



AdvaMed

Advanced Medical Technology Association



Lessons Learned in Medical Device Sector Voluntary Code Implementation & SME Challenges

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Brunei Darussalam

Christopher L. White, Esq.
Executive Vice President, General Counsel



Top Lessons Learned in Voluntary Code Drafting, Development & Implementation

- Integrate Ethics into the Association Mission
- An Effective Code is a Longstanding Commitment
- Address Top Industry-Specific Risk Areas & Focus on Industry Credibility
- Broad Industry Engagement: Include Every Sector
- Executive Level Commitment
- Tools & Training for Companies & Stakeholders
- Embrace transparency!





Who is AdvaMed?

Vision

AdvaMed will be the leader in advancing medical technology to achieve healthier lives and healthier economies around the world.

Mission

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.



AdvaMed's Commitment to Ethical Business Practices



AdvaMed
Advanced Medical Technology Association

- 1991: First AdvaMed Code of Ethics
- 2003: Board adopts revised Code
- 2005: Supplemental FAQs
- 2006: Code Logo program
- 2008: Endorsement of Physician Payment Sunshine Legislation
- 2008: Revised Code of Ethics
- 2009: Code Certification by Early Adopters
- 2010: Health Reform Statute incorporates Sunshine Legislation: Transparency
- 2010: Transatlantic Statement on Ethical Interactions
- 2011: Best Practices Tools & Resources
- 2011: Joint Distributor Guidance
- 2012: Off Label Guidance



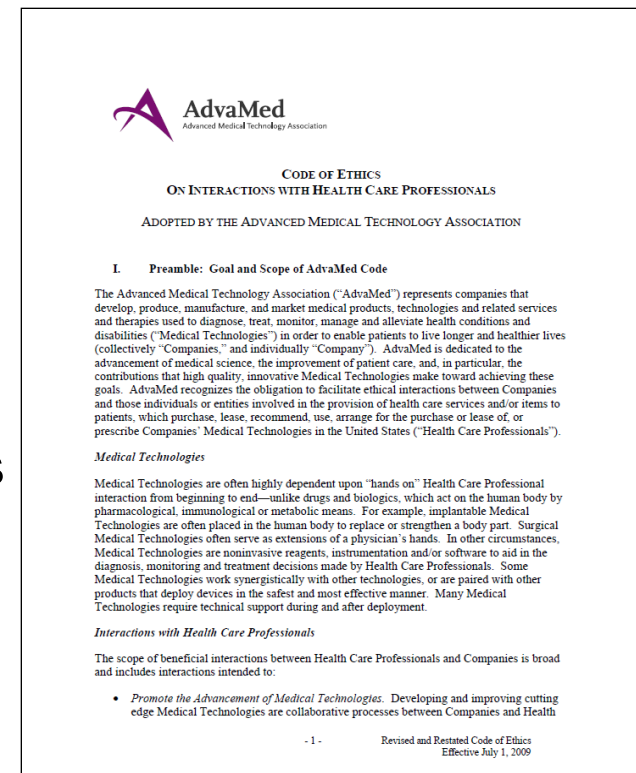
The AdvaMed Code as a Tool to Promote Ethical Business Practices



- Encourages voluntary, ethical interactions between Medical Device Manufacturers & Health Care Professionals
- Distinguishes between interactions that:
 - Advance Medical Technology
 - Have the Potential to Influence Medical Decision-Making Inappropriately

