AdvaMed Updates Code of Ethics On Interactions with Health Care Professionals

On December 18, 2008, the Advanced Medical Technology Association (AdvaMed) announced a major update of its voluntary Code of Ethics on Interactions with Health Care Professionals. The revised and expanded AdvaMed Code tightens the guidance from the original 2005 Code, adds new provisions addressing practices such as royalty arrangements, and establishes a new certification mechanism to foster compliance with the Code.

Though sharing many similarities with the recently-updated Pharmaceutical Research and Manufacturers of America's Code on Interactions with Health Care Professionals (the PhRMA Code),[1] the AdvaMed Code provides additional compliance guidance on certain types of interactions with healthcare professionals that are more relevant to, or prevalent in, the device industry, such as reimbursement support and providing free products for evaluation or demonstration purposes. The revised AdvaMed Code takes effect on July 1, 2009.

Tightened Restrictions

The updated AdvaMed Code contains significantly tighter restrictions on manufacturer interactions with health care professionals (HCPs) than the current version of the Code. Key changes include:

Entertainment, Recreation, and Meals. The updated Code contains an entirely new section providing that companies should not provide or pay for any entertainment or recreational events or activities for non-employee HCPs, including theater, sporting events, golf, or vacation trips. Under the updated Code, companies may continue to provide "modest" and "occasional" meals to HCPs when such meals are incidental to a bona fide presentation of scientific, educational, or business information. Like the corresponding section of the PhRMA Code, the updated AdvaMed Code now calls for meals to be provided predominantly in an in-office setting. The AdvaMed Code provides an exception from this restriction in some circumstances, however, such as where the medical technology cannot easily be transported to the HCP's place of business.

Gifts. The updated Code includes a new prohibition stating that companies should not provide branded, non-educational, non-patient benefit items to HCPs, even if such items are of minimal value. It permits companies to provide occasional modest items to HCPs that benefit patients or serve a genuine educational function, subject to a $100 cap. This provision largely parallels the recent changes to the PhRMA Code, but contains some differences, such as an exception from the $100 cap for medical textbooks or anatomical models used for educational purposes. The updated Code also makes clear that gifts to HCPs' office staff should be treated the same as gifts provided directly to HCPs.

Third-Party Educational Conferences. The updated Code removes Grand Rounds from the examples of permissible third-party educational conferences and states explicitly that the program sponsor should independently control content, faculty, and program materials.

Research Grants. While the updated Code treats as acceptable grants for research leading to clearly defined goals, it states that companies should not provide "unrestricted" research grants. This change marks a significant difference from past industry practice.

Consulting Arrangements. The updated Code provides, among other things, that compensation for consulting should represent fair market value for the services provided, be identified in writing in advance of providing the services, be based on the consultant's expertise, and be unrelated to the volume or value of a consultant's past, present, or anticipated business with the company.

Product Training and Education. The updated Code clarifies that companies may cover HCPs' expenses for travel to company sites to obtain training and education on medical technologies, but that such expense payments should be supported by objective business reasons. Because pharmaceuticals do not require the type of hands-on training that is needed to demonstrate the use of many medical technologies, the PhRMA Code contains no parallel provision.

New and Substantially Expanded Provisions

The updated Code addresses a number of device industry practices for the first time. These include:

Royalty Payments. The updated Code provides that arrangements involving the payment of royalties to HCP consultants should comply with the Code's standards for consulting arrangements; be entered into only where the HCP is expected to make or has made a novel, significant, or innovative contribution to product development; and be calculated based on factors that preserve objectivity of medical decision-making.

Product Evaluations and Demonstrations. The updated Code provides that products may be provided to HCPs free of charge for evaluation in clinical use, including single use consumables and multiple use capital equipment, to assess the appropriate use and functionality of devices and determine whether to purchase or recommend the product under evaluation. The Code also states that companies may provide non-sterile demonstration products or mock-ups to HCPs for HCP and patient awareness purposes. The Code establishes limitations on the numbers of such products provided for evaluation and demonstration purposes, sets forth documentation standards, and contains provisions relating to the length of the evaluation period.

Reimbursement Support and Health Care Economic Information. The updated Code substantially expands the current Code's provisions on reimbursement support, stating that companies may provide accurate and objective information on product reimbursement so long as the information is timely and complete. In addition, the expanded provisions clarify that companies may collaborate with HCPs, patient groups and organizations to advocate for government and commercial payor decisions to cover medical technologies and assist HCPs with obtaining favorable patient coverage decisions. Additionally, the updated Code states that medical technology companies may provide accurate health care economic information to HCPs. Because the revised Code also clarifies that the term "HCP" includes persons who do not provide medical services directly, such as group purchasing organizations, practice managers and purchasing agents, this provision would allow companies to provide healthcare economic information to such decision makers.

Compliance Provisions

Echoing the PhRMA Code's new emphasis on compliance, the updated AdvaMed Code "strongly encourages" companies to adopt the Code and implement an effective program to foster compliance with it. The Code also strongly encourages companies to submit annual certifications to AdvaMed that the company has adopted the revised Code and implemented an effective compliance program. AdvaMed has stated that it will publish the list of certifying companies on its website.

In addition, AdvaMed has required all of its members, regardless of whether they choose to abide by the voluntary Code, to provide AdvaMed with contact information for their compliance departments or anonymous hotlines to facilitate the reporting of violations. AdvaMed has begun publishing this list on its website.

Preparing for July 1, 2009

AdvaMed's decision to update the Code reflects the increased scrutiny on the device industry coming from whistleblower lawsuits, government investigations, state legislatures, Congress and elsewhere. In this environment, developing and implementing compliance rules is a continual effort that demands periodic reassessment. It also requires companies to stay abreast of emerging developments such as the recently proposed Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct code, which is also scheduled to become effective on July 1, 2009[2] so that companies can coordinate any revisions to their policies and procedures.

If you have questions about the updated AdvaMed Code, its relationship to the recently proposed Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct code, or general compliance issues relating to your business, please contact your regular Ropes & Gray legal advisor.

[1] See Ropes & Gray Alert, "PhRMA Adopts Revised Marketing Code," July 10, 2008, *available at* http://www.ropesgray.com/phrmaadoptsrevisedmarketingcode/.

[2] See Ropes & Gray Alerts, "Update on Massachusetts Pharmaceutical and Device Manufacturer Conduct Law: Massachusetts Department of Public Health Issues Proposed Regulations," Dec. 11, 2008, *available at* http://www.ropesgray.com/masspharmaanddevicelaw/; and "Massachusetts Imposes Compliance Requirements on Pharmaceutical and Medical Device Manufacturers," Aug. 15, 2008, *available at* http://www.ropesgray.com/massimposescompliancerequirements/.