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CMS Poised to Begin Requiring Cytology Proficiency Testing in 2005

CMS states on its web site that it "will be communicating with all laboratories that perform cytology and professional organizations in the near future to provide additional information regarding this program."

After more than a decade without a government approved proficiency testing program for gynecologic cytology, the Centers for Medicare and Medicaid Services appears on the brink of requiring labs to conduct cytology PT starting next year. The stage was set following CMS approval of the Midwest Institute of Medical Education (MIME) of Indianapolis as a national provider of cytology PT and the company's subsequent rollout of its 2005 program last month when it began signing up labs.

Clinical Laboratory Improvement Amendments (CLIA) regulations require labs that perform gynecologic cytology testing to undergo proficiency testing once an approved testing program becomes available. Until now, there has been only one gynecologic cytology PT provider, the Maryland Department of Health and Mental Hygiene, and it only provides this service to labs that are either located in Maryland or test specimens from Maryland residents. ➥ *p. 2*

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Leavitt to Succeed Thompson at HHS

President Bush Dec. 13 nominated Michael Leavitt, administrator of the Environmental Protection Agency and former governor of Utah, to succeed Tommy Thompson as secretary of the Health and Human Services Department.

There had been speculation that Mark McClellan, MD, PhD, administrator of the Centers for Medicare and Medicaid Services, was favored to succeed Thompson, who Dec. 3 announced his resignation, effective Feb. 4. However, sources later indicated a preference to keep McClellan at CMS to implement the Medicare prescription drug law.

When he announced his resignation, Thompson disclosed that he had opposed a key White House-backed provision of the Medicare Modernization Act that he nevertheless helped muscle through Congress. "I would have liked the ability to negotiate" prescription drug prices for seniors, the former Wisconsin governor told reporters. The Bush administration had staunchly opposed the idea, advocated by Democrats, saying it would have enabled federal price fixing, to the detriment of the pharmaceutical industry.

But on balance, MMA "is a wonderful law," Thompson said, particularly with its emphasis on welcome-to-Medicare physical exams and disease prevention and management.

So far, at least 1% of the estimated 3,000 to 4,000 labs that do gynecologic cytology have signed up for proficiency testing with MIME, said CEO Roger Wall. He expects that as many as 3% of the people who take the proficiency test will fail it on the first try.

Cytology Proficiency Testing, *from p. 1*
Judy Yost, who heads the CLIA program at CMS, confirmed to the *National Intelligence Report* that the agency approved MIME for cytology PT nationally. "Unfortunately," she added, "I cannot provide any specific details at this time." She said the agency will release more information "in the very near future."

MIME last month sent enrollment booklets to the directors of all labs certified under CLIA for cytology testing in 2005. According to a frequently asked questions page on MIME's web site, all labs that perform any gynecologic screening or sign-out of cases must enroll, as must all cytotechnologists and physicians who screen or sign out gynecological cases.

The two-hour test involves a review of 10 glass slides. They can be all conventional pap, thin prep pap or SurePath pap, or may include a combination of conventional with either thin prep or SurePath, depending on which types participants say they routinely screen or sign out. Each box of slides will include at least one UNSAT, one negative, one LSIL and one HSIL, AID or cancer, but no ASCUS cases.

The passing score is 90%. MIME says CMS told it the agency will not enforce sanctions against those who fail the test in 2005, though it will require re-testing. MIME only offers first and, if necessary, second re-tests at its testing facility in Indianapolis.

MIME also says:
- ❑ Labs in Maryland can use either MIME's or Maryland's proficiency testing programs.
- ❑ Labs cannot use any of the three glass slide continuing education programs, CytoQuest, CAP PAP or ASCP Star, in place of MIME's or Maryland's proficiency testing.
- ❑ MIME's base fee is $1,500 for each laboratory site, with $75 additional per participant.
- ❑ A 10% discount is available until Jan. 15 and a 10% late fee beginning April 1.
- ❑ Locum tenems may either enroll as employees at local labs for $75 or enroll independently at $300 per locum for testing at MIME's Indianapolis facility.

Effective Nov. 3, MIME began offering to enroll labs in its cytology PT program. Testing begins Jan. 3 and ends Dec. 23, 2005. For more information or to enroll, contact MIME at 866-678-6463 or *mime@mimeinc.org*, or visit its web site at *www.mimeinc.org*.

