



NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 27th Year of Publication

Vol. 27, No. 8, February 6, 2006

Tight Deadlines Set For 'Medically Unbelievable' Edits

The edits, proposed under Medicare's national Correct Coding Initiative, are being handled by Correct Coding Solutions LLC (Carmel, IN), which took over the job from Reliance Safeguard Solutions as of December 21, 2005.

A 60-day comment period ending March 20 has been set for Medicare's controversial "medically unbelievable" edits (MUEs) that the Centers for Medicare & Medicaid Services plans to have up and running by July 1.

The edits encompass most CPT/HCPCS non-surgical codes, including more than 1,000 of concern to pathology and laboratory groups (*National Intelligence Report*, 27, 7/Jan 23 '06, p. 2).

The MUEs would establish limits on the units of service that could be billed for a particular code reported by a provider for the same Medicare beneficiary on the same date of service. Claims that exceeded the limits would be automatically denied.

The American Medical Association has asked CMS to delay the MUE rollout until January 2007, but at press time, had yet to receive a response, an AMA spokesperson told *NIR*.

Meantime, the association has distributed a revised file of proposed MUEs for review by medical specialty and laboratory organizations. The file came from Correct Coding Solutions, the new contractor for Medicare's national Correct Coding Initiative (CCI). ➔ p. 2

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Physicians Get Medicare Fee Fix For 2006

Pathologists and other physicians can say good-bye to the 4.4% reduction in their Medicare fees that took effect January 1, now that the House has passed the budget reconciliation bill that rescinds the cut and grants a 0% update instead, retroactive to the start of the year (in effect, a freeze at calendar 2005 levels).

The bill had cleared the House and the Senate in December, but procedural issues in the Senate made a second House vote necessary and the House had already adjourned for the holidays (*NIR*, 27, 6/Jan 9 '06, p. 1). The House reconvened January 31 and approved the bill on February 1 by a razor-thin margin of 216-214. The measure now goes to the President, who has said he will sign it into law.

All physician fee schedule claims paid prior to the signing of the bill will be automatically reprocessed to account for the new, higher rates by no later than July 1, Medicare officials have announced (*NIR*, 27, 7/Jan 23 '06, p. 1). Providers will not need to resubmit claims to get the difference between the 4.4% cut and the 0% update. Up to 80 million claims may potentially have to be reprocessed, the agency has estimated. 🏠



'Medically Unbelievable' Edits, from p. 1

Some Clarifications Made

In a January 18 letter to affected organizations, Niles R. Rosen, the company's medical director, noted these key points:

- ❑ The file contains all CPT/HCPCS codes for which MUEs have been developed so far, but it may contain codes that were not included in the previous edit package distributed in early December by the former CCI contractor, Reliance Safeguard Solutions. Rosen said his company got the MUE file only in early January, so he cautioned, "We have not had an opportunity to perform quality control testing, such as verifying that all the listed codes are valid and active codes." Nonetheless, the file has been sent out to "allow as long a comment period as possible without delaying implementation of the edits."
- ❑ The MUEs are based on anatomic considerations, CPT code descriptors and coding instructions, and medical reasonableness. Their purpose is to "prevent overpayments resulting from the reporting of excess units of service due to entry errors, incorrect interpretation of CPT/HCPCS codes, etc."
- ❑ The MUEs consist of CPT/HCPCS codes and the corresponding maximum units of service assigned for local Medicare carriers and fiscal intermediaries. These units of service are generally the same for carriers and intermediaries, except for 21 codes with different values (these are for a physician's evaluation and management services for new and established patients during office or other outpatient consultations, emergency department services, and critical care evaluation and management services).
- ❑ There will be no modifiers to bypass the edits.
- ❑ CMS has yet to decide whether it will allow providers to appeal individual claims to their local carriers or fiscal intermediaries.

Concerns Remain Over Process & Policy

While Rosen's letter has clarified some details on the MUE project, medical specialty and laboratory groups remain deeply concerned about the proposed edits, the implementation deadline, and the way in which the initiative has been handled.

In a January 18 letter to CMS administrator Mark McClellan, MD, the AMA's executive vice president and CEO, Michael Maves, MD, MBA, reiterated major issues that other participants in the review process have raised, including the College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association.

