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CMS Officials Get An Earful On Cytology PT Launch

Anyone who performs gynecological cytology in the U.S. must enroll in an approved proficiency testing program this year—and pass the test by next year. For more on this sweeping mandate, don't miss our Feb. 18 audioconference; details on p. 2

During a recent open-door forum, officials with the Centers for Medicare & Medicaid Services fielded dozens of questions and angry comments from clinical laboratorians regarding the enforcement start-up this year of CLIA requirements for gynecological cytology proficiency testing (PT). News of the start-up surfaced late last year with little warning, catching many by surprise, a fact reflected in the number who participated in the January 21 forum on 663 phone lines.

CLIA rules for gynecological cytology PT have been on the books for more than a decade, but haven't been generally enforced because there was no approved PT vendor outside of a Maryland program. That all changed last November when CMS approved Indianapolis-based Midwest Institute for Medical Education (MIME) as a national PT provider (*National Intelligence Report, 26, 5/Dec 16, '04, p. 1*).

Many who called were upset to learn that in 2005, MIME will be their only choice. They had hoped that CMS would give them ➥ *p. 2*

INSIDE *NIR*

Bush To Push Healthcare 'Ownership'

At press time, President George W. Bush was expected to unveil a fiscal 2006 budget request that tightly limits domestic discretionary spending, while advancing his vision of an "ownership society" that would rely less on federal entitlements and employers for retirement and healthcare, and more on tax breaks for individual savings accounts.

In his State of the Union address on February 2, the President laid out the broad outlines of his healthcare legislative agenda, calling for expansion of health savings accounts, association health plans, and community health centers, as well as caps on damages in medical malpractice cases.

Mr. Bush also backs investment in healthcare information technology to help reduce medical errors and healthcare costs. In a domestic policy preview on January 28 at the Cleveland Clinic, he said he will seek $125 million in FY 2006 to promote healthcare IT. The next day, the *New York Times* reported, he wrote to Congress, saying he plans to restore $50 million to promote adoption of electronic health records that lawmakers had removed from the FY 2005 budget to put a small dent in the federal deficit.

Meet these cytology PT deadlines, and you'll avoid enforcement actions, CMS says: enroll by June 30, 2005; take the first test by April 2, 2006; pass the first test or a re-take by December 31, 2006 and annually thereafter

Cytology PT Launch, *from p. 1*

the option of using the College of American Pathologists or the American Society for Clinical Pathology. Like MIME, both offer glass-slide cytology continuing education programs. In response, Judy Yost, the top CLIA official at CMS, noted that the application deadline for 2005 was July 1, 2004. CMS will consider CAP, which applied in December, and ASCP (if, as expected, it files a formal application by July 1, 2005) as potential cytology PT providers for 2006. (Labs that process specimens from Maryland residents can use that state's CLIA cytology PT program for those specimens.)

"I really don't think you've given sufficient notice, and I don't think you're providing enough providers," said Sally Robinson, cytology section head at John D. Archbold Memorial Hospital in Thomasville, GA. "I wish you would address this, and I really do object to the CAP and ASCP programs not being included at this point. I realize they are able to apply, but to have their application not be effective for the 2005 testing, you are really cramming one vendor down our throat."

Thomas Hamilton, director of the CMS survey and certification group, replied that Congress established the cytology PT requirements 16 years ago when it enacted CLIA (the Clinical Laboratory Improvement Amendments of 1988), "so it's difficult for us or anyone to argue that there hasn't been adequate notice—there's probably been more notice than [for] any other similar kind of provision….I would respectfully suggest that if you have an objection, the proper place to lodge [it] is with the organizations that have not come forward with a suitable testing program and could have done so during that 16-year time period."

Robinson and others complained that CMS had approved MIME for 2005 too late for them to budget for MIME's test fees. They also complained that MIME was charging too much, while one caller, apparently familiar with its CytoQuest glass-slide program, asserted that the slides were of inferior quality. PT fees are a function of the marketplace, CMS officials said, speculating that competition might later drive them down. But the officials said CMS welcomed information about the performance of cytology PT vendors, which are subject to annual re-approval.

