Tuesday, April 9, 2013

Via Electronic Delivery and United States Mail

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-5060-F: Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interest

Dear Acting Administrator Tavenner:

On behalf of the members of the Advanced Medical Technology Association (“AdvaMed”), we write regarding the Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) final rule (“Final Rule”) implementing Section 6002 of the Affordable Care Act (the “Sunshine Provisions”)1 and the applicable data templates proposed by CMS related to non-research payments (the “Non-Research Payment Template”), research payments (the “Research Payment Template”), and physician ownership (the “Physician Ownership Template”) (the Non-Research Payment Template, the Research Payment Template and the Physician Ownership Template are referred to collectively as the “Data Templates”).2

We appreciate the open dialogue we have shared with legislators and CMS throughout the legislative and regulatory process related to the Sunshine Provisions, and welcome the clarification CMS provided in the Final Rule. We support the intent of the Sunshine Provisions – to provide patients with clear, meaningful information concerning industry relationships – while recognizing that such a process should not discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies. Although the Final Rule and Data Templates offer important guidance with respect to implementation of the Sunshine Provisions, implementation challenges and open questions remain.

2 78 Fed. Reg. 9,394 (Feb. 8, 2013); CMS Form Number CMS-10419, “Data Collection and Submission of Transparency Reports and Reporting of Physician Ownership or Investment Interests.”
Below we discuss certain issues and questions for which we believe additional CMS guidance will be beneficial. This submission is consistent with CMS’ comments within the Final Rule that it intends to publish or provide additional guidance or information related to the Sunshine Provisions in the future.

Section I identifies certain issues for which additional guidance or clarification is necessary in order to allow applicable manufacturers to fully and appropriately implement the Sunshine Provisions. Section I also includes issues for which definitive guidance, beyond that already included in the Final Rule, is necessary to assist applicable manufacturers in their interactions with other stakeholders. We structured these comments in a question and suggested answer format, as CMS has indicated it may use such a format in conveying additional guidance and information to users and stakeholders. Section II includes comments on the proposed Data Templates. Finally, Section III relates to the content and operation of the public website, including information regarding relationships between physicians and teaching hospitals and industry. AdvaMed previously shared similar information in its comments to the proposed rule implementing the Sunshine Provisions, but takes this opportunity to revisit the issue, given the importance of ensuring that the public website accurately and completely describes the nature of these relationships and the fact that CMS notes in the Final Rule that it will engage stakeholders regarding the content of the public website.

I. REQUEST FOR ADDITIONAL GUIDANCE OR CLARIFICATION ON THE SUNSHINE PROVISIONS

A. Suggested Questions and Answers for Additional CMS Guidance on the Final Rule

1. Payments and Other Transfers of Value to Teaching Hospital Employees

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are payments and other transfers of value made to non-physician employees of teaching hospitals reportable as payments made to the teaching hospital itself?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>No, teaching hospital covered recipients are limited to the corporate entities identified on CMS’ annual list and do not include employees of such corporate entities. Payments and other transfers of value made to non-physician employees of teaching hospitals are not reportable unless the applicable manufacturer requires, instructs, directs or otherwise causes the non-physician employee to provide the payment or other transfer of value, in whole or in part, to his or her teaching hospital covered recipient employer. In such case, the payment to the non-physician employee</td>
</tr>
</tbody>
</table>
Under the Sunshine Act, the term covered recipient means (1) a physician and (2) a teaching hospital. In the Final Rule, a teaching hospital is defined as any institution that received a payment under section 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available. The term teaching hospital does not include employees, officers, agents, or contractors of such institutions. Had Congress intended to capture payments to non-physician employees and other agents under the Sunshine Provisions, Congress could have easily drafted the statute to include such individuals. The fact that Congress in the statute and CMS in the Final Rule did not include reference to employees and other agents in the context of payments to teaching hospitals supports a conclusion that payments to employees of teaching hospitals are not reportable under the Sunshine Provisions with the exception of two specific scenarios.

First, payments or other transfers of value to physician employees of a teaching hospital would be reportable as payments to a physician covered recipient (as opposed to the teaching hospital). Second, payments or other transfers of value to teaching hospital employees (physician or non-physician) would be reportable as payments to the teaching hospital only if such payments or other transfers of value met the definition of an “indirect payment” to the teaching hospital covered recipient, and the applicable manufacturer was aware of the teaching hospital’s identity.

Under the Final Rule, indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. Accordingly, to the extent that an applicable manufacturer made a payment or other transfer of value to an employee of a teaching hospital (the third party) with an instruction to provide such payment to the employee’s employer (the teaching hospital), the payment would be reportable as a payment to the teaching hospital covered recipient.

These conclusions are further supported by CMS’ treatment of payments to non-healthcare departments of universities affiliated with teaching hospitals. Such payments are not included in the reporting requirements, unless payments are made through these departments to a covered recipient.

---

3 42 U.S.C. § 1320a-7h(e)(6).
4 42 C.F.R. § 403.902 (emphasis added).
5 See, e.g., 105 C.M.R. 970.004 (the definition of health care practitioner under Massachusetts’ Marketing Code of Conduct includes officers, employees, agents, and contractors).
recipient as indirect payments or other transfers of value, which would then have to be reported as required for indirect payments.\(^6\)

The following examples illustrate the distinction between reportable and non-reportable payments and other transfers of value as they relate to employees of teaching hospitals.

- **An applicable manufacturer provides medical textbooks directly to two physicians and two nurses who are employees of a teaching hospital.** The textbooks provided to the two physicians are reportable as transfers of value to the physician covered recipients. However, the textbooks provided to the two nurse employees are not reportable (either in the name of the teaching hospital or the names of the nurse employees) because the nurse employees are not covered recipients.

- **A representative of an applicable manufacturer attends a meeting with a materials manager in charge of purchasing and a pharmacy manager, both employees of a teaching hospital, at which lunch is provided by the applicable manufacturer.** The purpose of the meeting is to discuss appropriate inventory management. The meal is not reportable, either in the name of the teaching hospital or the individual employee attendees, because the meal was not provided to covered recipients.

