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March 6, 2006

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS Draft 2007 Formulary Guidance for
Medicare Part D**

Dear Administrator McClellan:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft 2007 formulary guidance for Medicare Part D plans. ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 65% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies. The new Medicare Part D benefit has the potential to play a crucial role in this country's cancer delivery system by ensuring that more patients have adequate coverage for the therapies they need. ACCC greatly appreciates CMS' efforts in implementing this important new part of the Medicare program.

ACCC appreciates CMS' recognition of the importance of continuing the policy requiring plans to cover all or substantially all therapies in the "Six Classes of Clinical Concern" included in the draft 2007 formulary guidance. It indicates willingness on the part of CMS to extend and improve the safeguards currently in place for the 2006 plan year. ACCC supports this direction in regards to the formulary guidance but also suggests that improvements be made to better enable cancer centers to provide quality care to their patients.

Specifically, ACCC recommends that CMS modify the April 17, 2006 cut off date for determining the range of products included in the Six Classes of Clinical Concern. The standard of care for patients receiving Part D coverage effective January 1, 2007 should not be determined more than 6 months earlier. This is particularly true in the field of oncology, where dramatic changes to the standard of care can occur virtually over night. ACCC's members are concerned that the establishment of a date so far in advance of a coverage year will needlessly leave patients to rely on their ability to use the exceptions process to obtain access to new drugs and biologicals not included on a plan formulary and that were approved by FDA after April 17, 2006. ACCC is particularly concerned about the burden this would place on the already strained resources of cancer centers.

ACCC's members are struggling to navigate the complicated and varied Medicare Part D exceptions process. In order to help patients access medically necessary therapies that are either not on formulary or in a non-preferred formulary tier, our physicians, nurses, social workers, and other oncology team members must determine the details of each plan's exceptions and appeals process. Currently, each of the numerous plans has its own forms and procedures, including the requirements for the clinical information physicians must provide. Even within a single plan these forms and requirements may vary for different drugs. CMS already has recognized the critical nature of ensuring that the full range of cancer therapies is made available to Part D beneficiaries.

ACCC urges CMS to apply this policy to all cancer drugs, not just those on the market prior to April 17, 2006. At the very least, A January 1, 2007 target date for determining the range of drugs included in the Six Classes of Clinical Concern would help limit the significant burden on physicians and other health care providers, as well as cancer patients, imposed by the cumbersome exceptions and appeals processes.

In the draft 2007 formulary guidance, CMS proposes that a plan not be permitted to impose management techniques such as prior authorization or step therapy on patients already stabilized on drugs within these "Six Classes of Clinical Concern" before enrolling in a plan. ACCC supports this proposed policy. ACCC

also is concerned that these management techniques may restrict access for patients *beginning* treatment with antineoplastic drugs and recommends that antineoplastic drugs, similar to HIV/AIDS drugs, be excluded from these management techniques at all times unless a plan can demonstrate extraordinary circumstances. Timely cancer treatment often means the difference between life and death. Any treatment delay for patients who have not been previously stabilized on antineoplastic therapies, such as newly diagnosed cancer patients or patients for whom a prior therapy has not been found to be ineffective, could cause significant negative outcomes to beneficiaries in a short timeframe. For many cancer patients, reliance on these strategies for obtaining access to necessary treatments is stressful and may result in harmful delays in care.

These management techniques also place a significant burden on physicians and other providers tasked with navigating the complicated prior authorization, step therapy, and other utilization management strategies imposed by Part D plans. Our members have been commenting that many approvals and exceptions can take hours of “on-hold” time that usurp cancer center resources that should be devoted to providing appropriate, quality patient care. This comes at a time when the physicians and centers are attempting to become more efficient as a matter of survival in the face of the reimbursement decreases that have been instituted as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Cancer includes a wide range of different diseases, and the treatment needs to be individualized. Utilization management tools such as step therapy often simply do not make sense in the context of cancer. CMS has recognized the importance of access to a wide range of therapies by requiring plans to cover all antineoplastics. We urge CMS to minimize the burden on cancer centers by restricting the ability of plans to impose restrictions on patients newly diagnosed with cancer.

CMS has requested feedback related to current managed care strategies that could be implemented within the context of standards that apply to the Six Classes of Clinical Concern and that would allow plan sponsors the flexibility to manage these drug classes where appropriate. Given the potential for feedback in this area to significantly alter the meaning, application, and value of proposed and existing standards that apply to the Six Classes of Clinical Concern and the patients who benefit from this policy, ACCC strongly urges CMS to exercise extreme caution in considering any such management techniques. As discussed above, such strategies often are not appropriate in the context of cancer care, and ACCC recommends that the protections provided to the Six Classes of Clinical Concern only should be strengthened, not diluted, for the 2007 Medicare Part D plan benefit year and beyond.

ACCC greatly appreciates the opportunity to comment on this critical aspect of the Medicare Part D implementation process. Please contact ACCC's staff person, Deborah Walter, at (301) 984-5067 if you have any questions or if we can be of further assistance. Thank you for your attention to this important matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. Strode Weaver". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

E. Strode Weaver, FACHE, MBA, MHSA
President, Association of Community Cancer
Centers