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Medicare Change Raises Specter Of More Claim Rejections

Dial in to our special May 24 audioconference for more on this new payment policy and other key Medicare changes. See p. 8 of this issue for registration details

In its zeal to catch providers who keep resubmitting claims until they find an ICD-9 diagnosis code that pays, the Centers for Medicare & Medicaid Services is placing an unfair burden on clinical labs, says the American Clinical Laboratory Association.

At issue is a policy change effective July 5, whereby carriers will stop re-reviewing denials and instead will perform only one medical review per claim (CMS Change Request 3622). Claims that are denied, medically reviewed, or awaiting documentation will thenceforth be denied as duplicates if resubmitted.

Clinical labs can expect to see many valid claims denied as a result, warns ACLA senior vice president JoAnne Glisson. "We're talking about thousands of rejected claims going to appeal per month, per lab," she told the *National Intelligence Report*. The problem, she said, is that carrier software systems can only process four ICD-9 codes at a time, while carriers accept claims with as many as eight ICD-9 codes. The current approach is for labs to submit each such claim twice—initially with the first four codes, then with any additional codes. ➥ *p. 2*

INSIDE *NIR*

Flu Scare Prompts Tighter PT Safeguards

In response to this month's global alert on a potentially dangerous influenza strain in proficiency testing samples sent to laboratories, the College of American Pathologists is taking steps to prevent a recurrence and the Centers for Disease Control & Prevention has pledged to develop new PT guidance for accrediting bodies. CAP and CDC have said the risk of lab workers getting infected is low.

Canadian scientists alerted CDC that the H2N2 influenza A virus, associated with the Asian flu pandemic in 1957, had been detected in a sample. This strain has not found outside a lab since 1968, so anyone born thereafter lacks immunity to it. CDC in turn alerted CAP and other providers, requesting destruction of all extant samples. CAP stopped shipments on April 8 and notified nearly 3,750 PT lab customers to destroy the samples via autoclave and incineration and attest by fax that they have completed the job.

CAP obtained the samples from Cincinnati-based Meridian Bioscience Inc., as did at least three other PT providers: the American Association of Bioanalysts, American Association of Family Practitioners, and Medical Lab Evaluators. ➥ *p. 6*

Medicare Change, *from p. 1*
ACLA and CMS officials met last month on the issue, but reached no resolution. Glisson said ACLA argued, to no avail, that CMS would spend more on appeals of valid claims than it would save on invalid claims. CMS plans to proceed with implementation as scheduled, without first adjusting systems to accept eight ICD-9 codes per claim. The agency told carriers to use a message with these denials saying they are "not appealable unless the provider can document that the service was not a duplicate because it was performed more often than indicated in the original line."

MIME Allows Local Cytology PT Re-Takes

Gynecologic cytology proficiency testing got a little easier for those who fail their first test. The sole national PT provider for this subspecialty in 2005—Midwest Institute for Medical Education (MIME)—will let individuals repeat the test at their own facility. Previously, MIME had required that all repeats occur at its site in Indianapolis. Now, only second and subsequent re-takes must be done there.

"We were hearing from our clientele that [the previous policy was] an inconvenience," Rhonda Metzler, MIME's director of proficiency testing, explained to *NIR*. "It was mainly a customer service issue."

Individuals who read Pap smears must be tested for proficiency every year, as required by CLIA (Clinical Laboratory Improvement Amendments) and implementing regulations codified in 1992. However, this requirement did not take effect until recently due to the lack of a federally approved national program. Then, in November 2004, the Centers for Medicare & Medicaid Services approved MIME's program, effective January 1, 2005 (*NIR, 26, 5/Dec 16, '04, p. 1*). Prior to that, there had been only one approved gynecologic cytology PT provider—the Maryland Department of Health & Mental Hygiene—but it serves only labs located in the state or testing specimens from state residents.

Change In Travel Requirement

MIME's policy of requiring travel to Indianapolis for re-tests was a source of major complaints aired by many cytologists and pathologists at various forums, including a CMS open-door forum and an audioconference hosted by Washington G-2 Reports. So MIME sought, and in late March obtained, CMS approval to change that requirement for the first re-test.

