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Unfinished Budget Business Tops Congress's Health Agenda

Lawmakers also are awaiting the CMS report on the Part B lab competitive bidding demonstration. The report, due Dec. 31, 2005, is still in clearance. Also delayed is announcement of the demo sites, to be followed by the demo contractor's meeting with potential bidders.

When the full Congress reconvenes at the end of this month, completion of work on budget reconciliation is expected to top its "to-do" list. Enactment of the legislation is especially important to pathologists and other physicians because it contains a provision that would undo the 4.4% reduction in their Medicare payments that took effect January 1 and grant a 0% update instead. Medicare officials have already spelled out how they would adjust claims for the new rates after the bill is enacted (*see related story below*).

For the rest of the healthcare legislative agenda shaping up on Capitol Hill, the outlook for 2006 is problematic at this point, with burgeoning budget pressures and the high-stakes mid-term elections sure to frame the debate. The Bush Administration has signaled that it is looking into initiatives to curb rising healthcare costs, and the Medicare Payment Advisory Commission has called for Medicare spending reductions for inpatient and outpatient services and a freeze on updates for skilled nursing facilities, home health agencies, and other providers. Congress also is expected to keep a close eye on implementation of the new Medicare drug benefit, especially if major problems continue to plague its rollout. For details, see the *Focus*, pp. 4-6.

CMS Ready To Raise Physician Fees

Local Medicare contractors will be instructed to automatically reprocess pathologist and other physician claims to reflect the higher pay rates authorized in pending budget reconciliation legislation, the Centers for Medicare & Medicare Services has told key congressional health leaders. CMS said it will issue instructions soon after the measure is enacted (expected in early February).

The bill would set the physician fee update for calendar 2006 at 0% (in effect, a freeze at the 2005 level), reversing the 4.4% fee cut that took effect January 1 under the statutory update formula.

The retroactive adjustment of claims will be automatic, said Herb Kuhn, director of the CMS Center for Medicare Management, in a January 6 letter to Senate Finance Committee chairman Charles Grassley (R-IA) and House Ways & Means Committee chairman Bill Thomas (R-CA). Physicians and other providers will not need to resubmit their claims, he emphasized. They will receive one lump-sum adjustment for the difference between payments based on the 4.4% cut and the 0% update.

➥ *p. 2*

INSIDE NIR

CMS Ready To Raise Physician Fees, *from p. 1*

The reprocessing will be phased in according to the volume of claims at each contractor, Kuhn said. For example, if final enactment occurs around February 1 and the effective date is January 1, approximately 80 million claims could potentially have to be reprocessed. All contractors must, however, complete the reprocessing by no later than July 1, he said.

Enrollment Period Extended

CMS also will reopen the enrollment period for doctors to reconsider their Medicare participation decision in light of the anticipated fee increase. The original period ran from November 15 to December 31, 2005 (*NIR, 27, 3/Nov 14 '05, p. 6*). The new period will run for an additional 45 days and start soon after the budget bill is enacted. A physician's decision during this period would be retroactive to January 1, Kuhn noted.

Cost-Sharing Relief For Beneficiaries

Kuhn acknowledged that under co-payment and deductible requirements, Medicare beneficiaries might owe more under the higher physician service payments than they were initially billed. He told Grassley and Thomas that CMS believes a short-term waiver of the additional cost-sharing amount in these instances "would unlikely [be] an inducement to the beneficiary" in violation of federal fraud and abuse laws. However, Kuhn added, the agency cannot speak for the HHS Office of Inspector General, which has the final say on this matter. He said CMS talked with the OIG on this issue, but "for more specific guidance, the OIG would need to be consulted." The OIG generally has regarded routine cost-sharing waivers as a prohibited inducement.

CMS will instruct contractors to forward adjusted claims to Medigap and secondary insurers, if their agreements accept adjustments, Kuhn said. But providers may need to bill secondary payers separately to get the balance due.

Lab, Pathology Groups Challenge 'Medically Unbelievable' Edits

The proposed edits establish limits on the units of service that could be billed per day for the same Medicare beneficiary. Claims for units of service in excess of the criteria would be automatically denied.

Clinical laboratory and pathology groups have called on the Centers for Medicare & Medicaid Services to withdraw the proposed—and highly controversial—"medically unbelievable" edits (MUEs) that have been proposed under Medicare's Correct Coding Initiative (CCI).

