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**PEDIATRICS**

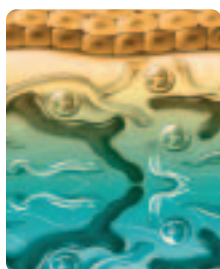
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**EDUCATIONAL REVIEW**



**Mucositis Following Cancer Treatment**

After page 18.

*In NSCLC ...*

## No Benefit To Docetaxel Consolidation

CHICAGO—In 2003, a Phase II study suggesting that docetaxel consolidation improves outcome in stage III non-small-cell lung cancer changed clinical practice.

Now, new data from a Phase III trial refute the findings of the Southwest Oncology Group (SWOG) study 9504. In the new study from the Hoosier Oncology Group, presented at the 2007 annual meeting of the American Society of Clinical Oncology (ASCO; abstract 7512), docetaxel consolidation did not improve survival and was associated with significant toxicity, including hospitalization and premature death. The new data are poised to

see *DOCETAXEL*, page 7 ►

**ADVISORY BOARD EDITORIAL**

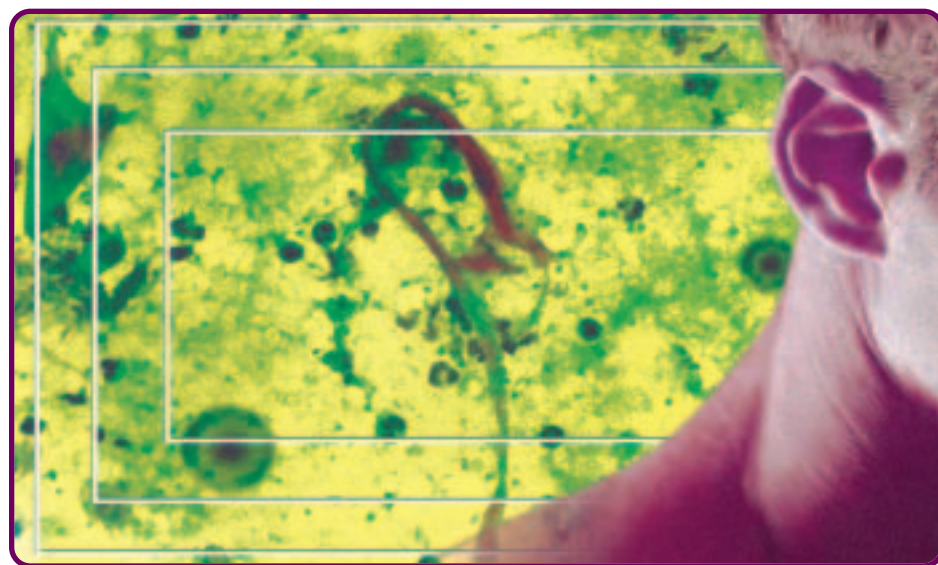
## The Second in a Six-Part Series End-of-Life Care: Ethics of Futility

Despite advances in cancer care, approximately 30% of patients die within six months of diagnosis and half eventually die from the disease (*J Clin Oncol* 2004;22:3438-3440, PMID: 15277538). These harsh realities, plus the toxicities of treatment and the frequently protracted nature of the deaths, make demands for futile treatment particularly distressing in oncology.

When patients with end-stage cancer who are unable to communicate are admitted to an intensive care unit

see *FUTILITY*, page 22 ►

## Cetuximab Prolongs Overall Survival in Head and Neck Ca



CHICAGO—Cetuximab prolongs overall survival by 2.7 months in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.

This was the news reported by investigators from the Phase III EXTREME trial, during the 2007 American Society of Clinical Oncology annual meeting (ASCO; abstract 6091).

“This is the first systemic treatment in 25 years to show a survival benefit over

see *CETUXIMAB*, page 12 ►

**POLICY & MANAGEMENT**

*Regulatory Review ...*

## What To Expect in 2008 and Beyond

This July, the proposed Medicare Physician Fee Schedule was published along with proposals for hospital outpatient and ambulatory surgical centers. It is that time of year when much of the news in medicine again seems to turn to Medicare, Congress, the Office of Inspector General and the Centers for Medicare & Medicaid Services.

Since July, the Office of Inspector General (OIG) has issued two reports about the availability of Part B Drug Acquisition for physician practices and the

cost to Medicare of paying average sales price plus (ASP+) versus average manufacturer price plus (AMP+). Congress passed bills related to payments to providers before the August recess. These reports may give us insight into the directions that reimbursement for medical services could take in 2008 and in the upcoming years.

In this recent session, the House passed a bill that would provide increases to the Medicare Physician Fee Schedule (MPFS) for the next two years and delay a

see *2008*, page 24 ►



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## Regulatory

## 2008

*continued from page 1 ▼*

scheduled decrease until 2010. Originally the House bill offered a permanent fix; however, the representatives could not find the money to fund this legislation. Representative Fortney Stark (D-Calif.) has indicated that he is interested in finding a permanent resolution to the annual reimbursement problem which creates a threat of non-participation by physicians due to proposed decreases in payment. However, neither the Senate nor the Executive Branch wants to make a

commitment to additional funds.

The U.S. Senate placed nothing in its legislation for healthcare that addresses the impending physician payment decrease. The president has threatened to veto any legislation that includes payment increases and increased federal spending. Thus, Congress will likely begin work to resolve the differences between the House and Senate bills for healthcare spending in September. Providers should watch carefully to see in which direction Congress goes. It is unlikely that there will be any interest in addressing this issue in 2008 because of the presidential election.

