The code of ethics that guides relations between medical device companies and health care professionals has had a major update. The trade group AdvaMed (Advanced Medical Technology Association) issued a comprehensive revision of its ethics code in December 2008. The revised code is effective July 1, 2009.

The purpose, AdvaMed says, is to help companies ensure their dealings with health care professionals are ethical, transparent, and meet laws and regulations.

“Overall, we’ve added greater rigor and clarity and expanded the code to address new areas,” AdvaMed’s general counsel, Christopher White, told OR Manager.

AdvaMed “strongly encourages” companies to adopt the code and to implement an effective compliance program. Companies also are strongly encouraged to sign an annual certificate of compliance. Those that do so will be listed on the AdvaMed website.

One state, Massachusetts, has incorporated the AdvaMed code into a new law that speaks to relationships between health care practitioners and drug and device companies.

The code’s revision takes place against a backdrop of closer scrutiny of device company dealings with physicians, including settlements reached in 2007 between the Department of Justice and 4 orthopedic manufacturers over alleged kickbacks.

**Expanded areas**

The code expands into several new areas:

- explicitly prohibits companies from providing entertainment and recreation to health care professionals—sports tickets, golf, skiing, and hunting trips, for example, are out
- explicitly prohibits gifts of any kind as well as branded promotional items that do not have an educational purpose, such as pens, notepads, and mugs
- sets guidelines for companies providing products for evaluation and demos
- expands the section on companies providing reimbursement, coverage, and health care economics information.

The term “health care professionals” is defined broadly to include not only clinicians such as physicians and nurses but also others involved in selecting or purchasing technology, such as managers and purchasing agents.

There is a new section on royalties and expanded sections outlining consulting, grants, and charitable donations.

White discussed provisions important to leaders in surgical services. He notes that the code outlines general principles, but details will need to be worked out in each company’s compliance plan.

**Company training and education**

Training and education are more specifically defined. As before, the code says training and education must be conducted in a setting “conducive to the effective transmission of information.” This can include a health care site as well as other venues.

Modest meals and refreshments are permitted. “The code states that it is appropriate to provide training and education and, moreover, to provide a modest meal in the context of education,” White says. But there are limitations: The meal must be modest in value and secondary to the educational value of the overall session. And meals are limited only to those with a bona fide interest in the education and training.
Product evaluation and demonstration
Under the code, companies can provide products for evaluation and demos at no charge, with certain limits. For example, the number of single-use items at no charge should not exceed the “amount reasonably necessary” for evaluation, and capital equipment should be furnished only for a reasonable amount of time to allow for evaluation. Companies should provide documentation and disclosure of the no-charge status of evaluations and demonstration products.

Reimbursement and payment information
A new section addresses information that companies provide about reimbursement, coverage, and economics of technology. The code says companies may provide such information if it is “accurate and objective.” They may also collaborate with health professionals, patients, and organizations to achieve payer coverage, with limits. But companies may not interfere with health professionals’ independent clinical decision making or provide an “unlawful inducement.” For example, a company couldn’t provide free services that help a health professional eliminate overhead or other expenses of business operations.

Educational conferences
Companies may support educational, scientific, and policy-making conferences that promote knowledge, medical advancement, and delivery of care. But attendees are likely to see fewer give-aways and less entertainment.

Gifts not related to education or patient care are out; for example, DVD players and iPods. Also not permitted are noneducational items with company names or logos, regardless of value.

Companies may fund meals and refreshments for conference attendees, again with restrictions. A cocktail reception might be provided; but companies would need to be careful not to cross the line into entertainment, White notes.

Companies may also pay “reasonable travel costs” for attendees when necessary, such as for a plant tour or demonstrations of nonportable equipment. But that may not include meals, travel, or lodging for guests of health care professionals or anyone else without a bona fide professional interest.

The AdvaMed Code of Ethics and related materials are at www.adamed.org/MemberPortal/About/code/