Anyone who fails the test the first time must re-take it within 45 days and may do so at their own lab. They may either use the same trained proctor or switch to a different one, as long as that individual has passed the proctor training program, Metzler said. Also, people who missed the first test due to an excused absence may take it at their own facility, along with any necessary first re-take. Or they can take the test whenever it is scheduled at other locations where they have an "employment relationship."

Metzler told *NIR* that MIME still requires travel to Indianapolis for second and third re-takes, in part because the individuals need to bring proof of remediation.

Approved Cytology PT Programs

Midwest Institute for Medical Education
9550 Zionsville Road, Ste. 110
Indianapolis, IN 46268
Tel: 800-575-2342 or 317-876-4169
www.mimeonline.com, www.cytoquest.com, or *www.mimeinc.org*

Maryland Cytology Proficiency Testing Program
Maryland Department of Health & Mental Hygiene
Office of Health Care Quality – Laboratory Care
Spring Grove Hospital – Bland Bryant Bldg.
55 Wade Avenue
Catonsville, MD 21228
Tel: 410-402-8028

Every individual subject to gynecologic cytology PT must enroll in an approved program by June 30, 2005, and must complete the initial test no later than December 31, 2005, says CMS

CMS Urges Labs To Participate

CMS has sent a letter to cytology labs reminding them that they must enroll and participate in either the MIME or Maryland cytology PT program for 2005, and warning that "enforcement will have to be applied against those that disregard the requirements." Sanctions can include placing limits on a lab's CLIA certificate for cytology or suspending the lab's Medicare/Medicaid payments for gynecologic cytology testing.

CMS has also determined that 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 take the test because they have completed their residency and have increased responsibilities. Those fellows who render final diagnoses of gynecologic specimens must take the test.

Separately, in a posting on the CLIA Website, *cms.hhs.gov/clia*, CMS expresses regret for confusion over certain cytology PT dates. The dates in the CMS memo to survey and certification agencies are internal deadlines for deciding whether to initiate sanctions against labs that fail to enroll and complete initial testing by the close of this year (*NIR, 26, 6/Jan. 10, '05, p. 6; 26, 8/Feb 7, '05, p. 2*).

Lab Groups Battle Medicaid Co-Pay In Pennsylvania

Clinical laboratory interests are lobbying against a 2005-2006 budget proposal by Pennsylvania Democratic Gov. Edward Rendell to require co-payments for laboratory tests under the state's Medicaid and general assistance programs.

The co-pay is part of an effort to close a $1 billion gap between available state and federal funds and projected Medicaid costs without eliminating Medicaid benefits for anyone, according to the governor's office. Cuts proposed by President Bush, if enacted, could force the state to go further, eliminating Medicaid services for at least 60,000 people, Rendell said in an April 18 letter to the Pennsylvania congressional delegation.

Save these dates on your calendar

October 19-22, 2005

You'll want to join us for our **23rd annual LAB INSTITUTE**, *Transforming the Lab in the 21st Century*, to be held at the Crystal Gateway Marriott Hotel, Arlington, VA.

The lead-off keynote speaker: Newt Gingrich, author of *Saving Lives and Saving Money*, former Speaker of the U.S. House of Representatives, and founder of the Center for Healthcare Transformation

The state budget proposal adds sliding-scale co-pays for a wide range of services to nearly 900,000 adult Medicaid recipients and nearly 317,000 general assistance recipients.

Fee Paid	Medical Assistance Co-Pay	General Assistance* Co-Pay
$10.00 or less	$0.50	$1.00
$10.01 to $25.00	$1.00	$2.00
$25.01 to $50.00	$2.00	$4.00
$50.01 or more	$3.00	$6.00

* Not bound by federal Medicaid co-pay rules

In an April 5 letter to Estelle Richman, secretary of the Pennsylvania Department of Public Welfare, Alan Mertz, president of the American Clini-

cal Laboratory Association, said the co-pay would do nothing to reduce utilization of lab services because treating physicians, not patients, order the tests. Further, it would be a hardship for labs to bill and collect the co-pay because they generally do not see patients and do not receive contact information with test requisitions. Thus, they cannot collect payment at the time of service and would have to locate the individuals before they could bill for it.