Nine Chosen for Lab Bidding Demo's Technical Expert Panel

RTI International Inc. has selected a nine-member Technical Expert Panel to advise the Research Triangle Park, NC, firm on technical, operational and performance issues related to the clinical laboratory competitive bidding demonstration project it is designing under a Sept. 30 task order with the Centers for Medicare and Medicaid Services (*NIR, 26, 1/Oct. 11, '04, pp. 1-2*).

Lab groups have been clamoring for a voice on that panel, which they view as a key factor in their ability to prevent the demonstration project from harming the interests of their members. Many groups proposed slates of panelists, which CMS project officer, Linda Lebovic MPH, MT (ASCP), forwarded to RTI with instructions to chose panelists solely on the basis of personal expertise, not professional affiliation.

The panel will not meet until next spring, when RTI will ask it to review a set of options it is developing for the demonstration's design, Lebovic told *NIR*.

Donna MacMillan, MT (ASCP), MBA, director of operations for Massachusetts General Hospital's pathology department, will chair the panel. MacMillan also is a consultant to RTI for the lab bidding demo. Lebovic said this is not a conflict, rather MacMillan will simply be providing her expertise in two ways rather than just one. However, due to conflict of interest concerns, MacMillan has recused herself for the duration of the contract from the Clinical Laboratory Management Association's Health Care Policy Committee, which she has chaired for the past year.

The other panelists are, in alphabetical order:

- Alfred Chiplin, JD, managing attorney for the Center for Medicare Advocacy Inc. in Washington;
- Carlyn Collins, MD, MPH, a nationally recognized lab quality expert and a senior laboratory advisor for, and former director of, the Laboratory Systems Division at the Centers for Disease Control and Prevention;
- Marc Grodman, MD, chairman, president and CEO of Bio-Reference Laboratories Inc., assistant professor of clinical medicine at Columbia University and assistant attending physician at Presbyterian Hospital in New York;
- Lee Hilborne, MD, MPH, director of the Center for Patient Safety and Quality, University of California Los Angeles Healthcare, professor of pathology and lab medicine at UCLA and consultant to RAND;
- Paula Patterson, chief of the Clinical Laboratory and Durable Medical Equipment Contracting Unit for California Medicaid (Medi-Cal);
- James Robb, MD, medical director at Integrated Regional Laboratories in Florida, and scientific advisor at Ventana Medical Systems, Intelligent Medical Imaging Inc.
- Bonita Warner, national vice president, Network Services for AmeriChoice Corp., one of the first private entities to serve Medicaid, SCHIP and Medicare beneficiaries; and
- Ronald Weiss, MD, MBA, president and chief operating officer of the University of Utah's Associated Regional and University Pathologists Laboratories, and professor of pathology at the university.

Pathologists See Part A Gold at End of Medical Director Rainbow

The Health and Human Services Department's acting Inspector General, Daniel Levinson, last month raised the hopes of pathologists that his organization may finally clarify that hospitals not only can, but must use proceeds from their Medicare Part A reimbursement to pay pathologists for non-patient-specific services they provide as medical directors of hospital laboratories.

With the advent of the inpatient prospective payment system in the mid-1980s, Medicare paid physicians for treatment of individual patients under Part B of Medicare, while paying hospitals under Part A for professional services performed for the general benefit of hospital inpatients. The hospitals in turn paid physicians for the general services they performed, as with their labs' medical directors.

However, certain hospitals soon reduced or stopped payment of pathologists under Part A for medical director services, due to the cost-cutting incentives inherent

Even if OIG agrees that failure of hospitals to pay the medical directors of their labs with Part A Medicare funds constitutes violation of the anti-kickback law, there is skepticism in many quarters that it would ever prosecute hospitals for such a violation.

in the IPPS. Pathologists have complained ever since, to no avail, that such hospitals were thereby violating the federal anti-kickback statute. In their view, hospitals were offering them a kickback—the opportunity to provide Part B services for which Medicare paid them—if in return they helped run the hospitals' labs free of charge.

The College of American Pathologists and many of its members complained to OIG after it appeared to condone nonpayment for lab medical director services in a June 8, 2004, Draft Supplemental Compliance Program Guidance for Hospitals. In the draft guidance, OIG said, "In an appropriate context, an arrangement that requires a hospital-based physician or physician group to perform reasonable administrative or clinical duties directly related to their hospital-based professional services at no charge to the hospital or its patients would not violate the anti-kickback statute."

