These decision trees are intended to provide a summary of the existing AdvaMed Code as it relates to the subject matter of the illustrative tool. These should not be utilized in lieu of the complete AdvaMed Code of Ethics. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.
Illustrative Charitable Donations Best Practices
Section XI: Research and Educational Grants and Charitable Donations

Purpose/Scope: The following decision tree is intended to provide a summary of the existing AdvaMed Code as it relates to Charitable Donations. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

**Is the donation being made to a bona fide charitable organization?**

Note: Relevant factors to consider in determining whether an entity is a bona fide charitable organization include (1) the entity’s tax status, (2) the entity’s corporate status under state law, and (3) whether the organization has a charitable mission or purpose [FAQ 51].

**Is the donation being made for a bona fide charitable purpose? [Section XI, FAQ 42]**

**Was this charitable donation request and/or dollar amount controlled or unduly influenced by sales personnel? [Section XI]**

**Is the charitable donation appropriately documented? [Section XI]**

**Is the donation offered as an unlawful inducement? [Section XI]**

Note: The Code recommends that Companies establish appropriate safeguards regarding such donations to ensure they are not offered as an unlawful inducement. [Section XI]

**This charitable donation is prohibited by the Code**

**This charitable donation is permitted by the Code**

**Is the donation being made to an individual HCP engaged in a genuine charitable activity for the support of a bona fide charitable mission?**

Note: one example is providing medical technologies to individuals who perform volunteer disaster relief abroad [FAQ 44]. This is not the only example, and such donations are not limited to disaster relief efforts.

**Does the individual HCP receive charitable donations only in rare instances? [Section XI]**

Note: a company should consider instituting policies limiting the frequency of charitable donations to individual HCPs.
Illustrative Consulting Arrangements Best Practices & Considerations

Section VI: Consulting Arrangements with Health Care Professionals

Purpose/Scope: The following chart is intended to provide a summary of the existing AdvaMed Code and other potential considerations as it relates to engaging HCPs as consultants. Under the AdvaMed Code, a consulting arrangement is any relationship between an HCP and a Company where services are provided to the Company by the HCP and are exchanged for remuneration. Please see FAQ 31 for a list of examples of consulting arrangements. This chart should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

Are the consulting services intended to fulfill a legitimate need identified in advance? [Section VI]

Note: A legitimate need arises when a Company requires the services of an HCP in order to achieve a proper business objective. Engaging an HCP for the purpose of generating business directly from such HCP is not a proper business objective [FAQ 35].

Has the consultant been selected based upon his/her qualifications and prior experience necessary to meet the company’s defined need? [Section VI; FAQ 18, 19, 20]

Note: When considering a consultant’s qualifications, it is acceptable to consider experience with, usage of, or familiarity with a particular medical technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement [FAQ 32].

Will the consultant receive no more than fair market value in exchange for providing the services? [Section VI]

Note: When establishing fair market value, a company should use objective, verifiable criteria and the methods used should be documented [FAQ 34].

Is the consulting agreement in writing, and does it describe all services to be provided? [Section VI]

Has the Company’s sales personnel controlled or unduly influenced the decision to engage the HCP as a consultant? [Section VI]

Is the consulting agreement being offered as an unlawful inducement? [Section VI]

Other Considerations - Meetings with Consultants

When meeting with a consultant, a Company should assess:

- Whether there is a bona fide business justification for holding the meeting;
- Whether the location and venue are suitable for and conducive to the exchange of information;
- Whether the value of any Company-sponsored lodging is modest;
- Whether any ancillary meals & refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and
- Whether the overall meeting has a genuine business purpose and tenor.

This consulting agreement is prohibited by the Code

This consulting agreement is permitted by the Code
**Illustrative Demonstration/Evaluation Unit Best Practices**

**Section XII: Evaluation and Demonstration Products**

*Purpose/Scope:* The following decision tree is intended to provide a summary of the existing AdvaMed Code as it relates to the provision of demonstration and evaluation units to Health Care Professionals (HCPs). It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

**Evaluation Units** may be provided at no charge to allow HCPs to assess the appropriate use and functionality of the product and determine whether to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

**Demonstration Units** are typically unsterilized single use products or mock-ups used, for example, to show a patient the type of device that will be implanted in the patient. Demonstration Units typically are not intended to be used in patient care, and are typically identified as not intended for patient use.

