Comparison of the AdvaMed Code of Ethics and the MEDEC Code of Conduct

Executive Summary:
The revised MEDEC Code of Conduct tracks closely with the AdvaMed Code of Ethics. Both Codes encourage ethical interactions between the industry and Healthcare Professionals (HCPs) and respect independent decision making by HCPs with regard to the health care of their patients. Noted differences include the MEDEC Code being silent on entertainment and payment of royalties. It permits modest gifts and branded promotional items to be given to HCPs. There is no equivalent section on the provision of reimbursement and health economics information, or the provision of evaluation and demonstration units. In a new section, the MEDEC Code defines “value added items” as part of a Request for Proposal only if they are related to the products or services being provided. Other industry Codes are silent on this point.

<table>
<thead>
<tr>
<th>AdvaMed Code of Ethics on Interactions with Health Care Professionals</th>
<th>MEDEC Code of Conduct with Healthcare Professionals</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Approved: December 18, 2008, Effective July 1, 2009</td>
<td>Approved: December 9, 2009, effective April 5, 2010</td>
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<tr>
<td><strong>I. Preamble: Goal and Scope</strong></td>
<td><strong>A. Goal</strong></td>
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<td>1. Defines the terms: “Companies”: companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. These products, technologies and services are defined as “Medical Technologies”. “Health Care Professional”: (HCP) those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States.</td>
<td>Canada’s Medical Technology Companies (“MEDEC”) is dedicated to advancing healthcare through innovative technologies, devices and diagnostics (“technologies”). MEDEC believes that access to high quality, cost-effective healthcare technology is paramount to the improvement of patient care. Recognizes that adherence to ethical standards and compliance with applicable laws is critical to the Canadian medical technology industry’s ability to continue its collaboration with Healthcare Professionals (HCPs), and encourages ethical business practices and socially responsible industry conduct related to interactions with HCPs. Respects the obligation of HCPs to make independent decisions regarding Company products. It supports and respects the guidelines and policies established by professional societies or organizations that outline the obligations of the profession, while interacting with the Canadian medical technology industry. Defines the term “Healthcare Professional”, broadly to include individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ medical technology products in Canada. The definition also includes both clinical and non-clinical people who make, or have material influence over product-related or purchasing.</td>
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<tr>
<td>2. Medical Technologies: makes a distinction between Medical Technologies which are highly dependent on “hands on” HCP interaction, and drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means.</td>
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<td>3. Interactions with HCPs: explains the scope and types of interactions with HCPs. a) Promote the advancement of Medical Technologies b) Enhance the Safe and Effective use of Medical Technologies c) Encourage Research and Education</td>
<td></td>
<td>This broad definition of HCP is carried over from the 2005 MEDEC Code.</td>
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</table>
d) Foster Charitable Donations and Giving

4. **The Purpose of the Code of Ethics:** recognizes that HCP’s first duty is to act in the best interest of patients, and the obligation to facilitate ethical interactions between Companies and HCPs.

5. A **footnote** notes that the principles are derived from a number of authorities, including the federal Anti-Kickback Statute. Reference to “unlawful inducement” relates to the Anti-Kickback Statute prohibitions.

<table>
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<tr>
<th>Point covered in Section I. 2. above.</th>
<th>B. Medical Technologies</th>
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<tr>
<td>MEDEC quotes the AdvaMed Code making the distinction between Medical Technologies which are highly dependent on “hands on” HCP interaction, and drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means.</td>
<td>In the 2005 MEDEC Code, Goal and Scope were sub-parts of the first section. In the revised Code, they are addressed individually and Section B was added.</td>
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<th>C. Scope</th>
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<td>Addresses points discussed in the Preamble of the AdvaMed Code, Including:</td>
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- **Advancement of Medical Technology.** Developing cutting-edge medical technology and improving existing products are collaborative processes between Companies and Healthcare Professionals.

- **Safe and Effective Use of Medical Technology.** The safe and effective use of medical technologies often requires Companies to offer HCPs appropriate instruction, education, training, service and technical support.

- **Research and Education.** Companies’ support of bona fide medical research, education and enhancement of professional skills serves patient safety and increases access to new technology.

Interactions with HCPs not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in decisions.
### II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.

1. **Annual Certification** Companies that adopt the Code are strongly encouraged to submit an annual certification that the Company has adopted the Code and has implemented an effective compliance program. Certification should be signed by the CEO and Chief Compliance Officer. AdvaMed will publish a list of Companies that have certified.

