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CMS To Suspend July Start Of Controversial Code Edits

The edits to limit units of service aren't dead yet. The draft proposal will be retooled and distributed for wider comment, say CMS officials. Pathology and lab groups have lobbied hard against what they see as flawed MUE policy and process.

The Centers for Medicare & Medicaid Services will suspend the July 1 implementation date for the controversial "medically unbelievable" edits (MUEs), which limit the units of service for which a provider may bill Medicare per beneficiary per day.

At the March 6 meeting of the Practicing Physicians Advisory Council in Washington, DC, CMS officials said that though they have pulled back on the start date, the MUE initiative will continue. The draft MUE proposal now in circulation will be revised and resubmitted for wider review and comment, they said.

Medical and laboratory interests opposed to the edits would like to see the change in writing, with more details. Nonetheless, they plan to meet the March 20 deadline to comment on the draft MUEs (*NIR, 27, 8/Feb 6 '06, p. 1*). Though the due date is "permeable," sources in CMS say, comments that arrive on time have a better chance of being reflected in the revised MUE proposal.

➥ *p. 2*

INSIDE *NIR*

ASCP Buys MIME's Cytology PT Business

The American Society for Clinical Pathology is now a nationwide provider of CLIA gynecologic cytology proficiency testing for 2006, following its recent acquisition of the complete cytology product line of the Midwest Institute for Medical Education (MIME, based in Indianapolis). The price was not disclosed.

MIME captured the market for national CLIA cytology PT business in 2005 when its program was approved by the Centers for Medicare & Medicaid Services. That year, CMS began nationwide enforcement of CLIA cytology PT requirements, and MIME offered the sole way for virtually all affected labs, pathologists, and cytotechnologists to satisfy those requirements (*NIR, 26, 5, Dec 16 '05, p. 1*).

Following the takeover, ASCP is offering its CMS-approved product, ASCP GYN PT™. Enrollment is available immediately, the Society says, at *www.ascp.org/proficiencytesting* or by calling 800-267-2727, option 2.

Other approved programs for 2006 are offered by the College of American Pathologists (nationwide) and the state of Maryland (limited to labs that test specimens from state residents).

Medicare initiated correct coding edits in 1996, targeting mutually exclusive and comprehensive/component code pairs. Since then, periodic updates typically have affected a limited number of codes. The MUE initiative, however, takes aim at virtually all CPT/HCPCS non-surgical codes. Aghast at its scope, pathology and lab groups say they are at a distinct disadvantage in commenting, since CMS and the MUE contractor have yet to disclose the rationale behind the proposed MUEs.

Controversial Code Edits, *from p. 1*

MUEs Ignited Fierce Opposition

The Practicing Physicians Advisory Council is the latest influential group to call CMS on the carpet for the MUE controversy. At the March 6 meeting, its members unanimously recommended that the agency "withdraw the plan to create a list of MUEs and resubmit through the normal rulemaking process and work closely with the medical community in this effort."

The MUE initiative surfaced last December, and the draft MUE edits impacted nearly all CPT/HCPCS non-surgical codes, including more than 1,000 of special concern to pathology and clinical lab groups. Contractors would use the edits to automatically deny claims exceeding the limits on units of service per Medicare beneficiary per day.

The MUEs ignited stiff and swift opposition from the American Medical Association, various medical specialty groups, a coalition of national and state pathology societies spearheaded by the College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association, among others. The groups have been lobbying in concert to get CMS to reconsider or at least provide more clues to the agency's intentions through more channels.

Among their objections, CAP and ACLA point to the lack of guidance on the purpose driving the MUEs and the methodology used to compile such a sweeping list of proposed edits. Kept in the dark, the provider community also has to shoulder the burden of proof. CMS and its contractor, Correct Coding Solutions, LLC (Carmel, IN), have asked stakeholders to come up with alternative MUEs. Lab and pathology groups counter that the government should pinpoint codes that it thinks are a problem and that they should not be asked to "do the contractor's work."

Despite the suspension of the July start date, ACLA still opposes the MUE initiative, says president Alan Mertz. He and others from ACLA met February 24 with CMS officials to express their objections and were told that the agency had no plans to pursue the July target. In a follow-up letter to Herb Kuhn, director of the CMS Center for Medicare Management, Mertz said: "ACLA still strongly believes that CMS should withdraw the MUE initiative because of the massive scope of the proposal, because of lack of due process and transparency in the methodology used to arrive at the MUEs, and because the complete burden of proof is placed on the medical specialties to defend this action rather than respond to a select number of MUEs that are extreme."

In that letter, ACLA also said it was surprised to learn during the meeting that CMS officials regard the MUEs as different from edits under the national Correct Coding Initiative, saying the MUEs are intended to identify extreme cases of medical coding that should not be controversial. The draft list is sweeping, however, encompassing thousands of reporting and billing codes.

