



AdvaMed

ADVAMED CODE OF ETHICS

Illustrative Best Practices Tools



ADVAMED CODE OF ETHICS

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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.

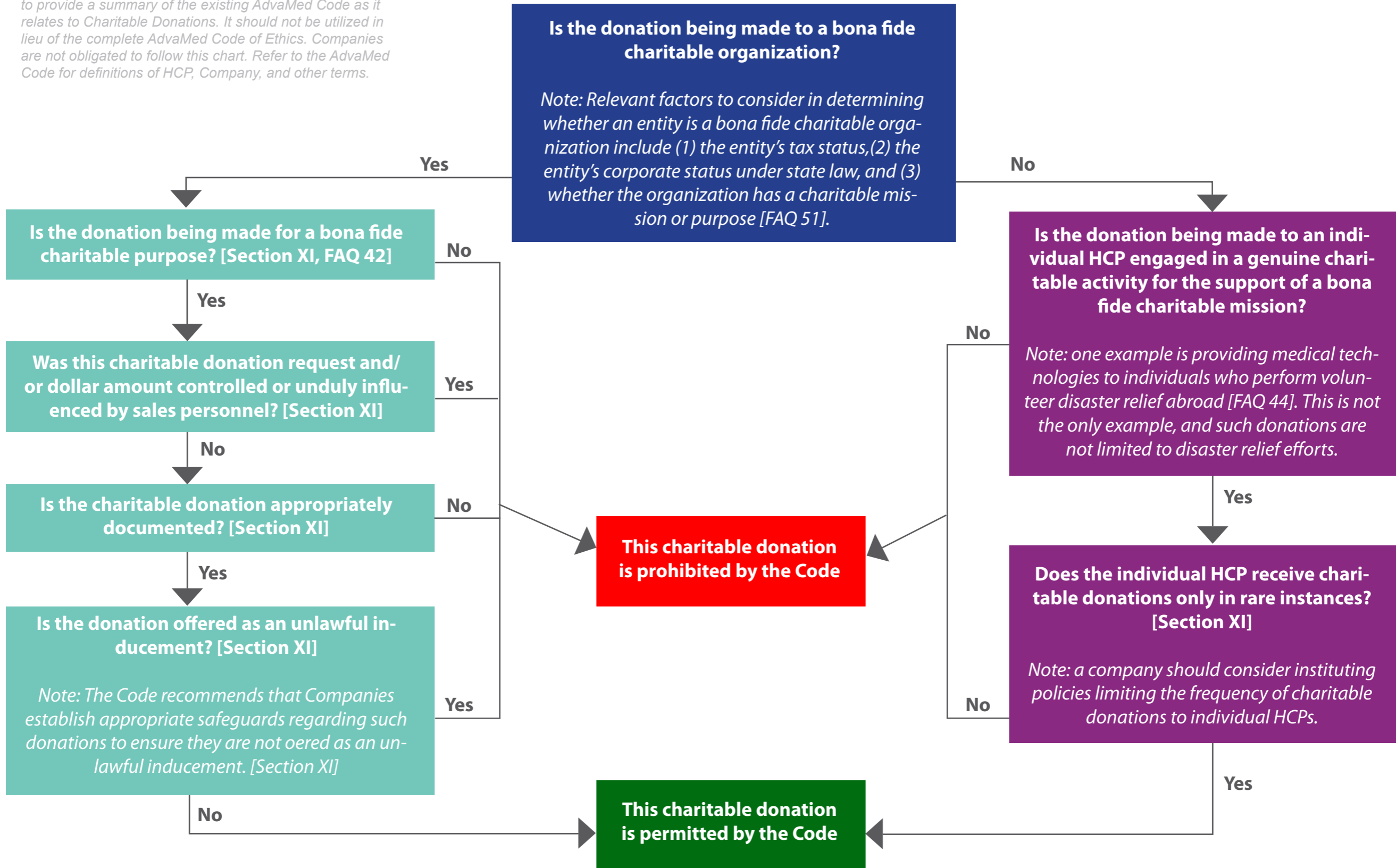
[Click on the Topic to Jump to the Tool](#)



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.



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 denitions of HCP, Company, and other terms.

Are the consulting services intended to fulfill a legitimate need identified in advanced? [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 qualications 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]

No
No
No
No
Yes
Yes

This consulting agreement is prohibited by the Code

This consulting agreement is permitted by the Code

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.

