THE ISSUES

Reductions in Medicare Reimbursement for Drugs Could Impact Entire Continuum of Cancer Care

The Centers for Medicare & Medicaid Services (CMS) issued the 2005 Proposed Physician Fee Schedule, which includes estimated payment rates for select chemotherapy drugs used to treat patients in physician offices. Although more current data will be used to set actual 2005 reimbursement rates for drugs, the estimates provide a glimpse into what the future may hold for providers and Medicare beneficiaries.

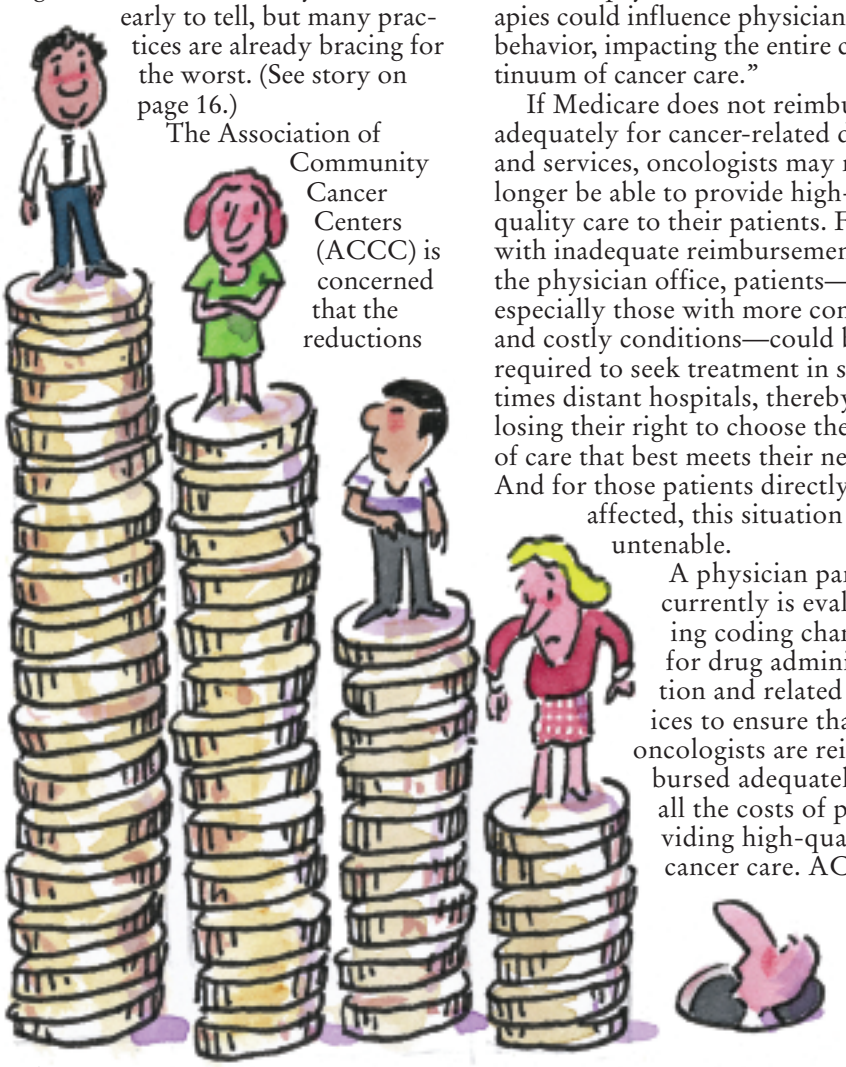
How will the changes impact oncology practices and cancer programs across the country? It's too early to tell, but many practices are already bracing for the worst. (See story on page 16.)

The Association of Community Cancer Centers (ACCC) is concerned that the reductions in Medicare payment rates for drugs could force physicians to alter their treatment protocols and adversely impact the delivery of healthcare provided to cancer patients. This scenario is particularly true if the reductions are implemented without the much-needed increases in payment rates for drug administration and other related services.

"The Medicare cuts for 2005 could threaten the viability of many oncology practices," said Deborah Walter, ACCC's Senior Director of Policy and Government Affairs. "Such significant reductions in Medicare payments for cancer therapies could influence physician behavior, impacting the entire continuum of cancer care."

If Medicare does not reimburse adequately for cancer-related drugs and services, oncologists may no longer be able to provide high-quality care to their patients. Faced with inadequate reimbursement in the physician office, patients—especially those with more complex and costly conditions—could be required to seek treatment in sometimes distant hospitals, thereby losing their right to choose the site of care that best meets their needs. And for those patients directly affected, this situation is untenable.