2. **Contact Information** AdvaMed member Companies must, and non-members may supply contact information for the Company’s Compliance Department or anonymous hot line to facilitate reporting of possible violations. AdvaMed will publish this information.

3. **Elements of an Effective Compliance Program:** Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program. 
   a) Written policies and procedures;
   b) Designated compliance officer and compliance committee;
   c) Conduct effective training and education;
   d) Develop effective lines of communication (including an anonymous reporting function);
   e) Conducting internal monitoring and auditing;
   f) Enforcing standards through well-publicized disciplinary guidelines; and
   g) Responding promptly to detected problems and undertaking corrective action.

4. **Note:** Companies adopting the Code shall communicate the principles of the Code to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

### D. Compliance with the MEDEC Code of Conduct

The MEDEC Code of Conduct applies to all MEDEC member companies. Non-member companies may use the MEDEC Code as guidance in their Company’s interaction with HCPs.

All Companies are strongly encouraged to adopt the Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with HCPs related to medical technologies. The main intent of a compliance program is to ensure that there is not any “undue influence” on a sale or transaction with a HCP.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely:

1. Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication (including an anonymous reporting function);
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines; and
7. Responding promptly to detected problems and undertaking corrective action.

Companies are encouraged to include an assessment of Code compliance in their internal monitoring and auditing process.

### III. Company-Conducted Product Training and Education

### E. Company-Sponsored Product Training and Education

Both Codes encourage non-member companies to follow their respective principles. They both reference the seven elements of an effective compliance program.

MEDEC does not have a certification provision, nor does it require member companies to provide contact information of their Compliance Department. It does, however, encourage Companies to include an assessment of Code compliance in their internal monitoring programs.
1. The Code defines:
   - **Training**: training on the safe and effective use of Medical Technologies
   - **Education**: communicating information directly concerning or associated with the use of Companies’ Medical Technologies, e.g., information about disease states and benefits to certain patient populations.

**FDA Required Training** The Code points out the FDA often mandates training and education to facilitate the safe and effective use of Medical Technologies.

2. Companies should adhere to the following principles concerning training and education:
   a) **Conducive Setting** Programs should be conducted in a setting conducive to the effective transmission of information. Settings may include clinical, educational or conference sites including hotels and other meeting facilities. They may also include the HCPs site.
   b) **Hands on Training** Training should be conducted at training facilities, medical institutions or laboratories. Training staff should be qualified. Sales employees may conduct the training if they have the technical expertise.
   c) **Modest meals and refreshments** may be provided if they are modest in value and subordinate in time to the training or education.
   d) **Travel and Lodging** Out-of-town travel and modest lodging may be provided the HCPs if there are objective reasons to support the need.
   e) **No Guests** Meals, refreshments, travel and lodging may be provided only to HCPs with a *bona fide* reason to attend the training.

Companies have a responsibility to make product education and training available to HCPs, a practice that is strongly encouraged. However, Companies also recognize the need for HCPs to preserve the freedom of the medical profession and maintain independence in ongoing education and assessment of Companies’ products and services.

The Code uses the following definitions: “Education” is defined as communicating information directly concerning or associated with the use of Companies’ medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations, and, “Training” is defined as training on the safe and effective use of medical technologies.

- Companies should ensure that the primary purpose of such programs is to address the educational needs of HCPs. Any hospitality, such as meals and refreshments should be modest in value and subordinate in time and focus to the educational component of the program. Activities primarily promotional in nature should not be considered as educational programs.
- Programs and events should be conducted in clinical, laboratory, educational, conference or other appropriate settings including the Company’s own facilities or commercially available meeting facilities that are conducive to effective transmission of knowledge. Where possible, programs requiring “hands-on” training in medical procedures should be held at training facilities, medical institutions, laboratories or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.
- Companies may pay for reasonable travel, lodging, meals and refreshment costs incurred by attending HCPs. (The Code defines “reasonable” as in accordance with the Company’s corporate travel policies and practices and the policies of the

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This section of the MEDEC Code carries over the term “hospitality” from the 2005 version. However, other pertinent sections:

F. Supporting Third-Party Educational Conferences,
H. Arrangements with Consultants, and
G. Sales, Promotional and Business Meetings,

Use the words “modest meals and refreshments”.

Throughout the revised AdvaMed Code the term “hospitality” was deleted in favor of, “modest meals” and “refreshments.”

The MEDEC Code provides guidance regarding the term “reasonable”, defining it as in accordance with a company’s corporate travel policies.
IV. Supporting Third-Party Educational Conferences

_Bona fide_ independent, education, scientific and policymaking conferences include educational conferences include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers.

Companies may support these through:

**Conference Grants** Grants must be provided to the conference sponsor to reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other HCPs in training. Grants may be provided when:

a) The gathering is primarily dedicated to promoting objective scientific and educational activities, and
b) The training institution or conference sponsor selects the attending HCPs in training.

- Grants should be paid ONLY to organizations with a genuine educational function
- The may be used to reimburse legitimate expenses for _bona fide_ educational activities.
- The conference sponsor controls the selection of program content, faculty, methods and materials.

**Conference Meals and Refreshments** Companies may provide:

- Funding to conference sponsors to support the provision of meals and refreshments to conference attendees
- Meals and refreshments themselves if they are provided:
  1. To all HCP attendees (note exception below)
  2. Consistent with applicable standards established by the conference sponsor

F. Supporting Third-Party Educational Conferences

_Bona fide_ independent, educational, scientific or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional or specialty medical associations, conferences sponsored by accredited continuing medical education providers and grand rounds.

Companies may support these conferences in various ways:

**Conference and Education Grants.** Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to institutions or relevant organizations to allow attendance by HCPs to support professional development. Companies may provide conference and educational grants when:

1. The gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and
2. The institution, organization or the conference sponsor selects the attending HCPs who are in professional development.

Such grants should be paid only to organizations with a genuine educational purpose or function and may be used only to reimburse the legitimate expenses for _bona fide_ educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organizations. The conference sponsor should be responsible for, and control the selection of, program content, faculty, educational methods and materials.

and any accrediting body.

**Note:** meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus to the purpose of the conference and separate from the educational portion of the conference.

**Faculty Expenses** Grants may be made for reasonable honoraria, travel, lodging and modest meals for *bona fide* faculty members.

**Advertising** Companies may purchase advertisements and lease booth space for Company displays.

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<tr>
<th>Companies may provide direct support for reasonable expenses (travel, modest meals, accommodation, and registration) to HCPs for professional development at third-party educational conferences when appropriate.</th>
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<tr>
<td><strong>Meals and Refreshments.</strong> Companies may provide funding to the conference sponsor to support the conference’s meals and refreshments. Also, Companies themselves may provide meals and refreshments for all HCP attendees, but only if it is provided in a manner that is also consistent with the sponsor’s guidelines. Any meals and refreshments should be modest in value and should be subordinate in time and focus to the purpose of the conference.</td>
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<tr>
<td><strong>Faculty Expenses.</strong> Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging and modest meals for HCPs who are <em>bona fide</em> conference faculty members.</td>
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<tr>
<td><strong>Advertisements and Demonstration.</strong> Companies may purchase advertisements and lease booth space for Company displays at conferences.</td>
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**V. Sales, Promotional, and Other Business Meetings**

Companies may conduct business meetings with HCPs:

- **Business Discussion** Discuss Medical Technology features, sales terms or contracts
- **Meals** Occasional modest meals and refreshments may be provided
- **Travel** When necessary, (e.g., plant tours or demonstration of non-portable equipment) reasonable travel costs and lodging may be provided
- **No Guests** Meals, refreshments, travel or lodging may not be provided for guests of HCPs or anyone without a *bona fide* interest in the information being shared at the meeting.

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<th>It is appropriate for Companies to conduct sales, promotional and other business meetings with HCPs to discuss, for example, product features, contract negotiations and sales terms, insofar as the relationship does not impede on the HCP’s ability to maintain professional autonomy and independence. It is also appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours, site visits or demonstrations of non-portable equipment). However, it is not appropriate to pay for meals, refreshments, travel, lodging or other expenses of guests of HCPs or any other person who does not</th>
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A notable difference between the Codes is the MEDEC Code permitting direct support for HCP professional development. This is a change from the 2005 Code. The AdvaMed Code requires that educational grants be paid only to organizations with a genuine educational function.

The 2010 MEDEC Code uses the term “meals and refreshments” rather than “hospitality” that was used in the 2005 Code.
VI. Consulting Arrangements with Health Care Professionals

Companies may pay HCP consultants fair market value for services that fulfill a legitimate business need and do not constitute an unlawful inducement. The following standards apply:

- **Agreements** should be written and describe all the services to be provided. Clinical research services should have a written research protocol.
- **Legitimate need** for the services should be identified and documented in advance of any arrangements.
- **Selection** should be based on the consultant’s qualifications and expertise to meet the defined need.
- **Compensation** should be fair market value and not based on past, present or anticipated business.
- **Expenses** Companies may pay for actual, reasonable and documented expenses, including travel, modest meals and lodging, incurred by the consultant to carry out the arrangement.
- **Venue** and circumstances of any meetings should be appropriate for the subject of the consultation, and conducive to the effective exchange of information.
- **Meals and refreshments** should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Recreation or entertainment should not be provided.
- **Sales Involvement** Sales personnel may provide input about the suitability of proposed consultant, but should not control or unduly influence the selection decision.

Provisions on Payment of Royalties

Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method.

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H. Arrangements with Consultants

It is appropriate to provide HCPs with reasonable compensation for performing bona fide consulting services, including research, participation on advisory boards, presentations at Company-sponsored training and product collaboration services. The following factors support the existence of a bona fide consulting arrangement between Companies and HCPs:

- **Company consulting arrangements** should be written, signed by the parties and specify all services to be provided.
- **Compensation paid to consultants** should be consistent with fair market value for the services provided.
- **Consulting agreements** should be entered into only where a documented legitimate need and purpose for the services is identified in advance.
- **Selection of consultants** should be on the basis of the consultant’s qualifications and expertise to address the identified purpose and should not be related to the volume or value of business generated by the consultant.
- **Company-sponsored meals, refreshments and meeting venues** that occur in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- **Companies may pay** for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Companies.

Both Codes emphasize this important point that there be a legitimate need for the services to be provided and that the need be documented in advance of any arrangements.

The 2010 MEDEC Code uses the term “meals and refreshments” rather than “hospitality” that was used in the 2005 Code.

There is no equivalent section on royalties in the MEDE Code.
Calculation of royalties should preserve the objectivity of medical decision-making and avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company’s product or technology or a requirement to market the product or technology upon commercialization.

Companies may elect to enter into separate agreements with HCPS for marketing services and are strongly encouraged to consider the appropriateness and practicality of excluding the HCP consultant’s purchases from the calculation of royalty payments.

VII. Prohibition on Entertainment and Recreation

Companies should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Examples include: golf, skiing, hunting, sporting equipment and leisure or vacation trips.

Such events or items should not be provided regardless of:

1. Their value,
2. Whether the HCP is a speaker or consultant,
3. Whether the entertainment or recreation is secondary to an educational purpose.

No equivalent section.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

Modest meals may be provided as an occasional business courtesy involving the presentation of scientific, educational, or business information, consistent with the following limitations:

**Purpose** The meal should be incidental to the *bona fide* presentation of scientific, educational or business information, and should provided in a manner conducive to the presentation. It should not be part of an entertainment or recreation event.

**Setting and Location** The setting should be conducive to *bona fide* scientific, educational or business discussion. Meals may occur at the HCP’s place of business, however, if that place is not available or conducive to such discussions, meals may be provided off-site. Examples include: (1) where the medical technology cannot easily be transported to the HCP’s
location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on site.

**Participants (No Guests)** Meals may be provided only to HCPs who actually attend the meeting, and may not be provided for an entire staff where everyone does not attend the meeting, i.e., no “dine and dash” programs. Meals may not be provided for guests of HCPs or anyone not having a *bona fide* professional interest in the information being shared.

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<tr>
<th>IX. Educational items; Prohibition on Gifts</th>
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<td>- Items that benefit patients or serve a genuine educational function occasionally may be provided to HCPs.</td>
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<td>- Items should have a FMV of less than $100, except text books and anatomical models.</td>
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<tr>
<td>- Items must not be capable of non-educational or non-patient-related uses.</td>
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<tr>
<td>- Non-educational branded promotional items may not be given to HCPs, even if of minimal value and related to the HCP's work or benefit patients.</td>
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<td>- Items such as wine, flowers, cookies, gift baskets, holiday gifts etc., or cash or cash equivalents are not permitted.</td>
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<tr>
<th>I. Gifts</th>
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<tr>
<td>Companies occasionally may provide modest gifts to HCPs. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from a Company should have a fair market value of less than $100 CDN. In addition, Companies may occasionally give HCPs branded promotional items of minimal value related to the HCP’s work or for the benefit of patients. Gifts may not be given in the form of cash or cash equivalents.</td>
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This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

This section remains unchanged from the 2005 version of the MEDEC Code and is similar to the previous version of the AdvaMed Code. This is the only reference in the MEDEC Code to samples or evaluation products.

