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CMS Extends Comment Time For Controversial Code Edits

Another round of comments on an MUE draft will be held in the fall, the agency says, with a view toward use of units-of-service limits in 2007.

The Centers for Medicare & Medicaid Services has agreed to extend by 60 days—from March 20 to June 19—the period for public comment on its medically unbelievable edits (MUEs), which limit the units of service that can be billed for a particular CPT/HCPCS code. Claims that exceed the limits would be automatically denied.

But this won't be the final opportunity for comment, said CMS's Program Integrity Group in announcing the change in deadline. Comments received in this first round will be considered, and a revised MUE list will be circulated for further comment this fall.

The extension is welcome news to the many medical and laboratory groups that opposed the initial due date, noting that more time was needed to respond to thousands of proposed MUEs for which there was no published rationale or methodology (*NIR, 27, 10/Mar 13 '06, p. 1*).

NIR verified with CMS that the draft on which initial comment is sought is the revised MUE list distributed last January 18 by the agency's MUE contractor, Correct Coding Solutions LLC ➥ *p. 2*

Spending Outlook Threatens Medicare Lab Outlays

There's mixed news in the latest annual report on national healthcare spending by the CMS Office of the Actuary. The growth rate will slow in 2005 and 2006, but healthcare costs will continue to rise faster than the rest of the economy. By 2015, healthcare spending will rise to $4 trillion and consume 20% of the gross national product, or $1 out of every $5.

The President's 2007 budget, its supporters in Congress, and the Medicare Payment Advisory Commission all say entitlement spending under Medicare needs to be curbed. And the Part B lab portion poses a tempting target because it's been rising faster than overall Part B and total Medicare spending.

With lawmakers facing the voters this November, deficit reduction looks problematic, despite outcries from fiscal hawks over mounting debt. The President's budget projects a $427 billion deficit in 2007, not including emergency funds for the war in Iraq and Afghanistan and for Gulf Coast hurricane recovery. Lawmakers this month raised the debt ceiling to $9 trillion (in comparison, it took from the founding of this country until 1989 to reach $3 trillion). Interest on the debt in 2005—$184 billion—was the fifth largest federal budget expense after entitlements and defense. For more on the trends, see the *Focus*, pp. 4-6.

INSIDE *NIR*

Controversial Code Edits, *from p. 1*

(Carmel, IN), to the American Medical Association and to pathology and lab organizations, among other provider groups. That list replaced the original MUE draft developed by Reliance Safeguard Solutions and distributed by the AMA last December, before the contract was assigned to Correct Coding Solutions.

MUE Initiative To Proceed, But With Changes

In not-so-welcome news, the Program Integrity Group reiterated that CMS intends to press ahead with the MUE initiative, but will not implement it earlier than January 1, 2007. The agency had planned to start using the MUEs on July 1 of this year. In scrapping that date, CMS said it will heed specific concerns voiced by medical and lab interests that have been sharply critical of MUE policy, which they say does not reflect accepted clinical practice in a huge volume of cases, and of the MUE process, which they fault for lack of transparency.

In addressing these specific concerns, the Program Integrity Group statement:

- ❑ Stressed that the edits are not intended to set Medicare payment policy, "but only to identify obvious billing mistakes." For example, said one CMS source, when the medical record indicates "2" units of service, but the data are incorrectly entered as "20." CMS said it would ensure that the edits are in line with medical practice and are used only as intended, to detect claims errors.
- ❑ Promised "open discussions" by CMS staff and Correct Coding Solutions LLC with the provider community "about the rationale and statistical basis for establishing the edits based on claims data."
- ❑ Will consider use of modifiers to allow for medically necessary services that may be clinical outliers. CMS had initially nixed modifiers to bypass units-of-service limits.
- ❑ Pledged to develop the appeals process to permit reconsideration, as needed, of specific claims and specific MUEs.

