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For Hospitals, Laboratories and Physician Practices

Delay Sought For "Medically Unbelievable" Edits

Unless the Centers for Medicare and Medicaid Services (CMS) agrees to a requested delay, healthcare providers could face having to deal with Medicare's controversial "medically unbelievable" edits (MUEs) beginning July 1.

The proposed edits, whose use will result in automatic denials of all claimed units in excess of the criteria units of service ceiling, are far-reaching. They affect the majority of pathology and clinical laboratory services and include CPT codes for all other specialties. While the proposed limit of two units for CPT 88305 (Level IV—Surgical Pathology, Gross and Microscopic Exam) has drawn the greatest concern and attention in the pathology community, the MUEs will have an impact on all areas of pathology and clinical laboratory services. Industry groups are calling on CMS to withdraw the plan to give concerned providers more time to review the changes. Currently, providers have until March 20 to submit their comments.

The American Medical Association (AMA) is also

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Inside this issue

Budget Bill Tightens Medicaid Eligibility, Reverses Physician Payment Cut

About three-quarters of the Medicaid savings achieved by the 2005 budget reconciliation legislation comes from increasing penalties on people who illegally transfer assets to qualify for nursing home care and other provisions tightening Medicaid eligibility, according to the Congressional Budget Office (CBO).

The Deficit Reduction Act of 2005 (S. 1932) cuts Medicaid spending by almost $5 billion and Medicare spending by almost $6 billion over five years. President Bush signed the bill into law on February 8.

In addition to cracking down on illegal transfer of assets, the law also restricts Medicaid eligibility for people with substantial home equity, requires beneficiaries to document their U.S. citizenship, and allows higher cost-sharing and premiums for beneficiaries, along with restriction of benefits.

President Bush on February 8 defended the bill's Medicaid cuts during a speech in New Hampshire. "We want to take care of the poor, but we don't want to reward people who game the Medicaid system," he said, adding that additional steps are needed to hold down the nation's spending on entitlements—Medicaid, Medicare, and Social Security.

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Up to 80 million claims may potentially have to be reprocessed as a result of the fee fix.

Budget Bill, *from p. 1*

In the president's 2007 budget plan submitted to Congress February 6, he requested a $65 billion cut in entitlement spending, with $36 billion coming from Medicare and $12 billion coming from Medicaid (*see related article, pg. 3*).

Physicians Get Medicare Fee Fix

The budget reconciliation bill also reversed a 4.4% reduction in Medicare payments for physicians, including pathologists, that took effect January 1. The measure freezes payment levels at 2005 levels, retroactive to the start of the year.

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, according to Medicare officials. 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.

Medicare Savings

The $6 billion in Medicare savings comes from a number of provisions affecting hospitals, skilled nursing facilities, rehabilitation facilities, and Part B providers. Among key provisions:

❖ ***Improves hospital quality.*** The law expands the requirements for mandatory hospital quality reporting. Hospitals will have to report on existing complications and comorbidities upon admission in fiscal 2007.

❖ ***Clarifies determination of Medicaid patient days for disproportionate share (DSH) computation.*** The measure codifies policy regarding exclusion of patient populations receiving medical assistance under Section 115 expansion waiver demonstration programs and excludes patients not receiving hospital benefits under such authority from the Medicaid days component of the calculation for purposes of Medicare disproportionate share inpatient hospital payments.

❖ ***Reduces payments to skilled nursing facilities for bad debt.*** The bill reduces Medicare program payments for unpaid coinsurance (bad debt) by individuals who are not dually eligible for Medicaid to 70%. Retains bad debt payment at 100% for dually eligible beneficiaries.

❖ ***Extends phase-in of the inpatient rehabilitation facility classification criteria.*** The measure adds an additional year in the transition period for the 75% rule, retains the 60% threshold for 2006, and increases the threshold to 65% in 2007 and 75% in 2008.

❖ ***Develops a strategic plan for physician investment in specialty hospitals.*** The law suspends issuance of new provider numbers at the earlier of six months or until the Department of Health and Human Services issues a strategic implementation plan on specialty hospitals to address investment, care for those with low income, and uncompensated care.

❖ ***Establishes a Medicare gainsharing demonstration.*** The law creates a demonstration program to evaluate gainsharing arrangements between hospitals and other providers at up to six sites, beginning on Jan. 1, 2007. A final report must be submitted to Congress on the outcome of the project by May 1, 2010.

