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6-Month Window Set For Unannounced Lab Inspections

Join our special November 22 audio conference on changes in lab accreditation and inspections for 2006. Speakers include top accreditation officials Margaret Peck from JCAHO and Bruce Williams, MD, from CAP. Register at www.g2reports.com *or call 800-401-5937, ext. 2*

Starting in January, two major CLIA accrediting bodies—the Joint Commission on Accreditation of Healthcare Organizations and the College of American Pathologists—will switch to unannounced routine inspections of laboratories they accredit, and COLA will do likewise for the facilities it accredits under its cooperative agreement with JCAHO.

The term "unannounced" means that the lab will not know the date of its accreditation inspection, nor will the inspectors and the lab staff have any contact until the day of the inspection.

JCAHO, CAP, and COLA will be on the same page when it comes to the timing of the surveys. Following consultations with the Centers for Medicare & Medicaid Services, they've agreed that unannounced inspections will occur up to six months before the lab's two-year anniversary date. To avoid conflicts with events already scheduled, a lab may indicate 10 blackout dates within which no survey will be conducted.

➥ *p. 2*

Labs, Pathologists Likely To Escape Budget Cuts

The return of a lab co-pay and a 4.4% projected cut in pathology and other physician fees under Medicare Part B appears to be off the table as Congress moves to enact spending cuts in accord with the 2006 budget resolution.

House bills from Ways & Means and Energy & Commerce stay away from Medicare, shunning a bid by GOP conservatives to make offsets to the program for Katrina costs (including reviving the lab co-pay), and focus instead on $11 billion in federal Medicaid cuts. The Senate Finance bill splits $10 billion in savings between the two programs, but includes a 1% update in Part B physician fees next year. The Finance package also clamps a permanent moratorium on physician specialty hospitals (*NIR, 26, 16/Jun 6 '05, p. 7*) but lets those in operation continue, with certain restrictions.

At press time, the bills were pending a floor vote. Veteran lab lobbyist Don Lavanty, who spoke at a Lab Institute 2005 special legislative session last week, predicts that the physician fee update will likely be endorsed when the bills go to conference to iron out differences. For more on this year's Institute program, see the *Focus*, pp. 3-6.

INSIDE *NIR*

Unannounced Lab Inspections, *from p. 1*

CAP announced its change to the six-month window in an October 20 press release; previously, the College had been considering a 90-day window before and after a lab's anniversary date (*NIR, 27, 1/Oct 17 '05, p. 2*).

Maryland Case A 'Wake-Up Call'

The transition to unannounced routine CLIA surveys was a major topic discussed by JCAHO and CAP officials at the Lab Quality Symposium held October 19 in advance of Lab Institute 2005 in Arlington, VA. In the backdrop was the Maryland General Hospital laboratory case and pending legislation to require unannounced inspections (H.R. 686), sponsored by U.S. Rep. Elijah Cummings (D-MD), whose district includes Maryland General. JCAHO had disclosed plans for "surprise" inspections before the case, but for CAP, Maryland General was what has been described as a "wake-up call."

Preparing for an unannounced inspection is a good time for a laboratory to ensure that it has a "continuous compliance" culture, said consultants Christine Diehl and Judy Lien at a Lab Institute workshop. And the mindset from the top down should be that quality is the way to do business

In that case, quality testing lapses went undetected by CAP and other survey bodies and came to light only when a whistleblower filed suit. HIV and hepatitis C testing was not validated, but results were released. As a panel from the hospital told the audience, the subsequent cleanup has involved a massive re-testing program to the tune of some $5 million; the results have verified that the original positive readings were, in fact, accurate for as much as 99% of these infections, said lab director John Braun, MD. In addition, the hospital has replaced key personnel, from its top executive down through the lab administrator.

Coordination & Disclosure

Another consequence of the Maryland General case has been a concerted effort to improve coordination and communication among CLIA accrediting bodies, state survey agencies, and CMS. All parties involved in an inspection will share their findings on a regular basis. The aim is to have in place a rapid response mechanism and avoid having the agencies stumble over themselves. In Maryland General, for example, there were 16 inspections over 16 months by six different agencies—the state of Maryland, CAP, JCAHO, CMS, the Food & Drug Administration, and the American Association of Blood Banks.