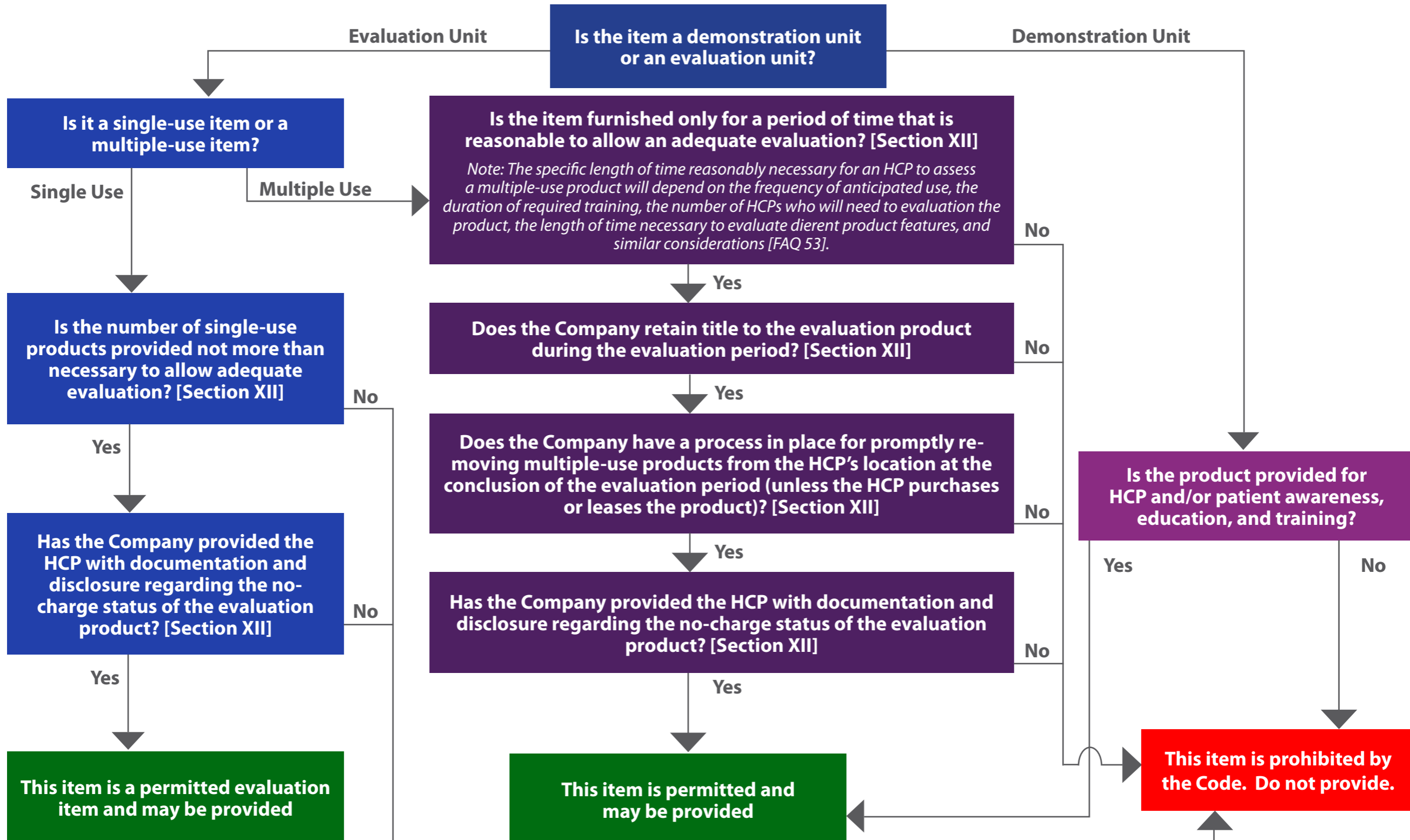
Illustrative Demonstration/Evaluation Unit Best Practices

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.

