ISSUES The

CMS Creates Code to Reimburse Hospitals for New Drugs

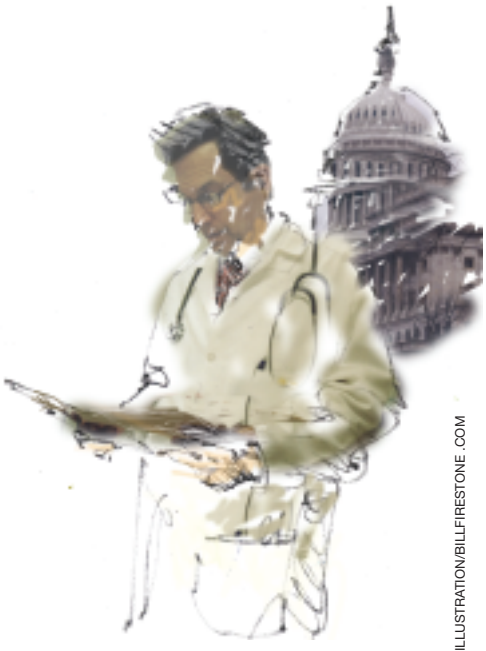
The Association of Community Cancer Centers (ACCC) is encouraged by the Centers for Medicare & Medicaid Services' (CMS) recently released instructions to contractors on reimbursement for newly approved drugs under the hospital outpatient prospective payment system (OPPS). Until now, hospitals did not receive payment for drugs newly approved by the Food and Drug Administration (FDA) until a unique drug code was assigned. Unfortunately this process often took several months after these drugs became available on the market. ACCC believes this action by CMS is an important first step to help ensure that Medicare beneficiaries have prompt access to innovative life-saving cancer therapies.

The instructions, which implement a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), authorize payment for drugs and biologicals administered on or after January 1, 2004. CMS has created a new code, C9399, unclassified drug or biological, for hospitals to use when billing Medicare for approved drugs that have not yet been assigned billing codes and that have not been determined to be eligible for higher payments. These drugs will be paid at 95 percent of average wholesale price (AWP), as determined by the Medicare contractor.

"For patients battling cancer, access to these cutting-edge drugs is their best hope for survival and often means the difference between life and death. Waiting months while CMS dealt with the bureaucracy of claims submission has simply not been realistic," said Deborah Walter, ACCC senior director, Policy and Government Affairs.

In addition to the miscellaneous code, the new approach will require hospitals to manually enter information that is not now routinely included on claims submitted to Medicare. In practice, adding this new information to each claim the hospital processes may prove challenging.

ACCC looks forward to working



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HIPAA: Year Two Update

by Melissa Markey, JD

Having passed the first year anniversary of the Health Insurance Portability and Accountability Act (HIPAA) Privacy enforcement, where are we now?

As of April 2004, the Office of Civil Rights (OCR) of the Department of Health and Human Services reported more than 6,000 complaints. Fifty percent of those complaints have been closed mostly due to a finding of no jurisdiction, no violation, or voluntary compliance by the covered entity. As promised, the primary enforcement approach has been education. Still, although there has been no announcement of imposition of fines against any "covered entity," OCR has stated that certain egregious cases have been referred to the Department of Justice for possible criminal investigation

The areas of greatest confusion are 1) release of protected health information (PHI) for purposes of treatment; 2) release of PHI to law enforcement; and 3) impact of HIPAA on non-traditional care settings, such as public health screenings and health fairs. Although state law may impose additional requirements, remember that under HIPAA:

- PHI can always be used or disclosed for treatment purposes. There is no need for an authorization or other patient consent.
- PHI can be used or disclosed even for treatment of a patient other than the individual to whom the PHI refers. This permits, for example, the use of a parent's PHI to provide health care to a child.
- The scope of "treatment" is relatively broad, and includes, for example, preventative health care.
- Requests by qualified personal representatives are, for the most part, treated as a request by the patient.
- Not all health information is PHI. For example, records held by a covered entity in its role as an employer are not included in the definition of PHI.