CMS will use its Web site and *listservs* to spread information about the MUE initiative as it progresses. Critics say a more formal review-and-comment process would allow more open access by provider and consumer groups to MUE proposals and related developments.

Senate Gives Cold Shoulder To Bush's Medicare Cuts

But senators approved the President's request for automatic cuts when the 45% general revenue threshold is exceeded. The Congressional Budget Office projects that will happen in 2011.

In passing its fiscal 2007 budget resolution by a scant margin of 51-49, the Senate on March 16 rejected the President's budget request to cut Medicare provider spending by $36 billion over five years, and also spurned his call to expand health savings accounts (HSAs), a key White House priority.

But the Senate did go along with the President's bid to control growth in entitlement outlays by requiring automatic cuts in Medicare spending in any year in which more than 45% of Medicare expenditures are financed by general revenues. This provision is tied to the 2003 Medicare reform law, which requires the President to propose legislation to trim the portion of Medicare funding derived from general revenues when it reaches a specified level.

The Senate-passed budget measure (S. Con. Res. 83) also added more money to the Health & Human Services discretionary budget, increasing it by a total of $10 billion, and authorizing a reserve fund to prepare for pandemic influenza. The Senate further boosted spending for certain HHS programs above the President's request, including $1 billion more for the National Institutes of Health (bringing its total

budget to $29.6 billion) to allow the agency to keep up with biomedical inflation, and $235 million more for rural health support provided by the Health Resources & Services Administration (bringing its total budget to $6.6 billion).

Several amendments to the new prescription drug benefit, Medicare Part D, were adopted by the Senate. One would allow Medicare to negotiate directly with pharmaceutical companies for drugs purchased under Part D, a practice prohibited when the benefit was created in the 2003 Medicare reform law. Another amendment would give the government the authority to extend the Part D enrollment deadline beyond May 15, after which enrollees must pay a penalty to sign up. The amendment also lets beneficiaries change their plan coverage once during the initial open enrollment period, including any extension.

House To Act In April

The House is expected to complete work on its 2007 budget resolution in April. Whether it will follow the Senate's lead in rejecting the President's $36 billion in proposed Medicare cuts is far from certain. In a March 3 letter, 62 GOP House members urged Budget Committee chairman Jim Nussle (R-IA) not to adopt the cuts, nearly $16 billion of which would come from hospital payment changes, the letter noted: "At a time when 32% of hospitals have negative total margins and 7 out of 10 are losing money on Medicare, we strongly believe now is not the time for further reductions." But the House GOP leadership could take heat from fiscal conservatives to push deficit reduction, arguing that this reinforces the party's fiscal-discipline image to the voters.

In line with recommendations of the Medicare Payment Advisory Commission, the President's budget proposes reduced inflation updates for Medicare inpatient and outpatient services through 2009, for a total savings of $8 billion. Skilled nursing facilities, home health agencies, and inpatient rehabilitation hospitals would experience a Medicare payment freeze in 2007, followed by a reduced inflation update through 2009 (*NIR, 27, 9/Feb 23 '06, pp. 4-6*).

OIG's 'Substantially In Excess' Proposal Back In The Spotlight

Ways & Means chairman says stalling on the proposal threatens the President's initiative for healthcare price transparency to help foster competition among providers.

Dormant since being proposed in 2003, the HHS Office of Inspector General's rulemaking to determine when Medicare is being overcharged has been thrust back into the spotlight this month. Delay in finalizing it will affect the success of the President's plan to use price transparency to foster healthcare competition and curb rising costs, said House Ways & Means chairman Bill Thomas (R-CA) in a strongly worded letter to HHS Secretary Michael Leavitt on March 10.

The OIG's proposal would impose sanctions on Part B providers, including clinical labs, that charge Medicare "substantially in excess" of their usual charges, which would be defined as any amount above 120% of the usual charge. The proposal triggered wide controversy in the clinical laboratory community amid fears that the rule could limit discounts to physicians and other third parties and even force labs to accept less than fee schedule rates to avoid program exclusion (*NIR, 24, 22/Sep 29 '03, p. 1*).