A physician panel currently is evaluating coding changes for drug administration and related services to ensure that oncologists are reimbursed adequately for all the costs of providing high-quality cancer care. ACCC is hopeful that CMS will carefully consider these needed reforms in the final rule. ACCC will continue to work with Congress, CMS, and other stakeholders in the cancer community to ensure that access to care for the millions of patients who rely on the government for their health insurance remains unaffected.



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HHS: New Rules for Savings on Drugs for Medicare Beneficiaries

The U.S. Department of Health and Human Services (HHS) has proposed new rules designed to deliver better benefits and savings on drugs for Medicare beneficiaries. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Title I and Title II regulations were published in the *Federal Register* on Aug. 3, 2004. The comment period lasts 60 days, closing on Oct. 4, 2004. Final rules are expected to be issued early in 2005. Enrollment for the new prescription drug plans will begin in the fall of 2005 for benefits starting on Jan. 1, 2006.

When the regulations are implemented, Medicare beneficiaries who would like to receive the prescription drug benefit can choose to enroll either in a Medicare health plan or prescription drug plan with a monthly premium of around $35. The drug coverage will be available to enrollees who choose the traditional, fee-for-service Medicare plan as well as any Medicare Advantage program.

In brief, here is how HHS outlined the Medicare benefits.

- About 6.4 million "dual-eligible" low-income beneficiaries will have no premium or deductible and nominal co-pays of as little as $1 or $3

Table 1: Comparison of Final 2004 and Proposed 2005 Physician Office Payment Rates

Drug Name	HCPCS Units	Average Dose	Final 2004 Rate+	Proposed 2005 Rate^	Change 2004-2005 Dollars	Change 2004-2005 Percent
Dolasetron mesylate	10 mg	100 mg	$13.85	N/A	N/A	N/A
Darbepoetin alfa	5 mcg	153 mcg	$21.20	$18.10	-$3.10	-14.6%
Irinotecan injection	20 mg	225 mg (125mg/m^2)	$130.24	$123.86	-$6.38	-4.9%
Doxorubicin HCl liposome injection	10 mg		$352.06	N/A	N/A	N/A
Amifostine	500 mg	1,638 mg (910mg/m^2)	$405.29	N/A	N/A	N/A
Gemcitabine HCl	200 mg		$111.33	$107.46	-$3.87	-3.5%
Trastuzumab	10 mg	273 mg or 28 (4mg per kg)	$52.01	$50.84	-$1.17	-2.3%
Granisetron HCl injection	100 mcg	682 (10 mcg/kg)	$15.62	N/A	N/A	N/A
Pegfilgrastim	6 mg	6 mg	$2,507.50	$2,260.77	-$246.73	-9.8%
Filgrastim injection	300 mcg	300 mcg (132 lb)	$158.50	N/A	N/A	N/A
Non-ESRD epoetin alfa injection	1,000 units	40,000 units	$11.62	$10.37	-$1.25	-10.8%
Rituximab	100 mg	675 mg (375 mg/m^2)	$427.28	$438.38	$11.10	2.6%
Paclitaxel	30 mg	243 mg (135 mg/m^2)	$138.28	$25.84	-$112.44	-81.3%
Docetaxel	20 mg	100 mg	$301.40	$287.59	-$13.81	-4.6%
Topotecan	4 mg	1.5 mg per kilo squared	$706.17	$731.46	$25.29	3.6%
Ondasetron	8 mg	32 mg	$27.22	N/A	N/A	N/A

Source: ELM Services, Inc.

+Data taken from CMS Program Transmittal 75, Pub. 100-04, Medicare Claims Processing, Change Request 3105 (Jan. 30, 2004), as modified by Program Transmittal 119, Pub. 100-04, Medicare Claims Processing, Change Request 3161 (March 15, 2002) and Program Transmittal 90, Pub. 100-20, One-time Notification, Change Request 3312 (June 25, 2004).

^Proposed 2005 payment rate data taken from Proposed Physician Fee Schedule for 2005, Table 28, available at *www.cms.hhs.gov/regulations/pfs/2005/1429p.asp/*

N/A means that data are not available.

per prescription. For these beneficiaries, the Medicare benefit will pay, on average, 97 percent of their drug costs.

- About 3 million Medicare beneficiaries who are not full benefit dual eligibles, but whose incomes are less than 135 percent of the federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) with limited assets will also pay only a few dollars per prescription. Medicare will cover 95 percent of their drug costs on average.
- For about 1.5 million beneficiaries with incomes less than 150 percent of the federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006, the Medicare benefit will provide 15 percent co-pays with a sliding-scale premium, covering on average 85 percent of their drug costs.