CAP argued that this goes against OIG's 1998 Compliance Program Guidance for Hospitals and 1991 management advisory report on financing arrangements between hospitals and hospital-based physicians, which indicated that token payment or nonpayment for such services "may violate the anti-kickback statute."

OIG should change the draft supplemental guidance to clarify that such nonpayment violates the anti-kickback statute, CAP said in a July 23 letter to Levinson's predecessor, Dara Corrigan. Several hundred pathologists, alerted by CAP, chimed in with their own concerns about it to the OIG.

At CAP's urging, two House Republicans from Ohio, Ralph Regula and David Hobson, wrote to OIG Oct. 1 requesting a "clear statement" that hospitals must dip into Medicare Part A revenues to pay pathologists for serving as medical directors for their labs to satisfy Congress and pathologists on the anti-kickback issue.

Levinson replied Nov. 1, saying his agency does not believe the new draft guidance contradicts its previous positions highlighted by CAP. However, he said, "we are carefully reviewing the points raised in your letter and the public comments. We plan to include a clear statement of our position on payments for Part A hospital-based physician services in the final Compliance Program Guidance."

CLIA Oversight Agencies Agree to Share Findings

"It's important for the public and the laboratories to realize that we are working together and that this is a very positive step," said Yost.

Federal and state agencies that regulate clinical laboratories under the Clinical Laboratory Improvement Amendments and the private organizations that accredit them agreed during a Nov. 16 meeting in Baltimore to share more information about the labs they oversee. However, the organizations involved have not yet revealed publicly what concrete steps they intend to take to achieve this objective.

The Centers for Medicare and Medicaid Services convened the meeting to deal with an apparent lack of coordination that came to light in the response to whistleblower allegations of botched HIV and hepatitis testing and related cover-ups at Maryland General Hospital in Baltimore.

In the Maryland General case, the state's failure to alert the hospital lab's accrediting body, the College of American Pathologists, to the whistleblower allegations delayed any response by the College. Also, the state and CAP had not shared ear-

lier findings of deficiencies that, if put together, might have led to further study (*NIR, 25, 16/June 7, '04, pp. 1, 4-6*).

Rep. Elijah Cummings (D-MD) has proposed federal legislation, the Clinical Laboratory Compliance Improvement Act of 2004 (H.R. 5311), that would require lab regulators to share information. Maryland General is in Cummings' district (*NIR, 26, 3/Nov. 8, '04, p. 8*). Similar state legislation also is in the works in the Maryland Senate.

Attending the Nov. 16 meeting were officials with the two CLIA-exempt states, New York and Washington, the three states with their own lab licensure laws, California, Maryland and Pennsylvania, accrediting organizations such as CAP and the Joint Commission on Accreditation of Healthcare Organizations, CMS regional officials and CMS staff in Yost's office who are responsible for approval of accrediting agencies.

There was a broad consensus at the meeting to communicate better and share more information, Yost told *NIR*. In fact, she said, "Everyone wanted everything from everybody." That might be difficult logistically, given the differences in the particulars of each organization's oversight processes and associated information systems. But even if much of the sharing must be done manually, at least in the beginning, "people felt it would be worth the effort," said Yost.

"It was a very constructive meeting," said Ron Lepoff, MD, chair of CAP's Commission on Accreditation. "We were very glad it happened."

"Everyone at the conclusion of the meeting felt that it was a very worthwhile time and that we had gained a lot just from that experience, and everyone also agreed to come back to further explore how we could work better together," said Yost. CMS will schedule another meeting in February 2005, with more likely to follow.

CAP Expected to Switch to Unannounced Lab Inspections

Although it has not taken an official position on unannounced inspections, the College of American Pathologists is likely to follow along with the Joint Commission on Accreditation of Healthcare Organizations in its decision to switch to unscheduled inspections for routine accreditation surveys, the chair of CAP's Commission on Accreditation, Ron Lepoff, MD, told *NIR*.

In the wake of disclosures earlier this year that CAP had missed problems with lab quality when it surveyed and re-accredited Baltimore-based Maryland General Hospital's laboratory in 2003, critics noted that by announcing survey inspections, CAP gave lab management time to potentially hide problems.

