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Via Electronic Mail and U.S. Mail

April 2, 2008

Maria Ellis
Executive Secretary for MedCAC
Centers for Medicare & Medicaid Services
Office of Clinical Standards & Quality
Coverage and Analysis Group
C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on list of evidentiary priorities

Dear Ms. Ellis:

The American Society of Clinical Oncology (ASCO), the leading organization representing physicians engaged in cancer research and care, appreciates the opportunity to comment on evidentiary priorities developed by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC). We understand this list, which was reviewed by an expert panel of researchers in February of this year, will be the topic of additional discussion at the April 30, 2008, MedCAC meeting.

ASCO shares the Administration's goal of applying research to improve the health of Medicare beneficiaries. At the October 2007 MedCAC meeting, the research priority setting process was described as one that would inform Medicare coverage decisions, influence funding for high-priority research, and enlighten the quality metric process of the Ambulatory Quality Alliance (AQA). The ultimate impact of this process will be substantial, not only for Medicare patients, but also for thousands of cancer patients relying on research that will lead to progress in the treatment of their disease. In this increasingly challenging research environment, we urge careful deliberation in priority setting, in subsequent research endeavors, and in CMS' application of research findings.

ASCO welcomes the transparency that characterized this initial process in setting evidentiary priorities. CMS has signaled that it will rely on these evidentiary priorities and related research efforts to make coverage decisions. Because these decisions will significantly affect Medicare beneficiaries' access to care, we urge the same openness and public scrutiny for these deliberations as well.

Many of the research questions identified as priorities are already the subject of ongoing investigation, including those of medical specialty societies seeking to improve care of the elderly. We strongly recommend that CMS assess ongoing research studies and, where appropriate, collaborate with researchers in these investigations. Like many professional

2008 Annual Meeting
May 30-June 3, 2008
Chicago, Illinois

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medical societies, ASCO has an active program for development of clinical practice guidelines. Based on systematic reviews of scientific evidence, these guidelines can lay a strong foundation for delivery of cost effective, high quality care. Because the federal government already maintains the National Guideline Clearinghouse and organizations that develop guidelines have strategies for dissemination of their guidelines, CMS and MedCAC should evaluate fully existing efforts to disseminate guidelines before embarking on a new initiative for guideline distribution.

We note with interest that the list highlights the need for additional research focusing on toxicities of cancer therapy in the elderly. This is a longstanding and important issue for oncology, as elderly patients may not receive appropriately aggressive care because of fears about their ability to tolerate the side effects of treatment. We recommend oncology clinicians and researchers be involved with CMS in prioritizing and designing these studies.

The list of priorities initially developed by MedCAC in October 2007 was revised significantly at the February 2008 workshop and now has a heavy emphasis on topics of health care policy. Several of these topics relate to Medicare coverage and payment policies and, consequently, will affect access to care. ASCO and other professional societies are currently engaged in analysis of many of these issues and can immediately contribute to the understanding of these topics.

One area of increasing activity across the cancer community is care coordination. For cancer patients, whose treatment crosses multiple specialties and disciplines, this can be particularly challenging. Over the past two years, we have developed template treatment plans and care summaries that are designed to improve coordination and communication of care for providers, patients and families. Developing and evaluating innovative strategies for better transition and follow up in this complex set of diseases is of great interest to ASCO and is a growing element in our portfolio of programs. There are many other opportunities for cooperation in the area of health policy and we look forward to working with CMS on these and other issues.

The revised list includes as a health care policy topic "improving enrollment in clinical trials of Medicare elderly and disabled." We recommend that financial barriers to Medicare beneficiaries' participation in trials continue to be addressed by a predictable and reliable clinical trials coverage policy. Repetitive reconsiderations of the Medicare clinical trial policy have created uncertainty among investigators and beneficiaries about Medicare payment for care provided in clinical trials. Eliminating uncertainty about payment for trials may be especially critical to ensuring enrollment of seniors in trials intended to assess the toxicities of cancer treatment.

The important and ambitious research priority setting enterprise undertaken by CMS and MedCAC will be a success only if there is consistent and constructive dialogue with clinicians and researchers. We look forward to the April 30, 2008, MedCAC meeting and to ongoing deliberations regarding priorities for research to benefit Medicare beneficiaries.

Sincerely,

A handwritten signature in cursive script that reads "Allen S. Lichter".

Allen S. Lichter, MD
Chief Executive Officer