❖ ***Allows beneficiary ownership of certain durable medical equipment (DME).*** The law provides for beneficiary ownership of certain DME items after the 13th month of rental (rental must begin after Jan. 1, 2006). It also provides for ownership of oxygen equipment after the 36th month of rental, pays for service and maintenance of such DME when maintenance is provided, and continues the previous first month purchase option for power wheelchairs.

❖ ***Improves preventive benefits.*** The law provides preventive screening for abdominal aortic aneurysms for beneficiaries at risk during a Welcome to Medicare physical exam. It also waives the deductible for the screening as well as the deductible for colorectal cancer screening tests that are covered by Medicare.

Resource

❖ House Committee on Ways and Means: *http://waysandmeans.house.gov/ResourceKits.asp?section=2233*

2007 Budget Calls For $36 Billion In Medicare Savings
Proposal Requires Lab Competitive Bidding

President Bush is proposing to cut $36 billion in Medicare spending between 2007 and 2012, primarily through an increased focus on appropriate payment for services and increased competition, including lab competitive bidding.

The budget proposal, submitted to Congress February 6, also calls for $12 billion in Medicaid savings over five years.

The $35.9 billion in proposed Medicare savings focuses on legislative proposals to encourage efficient and appropriate payment for services and promotes competition and beneficiary involvement in their healthcare decisions, according to the Department of Health and Human Services. Medicare savings for fiscal 2007 would stand at $2.5 billion.

The budget proposal notes that the administration will implement a competitive bidding program in July 2006 to enable physicians to obtain certain drugs used in their offices at lower prices.

"The administration will expand the use of additional competitive bidding programs in 2007, for example, into the purchase of medical supplies and equipment," the proposal states. "In particular, the budget proposes to integrate competitive bidding into payment of clinical laboratory services."

The budget proposal does not include any specifics on just how competitive bidding should be implemented.

The proposal to implement competitive bidding for lab services has met with fast opposition (*see box*).

Tough Sell

The president's plan is likely to be a tough sell, especially in an election year. The senior Democrat on the House Budget Committee has said the proposal to reduce healthcare entitlement spending would hurt vulnerable Americans.

"Despite recent administration statements about providing affordable healthcare for Americans, this budget includes increases in Medicare premiums, cuts to Medicare and Medicaid, and a misguided plan for health savings plans that will shift more of the cost of healthcare onto individual consumers," said Rep. John Spratt (D-S.C.), ranking member on the House Budget Committee, in a February 6 statement.

Senate Finance Committee Charles Grassley (R-Iowa) said additional Medicaid and Medicare cuts could be difficult, especially since Congress just cut healthcare entitlement spending by $11 billion (*see related article on pg. 1*).

"Congress just finished reducing the growth of Medicare and Medicaid by $11.1 billion over the next five years, and it wasn't an easy legislative accomplishment," he said. "Any more reduction of a significant scope could be difficult this year. If Medicare reductions do end up on the table, the Medicare Advantage [managed care plan] regional stabilization fund has to be front and center."

Limit Subsidies

Among the president's Medicare legislative proposals is a request to limit subsidies to high-income Medicare beneficiaries. The FY2007 plan would build on the 2003 Medicare Modernization Act (MMA) provision requiring higher-income beneficiaries to pay a greater portion of their Part B premium in 2007. Individuals with income over $80,000 and couples with income over $160,000 would be affected by this provision.

The president's plan would expand this MMA provision by eliminating annual indexing of thresholds for income-related Part B premiums, beginning Jan. 1, 2008.

In addition, the fiscal 2007 budget proposal calls for Medicare provider payment reforms. The administration said it

supports physician payment reforms such as differential updates initially for physicians who report on quality measures and later for doctors who achieve efficient and quality care.

The president is also calling for an automatic reduction of federal spending on Medicare when federal expenses surpass 45% of the program's total cost for two consecutive years. According to the Bush administration's projections, this would first occur in 2017, providing that Congress passes Bush's budget proposal.

HHS Secretary Gets An Earful

During a February 8 hearing held by the House Ways and Means Committee, lawmakers voiced their concerns about the Bush budget plan. HHS Secretary Michael Leavitt defended the proposal.