Thomas told Leavitt that the OIG's failure to move ahead was "unacceptable" and urged that the "rule be finalized as quickly as possible," adding that the OIG's inertia makes the committee question whether a funding increase for OIG operations is "warranted." The OIG had no comment. ➥ *p. 7*

focus on: Health Spending Trends

Health Spending Forecast: Balmy Now, Stormy Soon
Outlook Prompts Calls To Brake Medicare Growth Rate

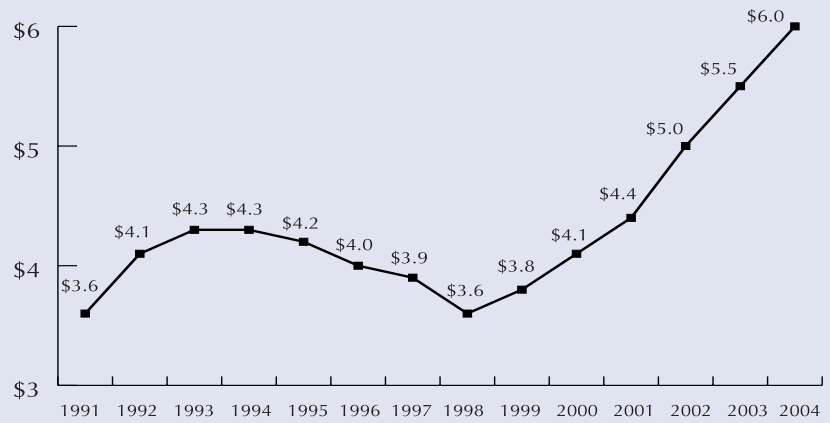
"Whenever Congress is in session, labs are in danger," a veteran lab lobbyist told *NIR* at the start of this year's legislative session. History bears out this blunt assessment, says the Clinical Laboratory Coalition. According to the Coalition, which represents 10 pathology and laboratory national organizations, Congress has denied inflation updates to Medicare Part B lab fees in 11 out of 15 years and has reduced the fee caps from 115% to 74% of the national median. In real terms, lab payments have been cut 40% from 1984, when the fee schedule debuted, to 2004.

The future too holds danger for labs, given the trends in healthcare spending—in particular, Medicare Part B lab spending, which is growing faster than total Part B outlays and total Medicare expenditures. Adding to the danger more immediately is the Administration's priority to use competition for lab services to save Medicare dollars.

Surge In Medicare Lab Spending

According to the latest data from the 2005 Medicare Trustees Report, Part B lab spending increased by 9.4% to $6.018 billion in calendar 2004, the latest year for which data are available. After declining through most of the 1990s, it has rebounded strongly over the past six years. From 1998 to 2004, it increased at an average rate of 8.8% per year. Over the same time period, total Part B spending rose 8.5% per year to reach $134.9 billion, and total Medicare expenditures increased 6.1% per year to reach $304.3 billion.

Part B spending on clinical lab services, 1991-2004 *($ billions)*



Note: Includes all Part B spending on lab services, including independent lab, hospital outpatient/outreach, and physician office labs Source: 2005 Medicare Trustees Report

In 2004, Medicare covered 41.7 million enrollees. Over the past six years, annual Part B lab spending per enrollee has increased by 7.6% per year to reach $144 (assuming that an average billable test of $14 equates to average utilization of 10 tests per year per beneficiary).

Mixed Projections For Health Spending Trends

Against the backdrop of concern by GOP health leaders in Congress and the Medicare Payment Advisory Commission (MedPAC) to put the brakes on Medicare's spending growth, the Office of the Actuary at the Centers for Medicare & Medicaid Services this month released its annual report on national healthcare spending trends.