The CAP coalition registered its key concerns in a February 16 letter to CMS administrator Mark McClellan, MD: "We believe the MUEs were developed without meaningful physician input and reflect a gross oversimplification of both the actual and desired practice of quality medicine. We strongly urge you to withdraw these proposed edits and establish a formal process, working in close concert with the medical community, to address the concerns about the current proposal."

CAP noted that "while the proposed limit of two units per patient per day for CPT 88305, Level IV-surgical pathology, gross and microscopic exam, has drawn the greatest concern in the pathology community, the MUEs will affect all areas of pathology, including the clinical side."

The MUE controversy also has raised the specter of congressional involvement. Not wanting to put all its eggs in one basket, CAP has already lobbied key House GOP members about their concerns. College president Thomas Sodeman, MD, has briefed Nancy Johnson (R-CT), chair of the Ways & Means health subcommittee, and Dave Weldon (R-FL), an internist and member of the Appropriations Committee. Both said they would express their concerns to CMS.

Bush's Plan Envisions Nationwide Medicare Lab Bidding

Congressional approval would be required to change the fee schedule payment method established by law in 1984. To date, only a limited demonstration has been authorized.

When the White House budget request was released in early February, the lab industry was jolted by terse new references to expansion of lab competitive bidding for Medicare services (*NIR, 27, 9/Feb 23 '06, p. 1*).

Currently, only a demonstration bidding project limited to Part B independent lab services is authorized. Further, the sole requirement in the law is that the Centers for Medicare & Medicaid Services report to Congress on the demo's progress by December 31, 2005, a deadline missed, though agency officials said at press time that the report was "in clearance."

Digging deeper into the details of the President's proposal for expanded lab competitive bidding contained in one document—the report on the budget prepared by the Office of Management & Budget—shows that the Administration favors a national rollout of lab competitive bidding for an estimated savings of $1.43 billion over 2007-2011 (all of it from 2008 on).

The specific language from the OMB report, under the chapter entitled "Savings from Mandatory Reforms and User Fees" reads:

"The 2007 budget proposes to build on Medicare competitive reforms by establishing a national competitive bidding program for clinical laboratory services. Fee schedules, initially established in 1984, currently serve as the basis for payment of clinical laboratory services. The budget assumes that payments would decrease by 5% if a competitive bidding program replaced the current fee schedule for payment of these services. Of note, the Inspector General of the Department of Health & Human Services has pointed to the potential for excessive payment and utilization of clinical laboratory services in the Medicare program."

How does the President's proposal mesh with the demo project now in the works at CMS? When *NIR* asked CMS project officials that question when the budget was released, they declined comment, but after we pressed further, they sent this statement to *NIR* via the CMS press office:

"The President's budget is the President's budget. Unless Congress tells us otherwise, the demonstration is the demonstration as mandated in Section 302 of the Medicare Modernization Act of 2003."

CLIAC Forms Workgroup On Cytology PT Overhaul

The government has launched a process for considering revisions to the CLIA requirements for gynecologic cytology proficiency testing written in 1992 and under which the program has been operating since nationwide enforcement of the rules began in 2005.

To kick off the revision process, the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advises the HHS Secretary on CLIA scientific and technical matters, has formed a special workgroup that will meet March 28-29 to develop recommendations and present them to the full committee in June.

CLIAC will then advise on a notice of proposed rulemaking to be crafted by the Centers for Disease Control & Prevention and the Centers for Medicare & Medicaid Services sometime in 2007.

CMS promised to consider revamping the rules when, in response to fierce lobbying by pathology and laboratory groups, it suspended CLIA enforcement penalties for cytology PT this year, effective January 1 (*NIR, 27, 8, Feb 6 '06, pp. 4-5*). The workgroup's review will focus on developing a proposed fast-track rule that addresses the major concerns of these groups, but CLIAC staff caution that the entire rulemaking still could take as long as three years to finalize.

CLIAC Workgroup on Cytology PT

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Formation of the workgroup was endorsed unanimously at a February 16, 2005 CLIAC meeting. The panel said: "Consideration [should] be given to revising the cytology PT regulations, with revisions based on updated comments from the professional organizations and the public to reflect current practice, evidence-based guidelines, and anticipated changes in technology."

Meantime, the College of American Pathologists, at the head of a coalition of national and state societies, continues to push to have the CLIA cytology PT program suspended until changes are made. CAP lobbied hard for House passage of legislation (H.R. 4568, introduced by Rep. Nathan Deal, chairman

of the Energy & Commerce health subcommittee) that would do just that and is now urging the Senate to approve the bill. H.R. 4568 was introduced on November 9, 2005, and passed the House on December 17, 2005.