Maves said the proposed MUEs are not the same as typical CCI edits, and thus a go-slow approach is prudent. In addition to involving a massive volume of codes to be reviewed, the MUEs are "based on anatomic consideration as to what is logical, and more problematic, CMS's expectations of what is medically reasonable." A cursory review has already uncovered a large number of errors.

"The AMA is concerned about the apparent lack of transparency in how the MUEs were developed," Maves continued. "CMS's criteria for assigning a number of units to a particular code are unclear and poorly communicated; therefore, it is difficult to develop comments ... Without a clear understanding of CMS's rationale, the AMA and medical specialty societies will be forced to speculate" on how "medical reasonableness" has been determined. "This will result in a more time-consuming process subject to potential misinterpretations, both of which could be avoided through increased communication." 🏠



President Backs Expanded Market Mechanisms In Healthcare

In 2006, the Administration says it will work to develop nationwide health information technology standards to accelerate patient access to e-health records. "This includes a 'medical clipboard' that can be accessed only with a patient's consent, electronic medication history, and lab test results, and ways to utilize health information tools to monitor potential disease outbreaks such as pandemic influenza."

In the annual State of the Union address to Congress on January 31, President George W. Bush advocated wider use of electronic health records and other health information technology, along with medical liability reforms, to help control healthcare costs and reduce medical errors. He also called for broader use of the private sector to make health insurance coverage more affordable and accessible, including expanded tax breaks for health savings accounts.

While Mr. Bush devoted only a single paragraph of the 51-minute address to healthcare, the White House that same day released further details that are expected to be fleshed out in the budget request the President will send to Congress the week of February 6. Among the highlights:

□ *Strengthening Health Savings Accounts:* Established under the Medicare Modernization Act of 2003, HSAs are tax-sheltered accounts to which individuals—and employers—can contribute to pay for routine medical expenses. HSAs must be linked to a high-deductible insurance policy to cover catastrophic costs. Some three million individuals currently are enrolled in HSAs. The President will propose to expand these accounts by:

- Giving individuals who purchase HSAs outside of work the same tax advantages as those who have employer-sponsored insurance.
- Increasing the amount of tax-free contributions to HSAs.
- Allowing individuals with HSAs and their employers to make annual contributions to their accounts to cover all out-of-pocket medical expenses tax-free.

□ *Making Health Insurance More Portable:* The President favors two main initiatives in this area:

- Enable employers to offer workers a portable HSA insurance policy that employees would own, control, and take with them wherever they go. Premiums would be tax-free and would not increase based on the employee's health status at the time he/she changed jobs, left the labor force, or moved. Employers could contribute to these policies no matter where they were issued.
- Permit the purchase of health insurance across state lines. According to the White House fact sheet, this would allow individuals to buy insurance issued in other states, thus increasing choice and competition, while "retaining the consumer protections that states currently provide."

□ *Making Healthcare Price, Quality More Transparent:* Mr. Bush urges medical providers and insurance companies to make information about prices and quality readily available to all Americans prior to the time of service or treatment.

□ *Creation of Association Health Plans:* The President will ask Congress to allow small businesses to form association health plans by which they can band together to purchase health coverage for their workers and enjoy the administrative efficiencies and negotiating clout that big businesses and labor unions have in providing health benefits for workers. Mr. Bush also favors expansion of association health plans to help civic, community, and religious groups obtain group rates for their members.

□ *Medical Liability Reform:* To curb what the White House calls "frivolous lawsuits and excessive jury awards," the President will again support reforms that "reserve punitive damages for egregious cases, impose a cap on non-economic damages, ensure that old cases cannot be brought to court years after an event, and provide that defendants pay judgments in proportion to their fault." 🏠



focus: Cytology Proficiency Testing

Change Is In The Air For Controversial CLIA Program

Commenting on CMS's commitment to consider changes to improve the PT program, the agency's top CLIA official, Judy Yost, told NIR, "We have expedited our process to be responsive, to keep things moving along." Her message to the cytology lab community, including critics of the current program: "We are working with you, not against you."

This year marks the second year of nationwide enforcement of requirements for gynecologic cytology proficiency testing under CLIA (the Clinical Laboratory Improvement Amendments of 1988). And the Centers for Medicare & Medicaid Services has pledged to take a serious look, in conjunction with cytology experts, at how to improve the program, including changes to the 1992 rules under which it operates.