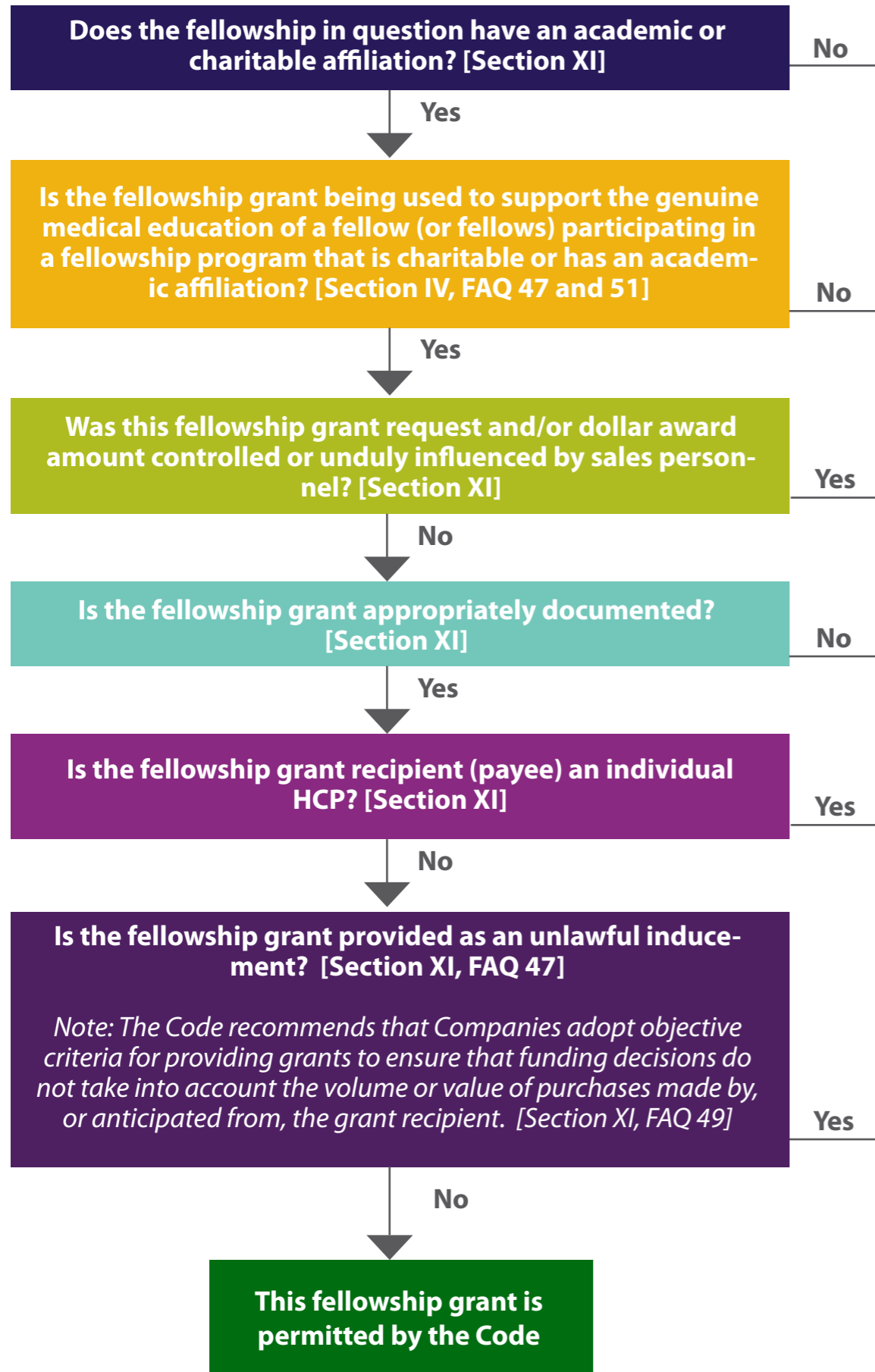


Illustrative Fellowship Grant Funding Best Practices & Considerations

Section XI: Research and Educational Grants and Charitable Donations

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.