**Cost Containment Looms Large**

On the regulatory front, there is a continued effort to contain costs. As much as one would like to blame the regulators, it is important to remember that they are working within Congressional requirements. It is their responsibility to create programs which meet those mandates. They do not have the ability to spend outside of those limits!

**Three Key Areas To Monitor**

Several areas are important for you to continually monitor for potential changes that could impact your practices in 2008 and beyond:

1. Drug payment
2. Procedure bundling; and
3. Imaging restrictions and business arrangements.

**Drug Payment**

Oncology reimbursement for drugs at ASP + 6% continues to be evaluated and attacked.

The OIG has issued two reports recently that address the adequacy of payment for cancer drugs. In the first study, the OIG evaluated the ability of 12 oncology physician practices to track Medicare reimbursement by drug Healthcare Common Procedure Coding System (HCPCS) and evaluated providers' ability to purchase drugs at costs comparable to payment rates.

The practices were selected to represent a variety of practice sizes in a variety of geographic locations. The study concluded that although relatively few if any practices could track drug payment rates by HCPCS, there was no significant problem with their ability to purchase drugs at less than Medicare's payment rate. For those practices with problems, Centers for Medicare & Medicaid Services (CMS) pointed out that the competitive acquisition program (CAP) would enable the practices to be covered.

In the second report, the OIG noted that it found 39 drugs with ASP rates exceeding the AMP rate by more than 5%. The Medicare Modernization Act (MMA) mandates that payment be reduced for physicians to ASP + 6% and that the ASP not exceed the AMP by more than 5%. The OIG indicated that Medicare could have saved \$13 million in the first quarter of 2007 by reducing payment for these drugs to 103% ASP, which CMS is allowed to do. CMS asked the OIG to work with them to better understand the source of fluctuations between ASP and AMP rates and to minimize the time lag between OIG's analysis and the implementation of quarterly price changes.

The Centers for Medicare & Medicaid Services intends to use these improved studies to exercise its right to disregard the required ASP pricing methodology. There were six oncology-specific drugs included in the 39 drugs reported, with three identified in a previous study:

- J8560 oral etoposide
- J9000 doxorubicin in HCl
- J9065 cladribine
- J9200 floxuridine
- J9214 interferon alfa-2b; and
- J9360 vinblastine sulfate.

CMS has proposed that drug payment be reduced for hospital outpatient programs to ASP + 5%. This is the second time that CMS has made this recommendation as part of its proposed rule changes for hospital OPPIs (outpatient prospective payment system) and is clearly an indication that CMS believes that drug purchases can be made for less

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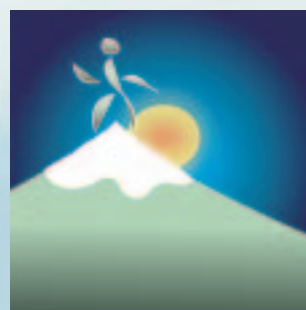
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than ASP + 6% including overhead costs for drug preparation. It is important for practices to recognize that the ongoing pressure to reduce payment for cancer drugs will continue indefinitely or until a cost-based methodology is effectively implemented.

Beyond reduced drug payments, there are messages that drug administration payments are holding steady or being decreased by small amounts. The averages projected include a 1% decrease on practice payments and a 2.5% increase on hospital outpatient administration payments.

### Procedure Bundling

There are many proposals by CMS to bundle services for hospital outpatient centers and ambulatory surgical centers (ASCs). CMS recognizes that newer, more complex procedures typically have a higher mark-up as compared with less complex procedures and thus result in greater profitability for hospitals. A MedPAC study indicated that costs continue to rise significantly. Between 2005 and 2006, there were an increased number of services provided per year and per individual beneficiary without significant benefits or quality gains.

Bundling hospital outpatient services is intended to result in payments that encourage physicians to choose cost-effective and clinically advanced methods. Imaging is a focus for these bundling payment practices. For example, in 2007, there are two technical codes for LDR prostate seed brachytherapy (55875 and 77778). In 2008, CMS is proposing to bundle the services into a single code. Similar bundling practices are taking place in fluoroscopic, nuclear and radio-pharmaceutical enhanced procedures, among others.

Hospital outpatient payment changes provide insight into what is on the horizon for physician providers. It is important for physicians with radiation oncology and diagnostic imaging services to understand how these services are being evaluated and to plan accordingly for change. The same theory and methodology is likely to be applied to the MPFS.

### Imaging Restrictions and Business Arrangements

Due to the high and rising costs of imaging services, imaging will continue to be targeted by CMS. Business relationships are certain to be impacted and it is likely imaging requirements will spread to other designated health services. Discussion of changes being considered appears under the *Self-Referral Provisions Relating to Diagnostic Tests* in the proposed rule.

Significant Department of Health Services changes in how business relationships are structured are not beyond the realm of possibility in 2008. There is a



hint that new requirements are in the works that will effectively alter what are now considered to be acceptable

business relationships between providers. A joint venture agreement that is acceptable today may be further scrutinized in the future. It is critical to keep abreast of changes being discussed related to business relationships and to carefully plan for their impact on your practice. It may be necessary to modify your relationships to meet imposed requirements.

### The Future Is Not Crystal Clear

One thing is for certain: Expect change! It is likely that quality initiatives and value-based purchasing will be part of the future in evaluating services

and setting future payments. Currently, participation in the physician practice area is voluntary with no loss to those who elect to opt out, whereas hospital outpatient settings must elect to opt in during 2008 or lose 2% of payments in 2009. Stay tuned as things heat up. Fall is a time of change and letting go!

—Mary Lou Bowers MBA, and  
Rhonda M. Gold, RN, MSN

Ms. Bowers and Ms. Gold represent The Pritchard Group and are members of the advisory board for Clinical Oncology News.



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