Update on Demonstration Project, Including Oral Anti-Cancer Drugs

Of the $500 million allocated by Congress for the widely anticipated demonstration project mandated under the MMA, the Centers for Medicare & Medicaid Services (CMS) has earmarked 40 percent, or $200 million, for oral anti-cancer drugs with the remaining $300 million distributed between other eligible disease categories.

The demonstration project was established to cover certain drugs and biologicals for 50,000 eligible Medicare beneficiaries with specific medical conditions. These beneficiaries will be selected through a "lottery" process, alternating between cancer patients and those with other serious diseases. Medicare will pay for certain drugs and biologicals that are: 1) used to treat cancer and other diseases; 2) taken by the patient at home; and 3) currently covered by Medicare Part B when given by injection or infusion in a doctor's office.

Although CMS had specifically stated that tamoxifen would not be covered (as it is not currently covered under Part B "incident to" a physician service), the agency has since reconsidered and recently decided to include this drug in the demonstration project. Conversely, Temodar® for (anaplastic astrocytoma) was inadvertently included under the demonstration project; however, this drug is already covered under Part B, and consequently it will not be part of the demonstration project.

Medicare *will* cover 25 drug products of which 12 are oral anti-cancer medications. In addition to the

already-mentioned tamoxifen, these include:

- Targretin® (Ligand) for cutaneous T-cell lymphoma
- Gleevec™ (Novartis) for chronic myelogenous leukemia and gastrointestinal stromal tumors
- Hexalen® (MGI Pharma, Inc.) for ovarian cancer
- Iressa® (AstraZeneca Pharmaceuticals) for lung cancer (non-small cell)
- Femara® (Novartis), Aromasin® (Pfizer Oncology), Arimidex® (AstraZeneca Pharmaceuticals), Nolvadex® (AstraZeneca Pharmaceuticals), Fareston® (Shire US Inc.) for breast cancer stages II to IV only
- Thalomid® (Celgene) for multiple myeloma. Please note that this drug has not been explicitly approved by the FDA for off-label use in this treatment.

Patients can switch from one drug to another during the demonstration project provided that it is another drug identified for the same indication by the demonstration project guidelines. Participants with more than one covered indication can apply for coverage for each condition provided that their physician submits one form per each covered indication.

The demonstration will end on December 31, 2005. To be included in the lottery, Medicare beneficiaries who qualify can apply anytime after July 6, 2004, at *www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp*, or call 1.800.MEDICARE. All applications must be submitted to CMS by September 30, 2004.

Individuals that are not selected for the demonstration project or who do not meet eligibility requirements will be notified as their applications are processed. Patients who have been chosen in the lottery will be sent a letter by Trailblazer, the CMS contractor for this project. However in order to access these covered drugs, patients must wait to receive a prescription card from Caremark, the project's pharmacy benefit manager.

Medicare will cover 25 drug products of which 12 are oral anti-cancer medications.

CMS Issues the Proposed Hospital Outpatient Rule for 2005

On August 9, CMS put on display a proposed rule making various changes and setting payment rates under the Hospital Outpatient Department Prospective Payment System (HOPPS) for 2005. Comments will be due on October 8, 2004.

The proposed rule continues the implementation process for various OPPS policies for drugs and biologicals contained in the MMA, which created special payment rules for specified covered outpatient drugs (SCODs) and mandated a number of other changes for drug and biological payments under the HOPPS.

A preliminary analysis of the impact of the proposed rule conducted by ACCC shows that hospital outpatient medical oncology departments could expect to see a decrease in revenue of approximately 3 to 4 percent in 2005 for services provided to Medicare beneficiaries.

In brief, single source SCODs will have a payment floor of 83 percent of AWP in 2005 rather than the 88 percent of AWP payment floor in effect this year. Thus, payment rates for most of the single-source drugs are proposed to decrease approximately 5 percent, as mandated by MMA. CMS may use its authority to apply an equitable adjustment for one drug and invites comments.

Check ACCC's web site for more information and analysis.

Collaborative Effort Seeks to Measure Quality of Cancer Care

On July 9, 2004, the Steering Committee for the Cancer Quality of Care Measures Project convened and selected three priority areas: breast cancer diagnosis and treatment; colorectal cancer diagnosis and treatment; and symptom management and end-of-life care. Each of these areas will be analyzed through an evidence-based process of evaluation.

