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Revised AdvaMed code urges stricter compliance program

Physicians should be aware of what is considered appropriate and inappropriate conduct when interacting with medical device firms.

by **Nicole Liffbrig Molife, JD and Anthony Choe, JD, MPH**

The Advanced Medical Technology Association, or AdvaMed, released a revised Code of Ethics on Interactions with Health Care Professionals on Dec. 18.

The revised Code will be effective July 1 and provides guidance on what conduct is



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appropriate and inappropriate between the medical technologies industry and health care professionals (HCP).

The revised Code encourages companies to adopt an effective compliance program, including the seven core elements of a compliance program outlined by the Office of the Inspector General.

AdvaMed intends to publish on its Web site the list of companies that have certified on an annual basis that they have adopted the revised Code and have implemented an effective compliance program.

The revised Code sets the standard for interactions between HCPs and companies that develop, produce, manufacture

and market medical technologies. Certain key revisions contained in the revised Code are highlighted below.

New guidelines

- **Payment of royalties.** A new section provides guidance on the payment of royalties to HCPs who contribute to the improvement of a company's medical technologies. The revised Code identifies criteria that companies should use when calculating royalty payments and determining when to enter into royalty agreements. Companies should enter into royalty arrangements only if the HCP is expected to make a substantive contribution. The revised Code also recommends that companies document any material contribution made by the HCP that affects the HCP's compensation. Royalty arrangements should otherwise comport with the revised Code's standards for consulting agreements.

- **Permissive evaluation and demonstration products.** A new section sets forth criteria for providing products to HCPs, at no charge, for evaluation or demonstration purposes. Evaluation products are divided into two categories: (1) single-use/dis-



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posables and (2) multi-use/capital items. Companies should provide the amount of single-use/ disposable products, without charge, necessary to evaluate the product. The provision of multiple use/capital product, without charge, should be set forth in writing; be limited to the minimum period of time necessary to evaluate the product; and provide for the product's return if the HCP does not lease/purchase the product at the end of evaluation period.

- **Prohibition on entertainment and recreation.** A new section contains an absolute prohibition on providing or paying for any entertainment and recreation events or activities for any HCPs who are not employees of the medical device company. This prohibition includes both the company itself and its employees and agents, even when they pay for such entertainment events out-of-pocket.

Strengthened guidelines

- **Limited out-of-town travel for company-conducted product training and education.** The revised Code clarifies that companies should pay for an attendee's reasonable travel and modest lodging costs only when out-of-town travel is required to

facilitate the efficient delivery of training and education programs, and an objective basis exists for such training and education programs.

- **Modest refreshments instead of receptions.** Companies should no longer provide or sponsor receptions at third-party educational conferences, company-conducted product training and education sessions, consultant meetings, and at sales, promotional and other business meetings. Instead, companies may only provide refreshments and modest meals in connection with such gatherings.

- **Occasional modest meals for bona fide business meetings.** The revised Code strengthens the existing provisions by clarifying under what circumstances meals may be provided to HCPs. Meals may be provided as an occasional business courtesy in connection with a bona fide presentation of scientific, educational or business information to those HCPs who attend the presentation. This provision sets forth three parameters: (1) the meals should be provided only occasionally; (2) the meals should only be provided to the staff who attend the meeting, not the entire office staff; and (3) clarifies that the meeting should have a substantial discussion or presentation of scientific, education or business information distinct from the development of good will and business relationships.

- **Permissive research and educational grants and charitable donations.** The revised Code makes the grant and donation provisions more rigorous by encouraging companies to adopt policies for making grants and donations, including establishing objective criteria, maintaining appropriate documentation, conducting due diligence regarding the bona fide nature of the charitable organization (if it is a charitable donation) and limiting sales and marketing personnel's involvement in the selection process. The scope of permissive grants and donations is limited to three categories: (1) independent medical research grants with well-defined goals without any link to purchases (not unrestricted research grants); (2) educational grants to organizations (not individual HCPs); and (3) donations to bona fide charitable organizations.

- **Occasional gifts that benefit patients or serve an educational function.** The revised Code limits the scope of per-

missive gifts to modest items that benefit patients or serve an educational function and the items have a value of less than \$100, except for medical textbooks or anatomical models used for educational purposes. Non-educational, branded promotional items, such as notepads and mugs, are not permissible. While patient starter kits are listed as appropriate gifts because they benefit patients, the Code encourages companies to adopt policies to ensure that such kits and similar items are not provided as an unlawful inducement.

- **Consulting arrangements.** The revised Code provides additional examples of permissible consulting service arrangements between companies and HCPs, including arrangements for product development, the development and/or transfer of intellectual property and marketing. Companies should document the legitimate business need for each consulting arrangement. Companies may base their selection of consultants on an HCP's experience with, usage of, or familiarity with a specific medical technology. Companies may also seek input from their sales personnel on an HCP's suitability if such personnel does not have the authority to make or unduly influence the decision to engage the HCP. Although companies may reimburse reasonable and actual expenses that are documented and incurred as part of the consulting arrangement (ie, travel, modest meals, lodging), they should not offer recreation or entertainment in connection with consultant meetings.

Expanded guidelines

- **Third-party educational conferences.** The revised Code updates the criteria that companies should follow when making third-party education grants and advises companies to follow the applicable standards of the conference sponsor and any entity accrediting the educational activity. Conference sponsors are advised to retain independent control over the selection of conference presentations. Companies may also offer modest meals and refreshments directly to all HCP attendees. A company may, however, offer meals and refreshments to fewer than all HCP attendees if the company can satisfy the revised Code's general guidelines for modest meals associated with HCP business interactions. Meals and refresh-

ments should be clearly separate from the continuing medical education portion of the conference.

- **Sales, promotional and other business meetings.** The revised Code tightens the existing provisions by clarifying that the selection of locations and venues for sales, promotional and other business meetings mirrors its guidance for training and educational meetings. Facilities should be appropriate for, and conducive to, the meeting's purpose. The revised Code also clarifies that companies may have other business meetings with HCPs, meaning that meetings are no longer limited to sales and promotional meetings. Companies may also sponsor an off-site sales, promotional or other business meeting that is ancillary to a third-party education conference, as long as there is a legitimate business purpose for the off-site meeting and the company satisfies the applicable conference sponsor guidelines.

- **Coverage, coding and reimbursement information and activities.** The revised Code provides an expanded list of several permissive interactions, such as helping obtain coverage and identifying the clinical value of a product, recognizing that obtaining coverage, coding and appropriate reimbursement for a product and associated procedure frequently involves input from, and collaboration with, HCPs. The provisions clarify that companies should not interfere with clinical decision-making and should not provide reimbursement support services as an unlawful inducement. Reimbursement support services, without charge, that eliminate a HCP's overhead or other expense that the professional would otherwise incur may be inappropriate.

Conclusion

As companies adopt and implement the revised Code, physicians should expect to see these guidelines shaping the scope and nature of their interactions with medical technology companies. Physicians are encouraged to visit AdvaMed's Web site to review the guidelines.



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