The Clinical Laboratory Coalition chimed in with a similar letter to Richman on April 14, calling attention to the Institute of Medicine's determination in its 2000 report on Medicare lab payment policy that it would cost more than $5 to collect each lab co-pay, well in excess of the $0.50 to $3.00 value of the co-pay itself.

ACLA and the American Association of Bioanalysts jointly retained a Harrisburg lobbying firm, Malady & Wooten, to help state legislators understand why they should reject lab co-pay. Also, AAB administrator Mark Birenbaum said the group's Pennsylvania members raised the issue with their elected representatives. For lab co-pay to take effect in Pennsylvania, legislators would not only have to approve the governor's budget request, but would also have to remove a state statutory provision that exempts labs from co-pay requirements.

JCAHO, CAP Officials Describe Surprise Inspection Plans

A major impetus for change has been quality testing failures, as in the Maryland General Hospital lab case, where the problems were concealed from private and state surveyors and surfaced only after whistleblower allegations (NIR, 25, 16/Jun 7, '04, pp. 4-6)

During an April 12 audioconference hosted by Washington G-2 Reports, two officials of leading private organizations that together accredit more than 8,600 clinical laboratories described how their groups intend to switch soon to largely unannounced inspections.

The Joint Commission on Accreditation of Healthcare Organizations is moving to unannounced inspections on January 1, 2006, not just to enhance public accountability, said Margaret Peck, acting director of JCAHO's laboratory accreditation program, but also to eliminate the anxiety and ramp-up that lab personnel experience when they know inspectors are coming. Inspectors generally will arrive within 45 days before or after the accreditation due date, but that policy is still under review, she said. In some circumstances, organizations can get exceptions from 100% unannounced surveys, she noted.

This year, some 100 organizations volunteered for unannounced pilots. "Feedback is overwhelmingly positive," Peck observed, with staff saying "they especially appreciate the lack of ramp-up anxiety." Even so, audioconference participants exhibited some anxiety about the idea of relying on unannounced inspections. One participant, an official with Genzyme Genetics, noted that inspections would lose some of their ability to disseminate best practices because key officials could not plan to be there.

The College of American Pathologists is switching to unannounced inspections, except at military bases and government-associated facilities where inspectors would need to pre-arrange access, said CAP secretary-treasurer Jared Schwartz, MD, PhD, who also is director of pathology and laboratory medicine at Presbyterian Healthcare in Charlotte, NC. Schwartz stressed, however, that there is no evidence comparing announced and unannounced inspection processes. "We're responding to the external environment, and we will learn," he said. "We might find we lost something. Only time will tell."

Judy Yost, who heads the CLIA regulatory program at the Centers for Medicare & Medicaid Services, later told *NIR* that CMS has no plans "at this time" to switch to unannounced inspections. Though CLIA rules allow them, CMS only uses them when following up on complaints. The rationale for announcing most inspections, as cited in the CLIA rules, is that, otherwise, inspectors could be interrupting the practice of medicine or surveying the lab on a day when the appropriate information or personnel are not there. That said, CLIA survey policy is to announce inspections no more than two weeks prior. "That isn't a long time for a lab to get away with fixing up things," Yost said. "If there are systematic problems, they will be identified."

Medicare Posts 'Hospital Compare' Quality Data Online

Blood culture performed before the patient receives an initial antibiotic is one of the quality measures for treating pneumonia

In an initiative that aims to help beneficiaries choose hospitals, but also puts market pressure on hospitals to excel, the Medicare program has posted online hospital performance data on up to 17 clinical measures related to heart attack, heart failure, and pneumonia.

Nearly all the eligible hospitals (some 4,200 facilities) voluntarily reported the data, said the Centers for Medicare & Medicaid Services. Hospitals that voluntarily report get a full marketbasket update this year to their inpatient prospective payment; those that don't report get 0.4% less. The Medicare Modernization Act of 2003 established the pay-for-performance (P4P) incentives. The Act required CMS to reward hospitals that reported 10 measures; CMS added the other measures later.

CMS head Mark McClellan, MD, PhD, said the agency is "working hard to make even more comprehensive information on quality available soon." The agency is working with the Hospital Quality Alliance, the National Quality Forum, and others to develop "a much stronger foundation for supporting and rewarding better quality care," he said.