The Cancer Quality of Care Measures Project is a public-private sector initiative launched in 2002. In this project, the National Cancer Institute (NCI) is collaborating with other federal agencies, a number of private-sector organizations, and the non-profit National Quality Forum (NQF) to identify evidence-based quality measures for diagnosing and treating certain major types of cancer, as well as "cross-cutting" measures that apply to multiple cancer sites, for example, measures for screening or palliative care.

Other federal partners in this project include the Agency for Healthcare Research and Quality (AHRQ), CMS, and the Centers for Disease Control and Prevention (CDC).

The project successfully launched and completed Phase I in 2002, and in May 2004 began a 29-month Phase II. The NCI has made improving the quality of cancer care a major priority. An important part of this priority is identifying, developing, applying, and evaluating quality of care measures. Achieving this goal requires that a number of groups work together closely over the project's more than two-year timeline, which calls for publication of final reports and recommendations in fall 2006. To

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follow the project's progress, go to *http://outcomes.cancer.gov/translation/canqual.*

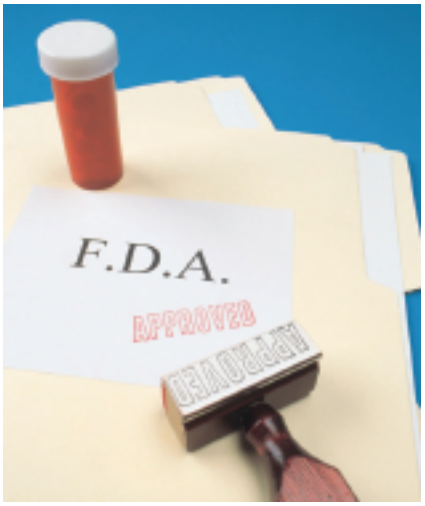
CMS, NCI, FDA to Collaborate

CMS announced plans to work together with the NCI and the Food and Drug Administration (FDA) to bring new treatments to patients with cancer as quickly as possible. Collaborations being developed will also seek to increase the body of information used to guide treatment decisions about how to most effectively use new drugs and technologies in cancer care.

"By working together, building on our existing system, and focusing on the need to develop better knowledge at a lower cost," said CMS Administrator Mark McClellan, MD, PhD "…we can deliver on the promise of higher value—much more targeted cancer therapy—as quickly as possible." He was speaking at a forum sponsored by the Coalition of National Cooperative Groups (CNCG) and *Newsweek* magazine in Washington, D.C., in June 2004.

McClellan talked about the benefits of a CMS collaboration with the FDA, where he had until recently served as commissioner. Over the last few years, the FDA has speeded up the drug approval process by relying on outside practicing oncology expertise and through collaborations with NCI, according to McClellan. Through this collaboration, new approaches were developed and implemented to bring down the high cost and lengthy time for developing new cancer agents and assuring that they are safe and effective, he said.

McClellan has long shown a commitment to joint NCI/FDA initiatives. NCI's collaborations with the FDA are examples of a new standard of interaction between agencies within the Department of Health and Human Services, particularly regarding the use of information technologies and fostering innovative ideas that are promoting translational research. NCI and FDA are working with the research community to develop a system for electronically submitting investigational new drug applications to the FDA via the cancer Biomedical Informatics Grid (caBIG) project. NCI and FDA are also launching new cancer fellowship training programs.



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This collaborative effort, according to the Jan. 27, 2004, *NCI Cancer Bulletin*, will "ultimately take all cancer research to a new plateau by strengthening the research and regulatory infrastructure and ensuring that promising molecularly targeted drugs and other novel agents in the pipeline make their way from the bench to the bedside as quickly as possible."

McClellan seeks to take some of these collaborative activities and ideas to CMS. "I think some of those same kinds of ideas apply to CMS as well," he said at the June CNCG meeting.

Under a new collaborative agreement between the NCI and CMS, the two entities will focus on:

- Defining a joint process for consultations between CMS and NCI to evaluate new diagnostic and therapeutic cancer treatments for the purpose of coverage and payment decisions
- Identifying high priority clinical questions about the optimal use of new cancer technologies
- Developing a process for conducting and supporting post-approval studies to make sure questions are answered
- Developing better methods for collecting clinical evidence, cheaper methods for conducting these trials, and making this information widely available to patients and clinicians and other cancer experts (for instance, exploring inclusion of CMS claims data on the NCI's Cancer Biomedical Informatics Grid)
- Identifying other areas for research to improve the quality of care for patients with cancer and address some additional concerns such as cancer health disparity issues, variation in treatment patterns, and ways to improve palliative and end-of-life care.