---

**Decision Tree: Evaluation and Demonstration Products**

1. **Is it a single-use item or a multiple-use item?**
   - **Single Use**
   - **Multiple Use**

2. **Is the number of single-use products provided not more than necessary to allow adequate evaluation? [Section XII]**
   - **Yes**
   - **No**

3. **Has the Company provided the HCP with documentation and disclosure regarding the no-charge status of the evaluation product? [Section XII]**
   - **Yes**
   - **No**

4. **This item is a permitted evaluation item and may be provided**

5. **Is the item furnished only for a period of time that is reasonable to allow an adequate evaluation? [Section XII]**

   - **Note:** The specific length of time reasonably necessary for an HCP to assess a multiple-use product will depend on the frequency of anticipated use, the duration of required training, the number of HCPs who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations [FAQ 53].

6. **Does the Company retain title to the evaluation product during the evaluation period? [Section XII]**
   - **Yes**
   - **No**

7. **Does the Company have a process in place for promptly removing multiple-use products from the HCP's location at the conclusion of the evaluation period (unless the HCP purchases or leases the product)? [Section XII]**
   - **Yes**
   - **No**

8. **Is the product provided for HCP and/or patient awareness, education, and training?**
   - **Yes**
   - **No**

9. **This item is prohibited by the Code. Do not provide.**
**Illustrative Educational Item or Patient Benefit Item Best Practices**

**Section IX: Educational Items; Prohibition on Gifts**

Purpose/Scope: The following chart is intended to provide a summary of the existing AdvaMed Code as it relates to the provision of educational items or patient benefit items to Health Care Professionals (HCPs). It is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII of the Code, nor should it be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

**Is the item to be provided to an HCP?**

- **Yes**
  - **Is the item intended for the patient (e.g., starter kit, educational brochures)? [Section IX, FAQ 42]**
    - **Yes**
      - **Is the item capable of a non-educational, non-patient related purpose by the HCP? [Section IX]**
        - **Yes**
          - **Is the item a non-educational branded promotional item? [Section IX]**
            - **Yes**
              - **Does the item have a fair market value of less than $100, except for medical textbooks and anatomical models? [Section IX]**
                - **Yes**
                  - **Is the item offered as an unlawful inducement? [FAQ 42]**
                    - **Yes**
                      - **This item is prohibited by the Code. Do not provide.**
                      - **No**
                        - **This item is a permitted patient benefit item and may be provided**
                - **No**
                  - **This item is a permitted educational item and may be provided**
            - **No**
              - **This item is prohibited by the Code. Do not provide.**
          - **No**
            - **This item is a permitted educational item and may be provided**
        - **No**
          - **This item is prohibited by the Code. Do not provide.**
    - **No**
      - **Is the item capable of a non-educational, non-patient related purpose by the HCP? [Section IX]**
        - **Yes**
          - **Is the item a non-educational branded promotional item? [Section IX]**
            - **Yes**
              - **Does the item have a fair market value of less than $100, except for medical textbooks and anatomical models? [Section IX]**
                - **Yes**
                  - **Is the item offered as an unlawful inducement? [FAQ 42]**
                    - **Yes**
                      - **This item is prohibited by the Code. Do not provide.**
                      - **No**
                        - **This item is a permitted educational item and may be provided**
                - **No**
                  - **This item is a permitted educational item and may be provided**
            - **No**
              - **This item is a permitted patient benefit item and may be provided**
          - **No**
            - **This item is prohibited by the Code. Do not provide.**