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

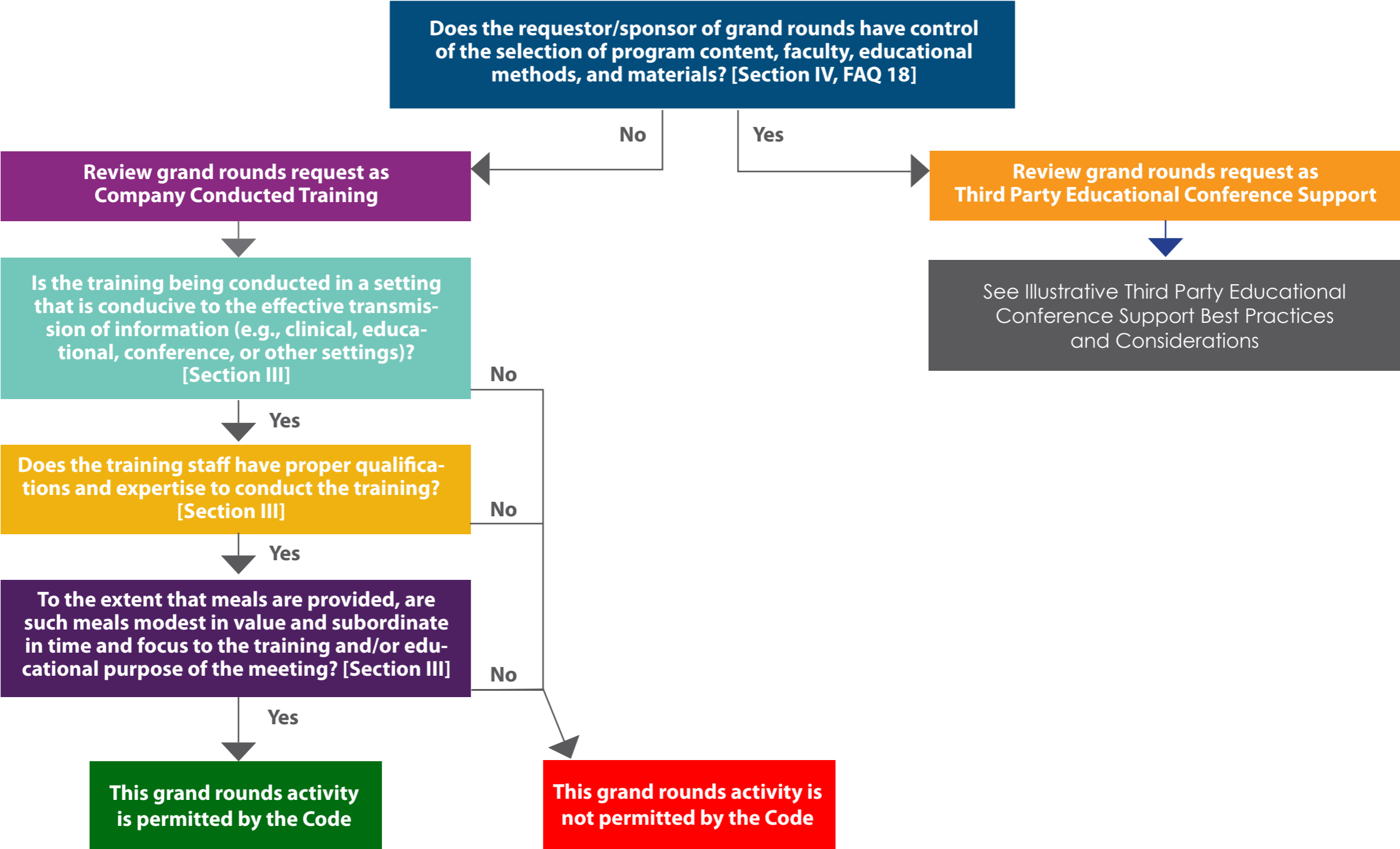
Illustrative Grand Rounds Best Practices & Considerations

Section III: Company-Conducted Product Training and Education

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 grand rounds. 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.

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:



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 in those states, 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."