In 2006, CMS says, no cytology PT sanctions will be imposed if certain conditions are met—in effect, the agency will continue the educational, non-punitive approach it followed in 2005. CMS also says it will work with program critics and other stakeholders to achieve consensus on a regulatory proposal to revamp the cytology PT rules.

The CMS pronouncements come roughly a month after the U.S. House of Representatives passed a bill (H.R. 4568) to suspend the entire CLIA cytology PT program for one year and not let it resume until it is overhauled along the lines advocated by the College of American Pathologists and a host of other national and state pathology groups (*NIR*, 27, 6/Jan 9 '06, p. 3).

Since the program went nationwide at the start of 2005, with only one CMS-approved national provider—the Midwest Institute for Medical Education (MIME, based in Indianapolis)—CAP has spearheaded lobbying efforts to get the HHS Secretary and members of Congress to intervene and force CMS to modify the program (*NIR*, 26, 17/Jun 20 '05, p. 3; 26, 18/Jul 11 '05, p. 6). CAP says the program is arbitrary and out of touch with changes in cytology science and clinical practice since the 1992 rules were finalized. CMS officials disagree on several key points, but acknowledge that some program elements merit review (*see box*, p. 5).

No Sanctions In 2006

In a January 23 letter to state survey agency directors, Thomas Hamilton, director of the CMS Survey & Certification Group, said that laboratories will not fail gynecologic cytology PT, be cited for deficiencies, or have sanctions imposed on their CLIA certificates for failure to comply with the PT requirements as long as all affected cytology testing sites, pathologists, and cytotechnologists enroll and participate in a CMS-approved program for the calendar 2006 testing cycle.

Failure to do so, he noted, could subject a lab to intermediate sanctions that include civil money penalties of up to \$10,000, limitation of the lab's CLIA certificate for cytology, and if applicable and serious, suspension of the lab's Medicare and Medicaid payments for gynecologic cytology testing.

Currently, there are three CMS-approved programs. Two are offered by national PT providers: MIME and the College of American Pathologists. One is offered by the state of Maryland, but it is limited to labs that test specimens from Maryland residents. (The American Society for Clinical Pathology also has an application pending for approval of its cytology PT program.)

With regard to the 2005 testing cycle, Hamilton noted that labs have until April 2 of this year to ensure that all affected individuals were tested at least once. "The fact that only 4% of laboratories have needed the extra time is testimony to the diligence and capability of the laboratory community," he said.

Program Improvements Promised

In a January 23 letter to cytology lab directors, Judy Yost, director of the division of laboratory services within Hamilton's group, said that CMS intends to fulfill commitments made last August to evaluate PT results at the end of 2005 and consider specific ideas to improve the program.

Based on concerns expressed by groups and individuals within the cytology laboratory community, she said CMS and the Centers for Disease Control & Prevention are engaging a workgroup, under the auspices of CLIAC (the Clinical Laboratory Improvement Advisory Committee), to consider changes to the regulations. CLIAC has already recommended a new look at the 1992 rules (*NIR, 26, 10/Mar 7 '05, p. 1*).

Cytology PT: Current Policy & Alternatives

In a January 20 letter notifying the College of American Pathologists that cytology PT penalties will be suspended this year, CMS administrator Mark McClellan, MD, told CAP president Thomas Sodeman, MD, that the agency is willing to work toward consensus on alternatives "within the CLIA statutory parameters."

What those alternatives might be has yet to evolve, but on certain issues the College has raised, CMS spelled out its position last August in a letter from Dennis Smith, director of the agency's Center for Medicaid & State Operations, to CAP official John Scott:

