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## CAP, COLA To Begin Unannounced Lab Inspections In '06

*Surprise surveys aren't new: they've been done for years in response to complaints or to validate compliance. But making them routine is a big change, flowing in part from lab quality failures like those at Maryland General Hospital that weren't detected during announced visits* (NIR, 25, 16/Jun 7 '04, pp. 4-6)

Starting in 2006, most of the thousands of clinical laboratories that are CLIA-accredited to perform moderate and/or high complexity testing will be subject to unannounced routine surveys once every two years.

The College of American Pathologists is the latest accrediting organization to make an official switch from announced routine surveys as of January 1. COLA will do likewise for the labs it accredits under its cooperative agreement with JCAHO, Max Williams, COLA's director of policy and external affairs, told the *National Intelligence Report*, adding that COLA is still in discussions with JCAHO to hammer out the details.

JCAHO, the Joint Commission on Accreditation of Healthcare Organizations, said earlier this year that it will shift to unannounced lab inspections as of January 1. At press time, JCAHO spokesman Mark Forstneger told *NIR* that the Commission is working out the implementation details with the Centers for Medicare & Medicaid Services and should wrap them up soon.

JCAHO and CAP together accredit more than 8,600 hospital and independent labs in the United States. The COLA subset of labs under the agreement with JCAHO numbers around 100, Williams said, noting that most labs in the COLA program are small and primarily based in physicians' offices.

➥ *p. 2*

## Budget Flux Makes Medicare A 'Moving Target'

With the federal budget in flux as Congress struggles with spending cuts and increases in the wake of Hurricanes Katrina and Rita, Medicare laboratory fees and payments to pathologists and other physicians remain a "moving target" at press time.

Laboratory groups were alarmed that the 20% co-pay for Part B lab services popped up in an "Operation Offset" proposal from conservative House Republicans. The idea was lifted from the Congressional Budget Office's options book, which suggested savings by imposing a 20% co-pay for all Part A and Part B services (10% for home health). CBO previously estimated that the lab co-pay could generate up to $18 billion in savings over 10 years.

To head off the issue, the American Clinical Laboratory Association met October 11 with U.S. Rep. Mike Pence (R-IN),

➥ *p. 2*

### INSIDE *NIR*

*Legislation introduced by U.S. Rep. Elijah Cummings (D-MD) would require unannounced lab inspections and whistleblower protections for employees who report problems in the lab. Accrediting bodies support the whistle-blower protections, but say the mandate for unannounced visits is unnecessary and adds little to what they are planning to do*

**Unannounced Lab Inspections,** *from p. 1*

Certain labs will generally be exempt from surprise visits, such as those where security is an issue (for example, military testing facilities and prison labs), though provisions will be made for advance security clearance of inspectors in particular settings. CAP notes that labs taking part in the Forensic Urine Drug Testing Program and the Reproductive Laboratory Medicine program, as well as international laboratories, will continue to have their inspections scheduled in advance.

CAP's switch to unannounced inspections will affect not only labs it accredits in the United States, but also in Canada and Puerto Rico. The inspection dates for labs undergoing their first CLIA inspection will be announced, but subsequent surveys will not. The unannounced inspection process will begin with reapplications that are created on January 1, 2006. The College anticipates that the first on-site unannounced inspections will occur in mid-April to early May.

According to CAP, "unannounced" means that the lab will not know the exact date of the inspection, nor will it be told in advance the name of the inspection team leader or team members. The inspection team leader and the lab staff will not have any contact until the day of the inspection. The survey will be pegged to a window of time before and after the lab's two-year anniversary date. To ensure that the appropriate staff is there for the inspection, CAP will have the lab indicate its days and hours of operation during the reapplication process. Ten blackout dates will be allowed per inspection group to avoid conflicts with events already scheduled.

For laboratories that are CLIA-certified under the federal program, routine surveys will continue to be announced. Judy Yost, the lead CLIA official at CMS, has told *NIR* that CLIA survey policy is to announce inspections no more than two weeks in advance (*NIR, 26, 13/Apr 25 '05, p. 5*).

