



**Association of
American Medical Colleges**

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July 20, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

I am writing to request that you extend by at least 15 days the 30 day comment period for the reconsideration of the Clinical Trial Policy (CAG-0071R). I understand from your staff that the length of the comment period for a national coverage decision (NCD) is mandated by Congress. However, the issues raised by the reconsideration of the clinical trial policy are complex and concerns about the policy have been vexing the research community for the nearly 6 years since the first NCD was issued.

The AAMC is attempting to work with our many and varied constituencies to produce comments that will be of value to CMS, an extremely challenging undertaking given the time constraints, the breadth of our membership, and the extent of their concerns. It is hard to imagine that Congress would object if in this instance CMS provides some additional time so that commentators will be able to reflect thoughtfully on the problems posed by the current policy and suggest improvements. I know we all desire a revised policy that allows Medicare beneficiaries to have the greatest possible access to clinical trials, and gives researchers and their institutions clear billing rules to follow. Some additional time would be extremely helpful in achieving this goal.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert M. Dickler".

Robert M. Dickler
Senior Vice President
Division of Health Care Affairs