"I recognize that every program is important to someone," he said in his prepared testimony. "But we had to make hard choices about well-intentioned programs. I understand that reasonable people can come to different conclusions about which programs are essential and which ones are not."

Rep. Fortney (Pete) Stark (D-CA) raised concerns about "bait and switch" tactics being using by some plans marketing the drug benefit and then scaling back on their formularies. Stark also told Leavitt that the federal government is overpaying managed care, or Medicare Advantage plans, under Medicare. Stark said that the government overpays Medicare Advantage at a rate of approximately 115% of what the government pays for care under traditional fee-for-service Medicare.

Stark noted that the Medicare Payment Advisory Commission (MedPAC) recommended in 2005 that Congress eliminate the $10 billion stabilization fund it set aside in the 2004 Medicare law for regional preferred provider organizations. MedPAC said that, even without the fund, regional PPOs still receive protection from excessive risk and are encouraged to participate in Medicare through the establishment of "risk corridors" in which they receive payments from CMS if their costs are above a certain threshold.

Leavitt responded to Stark that the goal behind the current payment structure is to improve consumer choice under Medicare.

ACLA Objects To Bush Plan

The American Clinical Laboratory Association (ACLA) wasted no time in voicing its opposition to the administration's plan to expand competitive bidding for laboratory services in Medicare.

"The Centers for Medicare and Medicaid Services (CMS) has not even launched its competitive bidding demonstration project for laboratory services," said ACLA President Alan Mertz in a statement. "To expand competitive bidding for lab work nationwide before we've even begun testing it on a pilot basis is most unwise. Prudence dictates that we see the pilot results first."

CMS currently is in the process of implementing a competitive bidding pilot for lab services. A report on the demonstration was due to Congress by Dec. 31, 2005, but remains in clearance. Also delayed is an announcement of the demo sites.

ACLA argues that the emphasis on obtaining best price, which is inherent in the competitive bidding process, will reduce quality and limit access to needed lab services, hurting Medicare patients.

"In an attempt to drive down lab costs in the short run, competitive bidding could well cause higher, not lower, healthcare costs in the long run," said Mertz. "It certainly would impair access and quality of care."

Many problems could arise from blindly expanding competitive bidding of laboratory services, says ACLA in its statement. There are more than 250 million lab tests for Medicare beneficiaries each year and more than 1,000 kinds of lab tests performed in over 13,000 hospital and independent labs and in more than 100,000 doctors' offices. No single laboratory offers every test, serves all Medicare patients, or reaches the entire nation, and some laboratory tests are unique to a single laboratory.

"This misguided proposal should be rejected," said Mertz.

COMPLIANCE PERSPECTIVES

Recovery Audit Contractor Demonstration Project: Is It The Answer To Improper Medicare Payments?

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The U.S. government continues to experiment with different methods of ensuring appropriate payments to healthcare providers for services furnished to beneficiaries of the federal Medicare program. Congress's latest project in this regard revolves around the engagement of private entities by the Centers for Medicare and Medicaid Services (CMS) to audit Medicare billings and identify overpayments to providers.

In 2003, Congress instituted section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 306 directs the Secretary of the Department of Health and Human Services (HHS) to conduct a demonstration project to determine the efficacy of using private companies contracted with CMS to identify overpayments and underpayments that were not previously detected through existing Medicare program integrity systems.[1] The entities performing these audits are known as Recovery Audit Contractors or "RACs."

The impetus for the RAC program is a belief by the federal government that providers are being overpaid billions of dollars each year by Medicare. Over the past seven years, the Office of Inspector General (OIG) for HHS has estimated the extent of fee-for-service payments that did not comply with Medicare laws and regulations—from $23.2 billion for fiscal year 1996 to $13.3 billion in 2003, which was approximately 6.3% of the $212.7 billion in processed fee-for-service payments.[2] The OIG determined that improper payments ranged from failure to document services to inadvertent mistakes to outright fraud and abuse.[3]

On March 28, 2005, CMS awarded contracts to five RACs, marking commencement of the recovery audit program. As the states with the largest Medicare expenditure amounts, California, Florida, and New York were selected for pilot RAC programs that will last for three years.

The Medicare Modernization Act Of 2003

The MMA was signed into law by President George W. Bush on Dec. 8, 2003. Most notably, the MMA provides seniors and disabled individuals with a prescription drug benefit. In addition, the law required that the Secretary of HHS establish a pilot program to evaluate potential measures to ensure proper reimbursements to healthcare providers from the Medicare program.