- **A representative of an applicable manufacturer brings a catered lunch costing $125 to a teaching hospital as part of a training session.** Two physicians and eight support staff members participate in the meal, all employees of the teaching hospital. Because the meal cost $12.50 per participant ($125 / 10 participants = $12.50 each), the meal must be reported in the name of the 2 physicians who participated in the meal because they are covered recipients. However, the meal is not reported for the eight support staff employees of the teaching hospital (either in the name of the teaching hospital or the names of the staff who partook).

- **A representative of an applicable manufacturer has an afternoon appointment with a physician who is an employee of a teaching hospital.** The representative parks her car in the teaching hospital’s parking garage, which charges a $15 fee. Because she arrived well before the afternoon appointment, the representative buys a $12 lunch for herself at the teaching hospital’s cafeteria and eats alone. After her lunch, the representative meets with the physician, and no transfers of value occur between the representative and the physician. Because there was no payment or transfer of value made to the physician employee of the teaching hospital, there is nothing to report in the name of the physician covered recipient. Because the parking and lunch payments were made to non-healthcare departments of the teaching hospital,

---

\(^6\) 78 Fed. Reg. 9,458, 9,468.
they are also not reportable. The applicable manufacturer need not report any payments or transfers of value associated with the representative’s appointment at the teaching hospital.

2. Definition of “New” Covered Product

<table>
<thead>
<tr>
<th>Question:</th>
<th>What does the term “new product” mean for the purpose of delayed publication of certain research payments?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>For purposes of delayed publication under section 1128G(c)(1)(E) of the Sunshine Provisions, the term “new product” means those products, or components of the same, that require a submission to FDA for approval or clearance as a result of new development (i.e., new products) or design changes to existing products.</td>
</tr>
</tbody>
</table>

In AdvaMed’s comments on the proposed rule implementing the Sunshine Provisions, we recommended that CMS permit delayed publication for clinical investigations for new applications of existing products and not just protection for clinical investigations only with respect to new products. In our comments, we noted that clinical investigations with respect to new applications are essential for innovation and advancement within the medical technology industry and are a huge part of the research activities in which our members engage. Further, the failure to protect company trade secrets and proprietary information related to these clinical investigations through delayed publication would be harmful to consumers as it may discourage important clinical investigations.

Nonetheless, the Final Rule distinguishes between new products and new applications of existing products for purposes of delayed publication. Under the Final Rule, publication of a payment or other transfer of value will be delayed when made in connection with (1) research on or development of a new product, or a new application of an existing product; and (2) clinical investigations regarding a new product. Therefore, under the Final Rule, payments related to clinical investigations of new applications of existing products are not eligible for delayed publication.

In the preamble to the Final Rule, CMS offers limited guidance with respect to what qualifies as a new product. Specifically, CMS states that new generic products will be considered new products,

---

7 42 C.F.R. § 403.910(a).
including drugs receiving approval under an Abbreviated New Drug Application, and devices under the 510(k) process.8

Additional clarity is necessary regarding the meaning of the term “new product.” Specifically, CMS should provide a bright-line test that applicable manufacturers can apply to determine whether research payments will be eligible for delayed publication. This bright-line test should be structured to broadly capture a variety of legitimate research efforts. We recommend that CMS clarify that any products, or components of such products, that require FDA approval or clearance as a result of new development or design changes, constitute new products eligible for delayed publication. For example, the following would constitute “new products”:

- A hip implant includes various liners used with the implant. A manufacturer develops a new ceramic liner for an existing hip implant, which must receive 510(k) clearance. Although the new liner is predicated on an existing liner, the new liner may have a new manufacturing process or new ingredient that alters the function of the liner (e.g., harder, more wear-resistant). Research and clinical investigations related to the hip implant using the new liner are eligible for delayed publication because the hip implant with the new liner qualifies as a new product.

- A manufacturer makes design changes to a currently-approved cryoablation needle so that the newly-designed needle can perform functions different than those for which the current needle is approved. As a result of such changes, the manufacturer is required to file with FDA a new submission for approval of the next generation cryoablation needle. Payments and other transfers of value related to research and clinical investigations regarding to the next generation needle are eligible for delayed publication because the product qualifies as a new product.

- A company develops an MRI-safe pacemaker system based on an existing dual chamber pacemaker and lead technology that has been FDA-approved and is already on the market. The new product is engineered and designed specifically to address the hazards related to pacing during magnetic resonance imaging. Extensive testing and evaluation is conducted to assess the safety of the new pacing system based on computer modeling, bench (in vitro) testing, animal (in vivo) studies, and clinical trials. The new system requires regulatory review and FDA approval that it is safe to use. Payments and other transfers of value related to research and clinical investigations regarding the new system are eligible for delayed publication because the product qualifies as a new product.

---

8 78 Fed. Reg. 9,458, 9,505.
• A manufacturer has an assay on a platform that currently tests for influenza. Using the same platform, the manufacturer adds a new test for streptococcus. As adjusted, the assay requires FDA approval or clearance. Payments or transfers of value related research or clinical investigations of the new capabilities of the assay are eligible for delayed publication because the diagnostic test is considered a new product.

• A manufacturer has two systems that received FDA approval individually, an alumina femoral head and a delta hip liner. As required, the manufacturer subsequently submits a Premarket Approval Application (“PMA”) to FDA for a combination product and receives approval for the same. Research and clinical investigations related to the combination product is eligible for delayed publication because the combination product represents a new product (alumina femoral head to be used with a delta hip liner).

• An excimer laser is PMA-approved and indicated for the treatment of myopia. A manufacturer engages in a clinical trial for the additional indication to treat hyperopia. No structural changes are made to the laser, but additional software is developed creating different treatment tables. With the development of the new software, the manufacturer is required to submit a new PMA supplement to FDA. Research payments and other transfers of value related to the additional indication are eligible for delayed publication because the newly-approved product qualifies as a new product.