- **No**
  - **Does providing the item to the HCP serve a genuine educational function for the HCP? [Section IX]**
    - **Yes**
      - **Is the item intended for the patient (e.g., starter kit, educational brochures)? [Section IX, FAQ 42]**
        - **Yes**
          - **Is the item capable of a non-educational, non-patient related purpose by the HCP? [Section IX]**
            - **Yes**
              - **Is the item a non-educational branded promotional item? [Section IX]**
                - **Yes**
                  - **Does the item have a fair market value of less than $100, except for medical textbooks and anatomical models? [Section IX]**
                    - **Yes**
                      - **Is the item offered as an unlawful inducement? [FAQ 42]**
                        - **Yes**
                          - **This item is prohibited by the Code. Do not provide.**
                          - **No**
                            - **This item is a permitted educational item and may be provided**
                    - **No**
                      - **This item is a permitted educational item and may be provided**
                - **No**
                  - **This item is a permitted educational item and may be provided**
            - **No**
              - **This item is a permitted patient benefit item and may be provided**
        - **No**
          - **Is the item capable of a non-educational, non-patient related purpose by the HCP? [Section IX]**
            - **Yes**
              - **Is the item a non-educational branded promotional item? [Section IX]**
                - **Yes**
                  - **Does the item have a fair market value of less than $100, except for medical textbooks and anatomical models? [Section IX]**
                    - **Yes**
                      - **Is the item offered as an unlawful inducement? [FAQ 42]**
                        - **Yes**
                          - **This item is prohibited by the Code. Do not provide.**
                          - **No**
                            - **This item is a permitted educational item and may be provided**
                    - **No**
                      - **This item is a permitted educational item and may be provided**
                - **No**
                  - **This item is a permitted educational item and may be provided**
            - **No**
              - **This item is prohibited by the Code. Do not provide.**
    - **No**
      - **Is the item a non-educational branded promotional item? [Section IX]**
        - **Yes**
          - **Does the item have a fair market value of less than $100, except for medical textbooks and anatomical models? [Section IX]**
            - **Yes**
              - **Is the item offered as an unlawful inducement? [FAQ 42]**
                - **Yes**
                  - **This item is prohibited by the Code. Do not provide.**
                  - **No**
                    - **This item is a permitted educational item and may be provided**
            - **No**
              - **This item is a permitted educational item and may be provided**
        - **No**
          - **This item is a permitted educational item and may be provided**

**Items not provided to HCPs are outside the scope of the AdvaMed Code.**

Note: For items provided directly to the patient, companies must undertake their own analysis of the federal prohibitions against offering remuneration to Medicare Beneficiaries to induce the selection of providers or products.

**Examples of prohibited gifts include:**
- All items capable of non-educational, nonpatient-related use (e.g., iPod, iPad, DVD player);
- Non-educational branded promotional items (e.g., pens, notepads, mugs);
- Gifts such as wine, flowers, cookies, chocolates, gift baskets, holiday gifts, or cash/cash equivalents;
- Giving flowers, fruit baskets, etc. to recognize HCP life events (wedding, birth, anniversary, death, etc.); and
- Raffling off items (or giving such items away at a tradeshow) to HCPs that would otherwise be prohibited.

[Section IX, FAQ 38, 40, 41, 42]
Purpose/Scope: Companies may provide grants to support genuine medical education and research. The following chart is intended to provide a summary of the existing AdvaMed Code and other potential considerations as it relates to fellowship grants. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

Illustrative Fellowship Grant Funding Best Practices & Considerations

Section XI: Research and Educational Grants and Charitable Donations

Does the fellowship in question have an academic or charitable affiliation? [Section XI]

Yes

Is the fellowship grant being used to support the genuine medical education of a fellow (or fellows) participating in a fellowship program that is charitable or has an academic affiliation? [Section IV, FAQ 47 and 51]

No

Is the fellowship grant being used to support the genuine medical education of a fellow (or fellows) participating in a fellowship program that is charitable or has an academic affiliation? [Section IV, FAQ 47 and 51]

Yes

Was this fellowship grant request and/or dollar award amount controlled or unduly influenced by sales personnel? [Section XI]

No

Is the fellowship grant appropriately documented? [Section XI]

Yes

Is the fellowship grant recipient (payee) an individual HCP? [Section XI]

No

Is the fellowship grant provided as an unlawful inducement? [Section XI, FAQ 47]

Note: The Code recommends that Companies adopt objective criteria for providing grants to ensure that funding decisions do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient. [Section XI, FAQ 49]

Support of this fellowship grant is not permitted by the Code

Support of this fellowship grant is permitted by the Code

Other Considerations - Fellowship Grant Funding

There are many factors, depending on the particular circumstances, that may be considered when providing a fellowship grant, although not every factor is necessarily relevant in each situation. A Company may consider some or all of the following factors, in a fellowship grant, but it is important to judge each fellowship and request for funding by the totality of the circumstances.

- Program accreditation status (where applicable)
- Faculty qualifications or expertise (e.g., board certified in this specialty)
- Program candidate selection process and/or eligibility requirements (including the Company’s involvement in program selection or candidate matching to ensure that the Company’s involvement cannot be construed as an unlawful inducement)
- Program training objectives (e.g., well established curriculum, what will the fellow learn during the program, etc.)
- Defined goals and objectives
- Use of funds for appropriate educational/research purposes
The term grand rounds may have various definitions, but often refers to a meeting of HCPs in an institution to review current cases, new advancements in medical procedure, difficult case presentations, and other topics related to the specialties of the group. Companies support grand rounds in various ways; for example, they can provide company-conducted training and education, or they can provide support in the form of a grant. For purposes of applying the AdvaMed Code, it is conceivable that these two approaches may apply as depicted below:

1. Does the requestor/sponsor of grand rounds have control of the selection of program content, faculty, educational methods, and materials? [Section IV, FAQ 18]
   - No
   - Yes

2. Review grand rounds request as Company Conducted Training
   - Is the training being conducted in a setting that is conducive to the effective transmission of information (e.g., clinical, educational, conference, or other settings)? [Section III]
     - No
     - Yes

3. Does the training staff have proper qualifications and expertise to conduct the training? [Section III]
   - No
   - Yes

4. To the extent that meals are provided, are such meals modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting? [Section III]
   - No
   - Yes

If all of the above conditions are met, the grand rounds activity is permitted by the Code. If any of the conditions are not met, the grand rounds activity is not permitted by the Code.
Illustrative Meal/Refreshment Provision Best Practices

**Code Section VIII - Modest Meals Associated with Health Care Professional Business Interactions**

**Purpose/Scope:** The following chart is intended to provide a summary of the existing AdvaMed Code as it relates to the provision of meals and refreshments to Health Care Professionals (HCPs). It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart.

Moreover, it is important to note that the guidance below is applicable as it relates to all meals provided to HCPs; however, some states have enacted laws that are more stringent than this guidance and for HCPs licensed in those states, the more stringent state law should be followed. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

All references to “meals” in the decision tree refer to both “meals” and “refreshments.”

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<table>
<thead>
<tr>
<th>Decision Tree</th>
<th>Meal(s) should not be provided</th>
<th>Meal(s) may be provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose (Q1): Is the meal being provided in conjunction with an HCP interaction with a bona fide business purpose?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Purpose (Q2): Is the meal subordinate in time and focus to the bona fide presentation of scientific, educational, or informational business purpose of the meeting? [Section VIII]</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Purpose (Q3): Is the meal part of an entertainment or recreational event?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Value (Q1): Is the business meal modest and occasional? [Section VIII]</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Setting &amp; Location (Q1): Is the venue/setting conducive to bona fide scientific, educational, or business discussions? [Section VIII]</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Participants (Q1): Is the meal for an individual who has a bona fide professional interest in the information being shared at the meeting?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Participants (Q2): Is the meal for only individuals in attendance at the event?</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note: The Code prohibits meals where the primary purpose of the meal is to develop general goodwill and business relationships. [FAQ 37]

Note: A business meal should not be used for entertainment or recreational purposes. [FAQ 37]

Entertainment and recreational events include, but are not limited to, the following: the theater, sporting events, golf, skiing, hunting, and leisure or vacation trips. [Section VIII]

Note: The Code precludes the extension of meals to all persons, such as HCP guests/spouses, without a bona fide professional interest in the meeting. [Section VIII, FAQ 22]

Note: The Code precludes “dine and dash” or take out drop off where the Company representative is not present. [Section VIII]

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Illustrative Plant Tours Best Practices & Considerations

Section V: Sales, Promotional, and Other Business Meetings

Purpose/Scope: The following chart is intended to provide a summary of the existing AdvaMed Code and other potential considerations as it relates to plant tours. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms. Moreover, it is important to note that the guidance below is applicable as it relates to plant tours; however, some states have enacted laws that are more stringent than this guidance and in those states, and for HCPs licensed in those states, the more stringent state law should be followed.

Does the HCP attending the plant tour have a bona fide professional interest in the information being shared? [Section V]

Other Considerations: A Company may consider the following factors in considering the bona fide professional interest of the HCP:
- Presence of non-portable equipment
- Exposure to quality processes
- Exposure to manufacturing processes
- Frequency of plant tours for individual HCPs

To the extent that meals are provided, are such meals modest in value? [Section V, FAQ 22]

- Refer to Section VIII for additional principles related to the provision of meals associated with HCP business interactions.
- Note: The Code precludes paying for meals for HCP guests/spouses, without a bona fide professional interest in the meeting. [Section V, FAQ 22]
- Note: Companies should also be mindful of the Code’s prohibition on entertainment and recreation. [Section VII]

To the extent that out-of-town travel is necessary to attend a plant tour, is the travel for attending HCPs reasonable with modest lodging (if applicable)? [Section III and V, FAQ 23]

- Note: The Code precludes paying for out-of-town travel for HCP guests/spouses, without a bona fide professional interest in the meeting. [Section V, FAQ 22 and 23]
- Note: A Company should be deliberate in selecting the location and venue of business meetings such as a plant tour [FAQ 22]
- Other Considerations: A Company may also consider the following:
  - Limiting payments for out-of-town travel to that necessary for the plant tour (e.g., no extension of travel days for HCP personal travel)
  - Following an agenda aligned with the HCP’s bona fide professional interest

This plant tour is not permitted by the Code

This plant tour is permitted by the Code
Section X: Coverage, Reimbursement, and Health Economics Information

Purpose/Scope: As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to Medical Technologies may be dependent on HCPs having timely and complete coverage, reimbursement, and health economics information. Consequently, a Company may provide such information in certain cases. The following chart is intended to provide a summary of the existing AdvaMed Code as it relates to the provision of coverage, reimbursement, and health economics information. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

Is the information being provided accurate & objective?

- Yes
- No

In providing the information, is the Company interfering with the HCP’s independent clinical decision making?

- Yes
- No

In providing the information, is the Company providing free services that eliminate an overhead or other expense that the HCP would otherwise have incurred as part of its business operations if doing so would amount to an improper inducement?

- Yes
- No

Is the information suggestive of mechanisms for billing for services that are not medically necessary?

- Yes
- No

Is the information suggestive of mechanisms for engaging in fraudulent practices to achieve inappropriate payment?

- Yes
- No

Is the information provided as an unlawful inducement? [Section X, FAQ 47]

- Yes
- No

Examples of Permissible Activities involving the provision of coverage, reimbursement, and health economic information:

- Identifying the clinical value of the Company’s medical technologies and the services and procedures in which they are used
- Collaborating with HCPs to conduct joint advocacy on coverage, reimbursement, and health economics issues
- Promoting accurate payor claims by providing information to HCPs regarding the Company’s medical technologies
- Providing information about the economically efficient use of the Company’s medical technologies
- Providing information related to the Company’s medical technologies regarding available reimbursement revenues and associated costs
- Providing information relating to changes in coverage or reimbursement amounts
- Providing information designed to offer technical or other support
- Providing HCPs with assistance in obtaining patient coverage decisions from payors

Providing this information is permitted by the Code

Providing this information is not permitted by the Code
Section XI: Research and Educational Grants and Charitable Donations

This chart addresses grants made to HCPs for independent medical research. It is not intended to address company-initiated or directed research involving a Company’s Medical Technologies.

Is the research grant intended to support independent medical research with scientific merit? [Section XI]

- Yes
- No

Does the research activity in question have well-defined objectives and milestones? [Section XI]

- Yes
- No

Note: A Company should not give research grants that are unrestricted or that can be used for any purpose [FAQ 49]

Was this research grant request and/or dollar award amount controlled or unduly influenced by sales personnel? [Section XI]

- Yes
- No

Is the research grant appropriately documented? [Section XI]

- Yes
- No

Is the research grant provided as an unlawful inducement? [Section XI, FAQ 47]

- Yes
- No

Note: The Code recommends that companies adopt objective criteria for providing grants to ensure that funding decisions do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient. [Section XI]

Note: While research activities may often be based on the use of a Company’s medical technologies, a research grant may not be directly or indirectly linked to a requirement to purchase the Company’s medical technologies. [Section XI]

Support of this research grant is NOT permitted by the Code.