The groups have fired off letters to CMS administrator Mark McClellan, MD, asking for clarification on the proposed changes and a dialogue to discuss revisions. As David Mongillo, vice president for policy and medical affairs at the American Clinical Laboratory Association, summed it up: "[These edits raise] very significant process and policy concerns."

The College of American Pathologists, the American Society for Clinical Pathology, and ACLA say the proposed MUEs are seriously flawed in terms of accepted clinical practice and don't mesh with the use for which many CPT/HCPCS pathology and lab codes were developed.

The groups further fault CMS for failing to follow standard comment-and-review procedures. In February 2005, the agency issued Change Request 2987 to "establish MUEs to catch typographical errors and unbelievable cases." The agency subse-

The American Medical Association has asked CMS to postpone the scheduled July 1 launch date for the MUEs until January 2007 at the earliest.

quently rescinded this transmittal. "To date," CAP noted to McClellan, "the program notice has not been re-issued, and there has been no formal notification from CMS regarding the comment-and-review process or implementation date."

ACLA echoed this concern, telling McClellan, that the draft MUE list "was developed without appropriate CMS guidance, without a process to appeal the edits, without disclosure of the methodology employed to develop the edits, and without appropriate stakeholder involvement."

CCI typically proposes a handful of edits at a time. But the MUEs cover most CPT/HCPCS codes, including more than 1,000 of concern to lab and pathology groups, and the American Medical Association says the edits contain a number of significant errors. This, together with the volume of codes involved, means that the review-and-comment process will be even more time-consuming and labor-intensive than usual. At press time, sources tell *NIR* that CMS plans to reissue the MUE program notice soon, with a 45-day comment period.

Examples Of Objections To Selected MUEs

• ***ASCP***

❑ CPT 88305 (Level IV, surgical pathology, gross and microscopic exam): Proposed MUE limit—two procedures. "There are numerous clinical situations requiring more than two biopsies for proper patient diagnosis and medical management. For example, [clinical] guidelines recommend that for patients with ulcerative colitis, two to four random biopsy specimens should be obtained every 10 cm from the entire colon for a total of approximately 40 biopsies per patient per colonoscopy, and additional samples should be obtained at any suspicious area. Routine colon cancer screening typically results in four to eight biopsies of possible polyps, the exact site of which is clinically important since one may be a cancer; these cannot be lumped into two containers."

❑ CPT 88342, Immunocytochemistry with tissue immunoperoxidase, each antibody: "The number of stains ordered should be based on clinical conditions … It's not uncommon for the number of required stains to exceed the MUE limit of four. A panel of seven immunohistochemical stains is needed, for example, to diagnose anaplastic tumors."

• ***ACLA***

❑ CPT 82784, Gamma Globulin, IgA, IgD, IgG, IgM each: Proposed MUE limit—one. "[This code] is ordered 77% of the time more frequently than the proposed [limit] … In the vast majority of instances, appropriate patient care dictates that a physician considering a diagnosis of multiple myeloma simultaneously order more than one immunoglobulin class to establish the nature of the specific ➥ *p. 7*

Correct Coding Initiative

What Is It? The CCI was developed by the Centers for Medicare & Medicaid Services to control improper coding leading to inappropriate payment of Part B claims.

The original CCI edits for comprehensive/component and mutually exclusive code pairs were developed under the aegis of Adminastar Federal, a Medicare contractor serving Indiana and Kentucky, and were inaugurated as of January 1, 1996.

Modifiers are used on claims to bypass the edits and get paid. A modifier is a two-digit code that further describes the services performed. Currently, 35 modifiers can be used to bypass CCI edits, including modifier 59 commonly used by pathologists and labs to report distinct procedures/services (*NIR, 27, 6/Jan 9 '05, p. 5*).

Who Came Up With The Proposed MUEs? The draft list that the American Medical Association was asked to circulate to medical specialty groups came from Reliance Safeguard Solutions in collaboration with CMS. Comments were to go to an official at Empire Blue.

Who Is Handling It Now? The CCI contract has been awarded to Indianapolis-based Correct Coding Solutions, LLC, as of December 21, 2005, the CMS press office told *NIR*. The medical director is Niles R. Rosen, MD, and the coding specialist is Linda S. Dietz, RHIA. Send comments to: National Correct Coding Initiative, Correct Coding Solutions, LLC, PO Box 907, Carmel, IN 46082-0907.

focus on: 2006 Healthcare Legislative Outlook

Many Key Issues Caught Between A Rock & A Hard Place

The fate of healthcare bills will play out amid the GOP and Democratic battle over control of Congress and the mounting pressure to staunch the flow of federal red ink.