• The cannula used for cardioplegia retrograde, which stops the heart during heart surgery, is currently indicated for 6 hours in the body. The manufacturer coats the cannula with heparin and conducts a new clinical trial. As required, the manufacturer obtains a “Substantially Equivalent” determination from FDA on a new 510(k) for the modification to the cannula with heparin. Payments and other transfers of value related to the clinical trial are eligible for delayed publication because the cannula with heparin qualifies as a new product.

In contrast, the following examples would not constitute “new products,” but instead new applications of existing products:

• A manufacturer has a device cleared by the FDA for treatment of essential tremor. The same device is later cleared for treatment of Parkinson’s and dystonia, without any design changes to the device. Payments and transfers of value related to research and clinical investigations related to the new indication are not eligible for delayed publication because the approval relates to a new application of an existing product.
• A manufacturer has an approved peripheral vascular stent. The stent is subsequently approved for indication for the superficial femoral artery. In order to qualify for such new indication, separate research and clinical investigations are conducted, but the design of the device does not change. Payments and transfers of value related to research and clinical investigations regarding to the new indication are not eligible for delayed publication because the approval relates to a new application of an existing product.

• A manufacturer has a straight spinal rod cleared by FDA. The manufacturer decides to release a pre-cut rod. Payments and transfers of value related to research regarding the design change of the rod are not eligible for delayed publication because this change does not require FDA approval or clearance.

We believe our recommendations with respect to characterizing “new” products represent the most administrable approach to addressing this very important and equally complicated issue. As noted, without additional guidance, it will be difficult to determine which products are subject to delayed publication. A bright-line test, intended to capture a broad variety of research activities, offers the simplest approach while still protecting research essential for innovation and advancement within the medical technology industry. Such innovation and advancement ultimately lead to better patient outcomes and opportunities, but these can only be fostered by protecting company trade secrets and proprietary information related to research, as Congress intended in enacting the Sunshine Provisions.

Applying a broad interpretation of the term “new product” to include changes requiring FDA approval or clearance would advance the purpose of the Sunshine Provisions to foster transparency. New products, no matter how defined, are still subject to the reporting requirements of the Sunshine Provisions, just on a delayed schedule. It is clear that the legislative intent of the Sunshine Provisions is not to regulate the business of drug and device companies, but instead to keep the American people apprised of the business such companies are doing.9 A broad interpretation of the term “new product” would allow manufacturers to continue to undertake important research efforts without fear of being placed at a competitive disadvantage as a result of disclosing proprietary information related to such research, while still providing the public with related information, albeit at a future date.

---

3. Accreditation and Certification Bodies for Continuing Medical Education

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are there additional accreditation or certification bodies that may qualify for the exclusion related to compensation for serving as faculty or as a speaker for an accredited or certified continuing education event?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>Yes. While the list of accreditation or certification bodies set forth in 42 C.F.R. § 403.904(g)(1)(i) is extensive, it is not intended to be an exclusive list. Other entities provide accreditation or certification as to the legitimacy of educational content beyond the Accreditation Council for Continuing Medical Education (“ACCME”), the American Academy of Family Physicians (“AAFP”), the American Dental Association’s Continuing Education Recognition Program (“ADA CERP”), the American Medical Association (“AMA”), or the American Osteopathic Association (“AOA”). Other independent third party accrediting bodies meeting the same requirements or standards may also qualify for the exclusion (e.g., state medical societies, and the European Accreditation Council for Continuing Medical Education (“EACCME”)).</td>
</tr>
</tbody>
</table>

The Final Rule establishes at 42 C.F.R. § 403.904 special rules for payments or other transfers of value related to continuing education programs. Specifically, 42 C.F.R. § 403.904(g)(1) provides:

Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:
   (A) The Accreditation Council for Continuing Medical Education.
   (B) The American Academy of Family Physicians.
   (C) The American Dental Association’s Continuing Education Recognition Program.
   (D) The American Medical Association.
(ii) The applicable manufacturer does not pay the covered recipient speaker directly.
(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a
distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

We recommend that CMS clarify that the list of accreditation or certification bodies included in the Final Rule is not exclusive and that other organizations meeting the same or similar requirements or standards may also qualify for the exclusion related to compensation for speaking at a continuing education program. Such clarification is consistent with the intent of exclusion – to protect the unique relationship of industry support for accredited or certified continuing education as long as certain safeguards are met – and also ensures that the Sunshine Provisions do not inappropriately regulate industry business.

If CMS determines that the list of accreditation or certification bodies set forth in 42 C.F.R. § 403.904(g)(1)(i) is exclusive, manufacturers will be encouraged to limit their support to only these enumerated organizations, likely opting not to support legitimate events by organizations meeting the same or similar requirements or standards but not included on CMS’ list. An exclusive list means that CMS will have created a de facto rule with respect to which organizations the industry may support, thereby regulating industry activity contrary to the intent of the Sunshine Provisions.

The legislative history of the Sunshine Provisions makes clear that the law is not intended to regulate business; instead, it is intended to provide transparency with respect to payments and other transfers of value. Specially, in introducing the Physician Payments Sunshine Act of 2007, Senator Grassley stated:

So let me be clear. This bill does not regulate the business of the drug and device industries. I say, let the people in the industry do their business. After all, they have the training and the skill to get the job done. Just keep the American people apprised of the business you are doing and how you are doing it. Let a little bit of sunshine in to this world of financial relationships – it is, after all, the best disinfectant.10

---

10 Statements on Introduced Bills and Joint Resolutions, S. 2028, page S11218 (Sept. 6, 2007).
4. Payments Sponsoring CME and Non-CME Events

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are general sponsorship payments or other transfers of value made to third parties for the purpose of sponsoring CME events reportable if such payments and transfers of value are not earmarked for any specific covered recipients or covered recipient activities? (Please note that we discuss non-CME events in a separately proposed question and suggested answer below).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>No, general sponsorship payments or other transfers of value made to third parties to sponsor CME events are not reportable. Such payments or other transfers of value are not restricted to, nor specifically earmarked for, covered recipients. However, payments or other transfers of value made to third parties for CME events are reportable if they are restricted to or earmarked for covered recipients, the applicable manufacturer is aware of the identities of the covered recipients ultimately receiving the payment or other transfer of value, and the payment or other transfer of value is not otherwise exempt.</td>
</tr>
</tbody>
</table>

AdvaMed recommends that CMS clarify that general sponsorship payments for continuing medical education (“CME”)

11 events, that is, those that are unrestricted and not earmarked for specific covered recipients, are not reportable. This conclusion is consistent with guidance included in the Final Rule.