Practical suggestion: Now is a good time to identify the most common HIPAA Privacy issues in your institution or practice over the past year, re-visit HIPAA Privacy policies, and refresh training, emphasizing those areas that are providing challenges. Another area worthy of evaluation is the process for tracking disclosures to permit the required accounting, if requested.

HIPAA Transactions and Code Sets. The HIPAA Transactions and Code Sets rule (TCS) mandates that certain electronic transactions be conducted using standard format.

with CMS as this provision is implemented. An alternative approach could be pursued that would enable hospitals to begin using a newly created unique code almost immediately upon a drug's FDA approval without the need to include any additional information on the hospital claim.

Hospitals to Get Higher Payments for Four New Oncology Drugs

Hospital outpatient departments will be reimbursed for four new oncology drugs, according to a CMS Transmittal, issued June 4, 2004.

Four New Oncology Drugs Approved for Pass-through Payment

Drug	HCPCS	APC	Payment	Minimum Unadjusted Copayment
Pemetrexed, inj, 10 mg	C9213	9213	$46.31	$6.92
Bevacizumab, inj, 10 mg	C9214	9214	$65.31	$9.76
Cetuximab, inj, 10 mg	C9215	9215	$54.72	$8.18
Abarelix, inj susp, 10 mg	C9216	9216	$89.72	$13.41

The transmittal states that beginning July 1, 2004, these drugs will receive pass-through payments equal to 95 percent of AWP.

The four injectable cancer drugs approved for payment are Pemetrexed (Alimta®), Bevacizumab (Avastin®), Cetuximab (Erbitux®), and Abarelix (Plenaxis®).

Under the MMA, hospitals can submit adjustment bills to receive

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Although the date for enforcement of TCS by most covered entities passed in October 2003, strict enforcement of TCS has been deferred by CMS under the contingency plan. The contingency plan was intended to be a short-term accommodation to providers, permitting Medicare payment of claims that are submitted in non-standard format. CMS has been consistent in viewing the contingency plan as an interim solution only. CMS has also emphasized the importance of completing testing and implementation of standard-format claim submission by announcing the implementation of a two-tier payment scheme for claims.

Starting July 1, 2004, non-compliant electronic (also called "legacy") claims will be treated as paper claims and reimbursed no sooner than 28 days. Electronic claims that comply with standard formats will be reimbursed after 14 days. Given the adverse impact on cash-flow, this two-tier payment scheme is expected to encourage increased submission of compliant claims.

If a clearinghouse submits your claims, it is important to remember that the issue is not whether your institution or practice *submitted* compliant claims to the clearinghouse; the issue is whether Medicare is *receiving* compliant claims. There have been reports that some clearinghouses are actually changing standardized claims submitted by the provider to non-standard claims to facilitate submission of "batches" of claims. If your clearinghouse is submitting your claims in a non-standard format, your claims will be paid as paper claims *even if* you submitted the claims in standard format to the clearinghouse.

Practical suggestion: Obtain from your claims-submission office a clear statement of whether claims submitted comply with EDI requirements, and if not, when compliance will be achieved. If possible, the agreement with the clearinghouse should require that claims be submitted in standard format and include penalties for failure of the clearinghouse to do so. If the clearinghouse is not submitting standard format claims, and will not be doing so by the deadline, it may be advisable to re-evaluate your relationship with that company.

HIPAA Security. Last, but not least, HIPAA Security is looming on the horizon. The Security Rule, which requires the development and implementation of an organized approach to ensuring the security of electronic PHI (e-PHI), becomes enforceable on April 21, 2005. To protect e-PHI, the Security Rule mandates assignment of security responsibility, performance of risk analysis and risk management activities, and implementation of administrative, physical, and technical safeguards. The importance of realistic approaches that adequately protect e-PHI without unduly disrupting patient care and business activities will only increase, given the impetus toward development of computer-based healthcare records. The growing momentum of this issue is demonstrated by the recent appointment of David J. Brailer, MD, PhD, to serve as the first National Health Information Technology Coordinator, the recently proposed federal legislation supporting the development of computer-based health records, and other technology-supportive initiatives.