CMS officials explained why they haven't officially notified every cytology lab about enforcement of the PT requirements. Their first official communication went to surveyors to prevent them from unilaterally taking enforcement actions now that the requirements are in effect. The agency established as relaxed an enforcement schedule as it could to allow time for an orderly testing process, Hamilton said. CMS still intends to notify every lab that does cytology PT, Yost added.

CMS officials said they intend to work on improving the cytology PT program over time. Yost confirmed that CMS is working with organizations such as CAP and ASCP to update the scoring system so that it reflects the latest science.

CMS Proposes System For Cytology Proficiency Records

The system is needed, CMS said, now that a national proficiency testing program has been approved for gynecological cytology testing (related story, p. 1)

The Centers for Medicare & Medicaid Services is proposing a new system of records to track proficiency testing for gynecologic cytology, the agency said in a January 14 *Federal Register* notice. CMS said it needs the system to monitor compliance with the enforcement of CLIA cytology PT provisions that begins this year.

The proposed Cytology Personnel Record System (CYPERS) will track and monitor the enrollment, participation, and performance of individual cytotechnologists and physicians taking part in CMS-approved gynecologic cytology PT programs. The system would maintain for 10 years the individual's name, their proficiency testing registration number, and their medical licensure number; the name(s), locations(s), and CLIA number(s) of the lab(s) that employ them; their test scores and which testing events they took part in.

Under the Privacy Act, CMS cannot disclose any of the information in CYPERS without the individual's consent, except for routine uses. In the notice, CMS proposed to consider "routine" any disclosures:

- To the contractors and consultants involved in maintaining CYPERS, and who in turn will be prevented from disclosure by the terms of their contracts.
- To members of Congress or their staff in response to written requests from constituents about their own records.
- To the Justice Department or the courts if CMS determines the records are relevant and necessary to litigation involving the U.S. government, a CMS employee acting in his/her official capacity or as an individual, but with DOJ representation.

Further, CMS said it would prohibit disclosure of non-identifiable data in cases where people could figure out the subject's identity due to the small volume of patients involved. CMS will consider comments sent to: Director, Division of Privacy Compliance Data Development, CMS, Room N2-04-27, 7500 Security Blvd., Baltimore MD 21244-1850. The agency gave no deadline.

Labs Hit In Slowdown Of Health Spending Growth

The first deceleration in national healthcare spending growth in seven years appears to have impacted the clinical laboratory sector, according to data from the Centers for Medicare & Medicaid Services.

Growth in clinical lab spending under Medicare Part B increased by 9.5% to $5.5 billion in 2003. That's down from the red-hot 2002 growth rate of 14.4%, but still very fast for a sector that saw annual spending declines through most of the 1990s, recovering just around the turn of the century.

National healthcare spending grew by 7.7% to $1.7 trillion in 2003, down from 9.3% in 2002. What helped rein it in? Most significantly, some 34 states dealt with budget crises by putting the brakes on Medicaid spending, which had been soaring along with unemployment just as state tax revenues plummeted during the high-tech bust. State and federal Medicaid spending grew just 7% from $249.4 billion in 2002

Lab advocates can point to the slower growth to alleviate some of the pressure on Congress this year to cut Medicare payments to labs and other providers as part of deficit-reduction moves

to $267 billion in 2003, down sharply from the prior year's 12.1% growth rate.

Meantime, Medicare spending growth slowed due to the expiration of supplemental funding for providers authorized by the Balanced Budget Refinement Act and the Benefits Improvement & Protection Act. It grew only 5.7% to $283.1 billion, down from 7.6% in 2002 and 10.8% in 2001. Part B outlays grew only 8.5% to $121.7 billion in 2003, down from 9.1% in 2002 and 13.4% in 2001.

After steadily declining through the 1990s, the lab share of Part B outlays increased for the second straight year to 4.5% in 2003.

As they have at least since 1991, hospital laboratories continued to slowly gain on independent and physician office labs in their share of spending under the Part B lab fee schedule. They got 45.7% of Part B lab outlays in 2003, up from 44.1% the previous year, with independent labs and physician office labs getting the other 54.3%.