CMS has displayed the hospital quality data characterizing performance on the 17 measures below at *www.hospitalcompare.hhs.gov* and *www.medicare.gov*:

• HEART ATTACK (acute myocardial infarction)

1. Aspirin at arrival
2. Aspirin at discharge
3. Beta-blocker at arrival
4. Beta-blocker at discharge
5. ACE inhibitor for left ventricular systolic dysfunction (LVSD)
6. Percutaneous transluminal coronary angioplasty (PTCA) within 90 minutes of arrival*
7. Thrombolytic agent (clot buster) within 30 minutes of arrival*
8. Smoking cessation counseling*

• HEART FAILURE

9. Left ventricular function (LVF) assessment
10. ACE inhibitor for left ventricular systolic dysfunction (LVSD)
11. Smoking cessation counseling*
12. Discharge instructions*

• PNEUMONIA

13. Initial antibiotic received within 4 hours of hospital arrival
14. Pneumococcal vaccination status
15. Oxygen assessment
16. Smoking cessation counseling*
17. Blood culture performed before initial antibiotic received*

** One of the seven additional measures added by CMS.*

Flu Scare, *from p. 1*

It's still unclear at press time how the flu virus problem arose. Typically, PT samples contain harmless strains. Meridian Bioscience reportedly is looking into possible causes. In a statement on its Website, CAP notes that its policy is to bar use in its PT products of microorganisms or other materials associated with a risk of potentially causing harm

In response to the incident, the College is making two long-term improvements, CAP's secretary-treasurer Jared Schwartz, MD, PhD, FCAP, told reporters. "We will become much more specific with our vendors, telling them what strains we want to use" and will verify that CAP receives the type and subtype requested. The College also will check with CDC annually to see whether the agency is considering changing the biosafety level for any viruses CAP is planning to send out in the next year's PT samples.

CDC also plans to develop new guidance as a consequence of this incident. "We are going to assemble the necessary experts and put this on a fast track," said agency director Dr. Julie Gerberding, "to create…guidance…that we hope the organizations will take seriously, will participate in, and then use as quickly as we can get the expert input together." She said CDC "can't comment on what the College and the other organizations responsible for accreditation actually knew or understood about the content of the PT panels, and that's something we will be exploring as we go forward."

Risk To Lab Workers Deemed Low

Schwartz said, "The risk of a lab worker becoming infected is extremely low." Lab workers handle the samples at Biosafety Level 2, which provides a substantial degree of safety. Further, the virus is sure to have attenuated due to repeated culturing, he noted.

CDC is asking labs involved in such PT to monitor their workers and test them for flu if they have symptoms "even remotely suggestive of influenza," Gerberding told reporters. "And if influenza is found, the individual should be treated, CDC should be notified, and that sample should come here."

CDC told CAP it has been working with the National Institutes of Health for the past several months to upgrade protection against the H2N2 virus to Biosafety Level 3. Canada and many other countries already require BSL 3 for this strain. "We believe Level 2 precautions would certainly protect workers," Gerberding said, "but we're erring on the side of extra caution, and in the future we will be urgently recommending a higher level of precaution for any novel flu virus."

Schwartz said the samples CAP received from Meridian were labeled as a Shanghai type of strain, H3N2. He noted there were media reports that Meridian used an Asian flu virus because it is a reference strain that grows quickly in culture and was unconcerned about virulence due to the substantial degree of attenuation that has occurred in labs over the years. Merid-

"Select Agent" Controls Finalized

The government recently finalized rules limiting possession, use, and transfer of biological agents and toxins that pose a severe threat to public health and safety. The H2N2 flu strain is not on the list, said CDC director Julie Gerberding, though several highly pathogenic Avian flu strains are.

The "select agent" rule took effect April 18. It:

- ❑ Revises the genetic element section to include nucleic acids that can produce infectious forms of any of "select agent" viruses.
- ❑ Clarifies that both registered and unregistered entities must report select agents presented for diagnosis, verification, or proficiency testing.
- ❑ Specifies who can access select agents.
- ❑ Requires annual drills or exercises of security, biosafety, and incident response plans.