*Lab Institute will hold a special session, "Legislative Alert for Labs & Pathologists," on Thursday, October 20, featuring veteran lab lobbyist Don Lavanty with the latest word from Capitol Hill*

**Budget Flux,** *from p. 1*

who chairs the House GOP Study Committee, comprised of more than 100 House Republicans. ACLA president Alan Mertz told *NIR* the purpose was to remind legislators that restoring the co-pay is "ill-advised" and that labs already have "given at the office," referring to the five-year freeze (through 2008) that was approved under the Medicare Modernization Act of 2003 and projected to save $7.8 billion over 10 years.

"We're finding that members of the study group aren't particularly pushing for the lab co-pay," Mertz said, "and some have indicated they are against it." The important thing, he noted, is what the committees of jurisdiction—Senate Finance, House Ways & Means, and House Energy & Commerce—will do. In Katrina's wake, House and Senate leaders postponed their markup of budget reconciliation legislation from the mid-September deadline until late in October (*NIR, 26, 22/Sep 26 '05, p. 1*).

There's also been talk on Capitol Hill that Medicare physician fees might be frozen because of disaster-related costs, and this has the College of American Pathologists and other medical groups worried. A freeze at current levels would still increase Medicare spending for physician fees by upwards of $6 billion, but organized medicine says a freeze "would be akin to a payment cut," said CAP and more than 120 other physician and healthcare groups in an October 3 letter to all House and Senate members. Absent congressional intervention, physician fees are projected to be cut by 4.4% in 2006 under the statutory update formula. Until Katrina, legislators had been expected to approve a modest hike similar to that granted this year, or 1.5%.

# Journal Creates Buzz Over Outsourced Lab, Pathology Work

*As noted in the Journal, critics fault referral deals for giving doctors an incentive for more profit by sending work to the cheapest lab, not necessarily the best lab. And by enticing them to order many tests, the deals drive up the nation's healthcare bill*

The *Wall Street Journal* has whipped up a buzz in the industry with its recent extensive coverage of how referring physicians can reap big profits by billing for outsourced pathology and laboratory work and how they can profit by billing Medicare for work done by off-site "condo" or "pod" labs.

Condo/pod arrangements have drawn fire from leading pathology organizations as a growing number of specialty physicians—in particular urologists, dermatologists, and gastroenterologists—have tapped relaxed benefits assignment rules to increase their Medicare revenue from pathology referrals (*NIR, 26, 4/Nov 22 '04, p. 4*).

## Referral Deals

Referral deals are common in the more than $40 billion clinical laboratory business, notes the article by David Armstrong, and are growing rapidly as doctors seek new revenue sources and demand grows for expensive lab work to detect diseases. As he describes these deals, often called client billing, a doctor sends a patient sample to an outside lab for testing, the lab charges the doctor a discounted price, and the doctor gets paid by the insurer for a much higher amount. Health plans typically pay the price they've set, Armstrong reports, unaware of the steep discounts doctors get for the work. One of the few private insurers to block doctors from profiting on outside lab work is Blue Cross Blue Shield of Georgia, he points out.

Medicare generally does not pay physicians for work done by others. Under direct billing rules, payment is made only to the person or entity performing the service. A growing number of states also mandate direct billing and/or prohibit physician markup to the insurer or require disclosure of charges the physician pays for a service and the markup (*see box*).

## Condo/Pod Labs

Of special interest to pathologists, the *Journal* article also looks at how condo/pod labs have proliferated because some companies have found a way to let doctors bill Medicare for off-site lab and pathology work, despite the program's direct billing requirements. In a condo/pod lab scenario, the physicians create the lab within a building anywhere that also houses labs for many other practices. Since they own the lab, they believe they are allowed to bill Medicare.

Medicare officials have taken a wait-and-see attitude, but remain concerned about the potential risks for abuse (*NIR, 26, 4/Nov 22 '04, p. 4*). The HHS Office of Inspector General first expressed its concern about condo/pods last year (*NIR, 25, 17/Jun 21 '04, p. 1*), and in an advisory opinion earlier this year concluded that one proposed condo/pod lab arrangement could face steep fines and risk Medicare exclusion for violating the federal anti-

### State Law Requirements: Billing For Anatomic Pathology Services

***Direct billing***

| | | |
|---|---|---|
| California (Pap smears) | Iowa* | Louisiana |
| Montana* | New Jersey | Nevada |
| New York | Rhode Island | South Carolina* |

**Legislation enacted this year*

***Physician markup prohibited***

| | | |
|---|---|---|
| California | Florida | Michigan |
| Oregon | Washington | |

***Disclosure of charges required***

| | | |
|---|---|---|
| Arizona | Connecticut | Delaware |
| Florida | Louisiana | Maine |
| Maryland | New Jersey | North Carolina |
| Pennsylvania | Tennessee | Texas |
| Vermont | | |

Source: College of American Pathologists

kickback statute (*NIR, 26, 6/Jan 10 '05, p. 3*). In that arrangement, the lab company provided the pathologists and equipment while receiving a monthly management fee from the referring doctors, who did the billing and kept the profit. The OIG saw a risk of illegal kickbacks since the lab company gave the doctors an opportunity for near-certain profits in exchange for the business.

