March 15, 2012

via Regular and Electronic Mail
Ms. Marie Mindeman, Director
CPT Coding and Regulatory Services
American Medical Association
515 North State Street, 5th floor
Chicago, IL 60654

Re: Industry Stakeholders and the Molecular Pathology Coding Process

Dear Ms. Mindeman:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to express our concern regarding the development, charge, and objectives of the Molecular Pathology Advisory Group (MPAG). The MPAG will play a pivotal role in the continued development of molecular pathology procedure codes. Despite this there has been little information disclosed regarding the formation of the group, its members, or the opportunity to become involved with its work. AdvaMed is concerned by the lack of transparency regarding the operation of the MPAG and would ask the AMA to respond to our concerns as identified in this letter.

AdvaMedDx member companies produce advanced in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx is the only multi-faceted policy organization that deals exclusively with issues facing in vitro diagnostic manufacturers both in the United States and abroad.

Transparency Concerns—

AdvaMed is concerned by the lack of transparency surrounding the formation and operation of the MPAG. For a number of months the Molecular Pathology Workgroup discussed forming a group of experts to assist in the future development of molecular pathology and, most recently, Multianalyte Assays with Algorithmic Analyses (MAAAA) codes. The advisory group envisioned by the AMA would expand upon the work of the Tier 1 and Tier 2(a) Molecular Pathology sub workgroups, which are expected to be disbanded at some time in the future, by reviewing and developing recommendations on applications for molecular pathology and MAAA codes. The MPAG recommendations would subsequently be presented to the PCC-- to assist in their deliberations.
In January of 2012 AdvaMed learned that the MPAG was operational and had conducted its first meeting. During its inaugural meeting the MPAG developed recommendations on several code change proposals that were being considered during the January 2012 Pathology Coding Caucus (PCC) meeting. The MPAG’s recommendations influenced the PCC deliberations yet many members of that body, AdvaMed included, had and still have no sense of who the MPAG members are or of the charge under which they operate. We understand that the group is currently developing standard operating procedures but are nonetheless troubled by the inability to get information related to the current operation or membership of the group especially since the group has already met. Repeated requests to the AMA for information regarding the current composition of the MPAG have gone unanswered.

Last and most importantly, AdvaMed is concerned by the seeming lack of opportunity for all former members of the Tier 1 and Tier 2 sub workgroups and/or other interested stakeholders to participate on the MPAG. AdvaMed believes that the process of developing Tier 1 and Tier 2 codes benefited from stakeholder input and anticipates that these same benefits will be realized in the future development of Molecular Pathology and MAAA codes if a broad range of stakeholders are included. AdvaMed participated on both the Tier 1 and Tier 2 sub workgroups and appreciated the opportunity to work with the AMA as it deliberated the structure and form of the molecular pathology codes that have been presented to the CPT Editorial Panel to date. While the AMA is currently preparing to phase most of the molecular pathology codes into the 2013 CPT book, the additional challenge of reviewing requests for new molecular pathology codes, as well as MAAA codes remains. AdvaMed is interested in continued engagement in the molecular pathology code development process.

**Conclusion**

It is critical for industry and other stakeholders to be engaged as the AMA moves forward with the development of molecular pathology and MAAA codes. AdvaMed urges the AMA to include representatives from industry and other stakeholders to participate on the MPAG and to be more transparent in its operation of the group. We also encourage the AMA to disseminate information regarding the identity of the current members of the MPAG and the work of the group to date as soon as is feasible.

AdvaMed appreciates your consideration of our comments and recommendations on this issue. We would be happy to address any questions or concerns. Should you have questions please contact DeChane Dorsey, Esq., at 202-434-7218 or ddorsey@advamed.org . Thank you and we look forward to your feedback.

Sincerely,

[Signature]

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy