishing fees for new tests added to the Part B lab fee schedule.

Industry Anxious Over Proposed New 'Home Brew' Controls

Sen. Kennedy said his bill will "focus the Congress and others on the need for an important role for the FDA in this area" by clarifying that the agency has authority to regulate lab-developed tests, which some have questioned, and by providing direction on how the FDA is to exercise this authority.

In a move that has triggered concern in the clinical laboratory industry, Sen. Edward Kennedy (D-MA) has said he plans to soon introduce legislation requiring expanded and tighter federal regulation of tests that labs develop in-house, commonly known as "home brew" tests.

The bill is expected to surface in the post-election "lame-duck" session. The aim, said Kennedy in a statement, is to get the measure on the table and position it for movement through Congress next year. Kennedy is the ranking Democrat on the Senate Health, Education, Labor & Pensions Committee, now chaired by Mike Enzi (R-WY). If the midterm elections give Democrats control of the Senate, Kennedy is expected to move into the top slot where he could advance the home brew legislation.

The American Clinical Laboratory Association has serious concerns about the bill and opposes it in its current form, ACLA president Alan Mertz told *NIR*. It would appear to cover potentially the majority of lab-developed tests—as many as 70% to 80%, he estimated—and could take out of circulation many tests recognized for their clinical benefit such as HIV resistance testing.

Heightening industry anxiety is the fact that Kennedy's announcement came soon on the heels of word from the Food & Drug Administration that it will expand its oversight of certain home brew tests. In draft guidance issued last month, the FDA said it intended to require premarket review for gene- or protein-based types of lab-developed tests, which the agency calls In Vitro Diagnostic Multivariate Index Assays (*NIR, 27, 22/Sep 25 '06, pp. 1, 4-5*).

Under the draft Kennedy bill circulating at press time—tentatively dubbed the Laboratory Test Improvement Act—virtually all home brew tests would be defined as Class II devices, requiring labs to submit a 501(k) application for each test developed in-house. FDA review would proceed on a volume basis, rather than a risk basis. Normally, Mertz pointed out, risk is the cornerstone criterion the FDA uses for medical devices.

Tests in the lowest 20% of volume would be exempt from FDA review. Molecular diagnostics would fall in this category, Mertz said. ACLA also is concerned about how the FDA intends to apply premarket review requirements to home brews already in use.

Noting rapid changes in genetic testing and the prospect of even more ahead, Kennedy said his objective is to protect patients by ensuring that lab-developed tests are of proven validity. Aware of lab industry concern that more regulation could stifle technological advances and their rapid use, Kennedy emphasized that he is committed to allowing room for innovations.

Legislative action is needed, he said, because "doctors and patients are making important medical decisions based on the results of clinical lab tests in the field of genetics," for example, whether a woman should have a prophylactic mastectomy or whether a particular drug is appropriate for a patient. "We need to ensure that they understand the clinical significance of the results, and are confident that the tests are accurately performed."

focus on: The Clinical Laboratory Workforce

The Changing Landscape Of Supply/Demand, Clinical Practice

Hospitals and other testing facilities can expect more difficulty in finding and keeping qualified testing personnel as demand continues to outstrip supply in the clinical laboratory workforce. The imbalance will only get worse over the next decade, most research studies show, as the aging lab workforce begins to retire and there aren't enough new graduates to fill vacated and new positions.

Faced with today's shortage, hospitals and other labs have resorted to offering special financial incentives to recruit and retain qualified testing personnel, including higher salaries, sign-on bonuses, even help with relocation expenses. Labs also have increased their use of per diem and contract workers and overtime. But more is needed to address the shortage, say clinical laboratory and pathology societies—the professions also must offer more avenues for career advancement to attract workers and reduce attrition in the ranks.

These issues got a full airing at the recent meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC). The mid-September meeting in Atlanta featured a special session devoted to briefings on the future of the lab workforce. CLIAC's look at the issues comes at a time of dwindling federal funding for lab workforce programs (*related story, p. 1*) and no congressional authorization of new funding (*see box, p. 6*).

Backdrop To The Future

The annual need exceeds the lab workforce supply by approximately 2 to 1, Kathy Doig, PhD, CLS(NCA), CLSp(H), told the CLIAC panel. Doig is director of the biomedical lab diagnostics program at Michigan State University in East Lansing. Roughly 10,000 to 12,000 workers are needed yearly, while only 4,000 to 5,000 are produced. (The Labor Department has estimated that each year until 2014, 15,000 jobs for lab personnel will open up due to industry growth or replacements of the aging workforce.)

The attrition rate for professionals in the first five years of practice is about 5%, Doig noted. Most recent statistics indicate a vacancy rate of approximately 6% overall for generalist professionals, lower than six years ago when the rate was 10% to 15%. But this is cyclical, she added: "When the economy turns down, healthcare careers look good."

The supply crisis is taking on a different dimension too, Doig observed. The average age of lab professionals is in the upper 40s, and a substantial number of retirements can be expected in the next 10 to 15 years, she said. And there aren't enough young people to meet demand in all areas of the economy. "We are competing with other sectors and with other healthcare professions."

Salaries In Clinical Laboratory Science Compared To Other Health Professions

To attract individuals and reduce attrition, any profession must offer enough pay to at least live on. In relation to comparable health professions, salaries for clinical lab scientists and clinical/medical lab technicians are on the low side.

	Mean
Physical Therapist	$61,240
Dental Hygienist	$58,730
Occupational Therapist	$54,890
Registered Nurse	$52,610
CLS/MT	$45,380
Radiologic Technologist	$43,410
Respiratory Therapist	$42,930
CLT/MLT	$31,420

Source: U.S. Bureau of Labor Statistics, 2003.

The shortage exacerbates chronic problems in the lab workforce, including career dissatisfaction, diminished morale, and attrition, Doig said, pointing to:

- ❑ Lack of clear distinctions between levels of practice for clinical laboratory scientists/medical technologists (CLS/MTs) and clinical/medical laboratory technicians (CLT/MLTs), leading staff to believe that they are doing the same job for less pay or that their skills are underused.
- ❑ Salaries that lag behind comparable health professions (*see box, p. 4*). CLS/CLT salaries have just kept pace with inflation since the 1970s.
- ❑ Market changes that undermine the value of professional education. Employers in states that do not require lab personnel licensure can hire anyone, including high school graduates, and often do so out of desperation. They must ensure, however, that their employees meet the CLIA personnel requirements.
- ❑ Perceived lack of appreciation by medical caregivers and hospital administrators.
- ❑ Lack of opportunities for advancement in clinical practice.

There is some good news, Doig said. "Anecdotally, many programs report higher occupancy rates and higher application numbers than in recent years." The bad news is that the capacity for educating professionals is reduced because of the steady decline in hospital and university-based CLS and CLT training programs. But having more programs will not solve the problem if young people are not motivated to enroll and graduate, she cautioned.

Broader Pathologist Role Urged In Interdisciplinary Consults

Clinical pathologists can play a key role in preventing a major source of error outside the laboratory—namely, improper selection of tests and incorrect interpretation of test results, Michael Laposata, MD, told CLIAC members. Medical error is becoming a more serious problem, he said, as the test menu gets larger and more complex, particularly in molecular diagnostics.

Board-certified in clinical pathology, Laposata is director and chief of the division of clinical labs at Massachusetts General Hospital (MGH) in Boston. He also is a professor of pathology at Harvard Medical School.

He said clinical pathologists should be proactive in establishing lab medicine consultations, both on and off the hospital floor. This would help shorten the time to diagnosis and improve the accuracy of diagnosis, thereby saving money and improving outcomes for the patient, whose care is subject to the variable knowledge of non-experts in lab medicine.

Minimal turf issues have occurred in lab medicine interpretative rounds at MGH, Laposata said. Currently active: coagulation, autoimmune disease, anemia, transfusion reactions, serum protein analysis, HIV, and hepatitis.

He recommended two strategies to improve test ordering and results interpretation:

— Use reflex testing as much as possible to increase the appropriateness of test selection. The MGH clinical lab uses about 100 reflex test algorithms in all areas of lab medicine.

— Provide patient-specific narrative interpretations of test results, as is done in anatomic pathology and radiology, for complex evaluations in lab medicine.

Forecast For The Future

The lab workforce of the future will still reflect diverse skill levels, Doig said—pathologists, doctoral scientists, bachelor's level scientists, associate level practitioners, aides and phlebotomists. The non-physician professional mix may change (increased use of lesser skilled staff as technology advances, for example) or the scope of practice may shift as clearer distinctions are made between CLS/MTs and CLT/MTs.

