

**AdvaMed / NEMA-MITA
Codes of Ethics Comparison
March 23, 2009**

OUTLINE

The two Codes of Ethics are substantially equivalent and in many cases are identically the same. Following are areas of significant difference.

Section II, Code of Ethics Compliance

- MITA does not provide for annual certification or publication of the names of companies that certify compliance with the Code.
- MITA does not provide for companies to supply contact information of their compliance departments or hot lines. Consequently, it does not provide for publication of this information.

Section III, Company Conducted Training and Education

- MITA provides slightly more detail in the explanation that programs may occur at centralized locations necessitating out-of-town travel for some participants and may extend more than one day. (P. 3-4)
- In the “venue” sub-section, makes reference to equipment not being transportable.

Section IV, Supporting Third-Party Educational Conferences

- MITA adds a footnote (P. 5) that Companies familiarize themselves with the standards of accrediting organizations, paying special attention to independence, conflict of interest, appropriate use of commercial support, promotion, **hospitality**, format and disclosure.
- The term “hospitality” is generally avoided throughout the Code, however, it is used in the footnote noted above as well as in Q&A under Goal and Scope of the Code, (P. 14), and Q&A under Sales and Promotional Meetings (P. 20).

Section V, Sales Promotional and Other Business Meetings

- MITA provides more detail regarding “venue” to include clinical, educational, conference or other settings including company facilities, hotel or other commercially available sites conducive to effective transmission of knowledge.

Section VI, Consulting Arrangements with Health Care Professionals

- MITA is silent on the restriction of sales input on the suitability of proposed consultants.

Section IX, Education Items, Prohibition on Gifts

- MITA explicitly allows the provision of “storage-only” media technology, (e.g., printed paper, tape, diskette, CD-Rom, DVD, or thumb-drive) on which material that has a genuine educational function may be provided. The AdvaMed Code is not as specific but by inference, such items could meet the “capable of other use” definition and be excluded.

Section X, Provision of Reimbursement and Health Economics Information

- While discussing prohibitions, (P. 9) MITA is slightly more explicit that under no circumstances should an agreement to purchase include a provision to provide coverage information that would constitute an unlawful inducement.
- MITA is silent on two acceptable provisions in the AdvaMed Code:
 - Collaboration and joint advocacy (Second bullet, P. 9, AdvaMed Code)
 - Facilitating patient access by providing assistance in obtaining coverage decisions (Last bullet, P. 9, AdvaMed Code). This bullet allows Companies to:
 - Provide information and training on payor policies
 - Provide sample letters on medical necessity and appeals
 - Facilitate the preparation and submission of requests for coverage, prior authorization, pre-certifications and appeals.

Section XI, Research and Educational Grants and Charitable Donations

Note: MITA separates Research Grants and Charitable Donations into two sections, Section XI, Research Grants, and Section XII, Charitable Donations. It does not discuss Educational Grants separately, but incorporates those principles in the Supporting Third-Party Educational Conferences.

Research Grants

- MITA states in a separate bullet that agreements should be evaluated by, and agreements negotiated by non-sales personnel or anyone who would receive benefit from the grant.
- MITA makes specific reference to the OIG Guidance on how Companies should handle “Educational and Research Grants”

Charitable Donations

- Companies should not fund a charitable donation request that describes past purchases as a reason to fund the charity.

- Members should adopt processes that ensures separation between members' commercial and charitable activities.

PARAGRAPH HIGHLIGHTS

The AdvaMed and MITA Codes of Ethics are very similar in providing guidance to their respective members regarding ethical interactions with health care professionals (HCPs). In most cases, differences concern the degree of granularity provided or the arrangement of where certain areas are discussed. Following is an analysis of the two Codes.

Section I, Preamble: Goal and Scope

The two Codes recognize that their respective represented technologies often require interaction with a health care professional for their safe and effective use on patients. While AdvaMed is more explicit in its comparison with pharmaceutical and biologic products, both Codes promote ethical interactions with HCPs and respect the obligation of HCPs to make independent decisions regarding the health care of their patients.