Three meetings to improve the sharing of inspection information have been held, and the next is set for early 2006, said Judy Yost, the top CLIA official at CMS. One area all agree needs to be tightened—ensuring that the lab director is actually involved in the day-to-day running of the lab and supervision of the testing being performed.

Should inspection findings be shared more widely? The Cummings' bill would require an annual report to Congress of the findings, though it is unclear how specific that report would have to be. Panel moderator Dennis Weissman asked, "If I were a physician sending test orders to a lab, or I were a patient being tested by that lab, shouldn't I know what deficiencies were found during an inspection?" Replied Ron Lepoff, MD, secretary-treasurer for CAP and immediate past chair of CAP's lab accreditation program: "Yes, I think you should."

focus on: *Lab Institute 2005*

Calls For Transformation From The Boardroom To The Bench

Quick fixes and tweaks to the separate pieces of the U.S. healthcare system have failed, with billions of dollars spent unwisely—it's time to start thinking in terms of transforming the system. That was the challenge Newt Gingrich posed at the opening session of Lab Institute 2005, held by Washington G-2 Reports/IOMA on October 19-22 in Arlington, VA.

Former House Speaker Newt Gingrich drew loud applause and cheers from Lab Institute participants when, in pointing to failures and illogic in the current healthcare system, he excoriated Medicare's policy holding labs liable for tests ordered by doctors and subsequently denying lab claims on medical necessity grounds. "Why go after the lab and not the doctor? How dumb is that?" he asked.

Instead of fixating on third-party payment methods and bureaucratic administration, "transformational thinking" starts with the premise that science-based innovations and the entrepreneurial free market provide more choice of higher quality at lower cost, said Gingrich, former Speaker of the U.S. House of Representatives and the founder of the Center for Health Transformation (Washington, DC).

As advances in molecular diagnostics and other gene-based testing transform medicine into clinical care that is increasingly more predictive, with effective interventions to prevent or manage diseases ("long-term living vs. long-term care," Gingrich said), the new healthcare paradigm will be "Know your DNA."

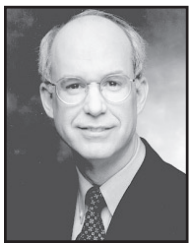
The personal electronic health record is one key driver of healthcare transformation, he said, and ultimately will help reduce errors, improve patient safety, measure quality and efficiency, and reduce costs. The White House has championed an e-health record for all Americans within 10 years, and both government and the private sector have mobilized to work toward that goal (*NIR, 26, 3/Nov 8 '04, pp. 4-6*). In tandem with the shift to personalized medicine, tax-free health savings accounts should be expanded to "incentivize and empower the individual," Gingrich said. These accounts enable people to put money aside to help pay for the kinds of care and services they choose.

U.S. Sen. Lindsey Graham (R-SC)

Entitlements & Cost Pressures

U.S. Sen. Lindsey Graham (R-SC), in a separate keynote address, stressed the need for transformational thinking about entitlement spending. Without reforms in this area, he warned, there can be no federal budget stability. Graham, a member of the Senate Budget Committee, pointed out that more than two-thirds of the budget is on autopilot—53% is mandatory spending on entitlements, including Social Security, Medicare, and Medicaid; 18% is interest on the national debt; and what's left to cut is discretionary spending.

Part of the solution to Social Security reform, Graham said, is to allow workers to invest some of the program's taxes they pay into personal savings accounts. Another part, he said, going against GOP orthodoxy, is to consider some tax increases to make up for the related revenue shortfall, such as raising the cap on Social Security taxes. He also advocated a new progressive pricing index for future benefits.



Kenneth Freeman

Cost pressures on healthcare spending (today about 13% of the gross national product, but projected to rise to 18% over the next 10 years) are a major force behind the healthcare revolution, an historic shift similar to the Industrial Revolution, said Kenneth Freeman, former chairman and CEO of Quest Diagnostics and, since May 2005, managing director at Kohlberg Kravis Roberts & Co. (New York City). Other key forces fomenting change are:

- ❑ Information technology. The e-health record will go from being the Holy Grail to a reality, resulting in lower costs and higher quality, he said.
- ❑ Science and innovation, with molecular medicine at the core of predictive and personalized medicine.
- ❑ Patients' desire for the "best" care and expectations of what that care is.