As pressure on policymakers mounts to curb rising costs, the strong growth in Part B lab spending makes it a choice candidate for payment reductions. The Clinical Lab Coalition counters that lab testing should be valued for its key front-line role in preventing, diagnosing, and treating disease and monitoring therapy.

The trends offer some immediate comfort:

- Growth in national health spending is projected to slow to 7.4% in 2005 and to 7.3% in 2006, down from 7.9% in 2004 and a peak of 9.1% in 2002. This year, such spending will surpass $2 trillion for the first time.
- Private health insurance premiums are projected to slow to 6.6% in 2005, but rebound in 2007.
- The introduction of Medicare Part D drug coverage this year triggers a dramatic shift in spending across payers, but has little net effect on aggregate spending growth.

However, over the coming decade, as baby boomers retire and as advances in medical technology—especially higher-priced procedures like genetic testing—proliferate in clinical practice, national health spending is expected to double, growing at an average annual rate of 7.2%. As a result, the health portion of the Nation's economic pie—16.5% this year—will soar to 20% by 2015.

Pulling The Reins On Medicare

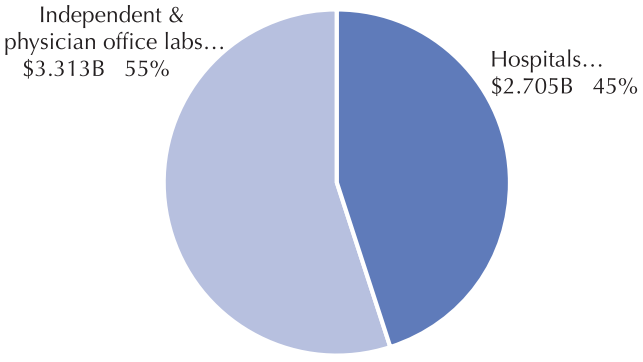
Soaring federal deficits and steadily rising healthcare costs make it harder for the provider community to fend off Medicare payment reductions, according to provider analysts. White House and MedPAC officials have said that hospitals and other providers can absorb the cuts by promoting efficiencies and competing on quality of care.

The President's fiscal 2007 budget request and its GOP supporters on Capitol Hill emphasize that the proposed $36 billion in Medicare cuts over five years represent a slowing of the program's growth rate by freezing or trimming the inflation update for hospitals, skilled nursing facilities, and other providers. In defending the budget, Health & Human Services Secretary Michael Leavitt said, "Medicare is not sustainable in the long term in its present form."

While the Senate-passed budget resolution for 2007 spurned the President's proposed Medicare cuts, it did approve his request for automatic program cuts when spending in any given year exceeds 45% of general revenues (*related story, p. 2*). That threshold is to be reached in 2011, only a few years after clinical labs are due to emerge from the five-year freeze now in place from 2004 through 2008.

While lab interests remain vigilant to combat any legislative efforts to reduce lab fees and fee caps or to restore a 20% Part B lab co-pay, their most pressing current concern is the provision in the President's budget that calls for a nationwide rollout of lab competitive bidding, for an estimated savings of $1.43 billion over 2008-2011 (*NIR, 27, 10/Mar 13 '06, p. 3*).

Part B Lab Spending By Sector



Note: After gaining throughout the 1990s, hospital labs' share of Part B lab spending has been stable for the past five years.

Cutting Costs Via Lab Bidding Competition

The budget embraces lab bidding as a way to inject more competition into Medicare and save money, arguing that bidding has proved successful for durable medical equipment. Critics advise that any consideration of expanding Medicare lab bidding should at least await the results of the demonstration that Congress has mandated for independent lab services. That demo is still in the design phase, and at press time, an overdue report to lawmakers on the demo's progress was still "in clearance," said CMS sources.

"No bidding model for clinical lab services can be developed to meet the objective of providing lab services at fees below current Medicare rates, while simultaneously maintaining quality and access to care, and keeping pace with improvements in diagnostic technology for patients in diverse segments of the healthcare system such as nursing homes, hospitals, dialysis centers, etc., and in geographic settings that range from highly centralized to remotely rural."