Notable Lab, Pathology Spending Changes

Medicare Part B spending for one major pathology code more than doubled in two years. In 2003, CMS allowed $91.8 million in charges for CPT 88180—Flow cytometry; each cell surface, cytoplasmic or nuclear marker—compared to just $41.1 million in 2001. Under pressure from CMS, the American Medical Association's CPT editorial panel deleted that code for 2005, switching to a new multi-code per-interpretation scheme. CMS then set fees for the new codes that pathologists complain will halve their flow cytometry reimbursement rate (*NIR, 26, 7/Jan 24, '05, p. 7*).

The CPT codes 83890 to 83912 that labs use for genetic testing saw a major increase in use, though totals still are very limited. The CPT editorial panel approved a series of genetic testing modifiers for 2005 to specify genetic conditions for the testing. Proponents hope their use will result in fewer claims denials and help payers determine the test's medical necessity and thus its coverage. In this area, spending increased 46% to $3.6 million in 2003 from $2.5 million in 2002. Similarly, utilization increased 47% to 358,000 genetic-testing processes in 2003 (with each test involving multiple processes).

Spending for one of the top five lab codes—CPT 85025, automated complete blood count with automated differential—increased 69% to $267.7 million in 2003 from $158.2 million in 2002, while the number of allowed services increased 67% to nearly 25 million. Meanwhile, spending for CPT 85024—automated CBC with partial automated differential—fell 86% to $13.4 million from $95.1 million. Notably, in 2003, the AMA deleted CPT 85023—automated CBC with manual differential—which had accounted for $16 million of allowed charges in 2002. This led to a great deal of uncertainty among clinical labs over how to handle billing for CBCs that reflex to a manual differential.

Utilization was up sharply for CPT 87086—Culture, bacterial; quantitative, colony count, urine—resulting in a 40% increase in payments to $34.4 million in 2003 from $24.6 million in 2002. Also registering a significant increase was CPT 83970—Parathormone (parathyroid hormone)—up 22% to $89.9 million in 2003 from $73.5 million in 2002.

California Rules Aim To Ease Lab Personnel Shortage

The emergency regulation takes effect immediately for 120 days and can be extended or replaced by a regulation adopted through the regular process. The state will consider comments received by March 21

The state of California last month took a major step toward alleviating the state's shortage of qualified clinical laboratory personnel with the January 13 approval by Secretary of State Kevin Shelley of emergency regulation R-13-03E, which enables the state to set standards for the training and certification of medical laboratory technicians (MLTs) and let national organizations handle the licensing exams.

Unlike most states, California has only been licensing clinical laboratory personnel who have four-year baccalaureate-level college degrees. Labs in the state have been hard-pressed to hire enough of these scarce clinical laboratory scientists (CLSs) to handle their workloads.

Under the new regulation, the state will be able to begin licensing MLTs with two-year associate-level degrees to perform much of the work in labs under the supervision of CLSs "without any diminution in the quality of testing," Mike Arnold, president of the California Clinical Laboratory Association, told *NIR*. "I think this is going to make a big difference over time in the profitability of labs" by expanding the workforce and improving the division of labor, he added.

"We're excited about it," said Karen Nickel, chief of laboratory field services for the California Department of Health Services. "It's going to be a big program for us. And it completes our career ladder."

State To Leave Licensure Exams To Others

The regulation also gives the state a way to turn over the job of administering clinical lab licensure certification examinations to organizations such as the National Accrediting Agency for Clinical Laboratory Sciences and the American Society for Clinical Pathology. Until now, the state has insisted on handling all exams itself. However, California's severe budget crisis forced the state to cut back testing from twice a year to once a year. This exacerbated the personnel shortage, with lab positions remaining vacant while trained laboratorians awaited testing.

"We are going to implement this provision over a three-year period and get out of the licensing business permanently," Nickel told *NIR*, noting that the state has been handling these exams for 50 years for CLSs and 30 years for chemists, toxicologists, microbiologists, and hematologists. DHS will phase out state-run exams as it establishes at least two choices for each license category, she said, starting with MLTs and then CLSs.

With national organizations handling exams, it will be simpler to hire nationally certified lab professionals from other states. And there'll be more opportunities for exams in California, which national organizations can administer on demand at places like Sylvan Learning Centers or online, Nickel said.