Practical suggestion: Start preparation for compliance with the HIPAA Security obligations now. Conduct a risk analysis, and begin development of reasonable and workable security policies and procedures. To be effective, HIPAA security is going to require a significant modification of behavior. Now is the time to start discussing with physicians and other members of the healthcare team why security matters. Finally, don't forget to include members of the healthcare team in the security preparation to ensure that workflow issues are minimized.

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payment at 95 percent of AWP if they furnished these specific drugs to beneficiaries prior to their approval as pass-through drugs.

CMS said it also is making a correction to the amount it pays hospitals for the drug Fulvestrant (Faslodex®), inj, 25 mg. The payment rate has increased from $78.36 to $81.57, with a minimum unadjusted copayment of $13.63.

Oncology Practices Prepare for ASP, ACCC Responds

Effective Jan. 1, 2005, reimbursement for cancer drugs in oncology practices will switch from the AWP-based system to one based on average sales price (ASP). Under ASP, pharmaceutical manufacturers will report to CMS their total unit sales and corresponding sales price for each drug, arriving at an "average" sales price.

In comments filed on June 7, 2004, with CMS, ACCC urged the agency to allow exceptions to the ASP formula where inaccurate data would limit patient access to lifesaving drugs. ACCC believes that the ASP plus 6 percent methodology that will be used to set physician drug reimbursement rates for 2005 and beyond may result in payment rates that are lower than the price at which most physicians will be able to purchase some drugs. Implementing an exception process where interested parties—including physicians and manufacturers—could petition the agency to review external data for the purpose of setting a more accurate rate would facilitate patient access to all drugs.

ACCC applauds CMS' efforts to implement the ASP requirements within the tight time frame required by the MMA. Stability in payment rates is critical to minimize disruption to providers. Accurate price reporting is essential to setting reimbursement rates that fully reflect the costs of providing cancer therapies. ACCC believes this could be accomplished by providing clear guidance to manufacturers, and by excluding certain data that could adversely impact ASP and thereby jeopardize physicians' and suppliers' ability to provide these vital and often lifesaving drugs to patients.

Line of Therapy and Off-Label Use

Over the past two decades, the cancer community has faced a familiar drama: a physician prescribes a drug for a cancer patient only to discover that the insurer will not pay because the drug is being used for an "off-label" indication. The physician and patient point to published research to support the use of the drug, the insurer counters with the concern that the research has not been vetted by the FDA.

The off-label issue has been so contentious—and of such great importance to the cancer community—that federal and state laws have been enacted. These laws establish off-label use as appropriate when there is a sufficiently strong body of research to have the indication listed in a national drug formulary.

Traditionally, anticancer drugs enter the market approved by the FDA as second- or third-line therapy. Attempts to use them as first-line therapy would constitute off-label use.

If you consider "first-line" to mean the optimal therapy to start with and "second-line" as the next best choice once the potential of the first-line had been exhausted, then concerns about beginning with a drug labeled as second-line therapy would have some merit. After all, substituting a second-line drug for a first-line drug (i.e., the drug seen as the first best choice) might constitute poor care.

The advent of a new drug for the treatment of metastatic colorectal cancer, however, has introduced a somewhat unique twist to the off-label issue.

Atypically, Avastin® (bevacizumab) entered the market labeled as a first-line therapy. Based on the drug's FDA label, Avastin should now be the drug of first choice for patients with metastatic colon cancer. At least one large health insurer, however, is questioning the use of this drug on patients who have received previous chemotherapy—even when that chemotherapy was given years earlier when the patient was initially diagnosed. In these situations, the insurer argues that giving Avastin is considered off-label use. The insurer's logic is that because these patients had another chemotherapy at a previous time, using Avastin, which is labeled for first-line therapy would be inappropriate—and therefore should *not* be covered.