### States Impose Curbs

Three states enacted legislation this year requiring direct billing for anatomic pathology services—South Carolina, Iowa, and Montana—making it nine in all that have this requirement on their books.

North Carolina became the latest state to require disclosure of charges. It enacted a measure that makes it unlawful to bill a patient, payer, or other third party an amount for anatomic pathology services greater than that charged by the clinical laboratory without disclosing the laboratory's charge. The bill sailed unopposed through the legislature and across the Governor's desk.

In Washington state, pathology interests welcomed an opinion they had sought from the state's attorney general Rob McKenna. In an opinion issued September 3, McKenna concluded that state law prohibits a physician from marking up the cost of pathology services obtained for patients but not performed or supervised by the physician. State law does not require direct billing, the opinion noted, but "to avoid conflict with the law, pass-through charges should be specifically identified as relating to pathology services, and the costs of the pathologist's services must not be increased by the referring physician."

## Run-Up Begins For New Medicare Rx, Managed Care Benefits

The new Medicare prescription drug benefit was launched October 1, the date when health plans could start marketing their coverage options to Medicare beneficiaries. The new benefit (Part D) takes effect January 1, 2006. All beneficiaries will be eligible for it, without regard to income. The enrollment period officially begins November 15 and ends December 31.

Marketers faced a rough sell at the launch. According to an October 4 USA Today/CNN/Gallup poll, 54% of beneficiaries said they don't plan to enroll in a drug plan, compared to 24% who said they do, while 22% had no opinion.

But things look good for expansion of Medicare managed care options in 2006, says the Centers for Medicare & Medicaid Services. The new Medicare Advantage program (MA or Part C) is set to begin January 1, replacing the Medicare+ Choice program established in 1999. The aim of the MA program is to shift more beneficiaries into managed care and away from Part B fee-for-service. Authorized by the Medicare Modernization Act of 2003, the MA program is backed by up to $12 billion in federal subsidies to encourage HMOs and PPOs to enter and stay in the Medicare market (*NIR, 25, 5/Dec 15 '03, p. 2*).

In 2006, CMS says, beneficiaries in 48 states can choose some variation of an MA plan (excepting Vermont and Alaska). In 37 states, beneficiaries will be able to get drug and healthcare coverage from regional PPOs.

### Get The Latest On The New Medicare

**Leslie Norwalk**, the deputy administrator of CMS, is a featured keynote speaker at Lab Institute 2005, sponsored by Washington G-2 Reports on October 19-22, in Arlington, VA. She will brief participants on the Medicare Rx benefit, the MA program, the preventive services benefit, including diagnostic screening, and CMS priorities for contractor changes and quality initiatives.

CMS has also announced that ten companies will offer nationwide Part D drug coverage. They include Aetna Life, Connecticut General Life, Medco Containment Life, Memberhealth Inc., Pacificare Life and Health Insurance, Silverscript Insurance, Unicare, United Health Care Insurance, Coventry, and Wellcare Health Plans.

Eight contractors have been hired to prevent fraud and abuse in the drug benefit program, says CMS. They will analyze claims data and conduct investigations. The Medicare Rx Integrity Contractors (MEDICs) include Science Applications International Corp., Perot Systems Government Services, Delmarva Foundation for Medical Care, Electronic Data Systems, IntegriGuard, Livanta, Maximus Federal Services, and NDCHealth.

# HIPAA Requirements Proposed For Claims Attachments

*Lab results and pathology reports are two of six types of e-attachments covered by the proposed standards*

As expected, the government's newly proposed HIPAA standards for attachments to electronic healthcare claims closely follow the consensus within the standards-setting industry (*NIR, 26, 17/Jun 20 '05, p. 6*). The standards, required by the Health Insurance Portability & Accountability Act, govern how to electronically request and receive additional documentation needed to support submitted claims.