First, the Final Rule states that applicable manufacturers are not required to report indirect payments or other transfers of value pursuant to unrestricted, non-earmarked payments not directed to covered recipients.12 Indeed, CMS has made clear that it does not require reporting of every payment that an applicable manufacturer makes through a third party that is ultimately provided to a covered recipient. Instead, reporting is only required with respect to indirect payments where the applicable manufacturer knows or should know the identity of the covered recipient who received the payment.13

---

11 Throughout this document we refer to continuing medical education or “CME.” CME is also known as continuing education or “CE.” We consider CME and CE to be synonymous.
12 78 Fed. Reg. 9,458, 9,491.
13 78 Fed. Reg. 9,458, 9,490.
Second, general sponsorship of continuing education programs is analogous to subsidization of attendees’ tuition fees, which CMS has said is not reportable. 14

Third, general sponsorship funding is similar to providing unrestricted donations to third parties, such as physician organizations, which are also not reportable because they do not qualify as indirect payments. 15

In the context of continuing education programs, general sponsorship payments or transfers of value made to third parties organizing events are not restricted to or earmarked for covered recipients. Instead, the manufacturer provides the funds for general use by the third party, at its discretion. If anything, rather than directing the use of the funds, the manufacturer may impose limits on what the funds may be used for. For example, the manufacturer may make a sponsorship payment with express instructions that such funds may not be used for entertainment. In addition, applicable manufacturers will often not know the identities of the covered recipients who ultimately attend events that they sponsor.

To require manufacturers to track and report payments and other transfers of value made by third party CME sponsors using funds provided by manufacturers would be extremely burdensome, if not impossible, and such payments do not qualify as the types of relationships the Sunshine Provisions are intended to address. Indeed, such payments and transfers of value are already subject to important safeguards, as recognized by CMS in the Final Rule. 16

We understand that direct or indirect payments and other transfers of value made to covered recipients attending continuing education events, such as meals and travel expenses, may be reportable in cases where the payment or transfer of value is directed to specific covered recipients. 17 However, if general sponsorship payments provided by applicable manufacturers to

---

14 See 78 Fed. Reg. 9,458, 9,481 (“We do not intend to capture the attendees at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events) . . .”); 78 Fed. Reg. 9,458, 9,481 (“Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees’ tuition fees for continuing education events.”)
15 See 78 Fed. Reg. 9,458, 9,490 (“For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization’s discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute ‘indirect payments’ because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. The physician professional association could have used the donation for another purpose at its discretion. In this situation, the applicable manufacturer would not be required to report the donation, even if a portion of the payment or other transfer of value was ultimately provided to a covered recipient as a grant (or some other type of payment or other transfer of value).”).
16 78 Fed. Reg. 9,458, 9,492.
17 See 78 Fed. Reg. 9,458, 9,481 (“. . . however, we believe that any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these events must be reported under the appropriate
a third party event organizer are used to fund tuition fees and such tuition fees include, at the event organizer’s discretion, meals, travel, and other items, such meals, travel, and other items should not be separately reportable, since the applicable manufacturer did not specifically earmark the sponsorship payment for meals, travel, or other items for specific covered recipient attendees.

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are general sponsorship payments or other transfers of value made to third parties for the purpose of sponsoring non-CME events reportable if such payments and transfers of value are not earmarked for any specific covered recipients or covered recipient activities? (Please note that we discuss CME events in a separately proposed question and suggested answer above).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>No, general sponsorship payments or other transfers of value made to third parties to sponsor non-CME events are not reportable. Such payments or other transfers of value are not directed to, nor specifically earmarked for, covered recipients. However, payments or other transfers of value made to third parties for non-CME events are reportable if they meet the definition of an indirect payment and the applicable manufacturer is aware of the identities of the covered recipients ultimately receiving the payment or other transfer of value.</td>
</tr>
</tbody>
</table>

AdvaMed further recommends that CMS clarify that sponsorship payments for non-CME events should be reportable only if such payments qualify as indirect payments, i.e., the applicable manufacturer earmarks the payment for covered recipients. This is likely a rare occurrence. More often, non-CME events are sponsored by multiple manufacturers and the funds provided are for general use. For example, a professional society may arrange a meeting for its members to discuss updates with respect to orthopedic care. The professional society may seek funds from multiple manufacturers to support the meeting. Although the society is not accredited or certified to provide continuing education and will not be providing continuing education credit to its members who attend, the program will nonetheless be educational in nature.

In addition, as with respect to CME events, reporting with respect to general sponsorship payments for non-CME events will be extremely burdensome. While manufacturers may expect that nature of payment categories.”); 78 Fed. Reg. 9,458, 9,481 (“However, as explained in the discussion of the nature of payment categories, payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required.”); 78 Fed. Reg. 9,458, 9,579 (stating that the reporting exception for food and beverages provided at conferences does not apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish the identities of the attendees).
physicians will be attending certain events, they would not automatically know the physicians’ identities and would be required to track down this information, assuming the third party sponsor even would be willing to share its attendee list. To the extent that CMS requires manufacturers to report broadly with respect to sponsorship payments for non-CME events, manufacturers will be discouraged from providing such support. As discussed above, this will result in the Sunshine Provisions effectively regulating business, in direct contradiction to the Act’s legislative intent.

We understand that payments or other transfers of value provided to covered recipients through a non-CME third party vendor will be reportable to the extent the payment or other transfer of value qualifies as an indirect payment as defined by 42 C.F.R. § 403.902 and the applicable manufacturer is aware of the identity of the covered recipient. Such indirect payments or other transfers of value may include meals and travel expenses provided to or for specific covered recipients, whose identities are known to the applicable manufacturer.