Other Considerations – Research Grant Funding

There are many factors, depending on the particular circumstances, that may be considered when providing a research grant, although not every factor is necessarily relevant in each situation. A company may consider some or all of the following factors, in a research grant, but it is important to judge each request for funding by the totality of the circumstances.

- The overall budget for the research
- The identity and expertise of the investigators involved in the research, including:
  - Any investigator’s status as a consultant to the Company
  - Any investigator’s listing on the Office of Inspector General’s List of Excluded Individuals
- Whether the grant amount is consistent with Fair Market Value for the research services to be performed (as established through objective, verifiable criteria)
- The scientific and clinical legitimacy of the proposed research
- Defined goals and objectives: Are milestones clear, well-defined, and tied to specific payments or expenses?
- Use of funds for appropriate educational/research purposes

This research grant is permitted by the Code.
Illustrative Royalty Best Practices

Section XI: Consulting Arrangements with Health Care Professionals; Provisions on Payment of Royalties

Purpose/Scope: The following decision tree is intended to provide a summary of the existing AdvaMed Code as it relates to the payment of royalties. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

- Is the Company entering into an agreement with an HCP to license existing intellectual property??
  - Yes
    - Is the royalty payment consistent with fair market value for the intellectual property in question? [Section VI]
      - Yes
        - Does the Company have a bona fide business need to license the intellectual property? [Section VI]
        - Yes
          - Is the HCP expected to make a novel, significant, or innovative contribution to the development of a product, technology, process, or method? [Section VI]
            - Yes
              - Is the contribution by the HCP appropriately documented? [Section VI]
                - Yes
                  - This royalty arrangement is permitted by the Code.
                - No
                  - This royalty arrangement is NOT permitted by the Code.
            - No
              - Is the payment consistent with fair market value? [Section VI]
                - Yes
                  - Is the royalty payment conditioned on a requirement that the HCP purchase, order, or recommend any product or Medical Technology of the Company? [Section VI]
                    - Yes
                      - This royalty arrangement is NOT permitted by the Code.
                    - No
                      - This royalty arrangement is permitted by the Code.
                - No
                  - Is the royalty payment conditioned on a requirement that the HCP market the product or medical technology upon commercialization? [Section VI]
                    - Yes
                      - This royalty arrangement is NOT permitted by the Code.
                    - No
                      - This royalty arrangement is permitted by the Code.
    - No
      - Does the Company have a bona fide business need to license the intellectual property? [Section VI]
        - Yes
          - Is the HCP expected to make a novel, significant, or innovative contribution to the development of a product, technology, process, or method? [Section VI]
            - Yes
              - Is the contribution by the HCP appropriately documented? [Section VI]
                - Yes
                  - This royalty arrangement is permitted by the Code.
                - No
                  - This royalty arrangement is NOT permitted by the Code.
            - No
              - Is the payment consistent with fair market value? [Section VI]
                - Yes
                  - Is the royalty payment conditioned on a requirement that the HCP purchase, order, or recommend any product or Medical Technology of the Company? [Section VI]
                    - Yes
                      - This royalty arrangement is NOT permitted by the Code.
                    - No
                      - This royalty arrangement is permitted by the Code.
                - No
                  - Is the royalty payment conditioned on a requirement that the HCP market the product or medical technology upon commercialization? [Section VI]
                    - Yes
                      - This royalty arrangement is NOT permitted by the Code.
                    - No
                      - This royalty arrangement is permitted by the Code.

Note: Arrangements involving the payment of royalties to an HCP should meet the contractual standards set forth in Section VI of the Code.

Note: The Code strongly encourages Companies to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the HCP and/or members of the HCP's practices.
Illustrative Third Party Educational Conferences Best Practices & Considerations

Section IV: Supporting Third Party Educational Conferences

**Purpose/Scope:** The following chart is intended to provide a summary of the existing AdvaMed Code and other potential considerations as it relates to supporting third party educational conferences. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms.