Implications For Labs

Freeman said these four prongs of the healthcare revolution have numerous and profound implications for laboratories:

- ❑ Labs must collaborate or perish.
- ❑ Labs will continue to bring most, but not all, diagnostic tools to clinicians. To be competitive, stay tuned to advances in diagnostics.
- ❑ Labs will be recognized as the primary source of information for healthcare decision-making. But the investment in e-health records will come at a high price, an estimated $100 billion to implement for all Americans.
- ❑ Labs will face new forms of competition, in particular as diagnostic imaging and diagnostic testing converge. This integration makes sense, Freeman said, because labs contribute about 60% of the content for clinical decisions, imaging about 20%. The convergence will occur over the next 5-10 years, he predicted.
- ❑ Labs must adjust to changes in healthcare delivery and payment, he said, citing initiatives by retailers like Wal-Mart and CVS to set up testing clinics in their outlets. This is good for people who don't get tested regularly, he noted, but the flip side is that the retailers gain more power.

Laboratory Lifetime Achievement Award

L. Joan Logue, a leader in the clinical laboratory community for more than 35 years, was honored with the 2005 Laboratory Public Service National Leadership Award for Lifetime Achievement, presented October 20 at Lab Institute 2005.

Mrs. Logue was the founder and first executive director of the Clinical Laboratory Management Association, and currently is the Founding Principal of Health Systems Concepts, Inc., and Health Software Consultants in Longwood, FL.

In addition to developing a national organization for lab professionals, she has directed lab operations for a 200-bed, acute-care hospital and worked closely with industry leaders and government organizations to establish international laboratory standards to assure quality and accuracy.

The award, presented annually by Washington G-2 Reports/IOMA, was sponsored this year by Kellison and Company. The recipient is selected by an independent committee of industry leaders, rotated annually. The panel's chair this year was Dr. Teresa Darcy, director of laboratories in the Department of Pathology and Laboratory Medicine at the University of Wisconsin Medical School in Madison.

The pace of consolidation in the lab industry will diminish dramatically over the next few years, Freeman said. The way to grow and win is science and innovation, with the focus on the patient, he emphasized. Diagnose early, or better yet, predict, he said—that's how labs will be seen as a cost reduction center, a strategic asset, as opposed to a cost center.

To Freeman, laboratories will prevail only by working together. In a stirring call to arms, he challenged the industry to overcome its splintered factions and create a unified front for visibility and traction on the policy and payment issues that matter most. Otherwise, labs will continue to be marginalized, he warned, citing as an example the failure of the industry to get one of its own appointed to the HHS advisory panel charged with developing a national e-health record system (*NIR, 26, 22/Sep 26 '05, p. 6*).

Following up on Freeman's call to arms, the Institute's program chairman, Dennis Weissman, at the closing session, urged the industry to consider formation of an independent entity to serve as a unified forum where lab and pathology groups would work together to reach consensus, educate Congress and the public on payment, quality, standards, and other issues, as well as conduct validation studies and other research to support the industry's positions.

Immediate Challenges

Complementing the focus on the macro transformational trends, Lab Institute attendees also had up-to-the-minute briefings on more immediate challenges:

Lab Competitive Bidding: Medicare is on track to launch, sometime next year, a competitive bidding demonstration for Part B independent lab services (excluding Pap smears and colorectal cancer screening). The demo design is being finalized, said Linda Lebovic, MPH, MT(ASCP), director of the project at the Centers for Medicare & Medicaid Services. She also noted some changes to the draft discussed at the August 24 open forum (*NIR, 26, 21/Sep 12 '05, pp. 4-6*):

- Along with independent lab and hospital outreach services, the demo will include reference services performed by large group practice labs. Most physician office labs would remain exempt, however.
- The two demo sites will be in different states, not a single one, but both sites will be served by a single carrier. CMS plans to announce the sites in the *Federal Register* early next year. The project has identified 22 metropolitan statistical areas (MSAs) that meet the demo's criteria. (At a separate session, attorney Jeff Boothe with Holland & Knight in Washington, DC, said he had identified cities/states that met the criteria, including Austin, parts of Ohio, and Orlando. Boothe predicted CMS would choose one site in the Midwest and the other in the South or Southwest. He didn't think California or Illinois would be picked because of their high rate of managed care penetration.)