The above discussions with respect to CME and non-CME sponsorship payments are distinct from the issue of applicable manufacturers providing compensation, directly or indirectly, to a covered recipient serving as a faculty or speaker at an accredited or certified continuing education event, at an unaccredited and non-certified continuing education program, or any other engagements that are not for continuing education.

Payments and transfers of value that are not excluded by the exclusion at 42 C.F.R. § 403.904(g)(1) related to compensation for serving as faculty or as a speaker for an accredited or certified continuing education event, would be reported under the nature of payment category for “compensation for serving as faculty or as a speaker for an accredited or certified continuing education event.” With respect to payments or other transfers of value made to a third party for the purpose of compensating covered recipients who serve as speakers or faculty for an unaccredited and non-certified continuing education program, we recognize that such payments or transfers of value would be reported by the applicable manufacturers under the nature of payment category of “compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program.” Finally, payments or other transfers of value for speaking engagements that are not for continuing education would be reported under the nature of payment category for “compensation for services other than consulting.”
Question: How are payments or other transfers of value that are made to third parties for the purpose of sponsoring CME and non-CME events reported, if multiple applicable manufacturers sponsor the same event?

Suggested Answer: In situations where multiple applicable manufacturers make reportable payments or other transfers of value to a covered recipient through a third party, the applicable manufacturers and third parties may work together to determine the best method for reporting the payment or, in cases where the third party will not or cannot provide the necessary information, the applicable manufacturer may make reasonable efforts to determine the appropriate information to report.

In situations where multiple applicable manufacturers make indirect payments to covered recipients through a third party for such speaker or faculty services, CMS noted in the Final Rule that the applicable manufacturers and third parties may work together to determine the best method for reporting the payments.\(^{18}\) This may require third party organizers to appropriately allocate speaker/faculty fees among covered recipients and applicable manufacturers and provide such information to applicable manufacturers for reporting.

To the extent that third party organizers are able and willing to work with applicable manufacturers to provide timely, necessary, and useful information related to reportable indirect payments, CMS’ suggestion with respect to payments involving multiple applicable manufacturers is acceptable. However, there are a wide variety of third party organizers involved with CME and non-CME programs, the capabilities of which vary greatly. Third party organizers may be unwilling or unable to provide information related to reportable indirect payments and transfers of value to applicable manufacturers in a timely and useful fashion. In such cases, applicable manufacturer should not be held liable for failing to report accurately information that they are not able to obtain. Instead, CMS should allow applicable manufacturers to make reasonable efforts to determine the appropriate information to report, based on the best knowledge and information available to them. For example, an applicable manufacturer should be allowed to allocate and report only with respect to its portion of a reportable payment or other transfer of value provided to a known covered recipient, based on the manufacturer’s knowledge of how many applicable manufacturers sponsored the program. This way, several companies would report smaller payments to the same covered recipient for the same event, and the total reported payments to such covered recipient would accurately reflect payments of transfers of value received indirectly from multiple applicable manufacturers.

\(^{18}\) 78 Fed. Reg. 9,458, 9,491.
5. Reporting Physician Ownership or Investment Interests

<table>
<thead>
<tr>
<th>Question:</th>
<th>Must applicable manufacturers and GPOs report physician ownership or investment interests in a private equity firm, which has an ownership or investment interest in the manufacturer or GPO?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>Applicable manufacturers and GPOs must report such indirect ownership or investment interests if the applicable manufacturer or GPO knows about such ownership or investment interest. An applicable manufacturer or GPO will be considered to know about such indirect interest if it has actual knowledge of the information, or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information. Such standard may require applicable manufacturers and GPOs to make reasonable inquiries related to indirect ownership or investment interests.</td>
</tr>
</tbody>
</table>

In the Final Rule, CMS makes clear that applicable manufacturers and GPOs must report both direct and indirect ownership interests. However, CMS includes some limitations with respect to indirect ownership or investment interests. Specifically, consistent with the physician self-referral rule, CMS requires that applicable manufacturers and GPOs will not have to report ownership or investment interests held by physicians or their immediate family members if they did not know about such interests. With respect to the requirement for obtaining information on ownership or investment interests, CMS notes that it does not have the authority to require physicians or owners or investors to report such information, but it states that it believes an applicable manufacturer or applicable GPO may inquire about these relationships.\(^\text{19}\)

*We recommend that CMS clarify that applicable manufacturers must make reasonable inquiries related to indirect ownership or investment interests and report with respect to known ownership and investment interests.* If after reasonable inquiry an applicable manufacturer is not aware of an actual ownership or investment interest, the applicable manufacturer should not be liable for failing to report such actual indirect ownership or investment interest.

\(^{19}\) 78 Fed. Reg. 9,458, 9,494–95.
**Question:** How is the value of a physician ownership or investment interest reported if the value of that ownership or investment interest fluctuates during a reporting year?

**Suggested Answer:** Applicable manufacturers and GPOs should value each physician’s (or immediate family member’s) ownership or investment interest on December 31 of a particular reporting year and report that value to CMS by the reporting deadline.

Recognizing that ownership and investment interests may fluctuate during any given year, the above proposed question and suggested answer proposes a definitive point in time during which all applicable manufacturers and GPOs can measure the value of a physician’s (or immediate family member’s) ownership or investment interests. Such a uniform measuring point will ensure consistent reporting and meaningful information for the public.

### 6. Products and Study Equipment Provided for Research

**Question:** Are products and study equipment provided by applicable manufacturers to covered recipients solely for use by the covered recipients to carry out research requested by the applicable manufacturer pursuant to an agreement or protocol considered reportable transfers of value?

