Oncology Issues March/April 2003

ISSUES

2003 Spending Bills Finalized

fter intense negotiations, Congress and the Administration finished and signed into law the 2003 funding bills. Included in this package were a fix to the physician fee schedule and the funding levels for cancer research.

The good news is that the new law prevented the Centers for Medicare and **Medicaid Services** (CMS) from implementing a 4.4 percent cut in physician fee schedule payments on March 1. This planned cut would have followed a similar 5.4 percent reduction in 2002. Both cuts were calculated based on inaccurate CMS estimates of GDP growth and fee-for-service (FFS) enrollment for 1998 and 1999. Since this calculation is cumulative, correc-

tions required by this new law will in fact result in an *increase* in the physician update. On average, a 1.6 percent increase was implemented March 1.

Unfortunately, this increase and other increases in spending resulted in less money for funding for cancer research than initially proposed by President Bush.

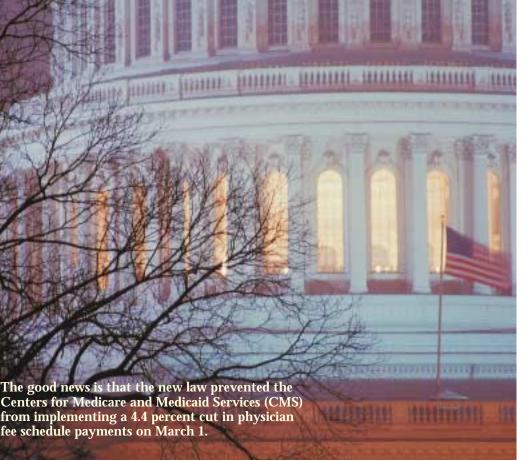
The final package fell just short of achieving the goal of doubling the budget of the National Institutes of Health (NIH) over five years. Supported by Congress, President Clinton, and President Bush, this doubling effort over the last four years has, thus far, resulted in significant yearly increases. In 2003 NIH will see an increase of \$3.8 billion over 2002 funding levels. This increase is about \$10 million short of reaching the doubling goal. Also the budget for the Centers for Disease Control and Prevention (CDC) will be \$107 million below 2002 levels.

Preliminary work has begun on funding levels for 2004. ACCC continues to monitor these issues and has joined others in writing members of Congress to reiterate the importance of protecting cancer research funding.

2003 Payment Rates for Cancer Drugs

Jeffery E. Shogan, M.D., deputy director for clinical business affairs at the University of Pittsburgh Cancer Institute, testified on behalf of ACCC at the January 2003 APC Advisory Panel. Shogan asked the Panel for assistance in convincing CMS that the problems with hospital outpatient reimbursement are real and deserving of the agency's immediate attention.

The 2003 payment rates for can-



cer drugs and chemotherapy administration have serious implications for patients battling cancer. Shogan made it clear to the Panel that outpatient cancer centers simply cannot absorb nearly \$300 million in cuts without substantial ramifications for patient care. He also highlighted the impact of the CMS proposal:

Separate payments for 47 commonly billed cancer and supportive care drugs have been eliminated.
Payment rates for 44 of the 49 cancer drugs that continue to be paid separately have been decreased an average of 33.1 percent.

 Total payments for cancer drugs and biologicals decreased by \$286 million, a 38 percent reduction from 2001 rates.

While ACCC applauded CMS for working to include more multiple procedure claims in the data, it continues to be concerned that most chemotherapy claims have been excluded from the calculation of each APC's median cost. Shogan asked the Panel to support ACCC's request for a separate analysis of the chemotherapy claims to determine whether there is a reasonable way to incorporate more of the data in the calculation of the APC weights for 2004. ACCC recommends including in the universe of "single claims" those charges that are associated with a unique single date of service, even if charges for services on other dates of service are on the same unique claim.