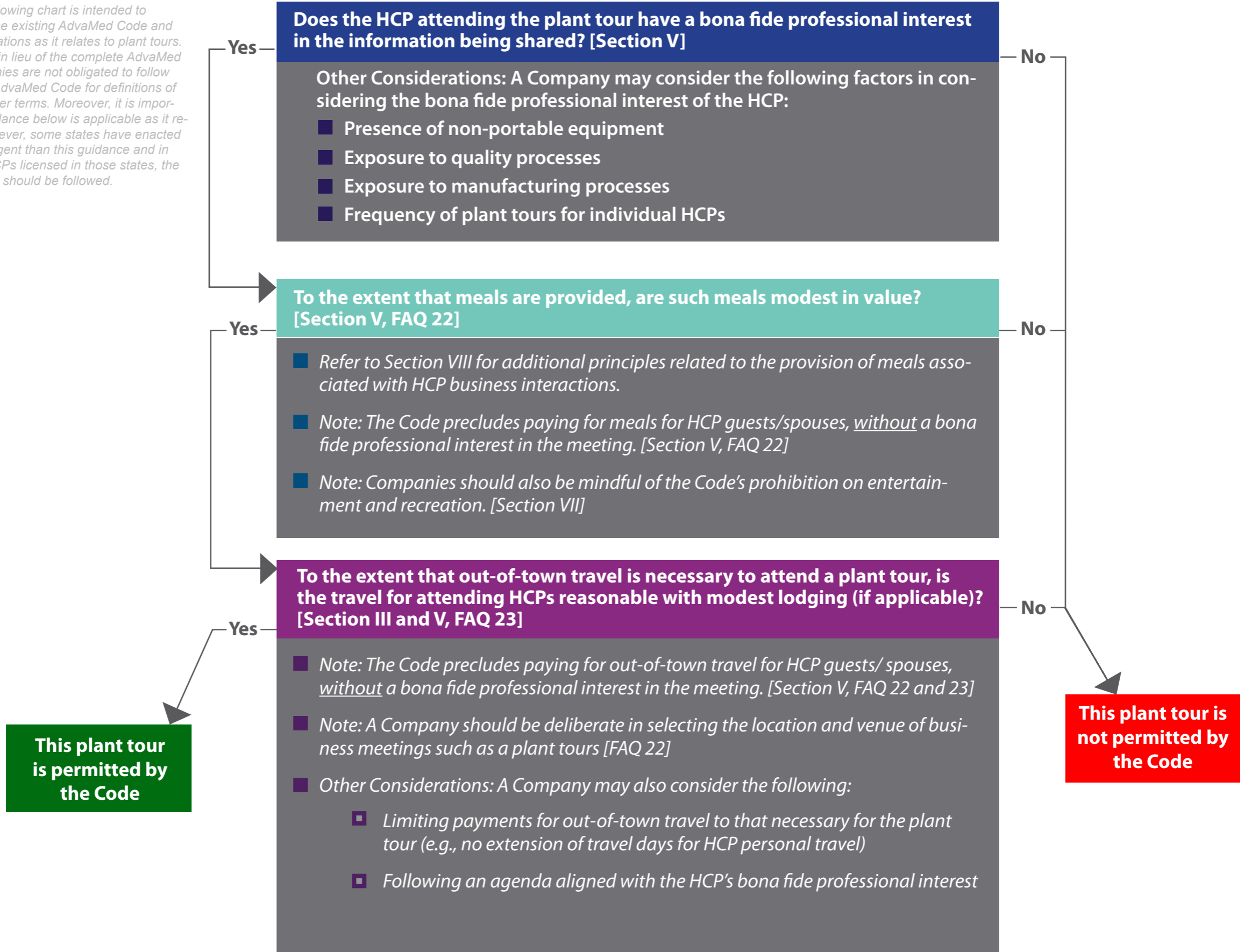
Meal(s) may be provided

Meal(s) should not be provided

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.

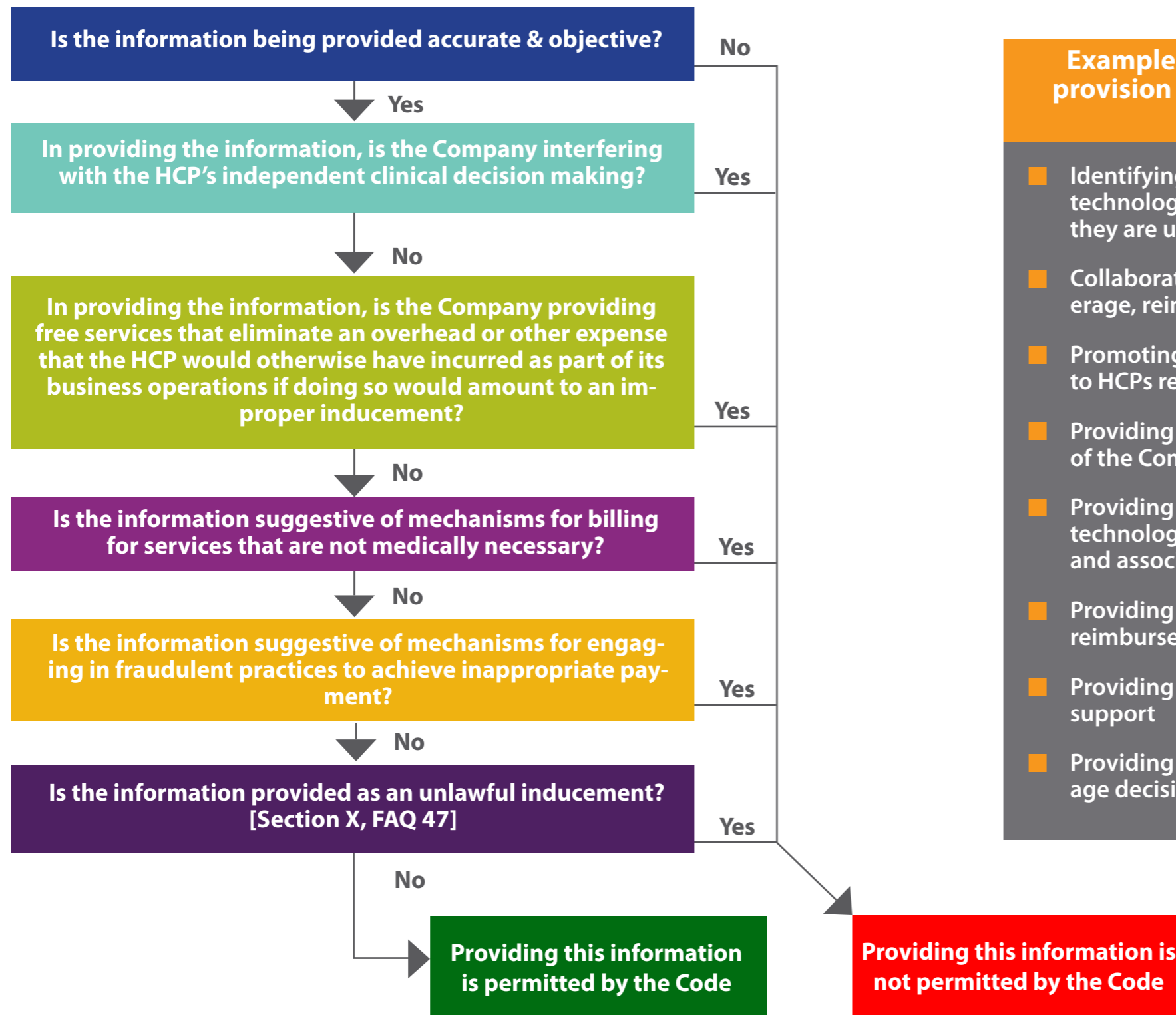


Illustrative Coverage, Reimbursement, & Health Economics Information Best Practices

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.