A big spot for the future, Doig said, is development of an advanced degree path for career advancement. (Work on this is already being done by the Professional Doctorate Task Force spearheaded by the American Society for Clinical Laboratory Science and including members from ASCLS, the American Society for Clinical Pathology, and the National Accrediting Agency for Clinical Laboratory Science. The latter also has a Graduate Programs Task Force looking into this degree.)

The doctorate degree would be an optional route for the CLS, with additional education to equip the individual to consult with pathologists and doctoral scientists on test ordering and interpretation, including participating in interdisciplinary rounds. The ad-

vanced practice lab professional could also consult with treating physicians and patients on test results and help develop research on improved patient care and reduced costs.

There definitely is interest in the advanced practice degree, Doig noted. She and colleague S. Beck surveyed 972 early-career CLSs in 2005 and got 299 responses to the question: *What is your impression of this proposed career option, assuming the salary is commensurate with the required doctoral degree?*

- ❑ I'd be interested in pursuing this option – 65.2%.
- ❑ This would be a good option for people who currently choose to become MDs, physician assistants, etc. – 28%.
- ❑ Not of interest to me; I prefer remaining in the lab – 10.2%.
- ❑ Not of interest to me; I wouldn't want to make the time or financial investment in a doctoral degree – 9.2%.
- ❑ Not of interest to me for other reasons – 5.8%.

Interdisciplinary Roles

Kathleen Hansen, CLS(NCA), briefed CLIAC on efforts at her institution to make the CLS the "face of the laboratory" in patient care units. She is interim president of Fairview Laboratory Services and director of lab operations at the University of Minnesota Medical Center (UMMC)—Fairview in Minneapolis.

When interdisciplinary process improvement (PI) teams were established for patient care units, the lab stepped forward to be sure that a CLS was appointed to each team, Hansen said. The PI teams address cost per case issues and support implementation of the Computerized Physician Order Entry (CPOE) program, Verisafe (positive patient ID, using bar-coded armbands), and a new process for ordering blood products.

There have been some short pilots where lab personnel joined clinical rounds on a daily basis. CLS staff from the core lab felt they made a contribution, Hansen said, but sometimes had to go back for answers about "special diagnostic" lab services. They would be more confident about commenting on test ordering patterns if they had more clinical training in test utilization and best practices.

This experience showed there is a need for and an interest in scientific and other skills training to support CLS involvement with clinical teams, Hansen said, and underscores the importance of the effort to establish a lab doctorate option for advanced practice.

Push For New Lab Training Money Falters

While pursuing allied health funding increases, clinical laboratory and pathology groups have also been lobbying in support of a series of bills introduced in the House that would authorize new funding support for allied health, including one measure specifically targeted to the lab workforce—H.R. 1175, the Medical Laboratory Personnel Shortage Act of 2005 (*NIR, 26, 12/Apr 11 '05, p. 2*).

The groups have tried without success to move H.R. 1175 by getting it attached to broader House legislation, and no companion measure has been introduced in the Senate, Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science, told *NIR*.

But the issue is getting more attention from lawmakers, she said. More members of Congress signed on as co-sponsors, following a lobbying blitz earlier this year by ASCLS, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association (*NIR, 27, 12/Apr 10 '06, p. 1*).

H.R. 1175 would authorize $11.2 million in new funding for scholarship and loan repayment programs for medical lab personnel, and for faculty development and public ad campaigns to promote medical lab careers.

Passiment said there is a lack of understanding on Capitol Hill of key lab workforce issues because "we don't have strong data, most is anecdotal." We can only count heads in states where lab personnel licensure is required, she noted. That currently includes California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee, and West Virginia, plus the Commonwealth of Puerto Rico.

Getting new authorizing funding is important, Passiment said, but getting the actual money is another thing. Several years back, she noted, Congress passed a bioterrorism bill that authorized $25 million for clinical laboratory science, but the money was never appropriated.

Medicare To Expand Physician Quality Measures In 2007

The quality measures—which include testing for blood glucose and cholesterol control in patients with diabetes, plus cytogenetic and flow cytometry services—could become a framework for implementing Medicare physician pay-for-performance initiatives.

Starting January 1, 2007, Medicare plans to increase the number and range of quality measures that physicians are encouraged to report when submitting Part B claims. The Centers for Medicare & Medicaid Services has identified 86 unique quality measures affecting 32 of 39 medical specialties that are expected to be available next year.

The list, released October 16, should be regarded as a "snapshot" of potential quality measures based on information current as of that date, said CMS. The agency will select a subset of these measures for 2007 "in order to achieve an appropriate balance in measures to be reported by different specialties."