Under the terms of the MMA, the demonstration project, which is authorized for up to three years, must involve at least two states with the highest per capita utilization rates of Medicare services, and involve at least three contractors, none of whom are Medicare Affiliated Contractors (MACs), such as fiscal intermediaries (FI) and carriers.[4] The RAC must have the appropriate clinical knowledge of and

[1] Pub.L. No. 108-173, 117 Stat. 2066 (2003).
[2] Office of Inspector General, Department of Health and Human Services, *Improper Fiscal Year 2002 Medicare Fee-for-Service Payments* (A-17-02-02202), January 16, 2003. *http://oig.hhs.gov/oas/reports/CMS170202202.pdf. See also*, Office of Management and Budget, Improving the Accuracy and integrity of Federal Payments, January 25, 2005, *www.whitehouse.gov/omb/financial/fia/ipia_gov-wide_report.pdf*.
[3] *See http://oig.hhs.gov/oas/reports/CMS170202202.pdf*
[4] *Id*. at § 306(b).

experience with Medicare payment rules and regulations, or the RAC must contract with another entity that has such knowledge and experience.[5] The law also provides that recovery of an overpayment identified by a RAC does not preclude the Secretary or the Attorney General from also investigating and prosecuting allegations of fraud or abuse arising from the overpayment.[6]

The MMA further requires that no later than six months after the demonstration project is completed, the Secretary must submit a report to Congress that identifies the impact of the savings to the Medicare program resulting from the RACs' efforts and recommendations on the cost effectiveness of continuing or expanding the project.[7]

The CMS Recovery Audit Contract Initiative

In accordance with the MMA, CMS designed the Recovery Audit Contract Initiative to determine whether the use of RACs is a cost-effective means of ensuring that physicians, providers, and suppliers receive correct payments from the Medicare program. According to CMS, RACs will identify and collect Medicare claims overpayments that were not previously identified by other MACs.[8] To accomplish this task, CMS instituted the following plan:

- There will be RACs for both Medicare Secondary Payer (MSP) and non-MSP claims and activity.
- Compensation for RACs will be provided through retention of a percentage of the overpayment recoveries.
- Claims reviewed by RACs will have been submitted to the carriers or FIs at least a year before to ensure that the ordinary processing will have been completed.
- RACs will: 1) perform data analysis to identify areas of investigation, and 2) request claims history information from the carriers or FIs.
- Non-MSP RACs will identify and recover claims overpayments only. They will not be permitted to establish cost report overpayments.
- RACs will apply national coverage policies and Local Coverage Determinations (LCDs) that have been approved by the MACs.
- The collection policies to be applied by this pilot will be the same as those currently in effect for the carriers/intermediaries, including assessment of interest on the portion of any debt that is unpaid 30 days after issuance of the demand letter.
- No new policy will be applied. In addition, providers will have full appeal rights, as they would if CMS or an MAC identified the overpayment. Once a provider appeals an overpayment determination, the RAC must stop pursuing the claim.
- If underpayments are determined, the information will be forwarded to the MACs for processing and payment.[9]

CMS identified a three-tiered review process for the RACs. The first level involves reviewing claims for inpatient hospital services under Part A of the Medicare program, which are based on Diagnosis Related Groups (DRG). These reviews normally involve making a request for medical records. The second level of review involves overpayments determined by the RAC's proprietary data-mining systems and will cover both Part A services as well as outpatient and other services furnished under Medicare Part B. The overpayments identified as part of the second level of review do not require a medical record because it will be clear that Medicare requirements have not been met and that an overpayment has occurred. The last level of review involves the actual request of medical records for Part B services.[10]

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[5] *Id*. at § 306(d).
[6] *Id*. at § 306(e)
[7] *Id*. at § 306(f)
[8] CMS Medlearn Matters, *MMA – The Centers for Medicare & Medicaid Services (CMS) Recovery Audit Contract (RAC) Initiative*, Medlearn Matters Number: SEO469, *www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SEO4669.pdf*
[9] *Id*.
[10] CMS Medlearn Matters, *MMA – The Centers for Medicare & Medicaid Services (CMS) Recovery Audit Contract (RAC) Initiative*, Medlearn Matters Number: SEO565, *www.cms.hhs.gov/medlearn/matters/mmarticles/ 2005/SEO565.pdf*

On March 28, 2005, CMS awarded contracts to five RACs and officially announced the beginning of the RAC demonstration project. Three of the five RACs are currently performing post-payment medical reviews in California, Florida, and New York, having at least three years of claims that they may review. Connolly Consulting is performing claim reviews in New York and Florida (durable medical equipment). PRG Schultz and its subcontractor, Concentra Preferred Systems, are performing claim reviews in California. HealthData Insights is performing claim reviews (except durable medical equipment) in Florida.