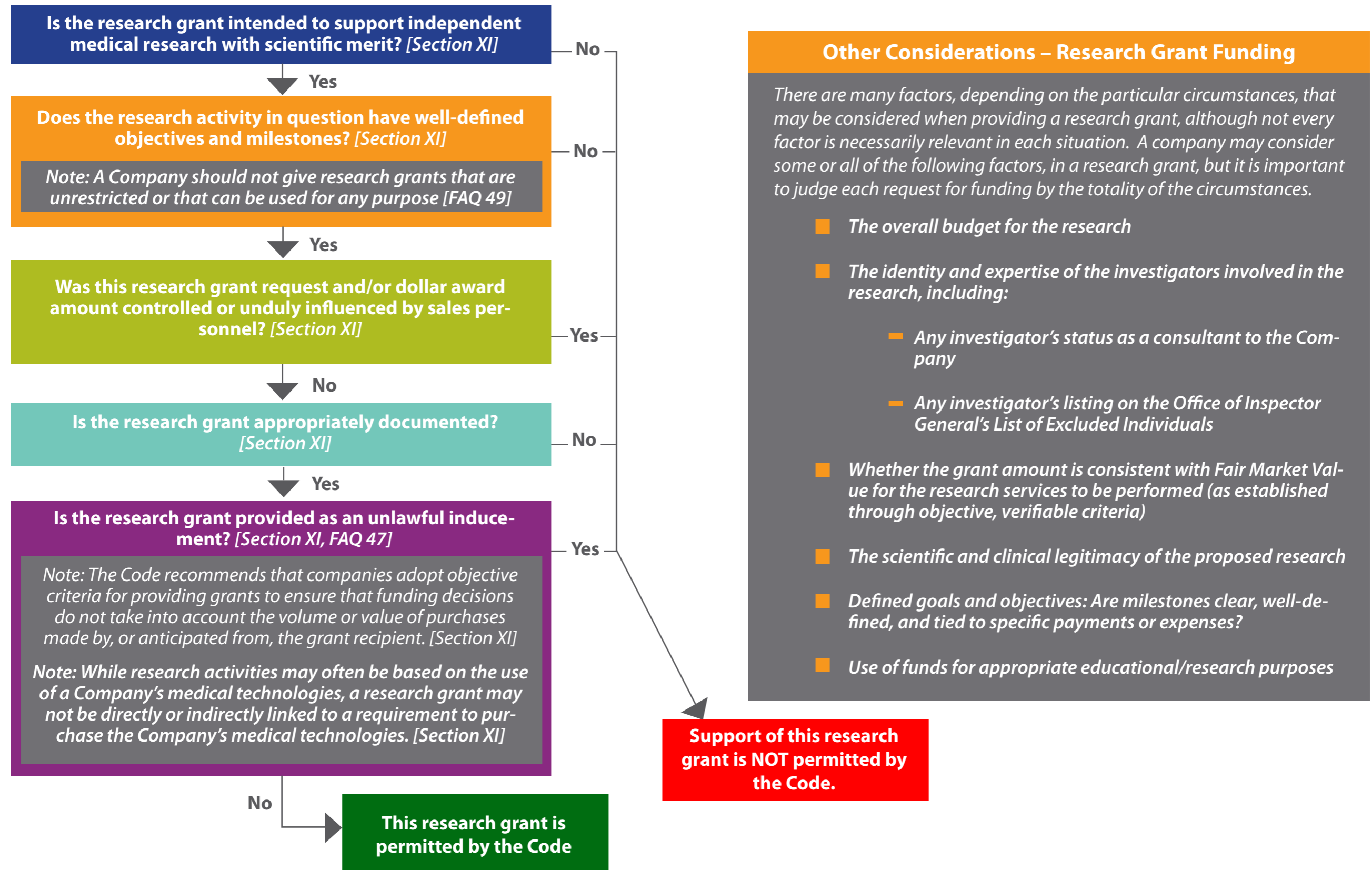
- ### Examples of Permissible Activities involving the provision of coverage, reimbursement, and health economic information
- Identifying the clinical value of the Company's medical technologies and the services and procedures in which they are used
 - Collaborating with HCPs to conduct joint advocacy 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

Illustrative Research Grant Funding Best Practices & Considerations

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.