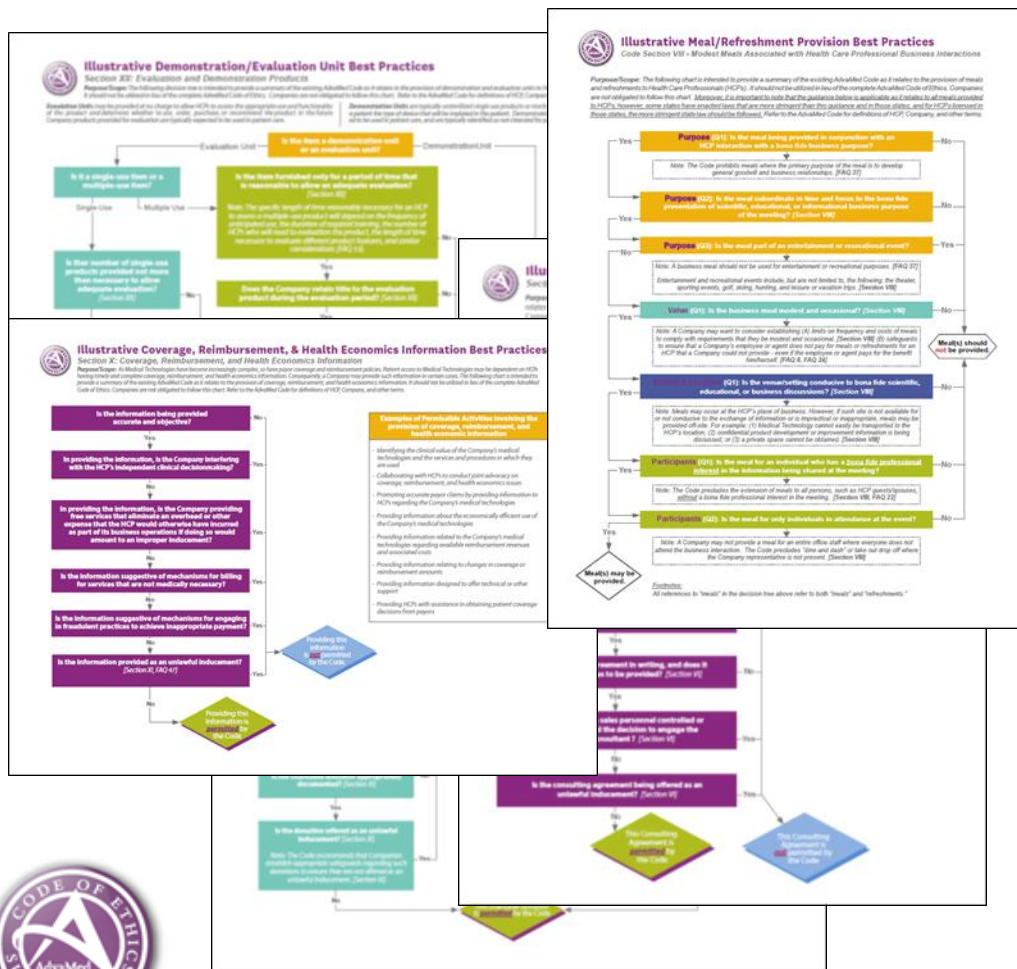
Code Addresses:

- Arrangements w/ Consultants; Royalties
- Member-Sponsored Product Training & Education
- Supporting Third Party Educational Conferences
- Sales & Promotional Meetings
- Demonstration Units; Evaluation Products
- Provision of Reimbursement & Other Economic Information
- No Entertainment; Recreation; Gifts
- Grants & Charitable Donations



Best Practices Guidance to Facilitate Implementation

Best Practices Guidance



Current Library:

- Charitable Donations
- Demo/Eval Units
- Fellowships
- HCP Travel
- Plant Tours
- 3D Party Conferences
- Consulting Arrangements
- Educational Items
- Grand Rounds
- Modest Meals
- Reimbursement Information

Next Working Group Topics:

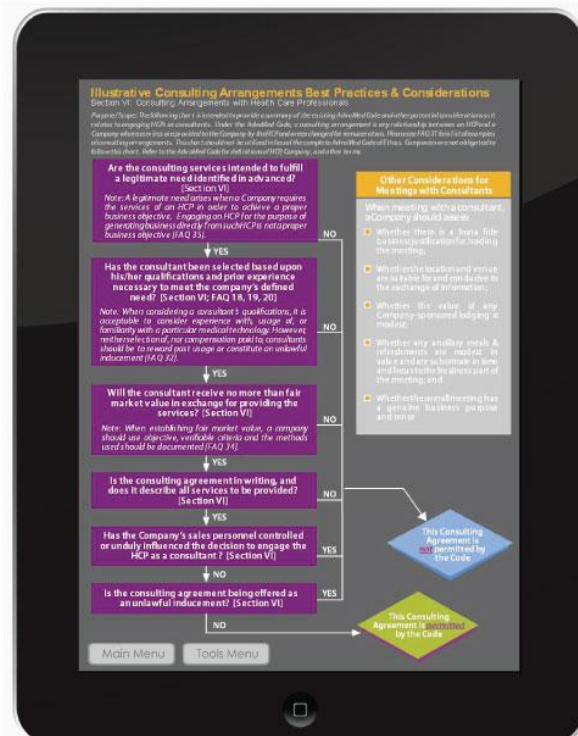
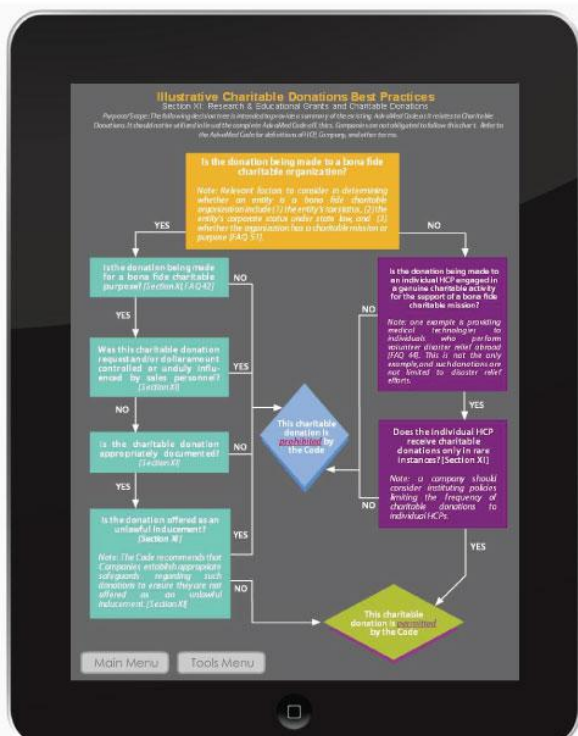
- *Royalty Arrangements*
- *Research Grants*