In response to those concerns, Rep. Elijah Cummings (D-MD) introduced legislation last month, H.R. 5311, that would forbid prior notice for lab accreditation surveys. The bill went nowhere in the waning days of the 108th Congress, but Cummings is expected to re-introduce it next year.

JCAHO, which relied on CAP's lab inspections as part of its decision to accredit the hospital, already had decided to switch to unannounced inspections in 2006 as part

of its Shared Visions—New Pathways initiative. In JCAHO's view, this would encourage hospitals to always operate as if they were about to be inspected, rather than sweep problems under the rug come inspection time.

Lepoff told *NIR* that JCAHO has asked CAP to switch to unannounced inspections as well, and that "we intend to maintain our relationship with the Joint Commission." At this point, he said, "we are anxiously waiting to hear about their inspection process." Lepoff noted that CAP already performs unannounced inspections on occasion, often as follow-ups or in response to specific concerns, and that sometimes these inspections have been as comprehensive as the biennial surveys.

CMS to Increase Outpatient Blood Payment 25% in 2005

Move hailed by America's Blood Centers official as "a step in the right direction."

After two years of declining or frozen reimbursement, the Medicare program Jan. 1 will begin paying 25% more for blood and blood products provided to hospital outpatients, after agreeing that it had been underestimating hospitals' costs.

The Centers for Medicare and Medicaid Services decided in a Nov. 15 final rule with comment period to use a new methodology for calculating the cost-to-charge ratios (CCRs) it uses to adjust hospital claims for blood and blood products provided to outpatients. Using the new approach, CMS calculated simulated median costs for each blood and blood product based on 2003 claim data, and estimated that the overall cost was 25% higher than it had estimated for 2004.

The payment increase is even higher, 32%, for the most frequently billed blood product, HCPCS Code P9016 (Red blood cells, Leukocyte reduced).

Under the new approach to calculating CCRs, CMS will tally blood-specific charges from hospitals that report them, and assume that charges are the same at hospitals that do not report them. Otherwise, the agency would have used the overall CCRs for hospitals without blood-specific charge reporting, which would have been nearly 50% less.

"The increase in reimbursement rates for blood products was good news," Mike Fitzpatrick, chief policy officer for America's Blood Centers, told *NIR*. However, he added, "It helps a lot, but it doesn't resolve the problem."

When CMS established the outpatient prospective payment system in 2000, it used external data to set reimbursement for blood and blood products. The next two years, it updated those rates for inflation. Then in 2003, CMS began calculating rates based on hospital Medicare claims data, which resulted in significant declines for some products, and howls of protest from blood centers. In response, the Government used a dampening methodology to limit the decrease for blood and blood products to no more than 15%.

In 2004, CMS froze rates at the 2003 levels to give it the time to study issues that the blood industry had raised in comments on the proposed 2003 and 2004 OPPS rules and at advisory panel meetings. Staff of the ABC, the American Red Cross, the AABB and AdvaMed met with the agency numerous times, and sent letters and data showing why they thought reimbursement should be higher. In the 2005 OPPS, CMS agreed based on its research that it had been underestimating hospitals' true costs for blood and products.

In the "near future," CMS said it intends to provide further billing guidelines for blood-related services, clarifying its April 12, 2001, Change Request 1585.

The 2005 rates, while better, still don't match actual costs, Fitzpatrick asserted. For example, payment will increase to between $86 and $112 per unit for leukoreduced blood, up from between $65 and $85 in 2004. But actual cost is between $145 and $225.

Even under the new approach, CMS will continue to believe hospitals are spending far less on blood than they actually are, and consequently will continue to set reimbursement too low, Fitzpatrick fears. The reason is hospitals will continue to underreport the cost and the amount of their blood use. Why? They need not report blood use to obtain reimbursement for procedures that require blood. And if they report blood use, but code it wrong, that could be a false claim.

Blood groups like ABC aim to continue pressing CMS for more favorable analysis of the data, while educating hospitals on how and why to code for blood and blood products properly and completely, Fitzpatrick said. He told *NIR* blood reimbursement for inpatients is an even bigger problem on a slower track because inpatient blood reimbursement is rolling into each diagnosis-related group. Fixing it would involve adjusting the market basket for all hospital inpatient spending.

Note: CMS will soften the impact of certain low-volume (less than 1,000 units) blood products, whose simulated median costs decline 14% for 2005. For those products, the agency will use a 50/50 blend of their product-specific median costs and its proposed 2005 simulated medians.

