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ACCC MEMBER • ASCO STATE/REGIONAL AFFILIATE • HOLN PARTNER

September 6, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Competitive Acquisition Program (CAP) File code CMS-1325-IFC

Dear Dr. McClellan:

We welcome the opportunity to comment on the rules for the Competitive Acquisition Program (CAP), published as an Interim Final Rule with comment in the July 6, 2005, Federal Register.

The Medical Oncology Association of Southern California (MOASC) is an advocate for, protects, and advances the interests of cancer patients and their treating physicians in providing effective and state of the art cancer care.

Upon review and discussions with major oncology organizations, MOASC supports the position as expressed by ASCO, COA and ACCC.

It is our belief that the CAP program will:

- **Increase administrative burden;**
  Some examples of this increase of administrative burden for a medical practice may be when the medical practice will need to: 1) to keep separate its inventory from the CAP program inventory, 2) need to identify and track which drugs are covered under the CAP program and which drugs will fall out of the CAP program coverage; 3) increase paperwork bureaucracy required for treatment changes to the vendor which will create time delay in receipt of drug by the medical practice and delivery to the patient.

- **Deny or hinder access to medically necessary drugs;**
  For example when a patient is unable to pay the co-pay of the drug to the distributor and therefore the distributor will not deliver the drug to the medical practice, the patient will not be able receive the recommended treatment. If patient experiences an increase in morbidity or early mortality due to the inconsistent administration of the therapy, who are the responsible parties to assign liability? Further, the physician is hindered from providing medicine from an alternative source as such would be Medicare fraud as presented by CAP program rules. CAP program allows for solvency of distributor and is not expected that the distributors will provide "free drug." Currently malpractice insurers would not provide coverage under this clinical scenario.

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It is our belief that the CAP program will: (cont.)

- **Increase burden on cancer patients;** cancer patient and physicians will be at the mercy of the distributor's drug delivery system on routine basis and adequate description of emergency medicine scenarios remains unresolved.

- **Adversely impact rural and small clinics;** all clinics regardless of size and location will be required to create a bureaucratic infrastructure will clinical and financial oversight. The compensation of such expense is anticipated to be for smaller and rural clinics a greater cost than the creation of the system. Rural and small volume oncology clinics will be the hardest hit. The CAP program will indirectly force patients into large urban centers.

- **Restrict physician autonomy;** given the high degree of flux and fluidity of the oncology reimbursement system, practices that make erroneous assumptions about the CAP system and the business model are required to be "lock-in" annually.

The CAP program rules are not comprehensive enough to define what will happen in the above scenarios. Many more clinical and financial examples have been provided by national oncology leadership such as ASCO, COA, and ACCC.

The Medical Oncology Association of Southern California, Inc. (MOASC) suggests holding implementation of the program until a comprehensive advisory panel has reviewed all possible concerns with the relevant stake holders. Such a panel could aid and advise CMS in the successful implementation of the CAP program in the future. MOASC would be willing to participate in such a panel. As constructed, CAP runs the risk of creating undue treatment delays, patient inconvenience, and a system that significantly reduces the quality of cancer care in the United States.

We believe that the fallacies identified in this letter are widely known and enough concern that the CAP vendor bidding process was suspended by CMS in August 2005.

Again, thank you for the opportunity to provide our comments on this important proposal. We continue to look forward to working together to provide the best care to, not only Medicare beneficiaries in California but to patients with cancer in the United States.

Sincerely,

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