**Suggested Answer:** No, such products and equipment are provided as tools for covered recipients to conduct research for an applicable manufacturer at the applicable manufacturer’s request and for the applicable manufacturer’s benefit. While compensation paid by the applicable manufacturer to the covered recipient for the research services is reportable, products and equipment provided for an applicable manufacturer’s research project or clinical study are not reportable transfers of value because they have no independent value, nor can they be used by the researcher for a use beyond conducting the research. Products and equipment provided by applicable manufacturers are essential tools required to conduct the research, which could not be completed by the covered recipients without them. Further, these are items intended to allow the researcher to provide services on the manufacturer’s behalf – not for the researcher’s own benefit. There is no benefit to the covered recipient because the tools are used solely for purposes of the research.
Further clarification is needed on the issue of products and study equipment provided to covered recipients for purposes of conducting research because the Final Rule offers conflicting guidance. On the one hand, the Final Rule states:

“material transfers (such as provisions of a protein) to a researcher for discovery collaboration does not need to be reported when not part of a commercial or marketing plan and precedes the development of a new product. We believe for the purposes of this regulation that due to the early stage of the research process, the transferred material does not have independent value.”\(^\text{20}\)

In contrast, the Final Rule elsewhere states that the lump sum research payments to be reported would include a variety of items, including “the provision of study drugs, devices, biological and medical supplies or other in-kind items.”\(^\text{21}\) Similarly, the Final Rule states, “we believe that products used for research studies should be included as a part of the larger research payment.”\(^\text{22}\)

The above conflicting guidance is confusing to manufacturers. It is common for manufacturers to provide researchers with the product to be studied as well as clinical supplies needed to successfully complete the research services. Such items have no independent value to researchers and are, in fact, essential tools needed by the researchers to complete their work. Furthermore, assigning a value to these items presents many challenges. It is not possible, for example, to assign a market value to a product still under development. Because the product is not yet available on the market, there is no list price or other reasonable means by which to measure or attribute a value to the product.

By way of example, a prototype for a product under development must be provided to the covered recipient in order for the covered recipient to conduct research on the product. Without the product, the purposes of the research would not be fulfilled. Such a product has no independent value to the covered recipient because it cannot be used for any other purposes. Thus, it makes little sense to require manufacturers to try to assign a value to that product and report it as a transfer of value to the covered recipient. In contrast, products and equipment provided to covered recipients for investigator-sponsored research would be reportable transfers of value because the research is not being conducted on behalf of and for the benefit of the manufacturer. In addition, if products are given to a covered recipient to conduct research on the product for the benefit of the manufacturer, but the covered recipient also charges the patient for the procedure and may or may not receive additional payment from the manufacturer, the provided products would be reportable because they have an independent value to the covered recipient.

\(^\text{20}\) 78 Fed. Reg. 9,458, 9,483.
\(^\text{21}\) 78 Fed. Reg. 9,458, 9,484.
\(^\text{22}\) 78 Fed. Reg. 9,458, 9,487.
B. Additional Clarification for Other Stakeholders

While the following issues are addressed by CMS in the Final Rule, AdvaMed believes additional clarification would assist applicable manufacturers’ efforts to educate other stakeholders of the manufacturer’s reporting obligations under the Final Rule.

1. Payments Made to Separately Incorporated Third Party Entities

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are payments or other transfers of value made to separately incorporated third party entities reportable if that payment or other transfer of value is ultimately received by a physician covered recipient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>Yes, applicable manufacturers must report payments that ultimately are paid, in whole or in part, to a covered recipient (physician or teaching hospital). Where an applicable manufacturer makes a payment to a separately incorporated entity, it must report the name of that entity (regardless of whether it is a covered recipient). In the context of research-related payments, the applicable manufacturer must also report the principal investigator(s) affiliated with the research.</td>
</tr>
</tbody>
</table>

Our members have reported a growing trend in physicians establishing limited liability companies (“LLCs”) and other legal entities to receive payments from applicable manufacturers intended for physician covered recipients. Referred to as the “blossoming LLC” phenomenon, this issue appears to be a product of certain covered recipients not fully understanding the Sunshine Provisions and the fact that payments intended for and ultimately paid to a covered recipient are reportable under the Sunshine Provisions, notwithstanding the fact that the payment was made to a separate legal entity. As the Final Rule makes clear, such indirect payments are reportable. The above proposed question and suggested answer is intended to serve as a tool to educate physician covered recipients of the Final Rule’s reporting requirements.

2. Payments Made By Distributors Who Do Not Take Title

<table>
<thead>
<tr>
<th>Question:</th>
<th>Are payments or other transfers of value to covered recipients made through distributors who do not take title to a covered product reportable by the applicable manufacturer who retains title to that covered product?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested Answer:</td>
<td>Yes, applicable manufacturers who retain title to a covered product must report payments or other transfers of value made to covered recipients through a distributor. Distributors that do not hold the title of a covered</td>
</tr>
</tbody>
</table>
product will not themselves be subject to the reporting requirements of the Final Rule, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological or medical supply. The applicable manufacturer who retains title to the covered product, however, is responsible for reporting payments or other transfers of value made by the distributor on its behalf.

As background, it is often necessary for medical device companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the companies’ products or services. Such engagements ensure and improve ongoing patient and clinician access to innovative, reliable and effective medical technologies. The form of, and terminology used by, companies to describe relationships with these third party sales and marketing intermediaries vary, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives. The size and capabilities of distributors also vary greatly. Certain distributors offer large-scale distribution operations, covering national and international territories, while other distributors may operate on a local or regional level. The capabilities of distributors, including with respect to tracking information regarding payments and transfer of value to covered recipients, vary greatly.

Similar to some of the confusion that appears to exist in the physician community, our members also report that some distributors do not appear to be fully aware of the requirements of the Sunshine Provisions, including the fact that applicable manufacturers will be required to report payments or transfers of value made to covered recipients through distributors that do not hold title to such manufacturers’ covered product. Certainly the level of awareness distributors have demonstrated varies from distributor to distributor. We recognize that there are many distributors that are aware of the requirements of the Sunshine Provisions and Final Rule and that are taking appropriate steps to prepare to work with applicable manufacturers to ensure that necessary information is tracked and reported to CMS.