The second and final session of the 109th Congress is set to open January 31 when the House reconvenes, and the outlook for a host of healthcare issues is dicey at best, mainly because of the uncertain political dynamics leading up to the November mid-term elections. The heat is on Republicans to show they're in charge and can deliver and on Democrats to persuade voters to give them the reins of power.

Money is tight too, as federal commitments escalate not only for defense, but also for recovery from Hurricane Katrina and other natural disasters, plus preparation for a potential avian flu pandemic.

The President's budget request for fiscal 2007, expected to go to Congress in February, is likely to call for curbs on rising healthcare costs, relying on market-oriented mechanisms and more competition in Medicare. In previous requests, the President has emphasized creation of association health plans to help small businesses obtain affordable coverage for employees and expanded access to health savings accounts, with tax credits to help individuals purchase private coverage.

Here's a rundown of major healthcare issues to keep an eye on this year:

Budget Reconciliation

For pathologists and other physicians, passage of this legislation is a top priority. It would reverse the 4.4% cut in their Medicare fees that was imposed as of January 1 and grant a 0% update instead, in effect freezing the fees at their 2005 levels.

The House-Senate conference compromise on the bill stalled late last year as Congress adjourned for the holidays, and getting it finalized is expected to be the first order of business when lawmakers return. The compromise passed the House on December 19 by a slim margin of 212-206 and cleared the Senate the next day by a vote of 51-50, with Vice President Dick Cheney flying back from Asia to cast the tie-breaking vote. However, procedural issues in the Senate made a second House vote necessary before the bill could go to the President and the House had already adjourned.

Overall, the bill would make roughly $11 billion in Medicare and Medicaid spending reductions over five years. The Medicaid cuts would be borne mainly by beneficiaries, while providers would shoulder most of the Medicare cuts (*NIR, 27, 6/Jan 9 '05, p. 2*). The bill also would extend the moratorium on new physician-owned specialty hospitals to August.

Future Physician Fee Fix

Don't expect lawmakers to rush to tackle much more than another short-term fix for Medicare physician fees. The American Medical Association, the College of American Pathologists, the American Society for Clinical Pathology, and various other medical specialty groups want Congress to scrap the sustainable growth rate (SGR) factor used to calculate fee updates and thus avoid a string of looming fee cuts projected to occur over the next few years. But the cost would be high, and lawmakers have indicated they want more information on how a new system would work.

The Medicare Payment Advisory Commission (MedPAC) this month voted to recommend in its annual report—slated to go to Congress in March—that Medicare physician fees be increased in 2007 by 2.8% to reflect higher input prices adjusted for improved productivity. This fee hike would cost $1.5 billion in the first year and $5 billion to $10 billion over five years, MedPAC estimated. MedPAC has criticized the SGR on grounds that it offers no incentives for individual physicians to control service volume and it treats physicians in all regions alike. The panel also faults the SGR for treating all volume growth the same, including that attributed to new and desirable technology.

While several bills are pending that would eliminate the SGR, the House-Senate conference bill on budget reconciliation asks MedPAC to study and report back on various alternative methods for updating physician fees.

Medicare Drug Benefit

Congress is likely to give considerable scrutiny to how the Centers for Medicare & Medicaid Services is handling the implementation of the new Part D prescription drug benefit that began January 1. Lawmakers will focus on enrollment numbers and the difficulties that beneficiaries are having in navigating the complicated program. The benefit's debut has been marred by major disruptions for low-income beneficiaries in getting vital medications because pharmacies had little or inaccurate information on their eligibility, prompting several states to step in with emergency aid to cover the costs.

Though the GOP generally favors giving the new benefit a year to work out the glitches, the oversight could result in some fine-tuning, including extending the enrollment period from mid-May through the end of December, postponing late enrollment penalties until 2007, and giving beneficiaries a year's grace period to switch drug coverage plans without penalty.

Opening the benefit to discussion could also prompt Democrats to renew their push to allow Medicare to negotiate directly with pharmaceutical companies for volume discounts, but such a change almost certainly would trigger strong opposition from the White House and the GOP congressional leadership.