California Lab Contracting Initiatives

The California Office of Medi-Cal Procurement is evaluating applications from independent laboratories for contracts that would allow them to continue performing CLIA moderate and high complexity testing for Medi-Cal, but only if they agree to a 20% cut in reimbursement. The state, which had reissued its request for applications last September 15, intended to release contract awards by February 1, 2005. But on January 31, the procurement office said "evaluation will continue past that time for an indeterminate period. A revised schedule will be announced later once the Department has determined a more precise timetable."

Meantime, CalOptima, the county-run managed care program that administers all Medi-Cal benefits in Orange County, last month issued a request-for-proposals for laboratory services (RFP 05-0232). CalOptima subsequently extended the proposal due date to February 22, 2005. The contact is Kathy Hoppe, senior buyer, *khoppe@caloptima.org*.

CBO: Drug Benefit, Other Factors To Drive Up Medicare Spending

The CBO report shows "too much of our spending is on automatic pilot," said new Senate Budget Committee chairman Judd Gregg (R-NH), who promised to work on "long-term control of our entitlement spending"

The Congressional Budget Office projects that annual Medicare spending will grow from $325 billion this year to $520 billion in 2010 and $766 billion in 2015, thanks mainly to the new prescription drug benefit, other spending increases, and a growing pool of beneficiaries.

This assumes, however, that Congress leaves untouched the sustainable growth rate (SGR) used to calculate annual updates to physician fees. Congress overrode cuts that the inflation-adjusted SGR would have dealt physicians in 2003-2005, providing an increase of 1.5% each year instead. CBO projects that physician fees will exceed the SGR target by $20 billion at the end of this year, and that they will grow well below inflation for the next decade if the SGR calculation resumes in 2006. Further increases of physician payments above the SGR "would lift outlays for Medicare considerably above baseline levels over the coming 10 years," CBO said.

CBO had given the green light to the Medicare drug benefit in November 2003 when it projected that the new benefit would cost $410 billion from 2004 to 2013. This, along with offsetting savings in the Medicare Modernization Act, kept the projected cost below the $400 billion threshold set by a congressional budget resolution, allowing it to become law. CBO now projects the outlays will far exceed the budget resolution's limit—totaling $760 billion just in the final eight years of the original 10-year forecast period.

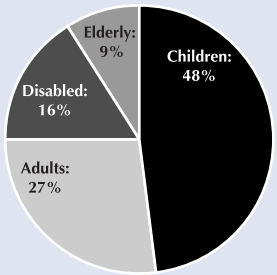
CBO projects three main sources of Medicare and Medicaid spending growth over the next decade:

- The Medicare Part D drug benefit will add $45 billion of spending in 2006, increasing annually to $172 billion additional in 2015, for a total of $1.085 trillion over the 10-year period.
- Other spending increases per beneficiary will add $14 billion in 2006, growing to $331 billion in 2015.
- Increases in caseload will add $7 billion in 2006, rising to $120 billion in 2015.

New HHS Chief Says Medicaid Spending Must Be Trimmed

The newly confirmed Secretary of Health & Human Services, Michael Leavitt, told a Washington, DC health conference on February 1 that his goal is to hold the rate of growth in spending for the federal-state Medicaid program to 7% per year. The current setup to provide medical care for the needy cannot be "financially sustained," he said.

Medicaid Population: 50 Million People Total



Source: Kaiser Commission on Medicaid and the Uninsured.

Leavitt said the Bush Administration would not propose converting the entire program to a block grant, as some Medicaid supporters had feared. As much as $40 billion over 10 years could be saved, he noted, by closing "loopholes" in reimbursement claims, including accounting practices that he said artificially inflated a state's costs.

Additional savings of $15 billion over 10 years could be sought by overhauling Medicaid's drug coverage—the government pays too

much, he said—and $4.5 billion more by tightening the assets test that the elderly must meet to qualify for nursing home coverage.