This position creates a serious problem for those colorectal patients diagnosed *before* the advent of Avastin onto the market because it denies them access to first-line therapy for their disease. Even more disturbing is the implication of this policy for the new generation of targeted therapies that are entering the market. Many, if not most, of these new drugs and biologicals have a chance to be labeled as first-line therapy. If a policy of denying coverage for first-line drugs for pre-treated patients is adopted, it will deny access to the therapies that are generally considered the optimal choice for treating the patient's condition.

PHOTOGRAPH/PHOTODISC

Senators Ask HHS to Expand Medicare Coverage of PET

In an April 29 letter signed by more than 30 senators, U.S. Department of Health and Human Services Secretary Tommy Thompson was asked to expand Medicare coverage of positron emission tomography (PET) to additional cancer diagnoses. CMS is currently considering a national coverage determination on PET for use with seven additional cancer indications: pancreatic, brain, small cell lung, cervical, ovarian, testicular, and multiple myeloma. In their letter, the senators also ask CMS to lift its national non-coverage status and leave PET coverage up to local Medicare carriers.

Billing for Prostate Brachytherapy in 2004

Administrative best practices every hospital should know

by Mary Lou Bowers, MBA, and Lynn M. Jones, MHA

The 2004 Medicare rule changes bring good news for hospital outpatient facilities that provide prostate brachytherapy services. This procedure is no longer bundled!

In 2004 providers are now reimbursed *separately* for the seeds and the procedure—with the payment amount for seeds based on their cost. These changes improve the reimbursement picture for brachytherapy because providers can now detail *all* services utilized in providing brachytherapy and cover the full cost of the procedure. However, providers must first understand exactly what they can and cannot charge when submitting claims for implantable seeds. Under the new rule, you can bill for items used to provide the treatment, including seeds, needles, and catheters.

Providers should put two immediate changes in place:

- Update your chargemaster with the correct codes for brachytherapy. In 2004 codes identifying the specific surgical and urological procedures are billed under 77778 and 55859.
- Bill for *each* seed used. Use codes C1718 (Iodine) and C1720 (Palladium). Remember, the cost of the seeds *is no longer* bundled in codes G0256 (Palladium) and G0261 (Iodine). Additionally, Medicare places *no limits* on the number of seeds allowed.

PHOTOGRAPH/COMSTOCK.COM

Investigate new purchasing patterns for this procedure, particularly in regard to purchase of seeds.

Use the Appropriate Cost-to-Charge Ratio

Medicare's intent is to reimburse for the actual costs of the seeds used, and multiplying the charges submitted by an outpatient surgery center by that center's cost-to-charge ratio (CCR) equals compensation. To determine appropriate reimbursement, providers should use the latest settled cost report from the department supplying the seeds. To ensure that you are using the correct CCR, ask your finance department for the appropriate last settled cost report. Do not use the most recent CCR as there is usually a two-year time lag between this CCR and the one accepted by Medicare. Do not use the hospital's CCR because Medicare requires using the relevant department's ratio.

Table 1 shows how using the wrong CCR can result in a provider receiving an excess payment for seeds. Even if this error is unintentional, the claimant would be subject to prosecution and fines due to prohibitions against overcharging federal health programs for services.

How to Bill for Seeds

In 2004 Medicare will reimburse hospitals for the invoiced cost of

Table 1: An Example of How Your CCR Can Affect Your Payment*

Basis	CCR	Charge	Payment	Implications
Department's Last Settled CCR	0.5	$7,000	$3,500	Appropriate Payment
Department's Current CCR	0.6	$7,000	$4,200	Overpayment of $700
Hospital's Settled CCR	0.7	$7,000	$4,900	Overpayment of $1,400

*Assumes a hypothetical total cost of $3,500 for seeds for one procedure.

seeds. So, providers should bill Medicare for the number of seeds ordered. For brachytherapy, three types of seeds may be purchased: stranded, loose, and Mick®. For each patient, the number and type of seeds needed for treatment will vary.