Another big concern that could weigh heavily on lawmakers during the election campaigns is how beneficiaries will react when they encounter the benefit's "doughnut hole." Under the current standard benefit, beneficiaries are liable for a $250 deductible and 25% of the next $2,000 in drug costs. Then, they are liable for 100% of the next $2,850 in drug expenses before Medicare picks up costs again.

Action Promising On Health IT

Bipartisan support has already coalesced behind pending bills designed to spur nationwide adoption of digital, interoperable electronic patient health records and the infrastructure needed to support them, a key priority of the Bush Administration.

Several of the bills include new funding to assist in the development of regional information-sharing networks, but many do not include related financial aid.

So far, the heavy lifting on health information technology has been done by the Department of Health & Human Services, the federally chartered American Health Information Community (AHIC), and private groups. Also, the HHS Office of Inspector General has proposed draft anti-kickback rules that would shield certain e-prescribing practices.

Hospital Spending

In recent years, Congress has granted a full market basket update to hospitals for Medicare inpatient and outpatient services. But for 2007, MedPAC advocates a reduced update for these services and none at all for other providers, including skilled nursing facilities, home health agencies, inpatient rehabilitation hospitals, and long-term care hospitals.

MedPAC has recommended that hospital inpatient and outpatient prospective payments increase by 0.45% less than the full market basket rate. Some have speculated that the President's budget request could embrace reduced inpatient payments to at least the level recommended by MedPAC. As one

Lab interests are also tracking the continuing research by MedPAC staff into Part B lab spending (steadily rising in recent years and now at $6 billion), the impact of increased service volume on patient care outcomes, and how well the current lab payment system works. Last year, as part of a bid to measure physician service quality, MedPAC said Medicare should require lab test results on claims, but Congress has yet to take up the idea (NIR, 26, 10/ Mar 7 '05, p. 1).

source put it, this is where the money is if deficit-cutters on the Hill are looking for major entitlement savings. But hospital interests already have warned lawmakers that any cutbacks would threaten their efforts to improve quality care, address the crisis in emergency care, and gear up for a possible influenza epidemic.

Some think Congress may avoid targeting Medicare providers altogether for savings in 2006. As Rick Pollack, executive vice president of the American Hospital Association, told the Bureau of National Affairs recently, "Cooler heads are likely to prevail, and [lawmakers] will say 'This is not how we want to be remembered right before an election.'"

Pay-For-Performance

A Senate bid to inject more P4P measures into Medicare failed to survive the budget reconciliation conference, but Finance Committee chairman Charles Grassley (R-IA) says he intends to push the issue again because Medicare is falling behind the private sector in adopting such programs. The Finance provision would have extended P4P to hospitals, physicians, home health agencies, Medicare Advantage health plans, and end-stage renal disease providers. Those showing improved quality would have received 1% to 2% more in Medicare payments.

Lab Personnel Training

Prospects this year remain uncertain for a slate of pending bills authorizing increased funding for allied health personnel, including one measure that is specific to medical technologists and medical laboratory technicians (*NIR, 26, 12/Apr 11 '05, p. 2*). The bills have not moved beyond the starting gate since being introduced in both the House and the Senate last year, and clinical laboratory groups say that getting any traction is an uphill battle, despite the growing gap between lab personnel supply and demand.

Genetic Discrimination

It's up to the House to move on this issue. The Senate last year unanimously passed legislation that would bar health insurers and employers from discriminating against individuals with a genetic predisposition to disease (*NIR, 26, 9/Feb 21 '05, p. 1*). The White House has weighed in with support for the ban, and the HHS Secretary's Advisory Committee on Genetics, Health & Society says enactment is a key priority.

Medical Malpractice Reform

This perennial issue is likely to be debated again, but unlikely to be resolved. The House last year approved a bill that would impose a federal cap on the amount of damages a plaintiff could collect against a physician or medical product manufacturer during litigation (*NIR, 26, 20/Aug 17 '05, p. 6*). In the Senate, efforts by the GOP leadership to pass a medical liability reform measure have been stymied by opposition from Democrats.

Oversight Of Tax-Exempt Providers

One sleeper issue in 2006 is whether Congress will make it harder for hospitals and other healthcare providers to qualify for tax-exempt status. Both the House Ways & Means Committee and the Senate Finance Committee have been investigating this area, but no proposals have been introduced. Finance's most recent target has been the American Red Cross, its disaster relief operations, and turmoil in its board and governance structure. The non-profit organization, which provides nearly half of the country's blood supply, has also been under Food & Drug Administration oversight for more than a decade to ensure that quality problems in blood processing and distribution are corrected and do not recur (*NIR, 26, 16/Jun 6 '05, p. 1*).

'Medically Unbelievable' Edits, *from p. 1*

immunoglobulin involved in the disease. Once a diagnosis is made, the patient would then be followed by serial orders of only the specific immunoglobulin."

❑ Molecular diagnostic codes 83890 through 83906: "[These codes] are routinely and appropriately ordered more frequently than the proposed edit of one. These codes were developed to recognize a series of steps of analyses required to amplify nucleic material, and thus these codes are intended to be ordered for more than one unit of service for appropriate specimen evaluation."

New York City Requires Labs To Report Diabetic Test Results

The city's move—the first by a governmental body in the country to track residents with a chronic disease—is seen as a sign that reporting requirements, historically limited to contagious diseases, could increasingly be applied to chronic conditions that have emerged as major public health concerns, such as diabetes, heart disease, and cancer.

Starting this month, the New York City health department is requiring clinical laboratories to report hemoglobin A1C test results for residents with diabetes. Labs that can transmit data electronically will have to submit the results within 24 hours.

City health officials say they will use the results to monitor the quality of care, pinpoint areas where diabetes is prevalent, and alert physicians and patients when blood sugar levels are too high. Some public health experts hail the move, saying it is important to track one of the country's major health problems, especially in light of the rise in obesity, and to help patients improve glycemic control and avoid severe complications. Other public health experts and consumer groups worry that the requirement would compromise patient confidentiality and privacy.

Clinical laboratory groups object to the reporting requirement on several grounds. No one argues with the importance of tracking diabetics, says Thomas Rafalsky, president of the New York State Clinical Laboratory Association, but city health officials have issued a regulation "that it is impossible for us to comply with" and did so "without listening to our concerns." He says his group and the American Clinical Laboratory Association submitted comments and requested meetings with city health officials, but to no avail.

In a joint letter last month to the Secretary of the city's Board of Health, Rafalsky and ACLA president Alan Mertz noted that the rule would mandate the reporting of the address of the person from which a specimen was taken. "Currently, a lab must report this information 'if known.' [The rule deleted these words.] Labs normally do not have direct contact with patients. Labs rely on ordering providers to supply demographic information, and such information is notoriously difficult to obtain. It is impossible for labs to guarantee that this information will be available so that it can be reported to the Department."

Rafalsky and Mertz also pointed out, "We have been advised…no action will be taken if the required information is not reported. This … misses the point. No governmental agency can or should require an action that everyone, including that governmental agency, acknowledges cannot be complied with."

Underscoring the practical burdens of the new rule, ACLA noted that New York City estimates there are 530,000 residents diagnosed with diabetes. "Based on the general standard of care, as provided under Medicare requirements, on average, diabetics have their hemoglobin A1C levels tested four times a year. That means there would be more than two million lab test results reported to the department each year, within 24 hours of being completed."

Study Finds Good News & Bad In Health Spending Growth

Overall, hospital spending accounted for 30% of the aggregate increases in healthcare spending between 2002 and 2004; prescription drugs constituted an 11% share. (The estimate does not factor in the new Medicare drug benefit.)

The rate of increase in healthcare spending in the United States slowed from 8.2% in 2003 to 7.9% in 2004, fueled mainly by a switch from more expensive brand-name prescription drugs to less costly generic drugs, according to the annual report released this month by the Office of the Actuary at the Centers for Medicare & Medicaid Services.

But this was still $140 billion more than in 2003. Moreover, for 2004, healthcare costs hit a high of $1.87 trillion (or $6,280 per person) and 16% of the gross domestic product, up from 13.8% in 1993 and 9.1% in 1980. "While the growth rate is declining, the cost of healthcare continues to be a concern for government, business, and individuals," noted HHS Secretary Michael Leavitt.

Medicare spending grew by 8.9% in 2004, to $309 billion, vs. a 6.6% increase in 2003. The report said the upswing was due to increases in home health and physician spending, plus the effects of the 2003 Medicare law that increased payments to rural providers and managed care plans.

Total Medicaid spending (federal and state) slowed from 8.8% in 2003 to 7.9% in 2004, for a total of $290.9 billion. The report attributed the slowdown to state drug cost-containment efforts.

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