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 research 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.



Other Considerations – Research Grant Funding

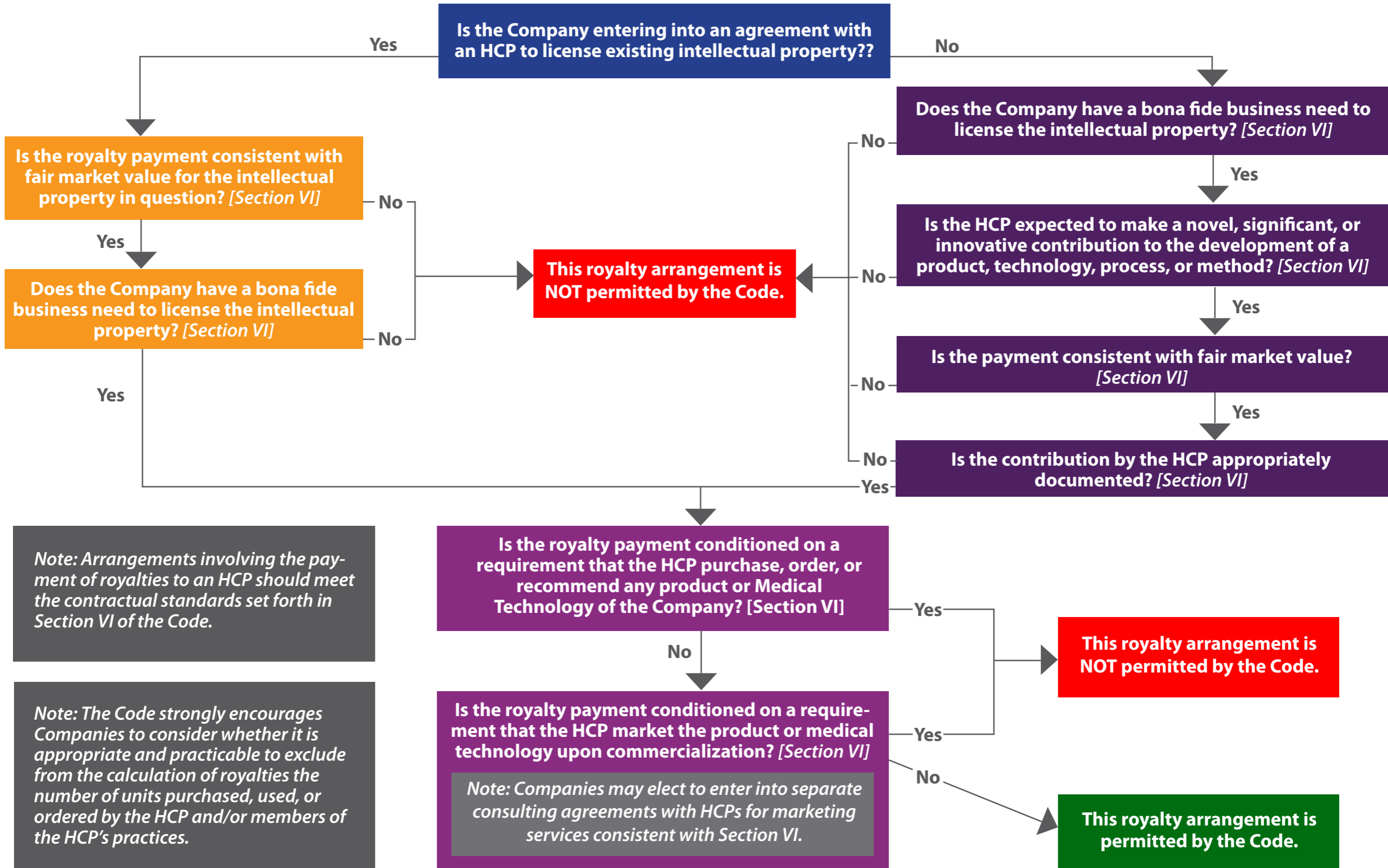
There are many factors, depending on the particular circumstances, that may be considered when providing a research grant, although not every factor is necessarily relevant in each situation. A company may consider some or all of the following factors, in a research grant, but it is important to judge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

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.



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.

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]

Is the royalty payment conditioned on a requirement that the HCP market the product or medical technology upon commercialization? [Section VI]
Note: Companies may elect to enter into separate consulting agreements with HCPs for marketing services consistent with Section VI.

This royalty arrangement is NOT permitted by the Code.

