

Code of Ethics Compliance Guidance Related to the COVID-19 Response

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Introduction

The extraordinary threat that COVID-19 has brought to human lives continues to place immense pressures on global healthcare systems. Now, more than ever, traditional medical technology manufacturers – and new producers of medical equipment – find themselves in extraordinary positions as they respond to the needs of the patients, healthcare providers and governments that they serve. The MedTech industry’s mission to utilize innovative medical technologies to save and improve lives means we must do all we can to help ensure that patients are provided both timely and ethical access to our equipment, knowledge and trained personnel.

MedTech manufacturers affirm the importance of doing business with integrity and continuing to abide by the foundational principles of the AdvaMed Code of Ethics. The Guidance in this document seeks to help Member Companies to develop processes that support both rapid decision-making in the context of the pandemic and mitigate compliance/corruption risks. This Guidance is not intended to supplant or supersede the AdvaMed Code of Ethics or any laws or regulations or codes of ethics, including company codes and internal policies.

AdvaMed and its Member Companies recognize that the COVID-19 pandemic has created a public health emergency of unprecedented scale, and emergency ordinances, decrees and other legislative mechanisms are creating a fluid situation of constant change. Companies should consult legal counsel and compliance departments before entering into any arrangements described in this document.

No “Coronavirus Defense”

A state of emergency does not normally, by itself, override existing contractual or legal obligations not expressly mentioned in the terms of the declaration of emergency. The Codes of Ethics and Codes of Conduct that we follow in ordinary times remain in effect during extraordinary times. The rapid response to the crisis is admirable, but some aspects of the response may attract attention from enforcement agencies seeking to uphold anti-corruption, customs and regulatory laws, among other requirements. If irregularities or non-compliant activities are found, it is highly unlikely that a “coronavirus defense” will prevail.

The AdvaMed Code of Ethics

MedTech support in times of crisis, including charitable donations of product, equipment, or services, financial support and volunteer personnel does not contravene the AdvaMed Code of Ethics as long as the decision to provide the support is:

- Made without undue commercial influence and free from any intent to inappropriately induce or reward purchase of products or services now or in the future; and
- Adequately documented to allow for appropriate record-keeping and applicable transparency reporting.

Donations

AdvaMed's Code of Ethics permits companies to make monetary or in-kind donations of product, equipment or services for charitable purposes, such as indigent care and patient or public education. Providing humanitarian support in response to COVID-19 is an appropriate charitable purpose, as long as it meets the following criteria:

- The donation addresses a humanitarian need directly related to the COVID-19 response and for a duration and amount that relates to the need during the COVID-19 crisis; and
- The donation is properly documented with inclusion of criteria related to duration of use and decision-making on timing and conditions for equipment retrieval (where applicable).

Donations and requests for donations related to the COVID-19 response fall into several categories, all of which are transfers of value that may trigger reporting under transparency legislation such as the U.S. Sunshine Act. These currently include but are not limited to:

- Loans of medical equipment (noting that such loans should not be undertaken to induce the purchase of related consumables);
- Software licenses/cloud service subscriptions;
- Donations of single/multiple use products; and
- Donations of financial support (on a humanitarian basis).

Donations made to hospitals or other clinical settings should be made to affiliated nonprofit entities with bona fide charitable and/or philanthropic purposes where possible but should be made in accordance with the above criteria in any case. Commercial personnel should not control or unduly influence the decision of whether a particular entity will receive support or the amount of the support. A Company's commercial personnel may provide input about a proposed charitable program or recipient but cannot make the final decision.

Volunteers/Staffing

Companies recognize the growing need for emergency staffing support where COVID-19 strains healthcare system clinical resources. In many cases, medically qualified employees seek to contribute their expertise by volunteering with healthcare providers in support of the COVID-19 fight. These can include field service, clinical specialist and qualified sales personnel.

Provided that the health of the volunteers and their coworkers can be reasonably safeguarded, AdvaMed supports these arrangements as long as they are appropriately documented and are not directed by commercial interests. Sales personnel who volunteer based on their expertise must not engage in any commercial activity during their volunteer service.

AdvaMed recommends that Companies:

- Create a process to approve and document any staff that seek to volunteer to support the COVID-19 response, including specifying the temporary nature of the service and the direct need related to the COVID-19 crisis;
- Involve legal, compliance and HR departments in this process and give consideration to the health and safety of Company staff both during and after the volunteer service;
- Require that all staff be properly qualified for the services; and
- Support nonprofit organizations where possible and avoid actual or the perception of favoritism.

Virtual Educational Events

The need for high-quality medical education and training grows ever greater even as restrictions on travel and large gatherings grow as well. Consequently, Companies are putting more resources into online and other virtual education events.

Supporting Third-Party Programs

The AdvaMed Code of Ethics allows MedTech Companies to support third-party educational and research programs through monetary, in-kind and other contributions, as long as they establish processes and guidelines so that decisions to support Third-Party Programs are made objectively and not used as unlawful inducements to Health Care Professionals. (Section III, IV) These arrangements can continue as third-party programs shift to a virtual format.

Company-Conducted Training & Education

The AdvaMed Code of Ethics allows MedTech Companies to pay for reasonable expenses to facilitate Health Care Professionals' participation in company-conducted training programs. Such expenses should continue to be considered under the Code's guidance on Educational Items (Section VIII), which allows the provision of educational items as long as they do not have a secondary, non-educational, purpose (e.g., it would be improper to provide a medical text on an iPad that is capable of personal use), and travel, lodging and meal expenses (Section VI, VII), which allow modest expenses for bona fide purposes to enhance the provision of presentation of scientific and educational information. These provisions continue to apply when meetings are held virtually.

Meals

Providing meals has given rise to some concerns specifically related to the COVID-19 response. In order to properly consider and manage the provision of meals to Health Care Professionals during Company-conducted training and education programs that are held virtually, AdvaMed recommends that Companies:

- Create a process to control meal ordering and delivery, addressing health and safety issues, in addition to ensuring that the meals are not used as an inappropriate inducement;
- Track attendance to ensure that only appropriate recipients of the training/education are receiving the meals; and
- Specify that no home delivery will be permitted.

Company Processes

In order to support rapid decision making, AdvaMed recommends that Member Companies explore all possibilities to expedite appropriate humanitarian efforts. This might include, among others: a centralized resource or site for submitting requests and tracking approvals; a simplified review and approval process; new and simplified forms; and a single approval committee with representatives from different divisions. In all cases, compliance personnel should be involved in whatever approval processes are chosen for the emergency support requests related to COVID-19.

All provisions of support should be properly documented. Where urgency may require acting before an internal process can be properly completed in advance, the required report should be completed as soon as possible after the support is provided. All provisions of support should be properly tracked to ensure relevant criteria are followed, including with respect to duration and equipment retrieval (where applicable).