The workgroup will address the major issues raised by the College and others, CMS officials have indicated. In addition to examining first-year cytology PT test results, scoring methods, and standards, the agenda will include the frequency of proficiency testing (every two years vs. annually, for example), the grading scheme, and the diagnostic categories (*NIR, 27, 8/Feb 6 '06, pp. 4-5*).

MedPAC Advocates More Scrutiny Of Physician Pay Rates

The latest MedPAC report makes no recommendations on Medicare lab payments, but Commission staff say they are continuing to study the growth in spending for lab services, asking questions such as: What is the program buying for the increased expenditures? Is the current lab payment method adequate and efficient?

As expected, the Medicare Payment Advisory Commission's annual report to Congress, released March 1, recommends cutbacks in Medicare payments to a host of healthcare providers, but it also calls for a significant change in how the government determines payment for a physician's work.

Medicare payment for physician services is based on relative value units (RVUs) assigned to work expense, practice expense, and malpractice expense. A conversion factor is used to translate the total RVUs for a service into a dollar amount.

Concluding that the current system "does a poor job of identifying services paid too high relative to others," MedPAC wants another set of eyes to look at recommendations from the American Medical Association's Relative Value Scale Update Committee (the RUC). The Commission is calling on the Health & Human Services Secretary to establish a panel of experts to review the RUC recommendations and help the Centers for Medicare & Medicaid Services pinpoint overvalued physician services.

MedPAC emphasizes that this select panel would supplement, not replace, the work currently done by the RUC. The Commission thinks that CMS relies too heavily on the RUC, to which physician specialty societies contribute input, and this system is tilted in favor of increases in how physician services are valued. The select panel would offset this bias, MedPAC argues.

By law, CMS is required to review the physician work component of Medicare payments every five years to see if revisions are necessary since the resources needed to perform a service can change over time. Such reviews have been completed in 1996 and 2001, and the third five-year review is now underway. In the two previous reviews, CMS accepted more than 90% of the RUC's recommendations.

Signs that valuations in physician work may need overhauling include changes in volume, increases in claims for multiple services, and adjustments to practice expense, the MedPAC report says, adding that "previous five-year reviews by CMS have led to substantially more increases in RVUs than decreases, even though many services are likely to become overvalued over time."

Meantime, MedPAC's recommendations for curbing the growth of Medicare spending by freezing or cutting payment updates to hospitals, skilled nursing facilities, home health agencies, and inpatient rehabilitation hospitals—reflected in the President's budget request for fiscal 2007—are already running into resistance on Capitol Hill (*NIR, 27, 9/Feb 23 '06, pp. 4-6*).

Sixty House Republicans have made public a letter to the President, opposing cutbacks to hospitals: "Hospitals are not just a safety net for their communities, but also anchor local economies. They also must stand ready to respond to natural disasters, pandemic diseases, and the threat of terrorism." Also, Rep. Nancy Johnson (R-CT), who chairs the Ways & Means health subcommittee, has noted that giving hospitals less than the full inflation update may hinder efforts to adopt information technology, a priority of the Bush Administration, and to respond to rising salaries and energy costs.

In the Senate, the Budget Committee on March 9 approved the President's fiscal 2007 budget blueprint, but rejected proposed Medicare cuts and expansion of health savings accounts. Committee head Judd Gregg (R-NH) had previously expressed support for the White House plan to cut Medicare by nearly $36 billion, but doubted that it would be politically feasible in this mid-term election year. Finance Committee head Charles Grassley (R-IA) also said, "Any more reductions of significant scope will be difficult to achieve this year."

Final HIPAA Enforcement Rule Effective March 16

As of March 16, 2006, the enforcement provisions of the federal healthcare privacy rule will apply to other federal rules implementing administrative simplification provisions for electronic data exchange under HIPAA (the Health Insurance Portability & Accountability Act).

The U.S. Department of Health & Human Services announced this change in a final rule in the February 16 *Federal Register*. Affected rules also include security, electronic transactions/code sets, and standard unique identifiers for healthcare providers.

The final rule also amends the process for imposing civil money penalties on HIPAA-covered entities that violate HIPAA rules. It allows an administrative law judge to review the number of violations when establishing the penalties. Moreover, the standard on joint and several liability is retained "unless it is established that another member of the affiliated covered entity was responsible for the violation."