In a pre-Institute e-mail survey of participants, Washington G-2 Reports asked which factor in the demo design poses the biggest problem for your lab? Nearly 50% of 117 respondents said: "Winning bidders will be paid for all Medicare tests while losers will get nothing." Nearly 38% said: "It still doesn't adequately reflect how labs do business."

CD recordings of the Lab Institute program are available for purchase as a complete set or as individual sessions. To order, go to www.g2reports.com. *The order form may also be downloaded and faxed to 212-564-0465. For more details, call 800-401-5937, ext. 2*

Medicare Advantage: Marketing is underway for the Part D prescription drug benefit and Medicare Advantage's expanded HMO and PPO managed care options, which take effect in January 2006. For labs, the main impact of Medicare Advantage will be that they'll have to negotiate pay rates with more payers under perhaps a wider array of coverage products, said William Rodgers, MD, medical officer in the Office of the CMS Administrator and director of the agency's Physicians Regulatory Issues Program.

Fraud & Abuse: Lewis Morris, Deputy Inspector General in the HHS Office of Inspector General, presented an overview of OIG priorities, including monitoring the rollout of the drug benefit and Medicare Advantage, greater collaboration with states against Medicaid fraud, and working to prevent fraud in health information technology and e-health records. In comments on controversial "condo" or "pod" labs, Morris said the OIG has raised several red flags about these arrangements which enable referring physicians to bill for pathology and other services performed off-site by others. He cited in particular the OIG's bulletin on contractual joint ventures and an advisory opinion that warned of potential kickback risks (*NIR, 26, 6/Jan 10 '05, p. 3*). Morris declined to answer specific questions about whether, if ever, the OIG would move forward on its proposal (now more than two years old) to exclude from Medicare certain providers, including labs, that charge the program "substantially in excess" of their usual charges. All he would say is that the proposal "is in the rulemaking process."

In a separate session, attorney Hope Foster with Mintz Levin (Washington, DC) warned labs to pay close attention to a new approach being taken by the U.S. Attorney's Office in Philadelphia to impose added, detailed compliance obligations on defendants who settle, even though most also sign corporate integrity agreements. Philadelphia is the only U.S. Attorney's Office she knows of that is doing this, but providers should be alert because it's a new strategy to hold them accountable for a broader range of specific behavior changes.

That's exactly the intent, said Paul Shapiro, Assistant U.S. Attorney in Philadelphia, who spoke on the same panel with Foster. These non-monetary obligations spell out the steps the government wants taken to ensure that behavior has changed in areas where Medicare/Medicaid are vulnerable. In recent cases brought by his Office, added compliance obligations have been imposed in false claims cases against Abington Memorial Hospital, Americhoice of Pennsylvania, a payor, and Central Montgomery Medical Center.

Cytology PT Update: Report Card On Initial Scores

In 2005, the first year of cytology proficiency testing enforcement, 87% of the 4,746 individuals enrolled passed the initial testing event (10 slides in 2 hours), while 13% failed, according to CLIA data as of August 26 from the two approved gynecologic cytology PT providers, MIME (the Midwest Institute for Medical Education in Indianapolis) and the State of Maryland program.

On the first retesting event (10 slides in 2 hours), 89% of 404 individuals passed, while 11% failed. On the second retesting event (20 slides in 4 hours), seven of 10 passed, three failed.

Primary physician readers had the highest failure rate. For the initial testing event, it was 41% (64); on the first retesting event, it fell to 33% (17); but on the second retesting event, it was three out of four. The failure rate for the secondary physician reader across all the events stayed steady in the 13%-14% range.

The update was presented at a special Lab Institute workshop by Judy Yost, the top CLIA official at CMS, and Rhonda Metzler, MIME's director of PT and CME.