Leavitt, who was confirmed by the Senate on January 26, succeeds Tommy Thompson who announced his resignation in December as part of a broad reshuffling of the President's cabinet for Mr. Bush's second term. Prior to being picked by the President to head HHS, Leavitt was administrator of the Environmental Protection Agency and served three terms as governor of Utah. In that post, he revamped Utah's Medicaid program, including obtaining a Section 1115 waiver enabling the state to trim benefits and impose cost sharing and to use the money thereby obtained to expand coverage to many of the state's uninsured.

CAP Official Picked To Head CLMA

Dana Procsal, PhD

The board of directors of the Clinical Laboratory Management Association has named Dana Procsal, PhD, as its new chief executive officer. He comes to CLMA after 10 years as vice president of laboratory improvement programs at the College of American Pathologists, where he focused on CAP's proficiency testing and laboratory accreditation programs.

In previous positions, Procsal was general manager for SmithKline Beecham Clinical Laboratories in Chicago, and before that, held various clinical laboratory management roles. He has an undergraduate degree in biochemistry from California State Polytechnic University in San Luis Obispo and a PhD in biochemistry from the University of California at Riverside.

♦CODING A·D·V·I·S·O·R·Y

Effective July 1, Medicare will implement a frequency edit to ensure correct payment of claims for HCPCS code Q0091—Screening Pap smear; obtaining, preparing, and conveyance of cervical or vaginal smear to a laboratory. This code currently is not in the Common Working File edits for Pap smears. Medicare notes this is a problem for physicians billing for patients who request an annual screening Pap smear. Only high-risk patients are covered annually; low-risk patients are covered once every two years.

On occasion, physicians perform a screening Pap smear that they know will not be covered because the low-risk patient has received a covered Pap smear in the past two years. In these instances, the physician should obtain an Advance Beneficiary Notice since the service will be considered "not reasonable and necessary."

In cases where the specimen is unsatisfactory and another must be sent to the clinical lab, the physician should bill for this reconveyance with Q0091 and the modifier –76 (repeat procedure by the same physician).

Also, Medicare is adding a new diagnosis code, V72.31, to the low-risk edits already established for Pap smears and pelvic exams. Source: CMS Transmittal 440, Change Request 3659 (January 21, 2005).

Medicare Begins Performance-Based Pay For Physicians

The drive to reward quality began with hospitals, now it's spread to physicians, and labs wonder if they'll be next

In the latest move to inject rewards for quality care into the Medicare program, the Centers for Medicare & Medicaid Services on January 31 announced that 10 large physician groups across the country will participate in the first pay-for-performance demonstration for physicians under Medicare.

During the three-year project, CMS will reward the groups that improve patient outcomes by coordinating care for chronically ill and high-cost beneficiaries in an efficient manner. The quality measures will focus on common chronic diseases in the Medicare population, including congestive heart failure, coronary artery disease, diabetes, hypertension, as well as preventive services such as flu and pneumonia vaccines and screenings for breast and colorectal cancer.

Physician groups in the demonstration will continue to be paid on a fee-for-service basis. Depending on how well they improve patient outcomes and avoid costly complications, the groups will be eligible for performance payments. The groups include Dartmouth-Hitchcock Clinic, Bedford, NH; Deaconess Billings Clinic, Billings, MT; the Everett Clinic, Everett, WA; Geisinger Health System, Danville, PA; Middlesex Health System, Middletown, CT; Marshfield Clinic, Marshfield, WI; Forsyth Medical Group, Winston-Salem, NC; Park Nicollett Health Services, St. Louis Park, MN; St. John's Health System, Springfield, MO; and the University of Michigan Faculty Group Practice, Ann Arbor.

Correction: *An article in our January 24 issue (p. 5) should have said that the Medicare Payment Advisory Commission backed a 2.7% increase for physician fees in 2006.*

G-2 SPECIAL AUDIO CONFERENCE

'Pod' Labs: Gain Or Bane for Pathologists?

Discover how the Feds are coming to grips with this fast-spreading business arrangement whereby certain physician specialty groups tap pathology referrals to boost Medicare revenue.

Join us for a special audioconference on the looming legal and economic implications of "pod" labs, scheduled for **February 10**, 2:00-3:30 p.m. (Eastern).

Featured speakers: legal experts Jane Pine Wood and W. Bradley Tully.

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