CDC has oversight of the HHS list of select agents; the "overlap select agent" list is subject to regulation by both CDC and the Agriculture Department's Animal & Plant Health Inspection Service (to view the lists, go to *www.cdc.gov/od/sap*). The final rule, which implements provisions of laws enacted in the aftermath of 9/11, was published in the March 18 *Federal Register*.

ian alerted investors April 13 about the issue, emphasizing that it didn't violate any regulations and that no one has become infected. If Meridian intentionally provided the 1957 flu virus for proficiency testing, it didn't violate any U.S. regulation but "probably did not use good judgment," Schwartz said.

♦CODING A·D·V·I·S·O·R·Y

Fees for two surgical pathology codes, new to the CPT system in 2005 and included in the 2005 Medicare physician fee schedule, are being lowered as part of a number of technical corrections recently announced by the Centers for Medicare & Medicaid Services and retroactive to January 1.

The lower fees result from corrections to the practice expense relative value units (RVUs) for the technical component of CPT 88367, In situ hybridization, auto, and CPT 88368, In situ hybridization, manual. For 88367, the practice expense RVUs are now 3.49 vs. the previously published 3.57; for 88368, the drop is much more severe, from 2.90 to 1.79. The corrections also impact the global fee for these services, as shown below.

Code	Mod	Description	Work RVUs	PE RVUs, Non-Facility	Malpract RVUs	Total RVUs, Non-F	Fee*
88367		In situ hybridization, auto	1.30	4.03	0.12	5.45	$206.54
88367	TC	In situ hybridization, auto	0.00	3.49	0.06	3.55	$134.54
88368		In situ hybridization, manual	1.40	2.39	0.12	3.91	$148.18
88368	TC	In situ hybridization, manual	0.00	1.79	0.06	1.85	$70.11

*Unadjusted for practice costs in specific Medicare payment locality; also, rounded up. The fee is derived by multiplying the total RVUs for the service by the 2005 conversion factor of $37.8975. CPT codes © American Medical Assn. TC=Technical component.

The changes, announced in the April 1 *Federal Register*, affect various other codes on the 2005 physician fee schedule that was published November 15, 2004 (*NIR, 26, 4/Nov 22, '04, p. 3*). Also, forensic cytopathology code 88125 has a new RVU total of 0.17 or $6.44.

Celebrating National Medical Laboratory Week ❖ April 24-30

We at Washington G-2 Reports/IOMA are proud to join in this nationwide salute to the 265,000 medical laboratory professionals and 15,000 board-certified pathologists who perform and interpret medical lab tests.

This annual event is a special occasion to educate the public about the key role these individuals play in healthcare, to promote the lab professions and recruit students for these professions. Many members hold displays, open houses, and other public activities in their institution or local area.

The 11 sponsoring organizations for this year's celebration are:

- American Association for Clinical Chemistry
- American Association of Blood Banks
- American Medical Technologists
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Society for Microbiology
- American Society of Cytopathology
- Association of Public Health Laboratories
- Clinical Laboratory Management Association
- College of American Pathologists
- National Society for Histotechnology

Broad Approach Proposed For HIPAA Penalties

HIPAA-covered entities include health plans, health clearinghouses, and healthcare providers that transmit health information in electronic form

The Health & Human Services Department is proposing to take existing rules for investigating non-compliance with privacy provisions of HIPAA (the Health Insurance Portability & Accountability Act) and apply them to all of the HIPAA administrative simplification rules as well, including standards for electronic transactions and code sets, security, and unique health identifiers.

The proposal, published in the April 18 *Federal Register*, would also amend existing rules for imposing civil monetary penalties. Among other things, it elaborates on the investigation process, bases for liability, determining the penalty amount, grounds for waiver, and the hearing and appeal process. It includes changes that, for example, say:

- ❑ If multiple HIPAA-covered entities are responsible for a HIPAA violation, all of them should be fined for it.
- ❑ Covered entities are jointly and severally liable for penalties against affiliates.
- ❑ The term "provision of this part" in Section 1176 (each violation of which is subject to a penalty of $100 or less) means any requirement or prohibition, including standards and specifications.
- ❑ A non-natural person is an entity.

Comments are due June 17 and can be submitted electronically at *www. regulations.gov*. Be sure to reference HHS and "RIN: 0991-AB29."

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