For example, a physician may order 100 seeds for two different cancer patients—Patient X and Patient Y. Patient X may be treated with 80 stranded seeds at $30/seed, 5 loose seeds at $20/seed, and 10 Mick® seeds at $25/seed, for a total seed invoice cost of $2,750. Patient Y, however, may receive 80 stranded seeds at $30/seed, 5 loose seeds at $20/seed, and 10 Mick® seeds at $25/seed, for a total seed invoice cost of $2,725. While Medicare only pays for each seed used under two codes—C1718 (Iodine) or C1720 (Palladium)—your internal system will need to keep track of and account for the different types of seeds ordered and used in order to ensure correct reimbursement.

When purchasing seeds, the right pricing decision can impact your program's revenue per procedure. Keep in mind that your charges for seeds should *not* be based solely on your Medicare reimbursement rates. Commercial payers usually pay a percentage of charges or a negotiated or capitated rate. Often commercial payers reimburse at higher rates than Medicare, based on the contract with the hospital.

Table 2 compares two providers' reimbursement rates based on a typical payer mix. Hospital A's seed charges are $5,000 per procedure. Hospital B's seed charges are $6,000 per procedure.

Table 2 shows that making the right business decision about seed purchase can directly affect your program's bottom line. Based on the payer mix in this example, hospital B, purchasing higher priced seeds, actually experiences $532.50 more in reimbursement per procedure. Over 100 procedures, a $53,250 increase would result. Even more important—future Medicare payments will be based on 2004 and 2005 data. So purchasing the lowest priced seeds today may not be to your programs overall advantage.

Billing for Waste

Seeds are ordered based on the patient's treatment plan. You can bill up to 15 percent of the number of seeds used as waste, but the reason for the waste must be documented in the patient's treatment plan, and it must be signed by both the physicist and the physician as part of the medical record. Establishing a department "seed wastage policy" can be a good administrative policy.

In determining what to pay for seeds, consider all the process factors involved with deliverying brachytherapy. For example, while pre-loaded seeds may cost more, they can save staff time, limit exposure of staff to radiation, and save time in the operating room. Another important consideration in seed purchase is the reliability of your supplier. Delays or cancellations due to vendor delivery problems are a tremendous inconvenience to the patient and your delivery team—not to mention the lost revenue to your cancer program when you are forced to cancel an operating room because the seeds did not arrive.

In the end, you should look at the 2004 rule changes as an opportunity to better identify *all* the costs involved in delivering prostate brachytherapy to patients. Cancer programs that carefully identify their costs and bill and code correctly and accurately for all services related to providing this important therapy, should see improved reimbursement for this service in 2004.

Mary Lou Bowers, MBA, is vice president, Consulting Division, and Lynn M. Jones, MHA, is managing director of consulting services at ELM Services, Inc., in Rockville, Md.

Table 2:
A Comparison of the Cost and Reimbursement of Differently-Priced Seeds

	Payer	Charge	Percentage Paid by Insurer	Payment Received	Percentage Payer Mix	Weighted Payment
Hospital A	Medicare*	$5,000	Cost	$2,500	50%	$1,250.00
	Commercial #1	$5,000	Capitated	$3,800	10%	$380.00
	Commercial #2	$5,000	65% charges	$3,250	25%	$812.50
	Commercial #3	$5,000	80% charges	$4,000	15%	$600.00
					Total Payment	**$3,042.50**
Hospital B	Medicare*	$6,000	Cost	$3,000	50%	$1,500.00
	Commercial #1	$6,000	Capitated	$3,800	10%	$380.00
	Commercial #2	$6,000	65% charges	$3,900	25%	$975.00
	Commercial #3	$6,000	80% charges	$4,800	15%	$720.00
					Total Payment	**$3,575.00**

* Medicare uses the cost-to-charge ratio from the department supplying the seed.