- ❑ **Annual testing:** The CLIA statute specifies periodic testing. In the final 1992 rules, CMS defined this to mean annual testing (twice per year had been originally proposed). "We agree that [this requirement] merits continued review based on the first two years of PT...to permit a comparison of test results from one year to the next" and to assess the value of annual testing vs. an alternate frequency, Smith said.
- ❑ **Penalties:** Smith took issue with CAP's assertion that the rules "call for escalating sanctions against participants who fail to achieve the minimum mark of 90% for satisfactory performance after two attempts." He said that individuals who fail the first test have three more chances to pass and they "are not impeded from continuing work...Only after a third failure" must they cease examining Pap smears.
- ❑ **Grading scheme:** The diagnostic categories used in the testing event reflect the nomenclature used in the 2001 Bethesda System and are routinely used in cytology labs, Smith said. He took issue with CAP's assertion that the grading scheme "is centered in triage and management guidelines that have changed substantially over the past 13 years." Replying to one example cited by CAP, Smith said the argument for not making a distinction between low-grade and high-grade lesions "depends heavily on certain recommended practices, such as universal colposcopy, that are not adopted by everyone or in all cases ... Although we may have a different view on the extent to which the distinctions are important, we agree that this is an area that merits further analysis and mutual deliberation."
- ❑ **Individual vs. lab testing:** While CAP argues for measuring proficiency at the lab level since much of the work is done via a team of pathologists and trained medical staff, Smith emphasized that proficiency testing of individuals performing cytology work is specified in the CLIA statute.

The process and timeline for revising the rules is scheduled to be taken up at the CLIAC meeting on February 8-9 in Atlanta, GA. One of the tasks of the workgroup—to be comprised of pathologists, cytotechnologists, and government agency representatives—will be to examine first-year test results, scoring methods, and standards. Other agenda topics, Yost said, will include:

- ❑ **Frequency of testing:** What are the merits and implications (for proficiency and for women's healthcare) if cytology PT occurred every two years, rather than every year?
- ❑ **Scoring:** Are there merits, and if so what are the implications, of adjusting the scoring system?
- ❑ **Diagnostic categories:** Is it advisable to adjust any of the diagnostic categories for Pap smears used in the testing? The categories currently include: unsatisfactory; normal or benign changes; low-grade squamous intraepithelial lesions; and high-grade squamous intraepithelial lesion and carcinoma.

Further, Yost noted, CMS will post cytology PT policy and practice updates on its Web site, www.cms.hhs.gov/cliia, and will set up an e-mail box to which any questions or comments about CMS policy or workgroup efforts may be addressed. 🏠



Online Medicare Secondary Payer Quiz Modified

For Medicare beneficiaries admitted to a hospital as either inpatients or outpatients, the provider must ask a set of questions to determine if the beneficiaries have other insurance coverage that may be primary to Medicare. To help obtain such information, the Centers for Medicare & Medicaid Services has a model questionnaire posted online that providers may use. Effective January 21, 2006, the agency instituted changes to the questionnaire, as specified below:

- Parts IV and V add the response: "No, never employed."
- In Parts IV, V, and VI, providers should use "Policy Identification Number" to mean a number that is sometimes referred to as the health insurance benefit package number.
- Parts IV, V, and VI add "Membership Number" referring to the unique identifier assigned to the policyholder/patient.
- Part V, Question 2 uses "spouse" instead of "family member."
- Part V, Question 4 now reads:
Are you covered under the group health plan of a family member other than your spouse? ___ Yes ___ No
Name and address of your family member's employer: _____
- Part V of the old Question 4 is changed to ask whether the beneficiary is covered under a group health plan (GHP) and a Question 5 is added to gather the pertinent GHP information.
- In Part VI, Question 6 now reads: "Was your initial enrollment to Medicare (including simultaneous or dual entitlement) based on ERSD?"

The online questionnaire is posted www.cms.hhs.gov/manuals/downloads/msp105c03.pdf. 🏠

Outlook In Congress Promising For Health IT Initiatives

As the 2006 legislative year gets underway, there is strong bipartisan backing on Capitol Hill to support an expanded federal role to promote the adoption of electronic health records and other health information technology designed to improve patient care, reduce medical errors, and help control healthcare costs. Among the dozen or so bills already in play, the frontrunner so far appears to be the bipartisan Wired for Healthcare Quality Act (S. 1418), which the Senate passed unanimously in December 2005 and referred to the House Energy & Commerce Committee.

Major provisions of the bill would:

- Authorize federal grants (1) to hospitals, labs, and other providers to purchase or upgrade their health IT systems, (2) to states to offer loans to these providers for this purpose as well, and (3) to consortia to implement regional or local health IT networks. The bill authorizes \$116 million in fiscal 2006 and \$141 million in fiscal 2007 for these grant programs.
- Authorize demonstration grants to health professions centers and academic health centers to integrate health IT into clinical education in community settings (\$5 million for fiscal 2007).
- Establish measures to track the progress and usability of the above systems.
- Reward providers that improve the quality of care to patients.