Additionally, CMS established new Ambulatory Payment Classification groups so each blood product can have its own, and it reassigned blood and blood products to the new APCs. However, payment for collection, processing and storage of autologous blood, CPT 86890, remains under APC 0347 (Level III Transfusion Laboratory Procedures).

CMS Closes CAH 'Draw Station' Loophole

H.R. 4257, proposed April 30 by Rep. C.L. "Butch" Otter, D-ID, would override the restriction. The Critical Access to Clinical Lab Services Act collected 29 co-sponsors, but languished in committee (see NIR*, 25, 15/May 24, '04, p.3).*

The Centers for Medicare and Medicaid Services has moved to closed a loophole that some critical access hospitals believed they saw in the agency's Aug. 1, 2003, inpatient prospective payment system provision allowing them to charge the "reasonable cost" rate only for laboratory tests performed on outpatient samples obtained at the hospital. For samples obtained elsewhere, they had to pay the lower lab fee schedule rates.

Rural CAHs had fought the IPPS provision, hoping CMS would let them charge the higher rate for tests on samples obtained at rural health clinics, skilled nursing facilities and private homes (*NIR, 24, 15/May 27, '03, p.1*).

Some CAHs have since concluded they could still bill Medicare on a reasonable cost basis for tests on samples they obtained at draw stations they established in non-CAH facilities. The theory was that the draw stations were part of the hospitals that established them, rather than part of the facilities where they had been established.

No dice, CMS said in Change Request 3439, Transmittal 379 of the Medicare Claims Processing Manual. In this memo dated Nov. 26, the agency clarified that "if CAHs set up 'draw stations' in non-CAH providers or facilities, payment for clinical diagnostic laboratory tests performed on those specimens will not be made on a reasonable cost basis."

Flow Cytometry Reimbursement Reduction Draws Fire

"Bottom line, Medicare reimbursement for flow cytometry services will decrease significantly starting January 1, 2005," Root said in a briefing last month.

Pathologists and clinical laboratories are reacting with concern to an analysis by Barrington, IL, coding expert Charles Root indicating major reductions in Medicare reimbursement are imminent for flow cytometry, thanks to changes in the physician fee schedule related to Current Procedural Terminology coding changes for 2005.

The American Medical Association deleted the 88180 per-marker code, replacing it with a set of codes designed to approximate a per-interpretation approach to paying for flow cytometry professional services. For a leukemia/lymphoma bone marrow evaluation of Total T-cell and NK cell counts plus 10 markers, lab charges would total $371.40 in 2005, compared to $595.40 in 2004—a 37.6% reduction. Pathologist charges would total $86, compared to $200 in 2004—a 57% reduction. Total payment would decline by 44%, Root said.

A number of pathologists called the Centers for Medicare and Medicaid Services' open-door forum for physicians and nurses last month to complain about the pending cut. The American Clinical Laboratory Association is likely to raise this issue with CMS in comments on the 2005 physician fee schedule interim final rule.

Flow Cytometry Coding Advisory Correction

In an editorial mistake, the five new CPT flow cytometry codes listed in our coverage of Medicare fees under the 2005 physician fee schedule (*NIR, 26, 4/Nov. 22, '04, p. 3*) had an incorrect digit. Instead of 88164-69, the codes should read 88184-89. The codes had been correctly reported in our previous CPT 2005 update coverage *(NIR, 26, 3/ Nov. 8, '04, p. 7; 26, 2/ Sep 27, '04, p. 2)*.

washington WATCH

Dialysis PTH Testing Subpoenas Cause a Stir

The Justice Department has generated a lot of head-scratching with subpoenas for information on dialysis related parathyroid hormone (PTH) testing and Vitamin D therapy. Subpoenaed were PTH test maker Nichols Institute Diagnostics and parent Quest Diagnostics Inc., Teterboro, NJ, Vitamin D therapy manufacturers Abbott Laboratories, Chicago, and Bone Care International Inc., Middleton, WI, as well as leading dialysis chains. Officials with the firms, investment analysts and lawyers say they can't imagine what prompted the investigation into this complex, low revenue aspect of dialysis that they say is driven by the treating physicians.

Reminder: December is a one-issue month for *NIR*. All of us at G-2 Reports wish you Happy Holidays!

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