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CLARITY VITAL IN CLINICAL TRIAL POLICY, AAHC PRESIDENT TELLS CMS

CMS Panel Debates Standards and Services for Revised NCD

WASHINGTON, Dec. 14 — AAHC President Steven A. Wartman, MD, PhD, called for harmonization of federal agency regulations governing clinical trials while serving as an expert panelist on the Medicare Evidence Development and Coverage Advisory Committee on Clinical Trial Policy of the Centers for Medicare and Medicaid Services (CMS). Meeting in Baltimore yesterday, the committee reconsidered the national coverage decision (NCD) on clinical trial policy, which describes the circumstances under which Medicare will cover certain items and services provided during the course of a clinical trial.

The NCD, enacted in September 2000 to help ensure that America's senior citizens have access to research studies on diseases that greatly affect this population, has created uncertainty and confusion in the research community regarding what services are eligible for payment.

Dr. Wartman voted to redefine what constitutes a good clinical study not only to ensure that scientific merit, institutional peer review, methodological standards, scientific integrity, and human subject protections are taken into account, but also to be sure that key Phase I trials, particularly in cancer, are not excluded from coverage.

Dr. Wartman cast votes on eight issues under reconsideration, including study objectives, payment criteria, populations to be enrolled in studies, processes to ensure Medicare standards are met, definitions of clinical services, and payment for humanitarian use device (HUD) costs.

Emphasizing a critical need for precise definitions and clear terminology, now lacking in the NCD, Dr. Wartman said the standard of therapeutic intent demands revision. CMS policy requires that a major objective of a clinical trial must be therapeutic intent—that is, the diagnosis or treatment of disease including the observation of benefit of the intervention under study. The vagueness of “major” in the definition, said Dr. Wartman, could result in a large number of cancer trials being ruled ineligible for CMS payment. “CMS should be clear that therapeutic intent can be a primary or secondary objective,” said Dr. Wartman, adding, “It is vital to the

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research community that the language be unambiguous.”

In voting to change CMS’ definition of “routine costs” to “routine clinical services,” Dr. Wartman applauded CMS for recognizing that routine costs referred to patients and services rather than actual costs. “Such a change ensures that determinations on services to be provided to a patient in a clinical trial are based on the patient, the patient’s condition, and the decisions that must be made by the treating physician,” said Dr. Wartman.

“It is gratifying to know that CMS is listening to its many constituents and acting to promote and enhance clinical research in the U.S.,” said Dr. Wartman. “I look forward to continued involvement on behalf of academic health centers throughout the nation.”

The Association of Academic Health Centers, representing almost 100 institutions throughout the United States, is a national, non-profit organization dedicated to advancing the nation’s health and well-being by mobilizing and enhancing the strengths and resources of the academic health center enterprise in health professions education, patient care, and research.

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