The Final Rule clarifies that distributors that hold title to a covered product meet the definition of an applicable manufacturer and are therefore subject to the reporting requirements of the Sunshine Provisions. Distributors that do not hold title to a covered product will not be subject to the reporting requirements of the Sunshine Provisions, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered product. However, even if a distributor is not itself required to report payments or other transfers of value made to covered recipients, the applicable manufacturer holding title to the covered product(s) to which the payment or other transfer of value relates may have an obligation to report such payments or other transfers of value. In order to do so, the applicable manufacturer may need specific information from the distributor regarding the payment or other transfer of value.
In the Final Rule, CMS notes that applicable manufacturers will need to work with third parties through which they make payments to covered recipients to ensure that the third parties are taking the appropriate steps to track the indirect payments. CMS also recognizes that this will, in some cases, require third parties to put in place new tracking systems. The above proposed question and suggested answer is intended to serve as a tool to educate distributors of the Final Rule’s reporting requirements and assist applicable manufacturers in negotiations with such distributors to obtain the necessary information for reporting. It is primarily directed to those distributors that are not as familiar with the Sunshine Provisions and that may not have begun the process of preparing for implementation of the Sunshine Provisions.

II. COMMENTS REGARDING THE DATA TEMPLATES

In the Final Rule, CMS notes that it will provide applicable manufacturers and GPOs with reporting templates and more details on reporting. Indeed, on February 8, 2013, CMS released the Data Templates and published in the Federal Register a summary of proposed collections for public comment. In response to CMS’ request for comments, we offer the following comments regarding the Data Templates. Our comments are divided into two sections. The first discusses general observations and recommendations with respect to the Data Templates. The second section discusses specific line items within the Data Templates.

A. General Comments and Recommendations on the Data Templates

*Inaccurate Cross-References.* Throughout the Data Templates, internal cross references inaccurately refer to previous Line numbers. For example, Lines 54, 55 and 56 on the Research Payment Template inaccurately cross reference Line 55 as the “Multi-year Payment Structure Indicator;” the “Multi-year Payment Structure Indicator” is set forth in Line 53. We recommend that CMS revise the Data Templates to ensure that accurate cross-references are included.

*Data Element Size.* The Data Templates currently include under the column for “Data Element Size” information regarding the proposed number of characters available for each line item within the Data Templates. It is not clear how these character limits were determined and the character lengths also vary between Data Templates (e.g., Line 46 of the Non-Research Payment Template related to Contextual Information has a data element size of 200 characters, whereas the corresponding Line 59 in the Research Payment Template related to Context of Research has a data element size of 500 characters). We recommend that CMS standardize the character lengths between the Data Templates. CMS should also ensure that the character lengths are sufficient to allow appropriate reporting.

---

23 78 Fed. Reg. 9,394 (Feb. 8, 2013); CMS Form Number CMS-10419, “Data Collection and Submission of Transparency Reports and Reporting of Physician Ownership or Investment Interests.”
Standardized Lists. Throughout the Data Templates, CMS refers to certain standardized lists that may apply to particular fields. In order to allow manufacturers sufficient time to prepare for implementation, CMS should timely make such lists available for review and comment by applicable manufacturers.

B. Specific Comments and Recommendations on Line Items in the Data Templates

1. Non-Research Payment and Research Payment Templates

Associated covered products; Lines 27 and 29. Line 27 of both the Non-Research Payment Template and the Research Payment Template (Name of Associated Drug, Device, Biological, or Medical Supply) requires applicable manufacturers to report (1) the name of an associated covered product, (2) that the product is a “non-covered product,” or (3) that there is “none.” Line 29 of both the Non-Research Payment Template and the Research Payment Template (Therapeutic Area of Product Category), which is not required, allows manufacturers to report the therapeutic area or product category of the primary device or medical supply associated with the payment, if applicable. With respect to devices and medical supplies, under the Final Rule, manufacturers must report either the name under which the device is or was marketed or the therapeutic area or product category for the device. Therefore, Line 27 should not be “Required” as written unless “therapeutic area or product category” is an acceptable response as well.

We also note that in Line 27 on the Research Payment Template, CMS indicates that the associated covered product should be selected from “Text of Standardized Selection based on validated industry lists,” or “None” or “Non-covered product” should be indicated. The corresponding Line 27 in the Non-Research Payment Template does not refer to the same three value options. The reason for the discrepancy between the two Data Templates is unclear. Similarly, in Line 29 on both the Non-Research Payment Template and the Research Payment Template, CMS indicates that the Therapeutic Area or Product Category will be selected from “Text from Standardized Selection,” which will include two characters. The Final Rule does not reference such standardized lists, and any lists should be available for review and comment by applicable manufacturers. In addition, if standardized lists are not provided by CMS, two characters is likely insufficient for reporting on the therapeutic area or product category.

Teaching hospital’s TIN; Line 8. For research and non-research payments made to a teaching hospital, Line 8 of both the Non-Research Payment Template and the Research Payment Template requires manufacturers to report the teaching hospital’s TIN. The Final Rule does not require manufacturers to report this information. accordingly, we recommend that CMS change the required field in both the Non-Research Payment Template and the Research Payment Template to indicate that such information is not required.

24 See 42 C.F.R. § 403.904(c); 78 Fed. Reg. 9,458, 9,498.
Physician and principal investigator specialty; Lines 24 (non-research) and 45 (research). In Line 24 of the Non-Research Payment Template and Line 45 of the Research Payment Template related to physician specialty, manufacturers are provided only two characters to report the physician’s or principal investigator’s specialty. The Final Rule requires manufacturers to use the NPPES provider taxonomy list as the list of accepted specialties. That list is available from the Washington Publishing Company and the relevant codes are longer than two characters (e.g., the code for Adult Reconstructive Orthopaedic Surgery is 207XS0114X). If manufacturers are required to conform physician specialty information to the NPPES, two characters are likely insufficient. Accordingly, we recommend that CMS revise the character limit.

2. Research Payment Template

Research payments to individual non-covered recipients; Lines 6, 9-12. Line 6 of the Research Payment Template requires manufacturers to identify whether the recipient of the research payment is a teaching hospital, physician, institutional non-covered recipient, or individual non-covered recipient. According to the “Required” Fields for Lines 8-12, manufacturers must report the name of the physician, covered recipient or individual non-covered recipient. By contrast, the “Definition/Description” Fields for Lines 7-12 imply that manufacturers are only required to report the name of the physician covered recipient. Because the name of an individual non-covered recipient, which must be reported under the regulations, manufacturers are only required to report the name of the physician covered recipient. Because the name of an individual non-covered recipient, which must be reported under the regulations,25 we recommend that CMS revise the Definition/Description” Fields to align with the “Required” Fields and the regulations.