Best Practices Guidance to Facilitate Implementation



AdvaMed Code Best Practices Smartphone App

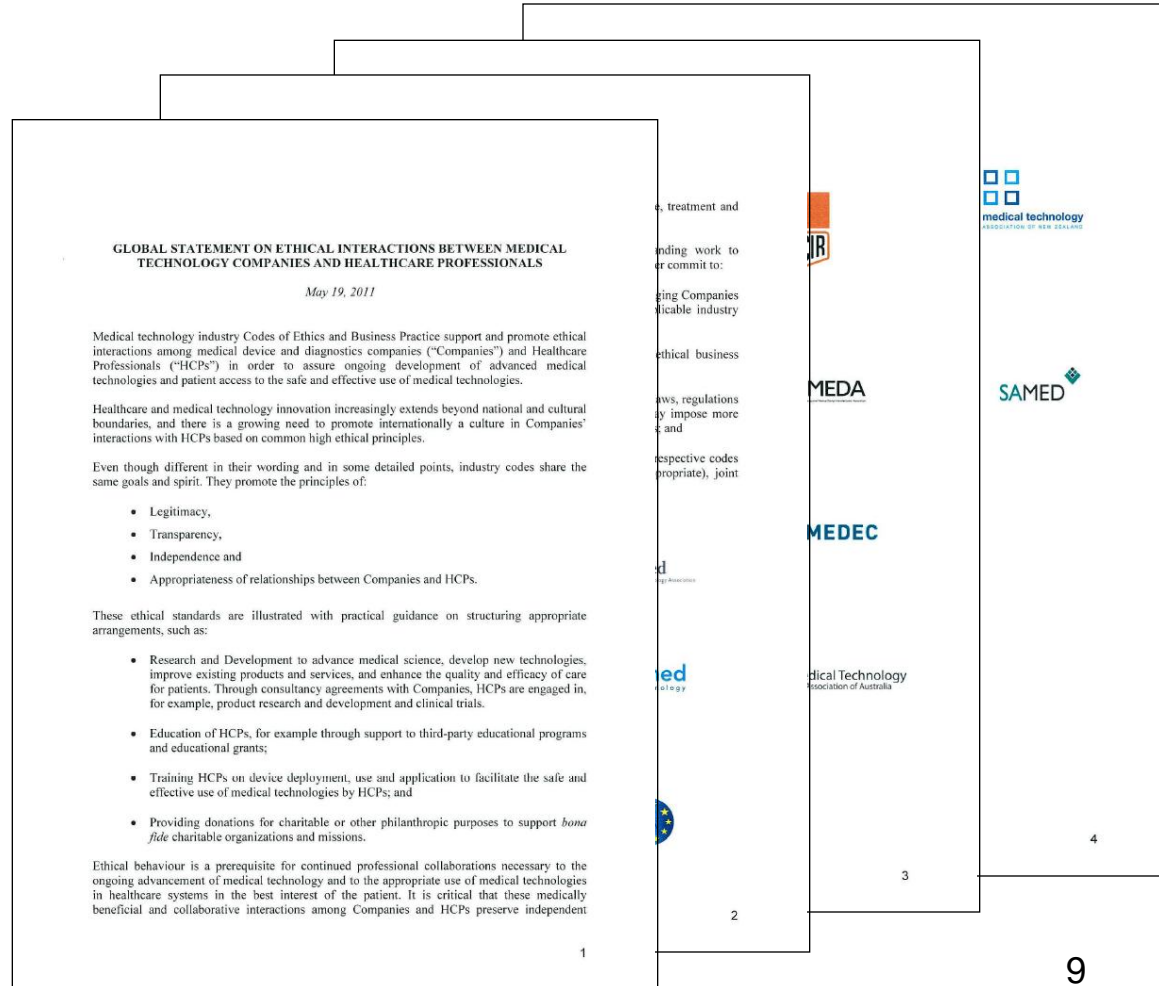


Ethical Business is a Global Commitment

Global Statement on Ethical Interactions:

Core Principles:

- Appropriateness
- Transparency
- Legitimacy
- Independence



GLOBAL STATEMENT ON ETHICAL INTERACTIONS BETWEEN MEDICAL TECHNOLOGY COMPANIES AND HEALTHCARE PROFESSIONALS
May 19, 2011

Medical technology industry Codes of Ethics and Business Practice support and promote ethical interactions among medical device and diagnostics companies ("Companies") and Healthcare Professionals ("HCPs") in order to assure ongoing development of advanced medical technologies and patient access to the safe and effective use of medical technologies.

Healthcare and medical technology innovation increasingly extends beyond national and cultural boundaries, and there is a growing need to promote internationally a culture in Companies' interactions with HCPs based on common high ethical principles.

Even though different in their wording and in some detailed points, industry codes share the same goals and spirit. They promote the principles of:

- Legitimacy,
- Transparency,
- Independence and
- Appropriateness of relationships between Companies and HCPs.

These ethical standards are illustrated with practical guidance on structuring appropriate arrangements, such as:

- Research and Development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. Through consultancy agreements with Companies, HCPs are engaged in, for example, product research and development and clinical trials.
- Education of HCPs, for example through support to third-party educational programs and educational grants;
- Training HCPs on device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs; and
- Providing donations for charitable or other philanthropic purposes to support *bona fide* charitable organizations and missions.

Ethical behaviour is a prerequisite for continued professional collaborations necessary to the ongoing advancement of medical technology and to the appropriate use of medical technologies in healthcare systems in the best interest of the patient. It is critical that these medically beneficial and collaborative interactions among Companies and HCPs preserve independent

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- **Patient Protection and Affordable Care Act (PPACA)**
 - Signed into law March 23, 2010
 - P.L. 111-148
 - Section 6002: Transparency Reports and Reporting of Physician Ownership of Investment Interest
 - First report due March 31, 2013
 - Information submitted will be available to the public on-line
 - Effective January 1, 2012, the federal law will preempt state laws that require disclosure of the same type of information, but not state laws that require information outside the scope of PPACA
- **Proposed Rule: “Transparency Reports and Reporting of Physician Ownership of Investment Interests”**
 - Published on December 19, 2011
 - Comments to the Proposed Rule filed on February 17, 2012
 - Now awaiting Final Regulations





Main Elements of Sunshine Law

- Section 6002 requires medical device manufacturers to report “payment or other transfers of value” to “covered recipients”
 - *“Payment or other transfers of value”* means a transfer of anything of value. Certain payments and transfers are excluded, including, e.g., transfers of value less than \$10/\$100 annual aggregate, certain educational materials, in-kind items for charity care.
 - *Covered Recipients* limited to physicians and teaching hospitals
 - Reportable information includes name/address of covered recipient, amount/date of payment, form of payment (e.g., cash, stock), nature of payment (e.g., consulting fees, gift, entertainment)
- Section 6002 also requires “any applicable manufacturer or applicable group purchasing organization” to report information regarding any physician ownership or investment interests