— Clinical Lab Coalition statement to MedPAC.

The demo and the proposed wider rollout are universally opposed by the Clinical Lab Coalition. At the March 9 MedPAC meeting, attorney Bob Waters, speaking on behalf of the Coalition, urged the panel to be wary of a one-size-fits-all model like competitive bidding. Lab services must be valued as a complex medical service, not a commodity, he emphasized.

MedPAC staff briefed the panel on their continuing critique of the Medicare lab fee schedule and alternative payment methods, including competitive bidding. Several MedPAC members voiced unease about the rush for lab bidding, especially since the CMS demo has yet to get off the ground. As one source summed it up to *NIR*, the Commission is "cautious about moving too quickly without more facts." Panel member William Scanlon, PhD, advised "waiting for the experience of the demo, but even then, it should not be assumed that the demo can be duplicated nationwide. One needs to think about how it has to be adapted." He also worried about how many labs would be disqualified because they cannot bid on everything required and how Medicare will maintain bidders over time.

Other Lab Payment Alternatives

In her summation, MedPAC staffer Dana Kelley said, "We are concerned that we are not paying accurately for lab services, especially at a time when use of tests has been growing and is likely to continue." Clinical practice guidelines and advances in medical knowledge "will also boost the use of screening and monitoring tests, as will pay-for-performance programs," she observed.

However, "the absence of cost data poses a pricing problem for Medicare," Kelley said. The current lab fee schedule is derived from 1983 prevailing charges and has not been regularly updated over the years. Competitive bidding is one alternative that addresses the cost data issue, she noted, but cautioned that "a bidding process that focuses solely on price, for example, might compromise access and quality." (In its report on Medicare lab payment policy in 2000, the Institute of Medicine advised against using competitive bidding to replace the current payment system, but said bidding might be useful in limited cases.)

Another payment option, Kelley continued, is based on the resources needed to perform a test. This lab RBRVS approach would be simpler to develop than the physician fee schedule was. There are about one-sixth as many codes for lab services as for physician services. But developing and maintaining the system would be time-consuming and costly, and it is not known, she said, whether various clinical lab groups would be able to undertake a job of this magnitude.

One thing Kelley asked MedPAC to consider is the fact that tests are ordered by physicians. Labs can do little to control volume. Limiting growth in test use across the board would not be desirable, since many screening and monitoring tests are underused, experts say. Commenting on lab volume growth, MedPAC member Ralph Muller observed that the biggest expenditures "will not be for blood counts, as is now the case, but for highly specific tests to direct treatment. They will be highly valued by the patient and the doctors because they can tell you how to proceed with therapy." But if Medicare has no way to price these tests, critics warn, test manufacturers will be able to extract large amounts from the current payment system.

Healthcare decisions are increasingly being driven by two related questions: "What do we get for what we spend?" and "Are we spending fairly and wisely?" So for labs, while payment alternatives are still in play in Washington, the next act is likely to be more quality reporting and pay-for-performance.

OIG's 'Substantially In Excess' Proposal, *from p. 3*

In pushing for greater transparency in healthcare pricing, the President's 2007 budget says Medicare and other federal healthcare programs will soon make publicly available the prices they pay for hospital and other provider services. Mr. Bush urged the private sector to follow suit. (Part B fees for physicians and clinical laboratories are already posted on the CMS Web site.)

Critics doubt the ability of pricing transparency to put the brakes on spending or even help the average patient or the uninsured. They say there is scant quality data at hand and that healthcare decisions are complex, not based solely on price. Moreover, patients tend to rely on doctors in deciding treatment and where it should be performed. The "open-pricing" push coincides with renewed congressional scrutiny of tax-exempt hospitals and whether they are fulfilling their "charity care" mission. The Senate Finance Committee is looking into whether these hospitals are overcharging uninsured and low-income patients.

