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August 16, 2007

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Re: Proposed Decision Memo for Clinical Trial Policy (CAG-00071R2)

Dear Dr. Phurrough:

On behalf of the Association of Academic Health Centers (AAHC), I would like to thank the Centers for Medicare & Medicaid Services (CMS) for providing the opportunity to discuss the proposed clinical research policy (CRP) and hear the perspectives from agency administrators at the August 7, 2007 Special Open Door Forum. In light of those discussions, we would like to emphasize and expand on a number of issues raised in our earlier comment letter, dated August 6, 2007.

The AAHC, a national, non-profit association representing more than 100 academic health centers nationwide, is dedicated to improving the nation's health care system by mobilizing and enhancing the strengths and resources of the academic health center enterprise in health professions education, patient care, and research.

As stated in our earlier letter, the AAHC strongly recommends that the policy implementation date be decided upon based on the date of initial IRB approval rather than the date of patient enrollment. The date of the first enrollment is not the milestone event in clinical trial administrative and billing processes. Using this marker may mean that studies that already have IRB approval will need to be re-reviewed and approved again by the IRB. All institutions track IRB approvals; few track enrollment dates. Thus, all studies with an initial IRB approval on or before the effective implementation date should be covered under the old Clinical Trial Policy and any studies without initial IRB approval should be subject to the new Clinical Research Policy.

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The AAHC would now additionally recommend that to provide clarity and consistency throughout the policy, CMS use "***date of initial Institutional Review Board approval***" in several sections of the proposed CRP. These sections are:

1. The first sentence of the NCD Manual 310.1: Clinical Research Policy, which would then read: "*Medicare covers usual patient care in a clinical research study initially approved by an Institutional Review Board as of October 17, 2007.*" [Presuming the final policy is issued on this date.]
2. Under the approval process section of the proposed policy: the description of the information that should be included in the certification letter should be changed to read the "*date of initial IRB approval*" rather than "*study start date.*"
3. Proposed standard bullet #10 should be changed to read: "*The clinical research study is registered on the ClinicalTrials.gov web site by the study sponsor/principal investigator, or designee of the principal investigator, after initial IRB approval.*"

Finally, to ameliorate the administrative burden during the transition from the current Clinical Trial Policy to the new Clinical Research Policy, the AAHC suggests CMS consider a process that would permit, at the institution's discretion, clinical research studies begun prior to the effective date of the final CRP to be brought under the new policy. This would occur by fulfilling the requirements of ClinicalTrials.gov registration and submission of the certification letter to CMS.

Thank you for considering these recommendations which were developed by members of the AAHC's Forum on Regulation, comprising chief compliance officers from academic health centers nationwide. The AAHC looks forward to continuing to work with CMS and stands ready to assist in any capacity.

Sincerely,



Steven A. Wartman, MD, PhD, MACP  
President/CEO

CC: Leslye K. Fitterman