Section II, Code of Ethics Compliance

Both Codes strongly encourage adoption of their principles and implement effective compliance programs. Both make direct reference to the OIG Guidance relating to the key elements of an effective compliance program.

In addition, the AdvaMed Code provides for annual certification and publication of the names of companies that certify to compliance with the Code. It also requires members (and encourages non-members) to provide contact information for their compliance departments or hot lines and will publish that information on its web site.

Section III, Company Conducted Training and Education

The Codes are essentially the same with MITA providing slightly more detail concerning the necessity of out-of-town travel to centralized locations for some participants, and that training may last for more than one day. As would be expected, reference is made to large equipment not being easily transportable for training purposes.

Section IV, Supporting Third-Party Educational Conferences

Although essentially the same, the MITA Code adds a footnote that Companies familiarize themselves with the standards of accrediting organizations, paying special attention to independence, conflict of interest, appropriate use of commercial support, promotion, hospitality, format and disclosure.

While AdvaMed has eliminated reference to the term "hospitality", MITA makes reference to it in this section and in two Q&As, one in *Goal and Scope* and one in *Sales and Promotional Meetings*.

Section V, Sales Promotional and Other Business Meetings

The Codes are virtually identical although MITA provides more detail defining "venue" to include clinical, educational, conference or other settings including company facilities, hotel or other commercially available sites conducive to effective transmission of

knowledge.

Section VI, Consulting Arrangements with Health Care Professionals

Both Codes parallel each other with respect to ethical behavior in this area, however MITA is silent on the restriction of sales input on the suitability of proposed consultants.

Section VII, Prohibition on Entertainment and Recreation

Both Codes are identical.

Section VIII, Modest Meals Associated with Health Care Professional Business Interactions

Both Codes are identical.

Section IX, Education Items; Prohibition on Gifts

While very similar, MITA explicitly allows the provision of “storage-only” media technology, (e.g., printed paper, tape, diskette, CD-Rom, DVD, or thumb-drive) on which material that has a genuine educational function may be provided. The AdvaMed Code is not as granular but by inference, such items could meet the “capable of other use” definition and be excluded.

In a related Q&A, the MITA Code adds that a Company should consider the value of the storage media (which should be negligible if it can be used for other purposes) and whether the storage capacity of the media corresponds to the size of the educational materials being stored.

Section X, Provision of Reimbursement and Health Economics Information

The Codes take similar paths approaching this area. MITA is more explicit stating that under no circumstances should an agreement to purchase include a provision to provide coverage information that would constitute an unlawful inducement.

MITA is silent on two acceptable provisions in the AdvaMed Code:

- Collaboration and joint advocacy
- Facilitating patient access by providing assistance in obtaining coverage decisions, allowing Companies to:
 - Provide information and training on payor policies
 - Provide sample letters on medical necessity and appeals
 - Facilitate the preparation and submission of requests for coverage, prior authorization, pre-certifications and appeals.

Section XI, Research and Educational Grants and Charitable Donations

MITA separates Research Grants and Charitable Donations into two sections, Section XI, Research Grants, and Section XII, Charitable Donations. It does not discuss Educational Grants separately, but incorporates those principles in the Supporting Third-Party Educational Conferences.

Research Grants

The MITA Code is more detailed than the AdvaMed Code, stating that agreements should be evaluated negotiated by non-sales personnel or anyone who would receive benefit from the grant. It also makes specific reference to the OIG Guidance on how Companies should handle “Educational and Research Grants”

Charitable Donations

The MITA Code is more specific on one point, stating that Companies should not approve a charitable donation request that describes past purchases as a reason to fund the charity.

While AdvaMed states that sales personnel should not control or unduly influence charitable donation decisions, MITA expands this concept stating that Members should adopt processes that ensure separation between members’ commercial and charitable activities.

Section XII, Evaluation and Demonstration Products

The Codes are identical in this area.