Providers in Florida began seeing medical record requests in connection with the first level of RAC review in August 2005. Medical record requests began for providers in New York in September 2005 and were followed by similar requests to California providers in October 2005. All of the currently operating RACs indicated they would start issuing record requests to physicians, related to the third level of review, during the later part of 2005. In this connection, the RAC project is well under way in the three pilot states.[11]

Perhaps the most troubling aspect of the RAC demonstration project for Medicare providers is that RACs are compensated through the retention of a percentage of the overpayments they recover.

During the demonstration project, MACs will continue to analyze claims and review case files in the current fiscal year to ensure that payments are accurately provided to physicians, providers, and suppliers. CMS will also continue other key initiatives, such as contractor reform; supplementary carrier quality controls and improved data capabilities; provider education; and training.[12]

Perhaps the most troubling aspect of the RAC demonstration project for Medicare providers is that RACs are compensated through the retention of a percentage of the overpayments they recover. Although RACs are also charged with identifying underpayments, CMS is not presently offering any incentives to the RACs to do so.

The Medicare Appeals Process

As mentioned, providers subject to an overpayment determination identified by a RAC have certain appeal rights. The implementation of the RAC project therefore is made more significant by the fact that it coincides with certain major changes to the rules governing Medicare payment appeals.

There are more than 41 million Americans receiving Medicare benefits. Fiscal intermediaries and carriers process approximately one billion claims year—approving payment for approximately 900 million claims and issuing denials for approximately 10% of total claims.[13] Federal law provides that Medicare beneficiaries and, under certain circumstances, providers and suppliers of healthcare services have the right to appeal an adverse determination regarding claims submitted to the Medicare Part A or Part B programs under sections 1869 and 1879 of the Social Security Act. Historically, two federal agencies, HHS and the Social Security Administration, participated in the Medicare appeals process, but neither agency had control over the entire process. As a result, there was concern that the lack of coordination between these two agencies resulted in enormous delays in resolving appeals.

In December 2000, Section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)[14] amended section 1869 of the Social Security Act, providing major changes to the existing Medicare claims appeals process.

Three years later, the MMA included additional changes to the Medicare appeals

[11] *See id.*
[12] CMS Medicare News, *Demonstration to Work Toward Assuring Accurate Medicare Payments*, March 28, 2005, *http://new.cms.hhs.gov/apps/media/press/release. asp?Counter+1*
[13] United States Department of Health and Human Services Report to Congress; Plan for the Transfer of Responsibility for Medicare Appeals, March 2004. *www.hhs.gov/medicare/appealsrpt.html*.
[14] Pub. L. No 106-554, 114 Stat 2763 (2000).

process. Section 931 of the MMA contains a number of provisions affecting the Medicare appeals process, including: 1) the transfer of responsibility for the Medicare appeals function to HHS between July 1, 2005, and October 1, 2005; 2) a mandate that the ALJs performing this function be organizationally and functionally separate from CMS and that they report to and be under the general supervision of the Secretary; 3) the establishment of a means for allowing providers and suppliers to correct minor errors or omissions to claims submitted under the title XVIII programs without initiating an appeal; 4) a requirement that all evidence must be presented at the Quality Improvement Contractor (QIC) level unless good cause is shown; and 4) the necessity for the QIC to review medical records when the issue revolves around medical necessity concerns.[15]

On March 1, 2005, CMS published the interim final rule that sets forth new regulations that implement the statutory changes to the Medicare appeals process. The new regulations, which apply to Medicare Part A and B claims, are found in the new subpart I of 42 Code of Federal Regulations, part 405.[16] Most importantly for providers, the new rules speed up the entire appeals process, require a full presentation of evidence at a much earlier phase of the proceedings, and make it unlikely that providers will participate in evidentiary hearings before an Administrative Law Judge regarding the overpayment.[17] These new rules, particularly the faster time frames, create a greater incentive than before for providers who are subject to significant overpayment determinations to promptly obtain legal assistance.