More Pathologists Exempt From Cytology PT Rules

In an update to its policy on gynecologic cytology proficiency testing, officials at the Centers for Medicare & Medicaid Services have announced that certain pathologists will be granted an exemption from federal CLIA requirements for cytology PT:

- Anatomic pathologists newly certified by the American Board of Pathology or American Osteopathic Board of Pathology are exempt in the calendar year they win board certification.
- Likewise for those who are certified in cytopathology from the ABP or AOBP.

In the CMS interpretation, newly certified anatomic pathologists and cytopathologists have already demonstrated their competency interpreting cervical cytology by passing the board exams. The agency also extended the PT exemption to new graduates of schools of cytotechnology who achieved a passing score on the certification exam administered by the American Society for Clinical Pathology Board of Registry. Those who have not obtained a passing score must comply with the federal PT rules, CMS said.

The latest decisions are an extension of a previous policy decision that exempted anatomic pathology residents (*NIR, 26, 13/Apr 25 '05, p. 3*). CMS said pathology residents won't have to undergo cytology PT because they are not board-certified and are under the constant supervision of fully licensed physicians. However, fellows in cytopathology programs may have to meet PT requirements because they have completed their residency and have increased responsibilities. Those fellows who render final diagnoses of gynecologic specimens must take the test.

G-2/IOMA Lab Scholarship Awarded To Kelly Lucht

Kelly Lucht, a University of Wisconsin-Madison student, received the 2005 Dennis Weissman/Washington G-2 Reports' Scholarship Award for Excellence in the Clinical Laboratory Sciences during a special presentation on October 20 at Lab Institute 2005.

Ms. Lucht, a senior in the clinical laboratory sciences field, has excelled in course work, maintaining a 3.66/4.00 GPS, while participating in many activities on and off campus. She is active in numerous lab professional organizations, including serving as president of the university's student clinical lab science forum, and has volunteered for various lab advocacy activities and educational efforts to recruit students to lab professions.

She also has worked part-time as a lab assistant in a rural hospital laboratory performing waived testing along with phlebotomy, and this summer participated in a renal clinic internship at the Mayo Clinic in Rochester, MN.

Presenting the $5,000 award for the sponsor, Per-Se Technologies (Alpharetta, Georgia), was Patrick J. Leonard, president of specialty operations for the company's Physician Services division. Also pictured: Dennis Weissman, the founder of Washington G-2 Reports, in whose name the scholarship program was launched last year.

Infobytes...

Public Health Labs Join Lab Tests Online: The Association of Public Health Laboratories is the latest medical lab organization to join the patient Web site, Lab Tests Online, produced by the American Association for Clinical Chemistry and supported by 16 lab and pathology organizations. Monthly traffic on the site, which was launched in 2001, averages more than 600,000 visitors.

'Landscape of Local Plans' Now Available: This is a new resource at *www.medicare.gov* to help find Medicare prescription drug plans by state or Medicare Advantage plans with prescription drug coverage by county. The list of drug plans includes a column "No Premium with Full Low Income Subsidy," which corrects the mistake in the Medicare & You 2006 handbook (*NIR, 27, 1/Oct 17 '05, p. 8*).

Patient Authentication Standard Needed: As part of the effort to create a national system of personal e-health records, the U.S. Department of Health & Human Services should create a uniform mechanism to authenticate a patient's identity and protect personal health information, a federal advisory panel said recently. The Commission on Systemic Interoperability, authorized by the 2003 Medicare Modernization Act, also urged government, insurers, and employers to provide financial incentives within the next two years to "encourage adoption of e-health records and prevent a fractured system of haves and have-nots."

washington WATCH

Gone But Not Forgotten

Heeding a call from a House-Senate bipartisan group of lawmakers, HHS Inspector General Daniel Levinson has said his office will look into the circumstances around former Food & Drug Commissioner Lester Crawford's abrupt resignation, just two months after being confirmed by the Senate *(NIR, 27, 1/Oct 17 '05, p. 7)*.

Crawford said in a statement that he was leaving because it was time to take the next step in his life. But lawmakers want to know if it involved a potential conflict of interest. Crawford had been under fire on charges he let political decisions override scientific and policy judgments, especially with regard to delaying over-the-counter sales of the Plan B contraceptive.

Lawmakers say the OIG probe is needed due to longstanding concerns that the Bush Administration's picks for the FDA post have been too close to the industries the agency oversees.

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