Of special interest to *NIR* subscribers, says attorney John Lessner, a shareholder with Ober/Kaler in Washington, DC, are the following aspects of the rule:

- ❑ It gives the government a lot of flexibility to take a "measured" approach to enforcement when non-compliance is identified, including steps short of a civil money penalty.
- ❑ Despite that, employers aren't off the hook if an employee is doing something within the scope of his/her employment that violates the rules or company compliance policies. For example, the compliance program requires verifying fax numbers every two months, the responsible employee fails to do so, and the numbers fall into another's hands. The employer is responsible for policing compliance.
- ❑ Providers may assert an affirmative defense and avoid civil money penalties when a violation is due to reasonable cause, not willful

Civil Money Penalties

The amount of a CMP that may be imposed is subject to the following limitations:

- ❑ It may not be more than $100 for each violation; or
- ❑ It is in excess of $25,000 for identical violations during a calendar year (January 1 through December 31).

If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a CMP may be imposed for a violation of only one of those administrative simplification provisions.

Source: *Federal Register*, February 16, 2006, § 160.404

neglect, and is promptly corrected within 30 days from being identified. In this instance, the government says it would not take steps to impose a civil money penalty.

On the thorny issue of business associate conduct, the rule states: "A covered entity that is in compliance with the business associate provisions of the security and privacy rules would not be liable for a violation of those rules by the business associate, even though the business associate is the covered entity's agent and was acting within the scope of its agency when it violated the rule."

While labs are considered covered entities under HIPAA, a hospital lab, for example, is not required to have a business associate contract with a reference lab to disclose protected personal health information to that lab for the treatment of that individual. Nor is a physician required to have a business associate contract with a lab as a condition for disclosing protected health information for the treatment of the individual.

♦CODING A·D·V·I·S·O·R·Y

ICD-9, CPT Changes To Uniform Lab Payment Policies

The April 2006 release of the Medicare edit software for the 23 laboratory national coverage decisions (NCDs) will contain several changes to the list of covered CPT procedural and ICD-9 diagnosis codes, the Centers for Medicare & Medicaid Services has announced:

- **All NCDs:** Delete V76.51 (special screening for malignant neoplasms, colon) from the list of non-covered ICD-9 codes.
- **Blood Counts:** Add V76.51 to the list of codes that do not support medical necessity.
- **Fecal Occult Blood Test:** Add new CPT code 82272 and delete 82270. The descriptor for 82272 is: Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, single specimen (eg, from digital rectal exam).
- **Hepatitis Panel/Acute Hepatitis Panel:** Add 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase (LDH), to the list of covered ICD-9 codes.
- **Lipids Testing:** Add new CPT codes 83700 and 83701 for lipoproteins. Remove 83715 and 83716 (they were deleted in the CPT 2006 update).

The 23 NCDs were developed by a congressionally mandated lab negotiated rulemaking process and published in final form on November 23, 2001. Since January 1, 2003, lab claims subject to tests covered under the NCDs have been processed uniformly nationwide. The NCD edit module is updated quarterly as necessary to reflect coding updates and other changes (for the previous update, in January, see *NIR, 27, 5/Dec 19 '05, p. 7*).

Hold On Medicare Payments

Medicare is taking a holiday from paying its bills for nine days at the end of September. The hold on payments for all claims, required by the Deficit Reduction Act of 2005, will run from the 22nd through the 30th. Claims held as a result of this one-time policy will be paid on October 2, according to CMS Change Request 4349 (February 10, 2006). No interest or late penalty will be paid to an entity or individual for any delay in a payment due to the one-time hold.

Managed Care Rates Up Nearly 7%, CMS Projects

Also in 2007, CMS can pay entry and retention bonuses to MA regional plans from the $10 billion stabilization fund created by the MMA.

Payment rates for Medicare managed care plans could increase by about 6.9% in 2007, according to a preliminary estimate by the Centers for Medicare & Medicaid Services. This is slightly more than 2% above the 4.8% rate increase this year and close to the 6.6% hike granted in 2005 (*NIR, 26, 12/Apr 11 '05, p. 1*).

The steady rate rise stems from financial incentives in the Medicare Modernization Act (MMA) to get private health plans to compete against traditional Medicare fee-for-service (FFS) via the Medicare Advantage program that debuted this January 1. CMS has approved 163 new MA plans for 2006. Under the MMA, the minimum percentage increase for MA plans is the higher of 2% or the national per capita growth percentage, an average based on estimated growth in Medicare FFS costs.

The final per capita percentage for 2007 could be higher or lower than 6.9%, CMS says, depending on rebasing average FFS outlays using more recent spending data. Actual capitation rates to individual MA plans will vary, based on adjustments for enrollees' health status, geographic area, and other factors. Final rates for all counties will be released in April.

Correction: In our February 23 issue, p. 8, CPT 85025 was cited as one of the fastest-growing lab tests in terms of Medicare-allowed services between 2003 and 2004. Alert reader Clay Cody with Rush Foundation Hospital in Meridian, MS, spotted a mistake in the code descriptor: instead of "CDC," it should read "CBC" for "complete blood count."

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