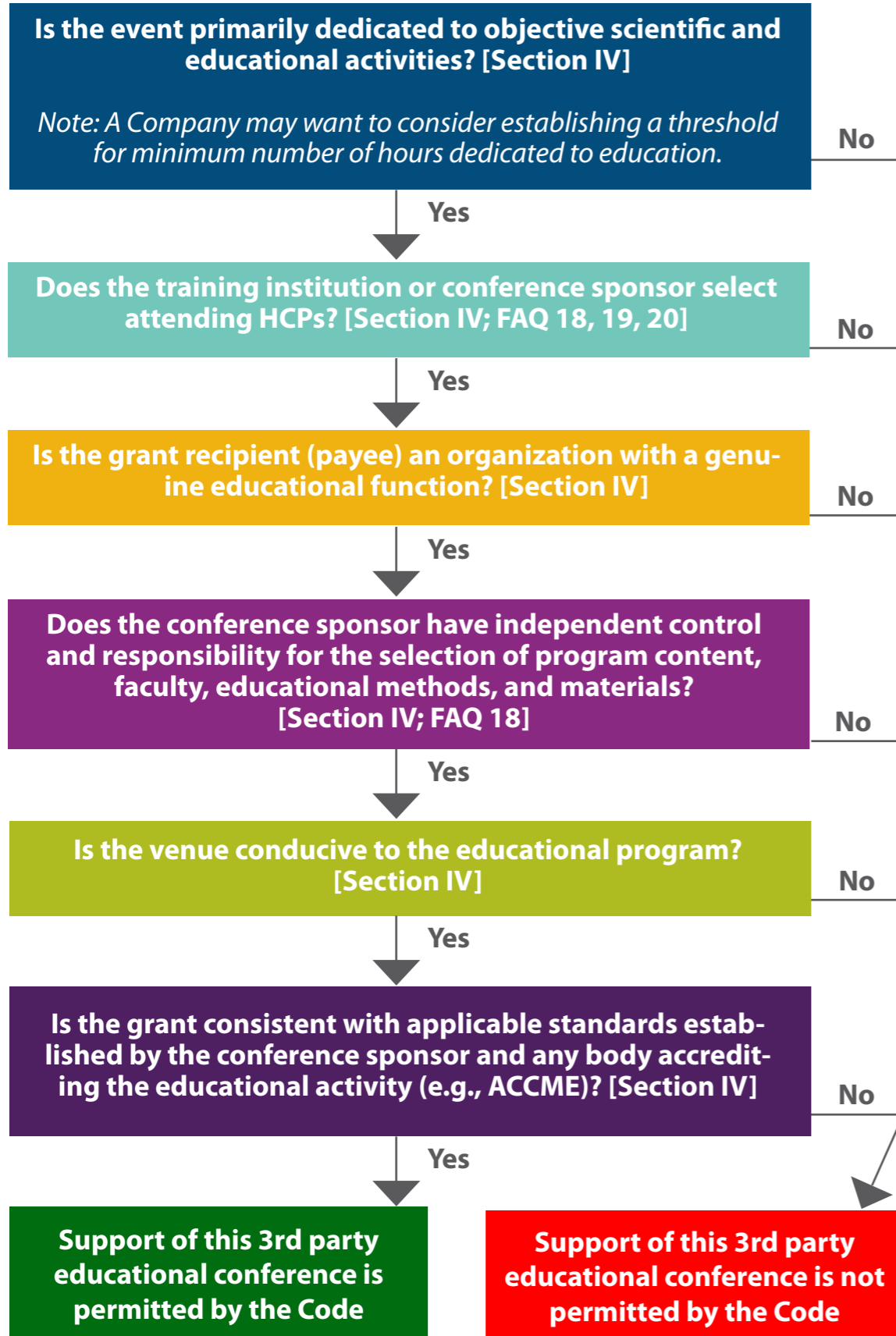
This royalty arrangement is permitted by the Code.

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

Term	Definition
Educational Support	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.
Non-Educational Support	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.
Company Conducted Training and Education	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.

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.

- | | |
|---|--|
| <p>VENUE</p> <ul style="list-style-type: none"> 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? | <p>MARKETING MATERIALS</p> <ul style="list-style-type: none"> How does the conference market itself to potential attendees? Is the education the focus, or is it recreation? |
| <p>CONFERENCE TOPIC (disease state/therapeutic area)</p> <ul style="list-style-type: none"> Is the topic relevant to the business & supportive of business objectives? | <p>BUDGET</p> <ul style="list-style-type: none"> 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? Note: Many companies request the total budget figures from the conference organizers. Are multiple companies providing support, or is my company the sole supporter? |
| <p>AGENDA</p> <ul style="list-style-type: none"> Is the agenda robust? Are there large gaps in the day for recreational activities? Are sessions mandatory, or are some labeled "optional?" | |

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]

