

# KnowledgeLine\*

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## Achieving compliance as a competitive advantage through the updated AdvaMed Code of Ethics

AdvaMed Code of Ethics overhaul gives medical device companies new impetus for competitive compliance strategy.

### Code revision offers opportunity to reshape compliance programs

A major overhaul of the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals presents an opportunity for medical device companies to rethink their approach to compliance as a business advantage that fosters innovation and contributes to sustainability.

This first major code update since 2003, which takes effect July 1, 2009, sets forth explicit guidelines about appropriate and inappropriate interactions and arrangements with healthcare professionals (HCPs). HCPs include physicians and other medical practitioners as well as anyone involved in decisions to purchase, lease, or recommend medical technology. Such interactions weigh heavily on the reputation of an industry whose critical business processes increasingly have come under scrutiny, namely: innovation, research and development, and adoption of new products. Under the

“Physicians are key partners in the development and improvement of medical technology. The innovative nature of medical device research and development involves ongoing collaboration with physicians.”<sup>1</sup>

pressure of ever-increasing legal challenges and regulatory constraints, the medical device sector must use this opportunity to forge paths that will fundamentally change how they operate their compliance programs.

For this industry, which is highly dependent on hands-on interaction with HCPs, the significant proactive step to promote transparency and build trust could drive innovation by fostering greater physician collaboration without the appearance of bias. HCP participation in medical device development and training would be impossible without close collaboration between the organizations that produce medical technologies and the professionals who design and use them.

### Revised code can serve as guidepost for embedded compliance principles

The revisions are designed to create transparency throughout the code. The most significant changes:

- Prohibit gifts of any type, including noneducational, branded promotional items such as pens, notepads, and coffee mugs, and the raffle of such items at trade shows, regardless of value.
- Allow royalty arrangements with HCPs in exchange for novel, significant, or innovative contributions that improve medical technologies. Under this new provision, criteria for royalty payments must preserve the objectivity of medical decision-making and avoid the potential for improper influence.
- Prohibit virtually all entertainment or recreation with HCPs. (Entertainment was previously allowed if modest in

value.) Tickets to sporting or theatrical events; golf, skiing, or hunting outings; gifts of sporting equipment; and leisure or vacation trips are specifically prohibited.

- Define appropriate parameters under which companies may provide products to doctors or patients to demonstrate or evaluate newer or improved medical technologies. For example, a physician may use a demonstration product to show a patient the type of device that might be implanted during surgery. A physician also is allowed to use a product at no charge to assess its appropriate use and functionality to determine whether and when to use, order, purchase, or recommend the product for patient care in the future.

Clearly, the revised code serves as a guidepost for transparency. A perfunctory adoption of the code and its posting on a company’s website, however, will neither change compliance strategy or tactics nor give the company a competitive advantage. In addition, such an approach will not give investors and customers confidence that the corporation will avoid incidents and violations outside the earshot of headquarters. A more authoritative approach that overlays the code on existing business processes as an afterthought also will fail.

Medical device companies that view collaborative relationships with physicians as key to their future need to take a different approach. They must transform their compliance programs from reactive and transactional to proactive and integrated, where the programs can complement business processes and nurture innovation. As emphasized by

<sup>1</sup> Christopher White, “Testimony on Physician Payment Disclosure Legislation, U.S. Senate Special Committee on Aging,” February 27, 2008, <http://aging.senate.gov/events/hr188cw.pdf> (February 16, 2009).

David Dvorak, Zimmer CEO, companies “are going to have to implement systems that are not all that dissimilar to the quality systems that have been implemented in medical device companies over the last many years to protect the ability to be able to collaborate with surgeons on a go-forward basis.” Companies will need to leverage technology as an enabler to compliance, making the program more sustainable, predictable, and complementary to business operations.

Building this type of sustainable compliance program that drives competitive advantage will require a rigorous, multistep approach. PricewaterhouseCoopers recommends that medical device companies start with the following steps:

- Establish an annual compliance program certification process by participating in the AdvaMed Ethics Logo Program.
- Analyze existing policies and procedures against the new code requirements.
- Train employees on the new code and updated compliance policies.
- Identify ways to integrate the new code requirements into commercial processes so that compliance is not an afterthought or overlay, but rather an embedded business function.
- Work to standardize business practices across commercial operations with compliance and business differentiation in mind.
- Leverage technology as an enabler to compliance, making the program more sustainable, predictable, and complementary to business operations.



### Transparency and compliance will help move the industry forward

Adopted widely, the revised AvaMed Code of Ethics can serve as a foundation to build and maintain trust with diverse stakeholders critical to the sustainability of the medical device industry—patients, physicians, investors, and regulators. Code-compliant processes and systems will help protect the ability of medical device companies to collaborate with physicians on a go-forward basis. Regulators and enforcement agencies will expect compliant systems, which may relieve some of the scrutiny and penalties the industry has faced in recent years. A company that does not have the right compliance program in place may find itself under increasing enforcement pressure. Ultimately companies that go beyond compliance, bring transparency to business processes, and enable ethical sales and marketing operations will grow their business as they fill the role of preferred manufacturers for HCP collaboration and transform themselves into industry leaders.

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<sup>2</sup> David Dvorak, “Zimmer Holdings Inc. Q4 2008 Earnings Call Transcript,” Seeking Alpha, Jan. 29, 2009, <http://seekingalpha.com/article/117413-zimmer-holdings-inc-q4-2008-earnings-call-transcript> (accessed February 16, 2009).

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