Association of
American Medical Colleges
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 **F** 202 828 1125
www.aamc.org

March 16, 2009

Mr. Kevin F. Neyland
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

Submitted to: oira_submission@omb.eop.gov

Dear. Mr. Neyland:

The AAMC acknowledges with appreciation the unusual opportunity presented by the Office of Management and Budget's February 26 invitation for public comments on the principles and procedures governing regulatory review. The Association of American Medical Colleges is a not-for-profit association representing all 130 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 70,000 medical students, and 104,000 resident physicians. The results of regulatory review profoundly affect our community across its missions of teaching, research, and patient care. This effort to improve the quality of public policy reflected in regulations and to make more responsive the process by which regulations are put into effect is extremely important.

Increased Transparency of the Regulatory Process is Needed

In terms of the best tools for encouraging public participation in agency regulatory processes, the AAMC strongly supports greater use by agencies of town hall meetings in key locations around the country, both as means to stimulate interest in affected communities about potential subjects of regulation but also to create the opportunity for real-time airing of different perspectives and in-person sharing of experiences. This tool is highly visible evidence of agency commitment to understanding its affected publics.

AAMC also strongly endorses much more frequent use of the Advanced Notice of Proposed Rulemaking process as another highly effective and efficient means of seeking background information and perspective prior to any attempt at initially codifying potential regulatory provisions. The ANPRM process is especially useful because it

provides a setting in which distributional considerations, fairness, and concern for the interests of future generations can be explored directly by the agencies with the affected publics without the narrower focus associated with a Notice of Proposed Rulemaking, which can have the effect of limiting exploration of these important issues. Our community welcomes the opportunity to comment on issues in the early stages of the regulatory process.

Data are important for supporting regulatory proposals, and also for conducting cost-benefit analyses. The AAMC encourages OMB to require greater transparency in the use of data. When used to support a regulatory proposal, the data should be made available to the public at the time the proposed regulation is released to the *Federal Register*. Without having access to the complete data at the start of a comment period, there often is insufficient time to conduct the data analyses that allow an understanding of the impact of the proposal, or to determine the validity of the methodology used by the agency to support its proposal. If the data are used to support a cost-benefit analysis, they also should be made available at time of publication in the *Federal Register*. Equally as important for a cost-benefit analysis is that the underlying assumptions of the analysis are realistic in terms of the burden that will be imposed and the benefit that is gained.

As required by the Paperwork Reduction Act, federal agencies must publish requests to OMB to approve forms in the *Federal Register*. Some of these requests are *pro forma*, but others, such as the recent requests by the Centers for Medicare and Medicaid Services (CMS) for approval of the Disclosure of Financial Relationship Report, can have a major affect on the regulated community. Currently CMS publishes these requests in the *Federal Register* Table of Contents as "Agency Information Collection Activities; Proposals, Submissions, and Approvals." Use of this generic phrasing means that the only way in which to distinguish one request from another is to read every request, something that is extremely burdensome on those who monitor federal regulatory activities. To increase transparency to the public, OMB should require that agencies publish in the *Federal Register* Table of Contents a list of topics that are subsumed under the information collection activities.

Over the past several years the AAMC has seen an increased use by CMS of the term "clarification" in *Federal Register* notices to describe what affected entities characterize as major policy changes. As required by the Administrative Procedures Act, such changes should be accomplished only through a notice and comment rulemaking. To increase the transparency of agency actions, OMB should develop clear guidelines as to how to make a determination of whether a specific action is a "clarification," or whether it is a major regulatory change. Examples of factors to be considered could include regulated entities' understanding of regulatory requirements since the implementation of the regulation; agency pronouncements in the *Federal Register* and through sub-regulatory guidance; and whether any audits have been conducted regarding the implementation of the policy and, if so, the results of the audits and the extent to which the results are made public.

The Regulatory Burden on Biomedical Research

The AAMC is highly concerned about the cumulative effect, both in terms of cost and in terms of administrative burden, of federal regulations on academic medicine, and in particular biomedical research. In this regard, we strongly support the comments filed in this process by the Council on Governmental Relations (COGR) on the pressing burden created by these regulations and the absence of meaningful recognition by the regulatory agencies of the substantial, unreimbursed cost to the academic research community. The COGR comments, which the AAMC endorses, indicate that it is imperative that OMB factor into the regulatory review process a consideration of the unique cumulative burden of regulations on higher education in general, including academic medicine, and that the NRC study of the amount and scope of federal regulations should be allowed and enabled to proceed. The highly productive research partnership between higher education and the federal government can continue to be fruitful only if there is recognition of the disproportionate financial burden, in relation to the federal government itself, that the academic research community is carrying as a consequence of the impact of federal regulations. Otherwise, the quality and productivity of the entire research enterprise is at risk.

If you would like to discuss any of these comments further, please contact Karen Fisher [redacted] or Ivy Bae[redacted]both of whom may be reached at [redacted] or Susan Ehringhaus [redacted] at [redacted].

Sincerely yours,

Joanne M. Conroy, M.D.
Chief Health Care Officer