Taking Necessary Steps To Be Prepared

The RAC project and the changes to the Medicare Appeals process will place enormous constraints on physicians, providers, and suppliers, from having to submit medical records for review to spending time and resources in appealing claims through a multi-leveled appeal process. There are several steps that can be implemented to ensure a smooth process, including:

- Making sure that medical record documentation is complete and accurate;
- Alerting and training all relevant staff to notify the appropriate person/department upon arrival of any correspondence from the RAC;
- Having only qualified and experienced personnel responding to requests from the RAC;
- Keeping a copy of all documentation provided to the RAC;
- Making sure that the response to a request for medical records is performed within the designated time frame and that the copies submitted are copied clearly;
- Making sure that any letters requesting repayment are directed to the appropriate person and that the medical records are reviewed for a possible appeal;
- Being familiar with the Medicare appeals process and deadlines;
- Instituting a tracking system of underpayment and overpayment determinations from the RAC and assessing the need for changes within the organization;
- Considering adopting a corporate compliance plan to address any billing and coding deficiencies; and
- Instituting education and training regarding any change in practice.

Conclusion

As described above, the RAC demonstration project creates greater incentive than ever before for Medicare providers to make every effort to comply with all applicable billing and reimbursement requirements. The RACs are private entities that have a direct financial incentive to identify provider overpayments and apparently are putting forth significant effort to do just that. The RACs already are well under way in auditing provider claims in California, Florida, and New York. Given the emphasis the federal government has placed on correcting Medicare overpayments, if the RACs are at all successful in increasing the recovery of erroneous payments, providers can expect the RAC program to expand beyond the three pilot states.

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[15] *See id.*
[16] 70 *Federal Register* 11422 (March 8, 2005).
[17] *See id.*

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

calling for a delay. In a January 18 letter to CMS Administrator Mark McClellan, AMA Executive Vice President and Chief Executive Michael Maves, M.D., urged CMS to delay the proposed edits for six months, until January 2007.

"While we support reasonable steps toward error rate reduction, we have serious concerns with the July 1, 2006, implementation deadline, as well as the manner in which the initiative has been rolled out," Dr. Maves said, noting that the proposed MUEs are not the same as typical correct coding edits and should not have the same review period.

"As opposed to updates for new and revised codes, a review of the entire CPT and HCPCS Level II code set for the MUE, in addition to being a much larger volume, is based on anatomic assumptions as to what is logical and, more problematic, CMS's expectations of what is medically reasonable," he said.

Even a cursory review of the MUEs reveals a "large volume of errors that will require careful scrutiny," the AMA said. "This is particularly concerning since it was our understanding that these edits were to be set high enough that the Medicare contractors will not need modifiers to override the edits; however, this appears not to be the case."

Resources

- College of American Pathologists: *www.cap.org*
- AMA letter to CMS: *http://www.cap.org/apps/docs/statline/ama_mue_letter.pdf*

HIPAA Security Rules Deadline Approaching

The privacy regulations applied to small health plans on April 14, 2004, and all other group health plans on April 14, 2003.

The deadline for small group health plans to comply with the HIPAA Security Rules is fast approaching. Small plans must comply with the rules by April 20, 2006 (large group health plans were required to comply with the rules as of April 20, 2005).

The Security Rules relate to and build on the rules established by the privacy regulations under HIPAA (the Health Insurance Portability & Accountability Act of 1996), notes an advisory issued by the law firm of Davis Wright Tremaine LLP.

The Security Rules require covered entities, including employer-sponsored group health plans, to: 1) ensure the confidentiality, integrity, and availability of all electronic protected health information that the covered entity creates, receives, maintains, or transmits; 2) protect against any reasonably anticipated threats or hazards to the security or integrity of such information; 3) protect against any reasonably anticipated uses or disclosures that are not permitted or required by the privacy regulations; and 4) ensure the compliance of its workforce.

Examples of activities that are regulated by the rules include: e-mail transmissions of protected health information; electronic records that are maintained, accessed, or transmitted in databases; information that is transmitted to or from a personal digital assistant (PDA); and the physical transport of any equipment that is used for electronic transfer, such as laptops or disks.