**KEY TERMS**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational Support</td>
<td>Refers to funds granted to a third party conference sponsor with the intent of reducing conference costs – that is, legitimate expenses and bona fide educational activities.</td>
</tr>
<tr>
<td>Non-Educational Support</td>
<td>Refers to funds paid to a third party conference sponsor with the intent of promoting the company. This can include purchasing exhibit space or other advertising during the conference; however, separate policies and procedures may govern, and these costs may be negotiated in a separate agreement.</td>
</tr>
<tr>
<td>Company Conducted Training and Education</td>
<td>Refers to training and/or educational programs designed and conducted by an individual company and not subject to the control of a third party conference sponsor. These types of programs may occur in conjunction with third party conferences; however, separate policies and procedures may govern.</td>
</tr>
</tbody>
</table>

**OTHER CONSIDERATIONS - Educational Support**

There are many factors, depending on the particular circumstances, that may be considered when providing Educational Support, although not every factor is necessarily relevant in each situation. A company may consider some or all of the following factors, in addition to other considerations, when determining whether to provide Educational Support to a third party conference, but it is important to judge each conference and request for funding by the totality of the circumstances. A potentially questionable resort venue, for example, may be outweighed by a robust agenda, attendance controls, and conference marketing that focus on educational content.

**VENUE**
- Is the venue a resort location?
- Is it easily accessible, centrally located for attendees?
- Is it a well-known conference location?
- Will the conference be the attendees’ main reason for being at the venue?
- Is this venue appropriate for the targeted attendees/intended audience?

**MARKETING MATERIALS**
- How does the conference market itself to potential attendees?
- Is the education the focus, or is it recreation?

**BUDGET**
- What is the total budget of the conference?
- How much of the total budget will go towards educational content and how much is overhead?
- What percentage of the total budget will the company’s grant represent?

**CONFERENCE TOPIC**
- Is the topic relevant to the business & supportive of business objectives?

**AGENDA**
- Is the agenda robust?
- Are there large gaps in the day for recreational activities?
- Are sessions mandatory, or are some labeled “optional?”

**Support of this 3rd party educational conference is permitted by the Code**

**Support of this 3rd party educational conference is not permitted by the Code**
Illustrative Best Practices & Considerations for Health Care Professional Travel

Purpose/Scope: The following chart is intended to provide a summary of the existing AdvaMed Code and other potential considerations as it relates to a Company paying for HCP travel. It should not be utilized in lieu of the complete AdvaMed Code of Ethics. Companies are not obligated to follow this chart. Refer to the AdvaMed Code for definitions of HCP, Company, and other terms. Moreover, it is important to note that some states have enacted laws that are more stringent than this guidance and in those states, and for HCPs licensed in those states, the more stringent state law should be followed.

Note: The AdvaMed Code covers interactions with HCPs to the extent that they provide services in the United States, even if the interaction occurs outside the country (such as a conference or other event). [FAQ 4]

Is your company considering paying for a Health Care Professional’s travel for Company-Conducted Training and Education? [Section III]

- Are there objective reasons to support the need for out-of-town travel (e.g., efficient provision of training and/or education in a central location)? [Sec. III, FAQ 16]
  - Yes
  - No

- Is the travel location appropriate for, and conducive to, accomplishing the purpose of the training? [FAQ 23]
  - Yes
  - No

- Is the travel provided reasonable in nature? [Sec. III, V, or VI]
  - Yes
  - No

- Is the travel being provided to the HCP as an unlawful inducement? [Sec. III]
  - Yes
  - No

- This travel is permitted under the AdvaMed Code

Is your company considering paying for a Health Care Professional’s travel for a Sales, Promotional, or Other Business Meeting? [Section V]

- Is there an objective need for the travel to conduct a business meeting (e.g., a plat tour or a demonstration of non-portable equipment)? [Sec. V]
  - Yes
  - No

- Is the travel location appropriate for, and conducive to, accomplishing the purpose of the meeting? [FAQ 23]
  - Yes
  - No

- Is the travel necessary to carry out the consulting arrangement? [Section VI]

- Are the venue and circumstances of the meeting appropriate to the subject matter of the consultation? [Sec. VI]
  - Yes
  - No

- This travel is not permitted under the AdvaMed Code