AAMC

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Lisa Jones
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, NW, Room 9013
Washington, DC 20503
By email: OMB_GCP@omb.eop.gov

RE: Proposed Bulletin for Good Guidance Practices

Dear Ms. Jones:

The Association of American Medical Colleges (AAMC) is pleased to submit these comments in response to the OMB's proposed bulletin for good guidance practices, as released on November 23, 2005. The AAMC is a non-profit organization representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies. Our member institutions are responsible for training new physicians and scientists and providing health care to millions of Americans, including some of the nation's most vulnerable populations. Our member institutions also perform more than half of the extramural research sponsored by NIH, as well as conduct research supported by other Public Health Service and federal agencies. As stewards of the public's trust and resources, our institutions must rely upon good guidance in interpreting and complying with myriad federal regulations, statutes, and policies that affect the discharge of these responsibilities.

The AAMC commends the OMB for its proposal to establish consistent and appropriate standards for developing good guidance practices within federal agencies. In particular the AAMC applauds the provision that agencies provide notice and post in the *Federal Register* draft "significant" guidance documents and provide for and respond to public comments on these drafts. In addition, we ask that in the case of guidance documents that do not meet the definition of *significant* as well as those that do, agencies be required to respond to public comments. Institutions can be profoundly affected by guidance documents, and substantial institutional alterations can occur as a consequence of them. The affected population is entitled to see the agencies' response to the public's expressions of concern, and be better able to understand the agencies' rationale supporting the resulting guidance. Only with such responsiveness can the public be assured that guidance is "developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements", as the OMB's proposal states.

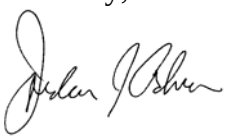
Similarly, we disagree that "public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and no formal response to comments by the agency is required." In the case at least of guidance meeting the *significance* definition, agency response to public comments should be required. Such input would help detect and address in advance particular problems or issues arising in implementation of the guidance, and reduce the instances when guidance must be withdrawn or re-written because it contains errors or is impossible to implement.

The AAMC is further concerned that the definition of a *significant guidance document* is so broad that it may allow agencies to avoid using the formal rulemaking process for certain important actions. The OMB proposed to define "significant guidance documents" as those documents that "set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy." The Administrative Procedures Act defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to **implement, interpret, or prescribe law or policy** . . ." (5 USC 551 (4) (emphasis added). There needs to be a clear distinction between a rule and a "significant guidance document." A "significant guidance document" may implement, interpret or clarify an existing rule, but it should not be used to establish or change policy; that is the role of rulemaking.

We strongly endorse the provision that guidance documents "not include mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe statutory or regulatory requirement." (II.2.vii) The general theme of this provision is to help maintain the distinction between guidance and regulations or requirements, as noted above.

Finally, the Association supports the provisions of the current proposed bulletin that leave senior agency officials, and not the OMB itself, responsible for approving significant guidance documents and for establishing approval procedures. These officials are accountable for the responsiveness of the agency and best understand the role of guidance in the context of the policies and mission of these agencies.

Sincerely,



Jordan J. Cohen, M.D.
President