Each employer sponsoring a group health plan that creates, maintains, or transmits electronic protected health information must take the following steps by April 20:

- Appoint a security official;
- Conduct a risk assessment and develop a risk management plan;
- Adopt appropriate safeguards;
- Develop policies and procedures;
- Conduct appropriate training and awareness programs;
- Adopt a sanctions policy;
- Amend the health plan document, if the plan sponsor receives electronic protected health information;
- Update or adopt business associate contracts to include the HIPAA security rules.

Resource

- Davis Wright Tremaine employee benefits advisory bulletin: *www.dwt.com*

JCAHO Issues Alert About Medication Errors

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is calling for "intensified" attention to the accuracy of medications given to patients who are in transition between care settings or practitioners.

In an alert issued January 23, JCAHO notes that medication errors often occur at the "interfaces of care," such as whenever a patient changes locations in a healthcare facility, between care facilities, between a healthcare facility and home, or between practitioners.

JCAHO recommends that providers use medication reconciliation to prevent errors. Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient is taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. The alert advises that medication reconciliations should be done at every transition of care in which new medications are ordered or existing orders are rewritten.

"Accurate and complete medication reconciliation can prevent numerous prescribing and administration errors," states the alert. "Failure to reconcile medications may be compounded by the practice of writing 'blanket' orders, such as 'resume pre-op medication,' which are highly error prone and are known to result in adverse drug events. Such orders are explicitly prohibited by the Joint Commission's Medication Management Standards."

JCAHO issued the "Sentinel Event Alert" after its Sentinel Event Database identified medication errors as one of the most frequently occurring threats to patient safety.

To reduce medication reconciliation-related errors, the alert recommends that healthcare organization put a list of medications in a "highly visible" place in the patient's chart and include essential information about dosages, drug schedules, immunizations, and drug allergies.

Organizations should also reconcile medications at each interface of care, specifically including admission, transfer, and discharge, according to the alert, which recommends providing each patient with a complete list of medications to be taken after discharge from the facility, as well as instructions on how and how long to take any new medications.

Resource

❖ January 23 Sentinel Event Alert: *www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_35.htm*

Risk Reduction Strategies

JCAHO recommends that healthcare organizations follow error reduction practices identified by the Massachusetts Coalition for the Prevention of Medical Errors. The core recommendation is to "adopt a systematic approach to reconciling medications, starting with reconciliation at admission." Additional practices include:

- ❖ Collect a complete list of current recommendations (including dose and frequency, along with other key information) for each patient on admission.
- ❖ Validate the home medication list with the patient (whenever possible).
- ❖ Assign primary responsibility for collecting the home list to someone with sufficient expertise, within a context of shared accountability.
- ❖ Use the home medication list when writing orders.
- ❖ Place the reconciling form in a consistent, highly visible location within the patient chart (easily accessible by clinicians writing orders).
- ❖ Assign responsibility for comparing admission orders to the home medication list, identifying discrepancies and reconciling variances to someone with sufficient expertise.
- ❖ Reconcile medications within specified time frames (within 24 hours of admission; shorter time frames for high-risk drugs, potentially serious dosage variances, and/or upcoming administration times).
- ❖ Adopt a standardized form to use for collecting the home medication list and for reconciling the variances (includes both electronic and paper-based forms).
- ❖ Develop clear policies and procedures for each step in the reconciliation process.
- ❖ Provide access to drug information and pharmacist advice at each step in the reconciliation process.
- ❖ Improve access to complete medication lists at admission.
- ❖ Provide orientation and ongoing education on procedures for reconciling medications to all healthcare providers.
- ❖ Provide feedback, ongoing monitoring.

Medicare Paid More Than $400 Million For Improper Ambulance Services: OIG

One out of four Medicare-covered ambulance transports in 2002 did not meet the federal program's requirements, the Health and Human Services Office of Inspector General (OIG) said in a January 23 report.

In a review of ambulance claims from calendar year 2002, the OIG found that approximately 25% of claims did not meet Medicare's coverage requirements, resulting in $402 million in improper payments. Medicare pays for ambulance services only when transportation by other means, such as taxi, private car, or wheelchair van, would endanger the beneficiary's health.