Meanwhile, the Bush Administration has taken steps toward the goal of a digital, interoperable system for exchanging electronic healthcare data, including estab-



lishing the Office of the National Coordinator for Health IT within the U.S. Department of Health & Human Services; providing \$100 million to fund projects to harmonize standards for e-information exchange; developing certification criteria to ensure that health IT investments meet proper standards; and developing models for a national Internet-based health information system.

HHS has also chartered the American Health Information Community (AHIC) to advise it on working with the private sector to advance these aims (*NIR*, 26, 22/Sep 26 '05, p. 6). The AHIC recently set up four offices to guide the effort: health IT adoption, programs and coordination, policy and research, and interoperability and standards. 🏠

◆ CODING A · D · V · I · S · O · R · Y

New Codes For Blood Clotting Factors

In a revision for prospective payment for blood clotting factors administered to hemophilia inpatients, the Centers for Medicare & Medicaid Services is replacing old codes with new ones as follows:

<i>Old</i>	<i>New</i>
Q0187	J7189
Q2022	J7188

The new codes are effective for dates of service on and after January 1 of this year. Fiscal intermediaries are to implement the change by March 6 and to instruct providers how and when to resubmit claims, where appropriate (CMS Change Request 4311, February 1, 2006).

Billing For Colorectal Cancer Screening

In previous coverage, we noted that effective April 3, 2006, Medicare will implement a redefined Type of Bill (TOB) 14X to avoid overpayments for laboratory services furnished by hospitals to non-patients (*NIR*, 27, 4/Nov 28 '05, p. 7). TOB 14X is to be reserved for non-patient (outreach) lab specimens.

In a February 1 transmittal (Change Request 4272), Medicare clarifies the use of TOB 14X when billing for colorectal cancer screening (covered under the Part B preventive services package), using HCPCS codes G0107 (fecal occult blood test) or G0328 (immunoassay, fecal-occult blood test) when the testing is performed in a hospital setting. Fiscal intermediaries are to allow these codes to be billed on TOB 14X for non-patient lab specimens, and payment is to be based on the Medicare lab fee schedule for all hospitals, including critical access hospitals and Maryland hospitals under the state's cost containment program. The Part B deductible and co-insurance do not apply. The implementation date specified in the transmittal is July 3.

Billing For Screening Mammography, Pap Smears

Mammograms, Pap smears, and pelvic examinations provided for screening purposes to hospital inpatients may be covered under Medicare Part B, even though the patient has Part A coverage for the hospital stay, as long as applicable conditions of coverage are met and frequency limits have not been exceeded. Currently, providers bill for these services using TOB 13X. That will change, effective July 1, when providers must switch to using TOB 12X. TOB requirements for these services when furnished to beneficiaries other than inpatients remain unchanged. The switch to use of TOB 12X is explained in CMS Change Request 4243 (February 1, 2006). 🏠



GAO Report On CLIA Lab Inspections Expected Soon

One key question the report will address is: How effective are CLIA lab inspections and complaint investigations conducted by state survey agencies or private accrediting organizations?

March 17 is the anticipated release date of the findings of an investigation by the General Accountability Office into how well federal, state, and private accrediting bodies are handling CLIA laboratory inspections and following up on deficiencies uncovered, GAO staffers told *NIR*.

The study was requested by Congressmen Elijah Cummings (D-MD) and Mark Souder (R-IN), who chairs a House Government Reform subcommittee, in the wake of hearings into quality testing failures at Maryland General Hospital, which went undetected by the College of American Pathologists and other survey bodies and surfaced only when a whistleblower filed suit (*NIR*, 25, 16/Jun 7 '04, pp. 1, 4-6). The hearings helped identify several shortcomings in the current CLIA oversight system, Cummings said, but "gave us little assurance that what was occurring in Maryland were isolated incidents." He said he and Souder requested the GAO report to "give us an idea of how widespread the problems are and to suggest additional steps to strengthen the system and further ensure patient safety."

Cummings introduced legislation mandating certain corrective measures, and though the bill has not been enacted, most of the remedies in it have been adopted by the leading CLIA accrediting bodies, including whistleblower protections, new protocols for information sharing among surveyor entities at all levels, and unannounced inspections (*NIR*, 27, 2/Oct 31 '05, p. 1).



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