

Code of Ethics

(Established on January 4, 2016, Amended on April 6, 2021)
American Medical Devices and Diagnostics Manufacturers'
Association

The mission of the American Medical Devices and Diagnostics Manufacturers' Association (hereinafter referred to as "AMDD") is to provide valuable medical technology and information to people's loved ones, so that they may live in good health. In order to enable a Healthier Japan as well as to realize a healthcare system that fully appreciates the value of innovative medical technology, to achieve prompt and appropriate introduction of advanced medical technology to medical sites, to realize comprehensive control and proper distribution of medical expenses, and to achieve sound growth for the healthcare market, AMDD is proposing revisions of medical device related regulatory requirements, in collaboration with the Government of the United States, the U.S.-based Advanced Medical Technology Association (AdvaMed), and domestic industry organizations, and is acting as a contact point, as a representative of AMDD member companies, in discussion with the supervisory agency of the Ministry of Health, Labour and Welfare in regard to revisions of medical insurance reimbursement prices, its system, etc. AMDD and its member companies (hereinafter referred to as "Member Companies") shall maintain high ethics and conduct activities with high transparency, and further shall endeavor to gain the trust and confidence of society in Japan as the business of medical devices is deeply related to people's lives. In addition, with the signing of the Japanese Consensus Framework for Ethical Collaboration at the 2018 APEC Business Ethics for SMEs Forum (Tokyo Conference), Member Companies shall comply with the following points in the aim of respecting and reflecting in their activities the spirit of the four overarching principles that comprise the framework, namely, putting patients first, supporting ethical research and innovation, ensuring independence and ethical conduct, and promoting transparency and accountability.

1. Placing top priority on health and improvement of the lives of people, Member Companies shall endeavor to research, develop, manufacture, and sell products, technologies, and services materializing advanced medical technology, and also to maintain a stable supply of products while ensuring their efficacy and safety under proper quality control.
2. Member Companies shall comply with all applicable laws and regulations, the laws and regulations relating to business activities of medical devices, and voluntary rules and

standards of the industry, and also various laws and rules applicable including corrupt practices prevention laws, and shall conduct appropriate and proper business activities with high ethics and transparency. Specifically, in the aim of ensuring a healthy market and achieving thorough compliance with laws, regulations, and rules, Member Companies shall cooperate with allied companies and make constant efforts toward establishing more transparent business practices and customs. Above all, Member Companies shall approve the Guidelines for Transparency with Medical Institutions in the Medical Devices Industry and thoroughly comply therewith, and shall also become well versed in and comply with the Compliance Provisions of the AMDD Competition Law, the Guidelines on Donations, and the other voluntary compliance-related rules and guidelines of AMDD.

3. With an awareness of the spirit of these principles and of their own roles in the achievement thereof, the management of Member Companies shall take the initiative to disseminate the message, work to ensure these concepts within their own companies and group companies, and also encourage their business partners to do the same. Further, the managers of Member Companies shall be self-aware of their duty to ensure a healthy market environment for their own company as a Member Company, and shall not only comply with laws, regulations, and rules but also shall not neglect the light of common wisdom. If a situation arises that could violate these principles, the management themselves shall, in the course of problem-solving, strive to seek the cause in the aim of ensuring a high level of ethics and transparency that is worthy of trust, to understand the opinions of internal and external parties at all times, and to establish an effective internal system while making efforts to improve continuously and to prevent such an incident from recurring. Further, as necessary, they shall promptly and accurately disclose information and be accountable, and, having clarified authorities and responsibilities, they shall implement strict punishment or corrective actions, including on themselves.
4. Member Companies shall establish appropriate internal procedures to ensure compliance with laws, regulations, and rules and shall maintain them and have all officers and employees regularly undergo training appropriate to their roles while also proactively utilizing the training, etc. on FCPA (the US Foreign Corrupt Practices Act) that AMDD offers to agents.
5. Member Companies shall endeavor to maintain high transparency by establishing proper business relationships through fair and free competition in any business transaction and maintaining proper relationships with medical institutions and health care professionals from the perspective of avoiding any conflict of interest. In particular, in interaction between

Member Companies and medical institutions and healthcare professionals, Member Companies shall keep foremost in mind the best interest of patients and contributing to patient health and welfare. Also, in the aim of contributing to the development of medicine and to the improvement of public health and social welfare, not only must Member Companies focus on providing accurate information on medical devices and on medical-related academic exchange and research support, they also shall not engage in any corporate activities that could potentially have an inappropriate impact on the adoption or evaluation of medical devices or on treatment decisions. Further, Member Companies, shall not, whether directly or indirectly, make payments to medical institutions, healthcare professionals, etc., under any pretense, that could have an inappropriate impact on their decision-making.

6. Relationships between Member Companies, agents, and other business partners (hereinafter referred to as “Business partners, etc.”) must be fair business relationships that are compliant with legal regulations such as competition law and rules such as voluntary industry norms. Further, considering that these transactions take place under the public medical insurance system, it is required to ensure that these relationships have a higher level of ethics and transparency than in other industries, and therefore Member Companies must, with regard to the terms of transaction for Business partners, etc., pay attention to the objectivity, reasonableness, and appropriateness with those standards.