Medicare began the Physician Voluntary Reporting Program (PVRP) in 2006 with a core starter-set of 16 quality measures. It covered primary care, surgery, nephrology, and emergency medicine and specific services to treat coronary heart disease, diabetes, end-stage renal disease, depression, and surgical complications. Participating physicians get confidential feedback on their data accuracy, reporting rates, and quality of care, but no extra payment.

The final list of PVRP measures for 2007 will be posted before January 1, CMS said, and could be updated throughout the year. The agency said it will continue to work to add measures for specialties that lack them. In determining specific quality measures, CMS gives preference to those approved by the AQA Alliance (the former Ambulatory Care Quality Alliance) and the National Quality Forum (NQF) and to measures for which electronic data collection are available.

Certain clinical laboratory and pathology procedures on the October 16 list include:

Specialty	*Clinical Topic*	*Measurement Statement*	*AQA Vote Expected*	*NQF Endorsement Vote Expected*
Hematology	Myelodysplastic Syndrome	Cytogenetic testing on bone narrow	1/22/07	Vote Unknown (Send Spring 07)
	Erythropoietin Therapy	Iron stores prior to therapy	1/22/07	Vote Unknown (Send Spring 07)
	Chronic Lymphocytic Leukemia (CLL) Multiple Myeloma	Multiple myeloma treated with biophosphonates	1/22/07	Vote Unknown (Send Spring 07)
	Acute leukemia	Flow cytometry evaluation in chronic lymphocytic leukemia patients	1/22/07	Vote Unknown (Send Spring 07)
General Practice*	Diabetes: Hemoglobin A1C Control	Hemoglobin A1C control in Type 1 or 2 diabetes mellitus	Adopted	Endorsed
	Diabetes: Lipid Control	LDL control in Type 1 or 2 diabetes mellitus	Adopted	Endorsed
Endocrinology	Diabetes: Hemoglobin A1C Control	Hemoglobin A1C control in Type 1 or 2 diabetes mellitus	Adopted	Endorsed
	Diabetes: Lipid Control	LDL control in Type 1 or 2 diabetes mellitus	Adopted	Endorsed
	Diabetes Blood Pressure Control	High blood pressure control in Type 1 or 2 diabetes mellitus	Adopted	Endorsed
	Treatment/screening dual x-ray absorptiometry (DXA), bone density measurement	General population – screening or therapy for women aged 65 years and older	1/22/07	5/21/07

Source: CMS. *From list of 21 measures that also address depression, coronary artery disease, urinary incontinence, and geriatric falls.

Medicare Payment Errors Continue To Drop, Says CMS

The agency says much of the improvement has come from targeting its efforts "more effectively on Medicare contractors and providers."

The error rate in reimbursing Medicare fee-for-service claims dropped in 2006 to 4.4% from 5.2% the year before, saving the federal program $1.3 billion in improper payouts, the Centers for Medicare & Medicaid Services recently announced.

Overall, the error rate has declined almost 10 percentage points in the last 10 years, down from 14.2% in 1996, when the Medicare improper payment rate was first reported, CMS said.

Senate Finance Committee chairman Charles Grassley (R-IA) welcomed the word from CMS. According to a statement from the committee, the agency already has met Medicare's target rate for 2006, which was set at 4.7%. "Today, while Medicare is still paying for medically unnecessary services and undocumented or poorly documented services, we see a major reduction and that deserves recognition," Grassley said in a statement.

The full annual report on Medicare payment accuracy is due out later this month. It will contain specific improper payment estimates, along with additional error rate information, CMS said.

Medicare Managed Care Watch

More Medicare Advantage health plans will be available to beneficiaries in 2007, including, for the first time, high-deductible coverage linked to tax-free medical savings accounts (MSAs), says the CMS Center for Beneficiary Choices.

In 2007, there will be 3,971 MA plans vs. 3,195 in 2006. These include employer group health plans and private plans available to the public. Special needs plans have increased from 272 to 471. They cover special enrollee groups—dual eligibles, the institutionalized, and those with chronic diseases.

Also in 2007, Medicare will introduce the MSA option. Two will be available in 39 states and the District of Columbia, and one demonstration will cover New York and Pennsylvania. The MSAs are being offered by UniCare, a subsidiary of Wellpoint Inc., and Blue Cross of California. The demo operates through MPower Health.

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