Coverage error rates were significantly higher for dialysis transports and nonemergency transports, the OIG's Office of Evaluation and Inspections said in the report, "Medicare Payments for Ambulance Transports." The error rate was 27% for dialysis transports and 20% for all other nonemergency cases. In contrast, the report said, emergency transports met Medicare requirements 93% of the time.

Ambulance Transport Benefit

Previous OIG studies indicated that Medicare's ambulance transport benefit was vulnerable to abuse. A 1994 report found that 70% of dialysis-related transport claims were paid in error, while results from a 1998 survey showed that two-thirds of the claims did not meet program requirements.

OIG inspectors said the culprit is a lack of contractor safeguards to identify and prevent improper payments. Despite prior OIG recommendations, CMS mandates very few specific safeguards to prevent improper ambulance payments, the report said. As a result, contractors use few prepayment edits to screen claims and less than half of all contractors conduct postpayment claim reviews.

The OIG recommends that CMS implement "program integrity activities" designed to target ambulance transports with the greatest risk for error. The activities should include:

- ❖ Instructing Medicare contractors to implement prepayment edits that would more closely scrutinize nonemergency and dialysis-related ambulance transport claims;
- ❖ Instructing Medicare contractors to obtain documentation from ambulance suppliers and at least one third-party provider associated with the transport when conducting postpayment medical reviews; and
- ❖ Directing contractors to educate third-party providers on when it is appropriate to use an ambulance for nonemergency transports.

Resource

❖ OIG report, "Medicare Payments for Ambulance Transports": *www.oig.hhs. gov/oei/reports/oei-05-02-00590.pdf.*

For the Record

No Sanctions For Cytology PT In 2006

The Centers for Medicare & Medicaid Services (CMS) says it will continue its "educational approach" to cytology proficiency testing (PT) during 2006. This means that laboratories will not have deficiencies cited or have sanctions imposed provided they: 1) enroll all affected individuals (i.e., cytotechnologists and pathologists) in a CMS approved testing program for the 2006 testing cycle, and 2) ensure that all such individuals are tested in a timely manner.

The decision not to impose sanctions in 2006 comes about a month after the House 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.

In a January 23 letter to state survey agency directors, Thomas Hamilton, director of the CMS Survey & Certification Group, said the agency will continue the educational approach as long as those affected meet the above criteria. However, failure to enroll in a program and ensure testing will result in intermediate sanctions that may include civil money penalties of up to $10,000, limitation of the lab's CLIA certificate or cytology, and possible suspension of the lab's Medicare and Medicaid payments for gynecologic cytology testing.

More details are available at *www.cms.hhs.gov/CLIA/02_CytologyProficiencyTesting.asp#TopOfPage*.

Combating Fraud In Drug Plans: The Centers for Medicare and Medicaid Services (CMS) is accepting comments on draft compliance guidance for Part D drug benefit plan sponsors. The document is designed to provide direction on how sponsors can implement a comprehensive program to prevent and detect fraud, waste, and abuse (FWA) in the prescription drug program. The 60-page draft, presented as an update to the FWA section (Chapter 9) of the Prescription Drug Benefit Manual, lays out the seven core elements of a compliance plan and also includes an eighth element regarding appropriate corrective action to take in response to potential violations. Comments will be accepted until March 1.

Billing Settlement: Pediatrix Medical Group Inc., a neonatal care provider based in Sunrise, Florida, will pay $25.1 million to settle a federal civil investigation into its Medicaid and TRICARE billing practices, the company said February 8. The tentative agreement between Pediatrix and the Department of Justice covers services provided by Pediatrix from January 1996 through December 1999. The settlement does not include billings from 2000 to 2002, a period that was also under scrutiny by the government. Company officials say the settlement ends the investigation.

More Billing Woes: A corporation overseeing more than 150 home health agencies (HHAs) paid $8 million to resolve allegations it overbilled Medicare and other federal healthcare programs, the Department of Justice and a federal prosecutor in Minnesota announced February 9. The settlement follows a False Claims Act qui tam action filed by two whistleblowers, former employees of Intrepid USA Inc, the corporate parent for about 86 providers operating 150 HHAs. The whistleblowers alleged that Intrepid submitted payment claims for Medicare and the military healthcare program (TRICARE/CHAMPUS) from Feb. 1, 1997, through Oct. 31, 2004, for home health services that were not provided by a qualified person, lacked physician orders and plans of care, and lacked sufficient documentation of the homebound status of the beneficiaries.

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