As proposed by the U.S. Department of Health & Human Services, two X12N transaction standards would be used: one to request information, the other to respond. Health Level 7 (HL7) standards would be used for the format and content of clinical information, and the LOINC code set (Logical Observation Identifiers Names and Codes®) would be used to specifically identify additional information requested and code answers that respond to requests.

Six types of attachments are covered by the rule proposed in the September 23 *Federal Register*: laboratory results, clinical reports (including pathology reports), emergency department services, ambulance services, medications, and nine rehabilitation specialties. E-attachment specifications for durable medical equipment, periodontal care, and home health are still under development.

### Proposed Code Set

The e-attachment rule proposes adoption of the LOINC code set, a voluntary database to facilitate the exchange and pooling of results for clinical care, outcomes management, and research.

LOINC stands for Logical Observation Identifiers Names and Codes (LOINC®). It provides universal names and codes for identifying individual lab and clinical results and other clinical information. The LOINC code for a name is unique and permanent and has no intrinsic structure except that the last character is a check digit and must always be transmitted with a hyphen before it (for example, 10154-3).

The LOINC database is housed with the Regenstrief Institute, an international nonprofit medical research organization associated with Indiana University. The database may be obtained from *www.regenstrief.org/loinc/loinc.htm* or by request to the Institute, c/o LOINC, 1050 West Wishard Blvd., Indianapolis, IN 46202.

### Key Provisions

❑ *Transactions:* X12N 277 version 4050 would be used to transmit information about a particular claim in question and the question codes; X12N 275 version 4050 would be used to return the claim identification information and, in the binary data segment, transport the responses to each question, with the response codes,

narrative text, or actual imaged documents.

- *New code set:* E-attachment requests and responses would use the LOINC code set, which provides universal names and codes for identifying individual laboratory and clinical results as well as other clinical information.
- *Limits on continuous loop:* For each claim, health plans may solicit only one e-attachment request, and it must include all of their required or desired questions and/or documentation needs relevant to that claim.
- *Keeping costs down:* To help providers, particularly smaller practices that are not yet fully automated, deal with the costs of e-record systems, HHS would allow e-attachments to be sent in one of three formats:

| Variant | Information Representation | Information Sent As * * * |
|---|---|---|
| Human decision | Scanned image | Scanned image of pages from the medical record. Repeats LOINC code from the request. |
| Human decision | Natural language text text and structured information | National language text with captions that match the specified questions. Repeats LOINC code from the request. |
| Computer decision | Natural language text | Natural language text, captions identified by LOINC codes and supplemented by coded information |

The deadline for comment on the proposed rule is November 23, 2005. HHS plans a final rule in 2006. HIPAA-covered entities would have to be compliant within two years of the date of the final rule (for small health plans, it's three years). But there's nothing to prevent entities from using the proposed X12N or HL7 standards voluntarily, HHS notes.

## ♦CODING A·D·V·I·S·O·R·Y

# Medicare Claims & Use Of The National Provider Identifier

The Centers for Medicare & Medicaid Services has laid out the timetable it plans to follow during the phase-in to mandatory use of the National Provider Identifier or NPI on Medicare fee-for-service claims. The NPI is required under HIPAA (the Health Insurance Portability & Accountability Act of 1996) as one of a series of national identifiers to facilitate the exchange of electronic healthcare data. In May, CMS began issuing NPIs, gave providers three ways to apply, and urged them to sign up as soon as possible (*NIR, 26, 15/May 23 '05, pp. 1-2*).

According to the timetable, providers may begin to use their NPI in January 2006; in May 2007 they will have to use it—Medicare will reject claims without it. The switch to sole use of the NPI will be staggered as follows:

- January 3, 2006-October 1, 2006: Medicare systems will accept claims with an NPI, but an existing legacy Medicare billing number must also be on the claim. Claims with only an NPI will be rejected.

- October 2, 2006-May 22, 2007: Medicare systems will accept an existing legacy Medicare billing number and/or an NPI.
- May 23, 2007-Forward: Medicare systems will accept only NPIs. Small health plans have an additional year to become NPI-compliant.

## New Coding For Disaster Claims

In the wake of Hurricane Katrina, the Medicare program has created a national modifier and condition code to be used by healthcare providers when submitting disaster-related claims. The new condition code is "DR (Disaster related)" and the new modifier is "CR (Catastrophic/Disaster related). Medicare contractors must recognize these additions by no later than October 31, 2005.