Many cancer centers have already sought advice from ACCC on whether to divert patients to physicians' offices or other settings of

care. "It is important for CMS to understand, however, that such a shift in settings is not a benign thing," said Shogan. He was referring to the fact that outpatient centers already see Medicaid and uninsured patients, not likely to be seen in other settings. In addition, where radiopharmaceutical elements are involved in a cancer treatment regime, sometimes the safest site of care is a hospital. Hospitals are also often the early adopters of cancer therapies, noted Shogan.

He advised that providers should select the best therapy available for an individual patient and administer it in the most clinically appropriate setting. Instead, he pointed out, the current payments threaten patient access to the most appropriate care in hospital outpatient departments—a setting that is a crucial part of our nation's cancer care infrastructure.

CMS Takes a Look at Hospital Inpatient Outlier Payments

n Dec. 3, 2002, CMS released a Program Memorandum (PM) announcing greater scrutiny of outlier payments to hospitals. Outlier payments are made to hospitals when a procedure or treatment exceeds the average expected costs assigned to it by CMS. The announcement came on the heels of allegations that 24 Tenet Healthcare Corp. facilities had higher than average outlier payments due to aggressive pricing strategies.

The PM directed fiscal intermediaries to review their hospitals' outlier billing practices by Dec. 10, 2002. Hospitals with outlier payments exceeding 10 percent of their total operating payments were flagged for additional review. Hospitals that received outlier payments for 80 percent or more of their inpatient operating reimbursements for patients discharged in October or November 2002, with an increase in average charges per case of over 20 percent in one year, will also be reviewed.

CMS Administrator Thomas Scully said that the agency plans to carefully review all of the billing practices of hospitals that have unusually high outlier payments to make sure treatment costs are not being inflated to garner additional outlier reimbursement. The agency will also revise its inpatient outlier policy to eliminate loopholes that allow for possible abuse.

Incidence of Cancer by State

n November 2002, the Department of Health and Human Services (HHS) released its report, U.S. Cancer Statistics: 1999 Incidence, which has a new section on cancer incidence rates by state. The report, which was produced by HHS, CDC, and NCI, lists cancer incidence in 78 percent of the U.S. population. Despite improvements in the collection of data from cancer registries, 13 states were not represented in the document, including a number of states in the southern part of the country.

The most common cancer diagnosed in males was prostate cancer, followed by lung and colorectal



cancers. For women, the most common malignancy continues to be breast cancer, again followed by lung and colorectal cancers. The incidence of prostate cancer in African-American men is around 50 percent higher than the incidence of this malignancy for men in general.

According to Brenda Edwards, M.D., of the NCI, further research is needed to determine why higher incidences of cancer exist in some geographic regions. Edwards thought this finding might be a result of better screening methods and early detection instead of a reflection on the health of an area's population, particularly in the case

ISSUES

of prostate and breast cancer. CDC officials and the NCI both said it was too early to determine geographic trends from the data.

To read the report, go to http://www.cdc.gov/cancer/npcr/ uscs/facts.htm.

National vs. Local Medicare Coverage Determinations

hether Medicare coverage decisions should be made at the national level or continue to be made by local carriers after more consistent guidelines are issued from the CMS continues to be a hot topic of debate in the health care industry.

CMS Administrator Thomas Scully told the HHS Secretary's Advisory Committee on Regulatory Reform last year that, while he favored more national consistency, he did not support more national coverage decisions and thought that no national coverage decision process would be faster than the local carriers.

Working with a local carrier can be challenging. After his practice received a number of denials for offlabel drug claims he felt were unjustified, Marcus Neubauer, M.D., the Oncology Carrier Advisory Committee (CAC) representative in Kansas, looked into the matter.

The written response from his Carrier Medical Director (CMD) stated that an FDA-approved drug must first be used to treat a patient for a specific condition. If it fails, an off-label drug can be tried. Because Neubauer had not documented his practice's initial use of an FDAapproved drug, the claims were denied.

The local medical carrier instituted the restricted policy after other providers in the region had CMS Administrator Thomas Scully told the HHS Secretary's Advisory Committee on Regulatory Reform last year that, while he favored more national consistency, he did not support more national coverage decisions and thought that no national coverage decision process would be faster than the local carriers.



made "questionable" uses of certain off-label drugs.

