



A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

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September 6, 2005

**Via Electronically**

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS: 1325-IFC  
Post Office Box 8013  
Baltimore, MD 21244-9013

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs  
and Biologicals Under Part B [CMS-1325-IFC]

To Whom It May Concern:

The Cancer Leadership Council (CLC), including cancer patients, physicians, and researchers, submits these comments in response to the interim final rule with comment period establishing the Competitive Acquisition Program (CAP) for Medicare Part B drugs and biologicals, published in the Federal Register on July 6, 2005. We understand that the process for evaluating and selecting bidders for CAP has been temporarily suspended, but we offer these recommendations for revision of the program before its implementation is resumed.

The CLC is concerned about several provisions of CAP which may adversely affect cancer patients' access to life-saving cancer therapies. These include:

**Patient Coinsurance**

The interim rule would permit CAP vendors to stop providing drugs to patients who have not paid their coinsurance within 45 days. The rule requires vendors to consider alternatives for collection of coinsurance, including establishing a payment plan or referring the patient to a charitable organization. However, the vendor has the right, if these options do not result in payment of coinsurance, to terminate a patient's access to drugs.

In the current system where the oncologist orders and purchases cancer drugs, it has been our experience that oncologists absorb the cost of any coinsurance that cannot be paid by patients. We do not anticipate or expect that patients will have the same experience with CAP vendors, and the result will be disruptions in care if patients cannot pay their coinsurance. This will be an

unacceptable situation, which patients may be able to avoid only if their oncologists decline to enroll in CAP. We urge CMS to amend the program to eliminate the ability of CAP vendors to terminate the provision of drugs to patients who cannot pay their coinsurance.

### **Patient Support Initiatives**

The regulations require vendors to have procedures to resolve complaints and inquiries about drug shipments, but there are no clear standards for systems or procedures that vendors must maintain. Although the establishment of a call center or other patient support center may not result in the easy resolution of conflicts related to payment of patient coinsurance, it may ensure that patients have ready answers to questions about billing, payment schedules, and other matters.

### **Prohibition on Movement of Drugs Between Offices**

The regulations would prohibit physicians from moving drugs ordered through CAP from one office to another, even if the offices are part of the same practice. We understand that these provisions were included at the urging of prospective CAP vendors as a protection against spoilage or breakage, but we recommend that they be eliminated.

Cancer patients benefit from the ability to receive chemotherapy in their physician's office, and those in remote areas have enjoyed the advantages of receiving treatment in satellite offices, a practice that has minimized the distance they must travel to receive care. The prohibition against movement of drugs between offices will either limit the access to care in satellite offices or will force those physicians who maintain satellite offices to forego enrollment in CAP.

We urge a revision of this standard to reflect the needs of cancer patients treated by physicians with satellite offices, including those in rural areas. Oncologists, nurses, and other staffers in oncologists' offices have significant experience in transporting and handling cancer drugs, which suggests that CAP vendors' concerns about breakage and spoilage are unfounded.

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We appreciate the opportunity to offer these comments that reflect the special needs of cancer patients under CAP. We urge revisions in the interim final rule to prevent disruptions of care under CAP.

Sincerely,

**Cancer Leadership Council**

American Cancer Society  
American Psychosocial Oncology Society  
American Society of Clinical Oncology  
Cancer Care, Inc.  
Cancer Research and Prevention Foundation  
Coalition of Cancer Cooperative Groups  
International Myeloma Foundation  
Kidney Cancer Association  
Lance Armstrong Foundation  
The Leukemia & Lymphoma Society  
Lymphoma Research Foundation

Multiple Myeloma Research Foundation  
National Coalition for Cancer Survivorship  
National Prostate Cancer Coalition  
North American Brain Tumor Coalition  
Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
Sarcoma Foundation of America  
The Susan G. Komen Breast Cancer Foundation  
Us TOO International Prostate Cancer  
Education and Support Network  
Y-ME National Breast Cancer Organization