Thomson Healthcare Assumes Responsibility for USP Off-label Content

As of May 1, 2004, the United States Pharmacopeia's *USP DI Volume I: Drug Information for the Health Care Professional* and *USP DI Volume II: Advice for the Patient* became the responsibility of Thomson Healthcare, a division of the Thomson Corporation, which specializes in healthcare information and publishing. Thomson Healthcare may edit, create content, and publish these texts under the *USP DI* name until 2007. Thomson Healthcare may also institute a name change at any time.

Thomson Healthcare will be responsible for off-label content, and its staff will develop or revise monographs for drugs selected to be included in the *USP DI*. The drugs are selected based on labeling approved by the FDA or by the Health Products and Food Branch in Canada.

ACCC will continue to post monthly updates of the "Oncology" *USP DI* on its web site at *www.acccancer.org/oncdrugs*. In 1998 Micromedex, a division of the Thomson Publishing Corporation, purchased the USP DI database from USP and licensed the USP DI trademark.

ACCC will also continue to publish its *Compendia-Based Drug Bulletin*, which has become the standard reference for oncology reimbursement among both providers and insurers.

Radiation Oncology Coding and Billing

by Sonya Wade

Author's Note: In answering these questions, I have referenced Medicare's Local Coverage Determination (LCD) source, formerly the Local Medical Review Policy. While the LCD in radiation oncology as discussed in this article is widely accepted around the country, some locations may vary.

Q *Suppose a patient comes in on a given day and has a breast simulation done with a CT. Our facility has been charging one complex simulation on that day and then one 3D simulation charge on the day that treatment is planned in dosimetry. Is this correct or should the 3D simulation charge negate the complex simulation charge (even though the actual simulation and the planning are done on different days)?*

A You may charge for the complex simulation performed on the day the patient had a breast simulation done with CT, and then charge one 3D simulation charge for the day the patient is planned for treatment.

Q *For prostate simulations, our patients come into our facility on a given day and have orthogonal films and a CT done. We charge a simple simulation for this procedure. Then on another day, dosimetry does the plan and charges a 3D simulation charge. Most of the time it is necessary for the patient to go back to simulation before starting treatment, because the plan calls for the patient to be shifted from the original marks. Do we charge a complex simulation for this second simulation—even though the 3D was already charged—as long as they are on separate days?*

A For prostate patients, you cannot charge for a second simulation. Portal changes based on unsatisfactory initial simulations cannot be reported as additional simulations. During treatment, however, additional simulations may be necessary to account for changes in port size, boost dose, or tumor volume. You may charge for these additional simulations that are required during treatment.

Q *Our facility has its own CT equipment and is now providing IMRT services. When can we bill CPT codes 76370 (CT guidance for placement of radiation therapy fields) and 76375 (coronal, sagittal, multiplanar, oblique 3-dimensional and/or holographic reconstruction of computerized tomographic magnetic resonance imaging, or other tomographic modality)? I am new to radiation oncology billing and am not sure when these codes are appropriate to bill or when they are bundled with other codes for Medicare. Also, what documentation must be on file for these procedures?*

A Indications of coverage for IMRT are when CPT code 77301 (IMRT Planning) is submitted. When you submit 77301, CPT code 76370 and CPT code 76375 are bundled into the 77301 code and cannot be billed separately.

When you bill for IMRT treatment, the following documentation is required:

- The prescription that defines the goals and requirements of the treatment plan, including specific dose constraints for the targets and nearby critical structures
- A statement by the treating physician documenting the special need for performing IMRT on the patient rather than performing conventional or 3D treatment planning delivery
- A signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue using either a dynamic multileaf collimator or a segmented multileaf collimator, or inverse planned IMRT solid compensators to achieve IMRT delivery.

The target verification methodology includes the following:

- Documentation of the PTV and the clinical treatment volume (CTV)
- Documentation of immobilization and patient positioning
- Means of dose verification and secondary means for verification
- The monitor units (MUs) generated by the IMRT plan must be independently checked before the patient's first treatment plan
- Documentation of fluence distributions recomputed in a phantom is required
- Documentation that accounts for structures moving in and out of high- and low-dose regions created by respiration. Voluntary breath holding is not accomplished with gating technology

Q *Does our facility have to generate films in order to charge a simple simulation? Can CT images qualify as films?*

A A simulation may be carried out on a dedicated conventional simulator or CT scanner, radiation therapy treatment unit (e.g., linear accelerator), virtual-reality-based 3D simulation system, or other diagnostic X-ray (including CT, MRI, or PET scans), ultrasound, and nuclear medicine equipment that have been modified to localized treatment volumes. The LCD does not specify that the films must be "hard copy," so you should be safe with the electronic images.

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