Neubauer contacted CMS and was told that if improper actions were taking place the agency would step in, otherwise the local carrier was allowed to make its own coverage determinations. Believing that that the CMD ultimately wanted local Medicare beneficiaries to have access to the best care available, Neubauer scheduled a face-to-face conversation with the CMD, at which he explained that using an off-label drug for certain indications prior to FDA approval was in the best interest of the patient.

The CMD was receptive to Neubauer's explanations, dialogue was initiated, and eventually a fair compromise was reached. Medicare now pays Neubauer and other providers in the region for most off-label drugs. Local coverage determinations have been favorable for drugs such as Rituxan[®], Camptosar[®], Gemzar[®], Sandostatin LAR[®], and Herceptin[®].

Some states, however, are notoriously difficult about Medicare coverage determinations. In some states, CMDs are hard to contact, which makes negotiating coverage decisions even more troublesome. Other CMDs are less flexible and make determinations strictly by the "letter of the law documentation." CAC representatives maintain that a great number of subjective decisions are made about coverage determinations on the state level. Some medical directors have more liberal interpretations of what constitutes good data, and others are noted for being more restrictive.

Local coverage determinations can cause problems for beneficiaries who start a treatment program in one area of the country, move to a different state, and find out that their drug regimen is not paid for by the new local carriers. This situation can be particularly troublesome for elderly people who live in the North in the warm months and move to the South during the colder months of the year.

Another part of the equation is that some regional carriers are consolidating services to cut administrative costs. Virginia, for example, used to have only one carrier that was based in Richmond. Now Trailblazer Health Enterprises is based in Texas, but serves as a carrier for subscribers in Delaware, the District of Columbia, Maryland, and Virginia. In fact, Virginia no longer has a full-time Medicare CMD, but is splitting one with Maryland. The primary motivation behind this move seems to be cost cutting. Since this is a relatively new situation, it is too soon to say what effect this change will have on Virginia's providers.

Several ways to deal with objections to local and national coverage determinations exist. The Benefits Improvement Protection Act of 2002 established a formal appeals process for beneficiaries who want to challenge local medical review policy. The process goes through the carrier involved; but if no solution is reached, the next step is a hearing in the courts.

In August 2002, CMS issued proposed regulations that would allow national coverage decisions to be appealed. The HHS Departmental Appeals Board will review these cases, but the board's decision can be taken to the federal courts if the complainant so desires.

New Model of Palliative Care Integrated Into Five-Year National Clinical Study

A new theoretical model of palliative care, called Simultaneous Care, has been developed and will be tested as part of a five-year national study funded by NCI. The outcomes examined will be quality of life, distress, satisfaction with care, and health care utilization/costs.

The model program will be integrated into phase I and II clinical trials at the University of California-Davis in Sacramento, Calif., the Johns Hopkins Oncology Center in Baltimore, Md., and the City of Hope Medical Center in Duarte, Calif.

The program was approved by the Institutional Review Boards of the various facilities in early 2003, and a study cohort of 500 patients and 500 caregivers will be accrued over the next five years. Simultaneous Care therapy will begin on the day the patient first comes to the center for treatment.

According to James R. Zabora, Sc.D., dean of the National Catholic School of Social Service at the Catholic University of America, Simultaneous Care was developed because experts claim that palliative care has not worked in cancer centers. Zabora spoke at the Fourth Annual Conference, "Vexing Challenges in Palliative Care," co-sponsored by The Hospices of the National Capital Region and Georgetown University Hospital on Nov. 15, 2002. Other members of the national study present at the conference were Matthew Loscalzo, M.S.W., associate dean and associate professor of internal medicine at the Eastern Virginia Medical School, and Sage Sipsma, M.S.W., clinical and research social worker at the Sidney Kimmel Cancer Center at Johns Hopkins.

"Patients continue to suffer needlessly because palliative care is not well defined, cannot be measured and evaluated, and cannot demonstrate a benefit to the patient," Zabora said.