## ♦NAMES *in the* N•E•W•S

**Abrupt Departure:** Lester Crawford, the new Commissioner to head the Food & Drug Administration, has resigned, just two months after being confirmed by the Senate for the job. His departure came amid sharp criticism of his decision to delay over-the-counter sales of the "morning after" Plan B emergency contraceptive. Under his tenure the FDA also came under fire for lax oversight of Vioxx marketing despite reports of risks to health and even death. Critics say Crawford's main fault was that he allowed political considerations to trump scientific decisions.

Crawford won Senate clearance, 78-16, only after promising that the FDA would issue rules by September 1 for the Plan B pill and after he was exonerated of alleged travel irregularities (*NIR, 26, 19/Jul 25 '05, p. 8; 26, 9/Feb 21 '05, p. 8*). Crawford has been acting FDA Commissioner for the last year and previously was the deputy Commissioner. In explaining his resignation, Crawford said, "After three and a half years [in these positions], it is time at the age of 67 to step aside." The Bush Administration has named Dr. Andrew von Eschenbach, a urologic surgeon and the director of the National Cancer Institute, as acting FDA Commissioner. Senate Finance Committee chairman Charles Grassley (R-IA) has urged the President to name a permanent FDA Commissioner soon.

**Reassigned & Excluded:** Sean Tunis, MD, the former chief medical officer at CMS who was sanctioned for falsifying continuing education credits, has been reassigned to the HHS Agency for Healthcare Research & Quality, as of September 22, and has been put on the HHS Inspector General's Medicare/Medicaid exclusions list. To comply with the exclusion, he will no longer be involved in federal medical decisions; instead, he will help train federal medical researchers.

Tunis was put on administrative leave from CMS last April and later agreed to a $20,000 fine and a one-year suspension of his medical license from the Maryland Board of Physicians (*NIR, 26, 18/Jul 11 '05, p. 7*). He admitted to altering documents to show he complied with state CME requirements, but said he did so to reproduce the records of credits he had legitimately obtained. Barry M. Straub is serving as acting CMS chief medical officer and has taken Tunis's place as acting director of clinical standards and quality.

## Infobytes…

**Safe Harbor Proposed For E-Prescribing:** In a bid to promote adoption of electronic prescriptions and e-medical records, the HHS Inspector General and the Centers for Medicare & Medicaid Services on October 11 proposed exceptions to the Stark physician self-referral law and the federal anti-kickback statute that would allow hospitals and certain healthcare organizations to furnish non-monetary remuneration in the form of software, hardware, and related e-record training to physicians, but the technology must be used solely to receive and transmit e-prescription drug information. CMS says it is considering a cap on donations to reduce the potential for kickbacks in exchange for referrals. Bipartisan legislation mandating a safe harbor to encourage investment in health information technology is pending on Capitol Hill (*NIR, 26, 17/Jun 20 '05, p. 6*).

## washington WATCH

### Medicare Still Can't Get It Quite Right

Though the Centers for Medicare & Medicaid Services corrected several major gaffs in a draft "Medicare and You" Handbook explaining expanded benefits, including a rosy assessment of new prescription drug coverage (*NIR, 26, 17/Jun 20 '05, p. 8*), the final version recently mailed to more than 38 million beneficiaries still contains an error, the agency has acknowledged. It significantly overstates the number of drug plans that will be available without any premiums for low-income people.

Underscoring the complexity of the new program, Medicare officials also incorrectly described the standard minimum drug benefit in a recent ad run in a national newspaper supplement. The Bush Administration has alerted Congress about the errors and says they will be corrected in future brochures and on the Medicare Website.



**HIV-Exposed Health Workers:** The Centers for Disease Control & Prevention on September 30 released an update to its 2001 guidelines for treating job-related exposure of healthcare workers to HIV. The agency now recommends two or more drug regimens based on risk for HIV transmission and the start of prophylactic regimens as soon as possible—within hours rather than days of exposure. If there are any questions about which drugs or regimens to use, the CDC said, the basic regimen (zidovudine for four weeks) should be started immediately. The latest guidelines were published in the CDC's *Morbidity & Mortality Weekly Report*, *www.cdc.gov/mmwr/pdf/rr/rr5409.pdf*.



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