CMS Update On CLIA Cytology PT Changes Ahead

The educational approach to enforcement of CLIA cytology proficiency testing requirements will be continued this year, said top CLIA official Judy Yost during an open-door conference call held March 22 to discuss the status of the cytology PT program and regulatory steps to revise the 1992 rules under which the program now operates.

The educational approach, Yost explained, means that labs will not have deficiencies cited or have sanctions imposed as long as all affected sites, cytotechnologists, and pathologists enroll and participate in a CMS-approved program for the calendar 2006 testing cycle (*NIR, 27, 8/Feb 6 '06, p. 4*). Approved programs include the College of American Pathologists, the American Society for Clinical Pathology (which bought MIME's cytology PT business), and the State of Maryland (limited to labs that perform tests on specimens from state residents).

Another CLIA official, Cheryl Wiseman, reported that in the 2005 testing cycle, the first year of nationwide enforcement, there were approximately 13,000 participants and a 91% pass rate. And consistent with other studies, "primary physicians" (those who screen alone) appeared to have the greatest difficulty in passing the test (*NIR, 27, 9/Feb 23 '06, p. 2*).

The plan to develop a revised cytology PT rule is on a fast track, Yost said. The Clinical Laboratory Improvement Advisory Committee has established a cytology PT workgroup which will meet March 28-29 and present its findings to the full CLIAC in June (*NIR, 27, 10/Mar 13 '06, p. 4*). CLIAC will then make its recommendations to the HHS Secretary on a proposed rule. But getting the rule through clearance could take a year or more, she cautioned. "We hear what the issues are," Yost said. "We need your input."

CMS has established a mailbox to receive comments on the cytology PT rules: **cytologypt@cms.hhs.gov.** ***It is reviewed during each week, Wiseman said, and "we do our best to get answers ASAP." When e-mailing, include your telephone number, she advised, because it is sometimes easier and quicker to clarify issues by direct contact. You also can send comments and questions to*** **Cheryl.Wiseman @cms.hhs.gov,** ***or call 410-786-3340.***

Eleven labs did not enroll and participate in required cytology PT for 2005, Yost reported, and the deadline to comply is this April 2. Thereafter, labs not in compliance are subject to sanctions that may include a fine of up to $10,000; limits on the lab's CLIA certificate; and/or suspension of Medicare payment for cytology testing.

AHIC Plans E-Health Prototype For Sharing Lab Test Results

In the House meantime, bipartisan voices on the Energy & Commerce health subcommittee advise caution in moving forward on health IT legislation, so as not to interfere with market developments. Federal leadership in coordinating with the private sector on national e-health records is handled by the HHS Office of the National Coordinator for Health IT.

Digitizing laboratory test results for sharing among a patient's physicians is one of several pilot projects discussed at the American Health Information Community meeting earlier this month in Washington, DC. The 16-member AHIC advises the Health & Human Services Secretary on creation of a national e-health record system (*NIR, 26, 22/Sep 26 '05, p. 6*).

At the March 7 meeting, the fourth since AHIC first convened in October 2005, members discussed plans for operational "breakthrough" prototypes by year's end to spur efforts to create digital, interoperable e-health records. The President has called for e-health records for most Americans by 2014, relying mainly on privately run systems.

In discussing the lab project, Secretary Michael Leavitt suggested that patients, not doctors, should own their e-health records and decide where to keep them—for example, with an Internet service provider, a pharmacy, or other entity. Patients would get test results before doctors and would decide which doctors could see their records. Several AHIC members disagreed, saying physicians need the results to counsel patients about abnormal results, especially for cancer, HIV, and other serious conditions. Lab test results usually go to the doctor ordering the test, and Leavitt directed AHIC to concentrate on this "peer-to-peer relationship." An AHIC e-health workgroup is working on such a prototype.

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