"If we can access the [internal and external] resources patients have at their disposal when they are diagnosed with cancer, then we can begin to make reasonable decisions about how to manage their care," Zabora said. "Patients with a higher level of resources will be able to manage this disease more effectively. However, we need to find those patients with lower levels of resources and bring them up to speed."

Zabora also discussed a problemsolving education program, called Social Competence, which has been tested on cancer patients and has proven to be very effective. The program involves 10 consecutive sessions, and Zabora and others in the field believe it should be offered to cancer patients as they begin treatment.

Resources for home caregivers discussed at the conference included The Home Care Guide for Cancer, which was developed by Peter Hauts, Ph.D., a psychologist at Penn State University and published by the American College of Physicians in 1994. ¶

"If we can access the resources patients have at their disposal when they are diagnosed with cancer, then we can begin to make reasonable decisions about how to manage their care."

PHOTOGRAPH/PICTURE QUE ST



Billing Correctly for Radiation Treatment Devices

by Kimberly Partlow, M.S., C.M.D., R.T. (T)

hile this article presents general guidelines for proper device coding, you must also review your local medical review policy. Properly coding your treatment devices is critical because the Centers for Medicare and Medicaid Services uses coding data from past years to evaluate pricing and set future policy changes.

Q What is a treatment device?

A Treatment devices shape radiation beams, immobilize patients, and shield critical structures in the body. Sometimes pre-made devices can be used, but most of the time these aids are custom-designed and fabricated for each patient.

Q How do you determine the level of complexity of the device?

A Simple devices (CPT code 77332) are generally prefabricated and can be used on multiple patients. They include pre-made, straight-edge blocks; prefabricated, multi-use boluses; and asymmetrical collimators or independent jaws. Intermediate devices (CPT code 77333) range from bite blocks, stents, and fabricated single patient-use boluses to multi-port blocks, which include three or more pre-made blocks or a midline spine block. *Complex* devices (CPT code 77334) include custom-made blocks, multi-leaf collimators, wedges, customized compensators and molds, or casts. The patient's radiation oncologist must be directly involved in the selection, design, and placement

of a device at all levels of complexity.

Q What documentation is required to justify the device?

A Medical records must contain information that justifies the need for and reasonableness of the device and verifies that coverage guidelines have been followed. This explanation is usually found in the physician's simulation note. Each billable device should be clearly affiliated with a treatment field or simulation procedure.

Q How frequently are treatment devices billed?

A Devices are billed, with full documentation, at the beginning of a course of treatment, and may also be billed later in the course if additional or new devices are required. Payment is allowed for one set of devices per treatment port.

Q If the patient has opposing treatment fields, and there is a device for each field, how many devices should be billed?

A It depends on the number of films needed to construct the devices. Devices for a pair of opposing ports, for instance left and right lateral or anterior-posterior and posterior-anterior, constructed from a single film are considered to be one device for billing purposes. However, if each device requires a separate film for its construction, then the devices may be billed separately.

igvee If the patient uses multiple

devices for a single treatment field, how should this be billed?

A Only one device can be billed per port. When the patient has a wedge, a compensator, and a custom block on a single field, this combination should be billed as a single device instead of submitting separate charges for each item.

Q If multiple devices with different elements of complexity are used on one port, how are they billed?

A Since only one device may be billed per port, choose the device with the highest complexity level and bill for that. Make sure the device is affiliated with the appropriate treatment port.

Q How many treatment devices are typical per course of radiation therapy?

A typical course of radiation therapy will have two to 12 charges for devices, depending on the complexity of the treatment and the disease site.

When should the treatment device be billed?

A Patient immobilization devices should be billed at the time of the simulation. Treatment-field devices should be billed on the first day of treatment. Billing in this fashion will minimize confusion for auditors by identifying why and for what each device was used.

Kimberly Partlow, M.S., C.M.D., R.T. (T), is a senior associate in the Consulting Division of ELM Services, Inc., in Rockville, Md.