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<th>X. Provision of Coverage, Reimbursement and Health Economics Information</th>
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<tr>
<td>Companies may provide accurate and objective reimbursement information on their products to HCPs, professional or patient organizations, patients and payors as follows:</td>
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<tr>
<td>- Identifying the clinical value of their technologies and services</td>
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<td>- Collaborating on joint advocacy on coverage, reimbursement and health economics issues</td>
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<td>- Providing information identifying coverage, codes and billing options regarding technologies on which they may be used</td>
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<td>- Providing information about the economically efficient use of their technologies</td>
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<td>- Providing information related to available reimbursement revenues and associated costs</td>
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<td>- Providing information relating to changes in coverage</td>
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**No equivalent section.**
or reimbursement amounts
- Providing support in the appropriate and efficient use of their technologies
- Assisting to obtain coverage decisions and in the preparation and submission of coverage requests, prior authorizations and appeals.

Companies may not interfere with HCPs independent clinical decision making or provide information as an unlawful inducement or suggest mechanisms for billing for unnecessary services or fraudulent practices to achieve inappropriate payment.

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<th>XI. Research and Educational Grants and Charitable Donations</th>
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| Companies may provide such grants and donations but not as an unlawful inducement. Companies should:
  a) Adopt objective criteria that exclude purchasing value of the recipient
  b) Implement procedures to ensure such grants are not used as an unlawful inducement
  c) Document such grants and donations. |

Companies’ sales personnel may provide input to, but not unduly influence grant and donation decisions or recipient selection.

**Research Grants** should have well-defined objectives and milestones and may not be linked to purchases of Medical Technologies

**Educational Grants** companies may make such grants to conference sponsors or training institutions but not to individual HCPs
- *Advancement of Medical Education* Companies may make grants to support genuine education of medical students, residents and fellows (See also Section IV)
- *Public Education* - Companies may make grants to support patient or public education on health care topics

**Charitable Donations** Companies may make donations to organizations with *bona fide* charitable missions such as supporting indigent care, or patient and public education.

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<tr>
<th>J. Grants and other Charitable Donations</th>
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<tr>
<td>Companies may make donations for a charitable purpose, such as supporting genuine independent medical research for the advancement of medical science or education, patient education, public education, improvement of healthcare delivery and increased patient access to healthcare technology, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. It is not appropriate for Companies to make such donations for the purpose of unlawfully inducing HCPs to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Companies' products. All donations should be appropriately documented.</td>
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Other than changing the term "members" to "companies", the content of this section remains unchanged from the 2005 version of the MEDEC Code.
### XII. Evaluation and Demonstration Products

This section of the Code discusses the provision of evaluation and demonstration products and is not intended to address any other arrangement.

**Evaluation Products:**
- Provided at no charge to assess functionality and to determine future purchase and use of that product
- Expected to be used in patient care
  - Single Use/Consumable/Disposable- may be provided in quantity reasonably necessary for adequate evaluation
  - Multiple Use/Capital- furnished only for the time reasonably necessary for adequate evaluation. The terms of such an evaluation should be set in writing, Companies should retain title to the product, and the product should be removed promptly upon completion of the evaluation.

**Demonstration Products:**
- Typically unsterilized single-use products typically used for HPC and patient awareness, education and training.
- Not expected to be used in patient care.
- Identified as not intended for patient use and typically designated as “Sample,” or “Not for Human Use,” on the packaging and/or other documentation that accompanies the product.

Companies should provide HCPs with documentation disclosing the no-charge status of evaluation and demonstration products.

### K. Value Added with Request for Proposals (RFP) and Tenders

It is not unlawful for healthcare facilities to request “value added” items, grants or donations from Companies in conjunction with a Request for Proposals (RFP) or tender process. Therefore “value added” requests are not unlawful inducements. However, MEDEC does not consider all “value added” requests as procurement best practice, unless the “value add” relates to the product and services requested in the RFP and are clearly defined (documented) within the RFP document.

Mention of sample products is made in Section I, Gifts, where the MEDEC Code states: "This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation."

In Canada, there is an issue with “value add” clauses in RFPs and Tenders. This section seeks to define that practice more clearly for companies.