



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

February 27, 2006

Comments Submitted Via E-Mail

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Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Ave., S.W.
Room 314-G – HHH Bldg.
Washington, DC 20201

Dear Dr. McClellan:

The undersigned organizations, members of the Cancer Leadership Council (CLC), represent cancer researchers, providers and patient advocates. We appreciate the opportunity to comment on the current review of the authoritative drug compendia by the Medicare Coverage Advisory Committee (MCAC). For a number of years, the compendia system has served cancer patients and providers well by making Medicare decisions on the all-important coverage of off-label cancer drug usage more predictable and consistent. The focus of MCAC and the Centers for Medicare & Medicaid Services (CMS) should be on ensuring the continued smooth operation of the compendia and, whenever possible, enhancing the timeliness and quality of compendia review.

As noted in the notice for the MCAC review, one of the two remaining compendia, the United States Pharmacopoeia-Drug Information (USP-DI), faces an uncertain future with its new ownership and impending change of name. We urge the Secretary, hopefully with the endorsement of MCAC, to utilize existing statutory authority, reaffirmed recently by Congress through inclusion of a provision in the Deficit Reduction Act of 2005, to substitute the newly named USP-DI entity when the name change occurs.¹ USP-DI has been a valuable participant in compendia review, and recent adjustments have made its process more efficient and reliable. Regardless of its new name, the USP-DI entity should remain a part of the compendia review effort, and the Secretary should act to ensure that result, consistent with the Medicare statute.

¹ Social Security Act § 1873, 42 U.S.C. § 1395jj (2004); Deficit Reduction Act of 2005, Pub.L. No. 109-171, § 6001.

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Other compendia could be included among those assigned responsibility for Medicare coverage advice if they demonstrate competence comparable with that of the existing compendia explicitly recognized by Congress in the 1993 legislation. But such new compendia should be additive to the two historically recognized publications.

The very specific exercise being undertaken by MCAC should provide important guidance to current compendia as well as to those who seek to be added to the exclusive list of publications that can be considered as authoritative drug references. But that exercise should not lose sight of the fact that, for more than a decade, the current compendia system has been successful in regularizing coverage decisions, and it should be maintained for the benefit of Medicare cancer patients who need access to potentially life-extending off-label cancer drugs.

As always, Dr. McClellan, we appreciate your personal engagement on these issues of such importance to people with cancer.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology
& Oncology
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Kidney Cancer Association

The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Us TOO International Prostate Cancer
Education and Support Network
Y-ME National Breast Cancer Organization

cc (via E-mail):

Michelle Atkinson
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Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services