Research payments to institutional non-covered recipients and reporting TINs; Line 8. For research payments made to an institutional non-covered recipient, Line 8 of the Research Payment Template requires manufacturers to report the entity’s TIN. While the regulations require manufacturers to report the name of the research institutional, individual or entity receiving the payment or transfer of value, the regulations do not require manufacturers to report the TIN. Accordingly, we recommend that CMS change the required field in the Research Payment Template to indicate that such information is optional.

Principal investigators; Lines 30-47. It is unclear how manufacturers will report a research payment that involves multiple principal investigators. Additionally, the Research Payment Template does not contemplate reportable payments to teaching hospitals for research where the principal investigator is not a physician. We recommend that CMS revise the Research Payment Template to address these issues.

Principal investigator’s zip code and state; Lines 39 and 40. Line 39 requires applicable manufacturers to report a principal investigator’s zip code if the applicable manufacturer

previously indicated (1) the recipient of the research payment was a physician covered recipient (Line 6); (2) the physician receiving the research payment is not the principal investigator (Line 32); and (3) the principal investigator’s country is the United States (Line 40). By contrast, Line 40 requires applicable manufacturers to report a principal investigator’s state if the applicable manufacturer previously indicated (1) the recipient of the research payment was a physician covered recipient or an individual non-covered recipient (Line 6); (2) the physician receiving the research payment is not the principal investigator (Line 32); and (3) the principal investigator’s country is the United States (Line 40). The requirements for reporting a principal investigator’s zip code and state, should be consistent. Therefore, we recommend that CMS revise the requirements outlined in the “Required” fields for Lines 39 and 40. We also recommend that CMS review the “Required” fields generally to ensure that all requirements are accurate and consistent where necessary.

Multi-year research payments; Lines 53-56. Lines 53 through 56 of the Research Payment Template are identified as “Required” if a payment or transfer of value is part of a multi-year payment structure. Information to be reported includes: (1) total number of years for this research payment; (2) total number of years for this research project; and (3) the total budget of this research project. This information is outside the scope of the Final Rule and therefore not required to be reported. It is also unclear how to capture such information in an automated, physician-spend system. Accordingly, we recommend that CMS change the required field in the Research Payment Template to indicate that such information is optional.

Context of research; Line 59. Line 59 requires applicable manufacturers to provide a “Textual description of research context or research objectives.” The Final Rule, however, makes clear that CMS has “included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research.” Therefore, we recommend that CMS revise Line 59 to be optional only.

Reason for delayed publications; Line 61. Line 61 of the Research Payment Template requires manufacturers to report the reason a research payment is subject to delayed publication (if any). CMS provides the following options: (1) New Product; (2) Research on Medical Technology; (3) Clinical Investigation; or (4) None. These options are not consistent with the Final Rule, and it is not clear why this line is in the Research Payment Template when the Final Rule clearly states the criteria that must be met for a payment to be eligible for delayed publication. The Final Rule states that payments and other transfers of value related to research (excluding clinical investigations) of new products and new applications of existing products and clinical investigations of new products will be eligible for delayed publication, at a manufacturer’s discretion. If this line is kept in the

---

26 Please note that the internal cross references used by CMS in Lines 39 and 40 are inaccurate.
27 78 Fed. Reg. 9,458, 9484.
Research Payment Template, we recommend changing the options to: (1) Research (Excluding Clinical Investigations); (2) Clinical Investigations; or (3) None.

Lift delay in publication indicator; Line 62. Line 62 requires applicable manufacturers to indicate whether a “delay in publication” should be lifted according to the requirements of the Final Rule (i.e., expiration of the four-year maximum time allotment or FDA approval, licensure or clearance). Line 62 also implies that CMS can change a “No” response to “Yes” as a result of FDA approval or expiration of the four-year time allotment. While the Final Rule provides that “[f]ailure to notify CMS when FDA approval occurs may be considered failure to report,” the Final Rule does not provide that CMS may unilaterally report a payment identified as subject to delayed publication solely because FDA approval has occurred. By contrast, CMS may unilaterally report a payment identified as subject to a delay if the four-year maximum time allotment has expired.28 We recommend that CMS can only lift the delay in publication indicator in situations where the applicable payment or transfer of value has reached the four-year maximum time allotment.

Expenditure category; Line 64. Line 64 of the Research Payment Template is not required but allows manufacturers to report a contextual category for a research payment or transfer of value from an enumerated list to be provided by CMS at a later date. CMS provides the following examples: professional salary support, medical research writing or publication, patient care, non-patient care, overhead or other. Providing an enumerated list at some later date does not, however, afford manufacturers the opportunity to incorporate such information into their automated physician-spend systems. We therefore recommend that CMS provide the enumerated list within a reasonable time period with an opportunity for manufacturers and other stakeholders to comment on the same.

3. Non-Research Payment Template

Nature of payment – research; Line 39. Line 39 of the Non-Research Payment Template includes “09=Research” as an option for describing the nature of a payment. This option should be removed because such payments should be reported using the Research Payment Template.

Indirect payments and payments at the request of or designated on behalf of covered recipients; Lines 32, 44 and 45. Line 32 requires applicable manufacturers to report the name of the third party entity involved in an indirect payment to a covered recipient. Line 45 requires the manufacturer to report the name of the entity that received a payment or other transfer of value if (a) the covered recipient directed the manufacturer to pay a third party, or (b) the fee was waived and the manufacturer donated the payment to an entity. Line 44 requires manufacturers to report whether a payment or other transfer of value was (1) paid to the covered recipient, (2) paid to a

third party at the covered recipient’s request, or (3) waived by the covered recipient. In effect, Lines 32, 44 and 45 require applicable manufacturers to distinguish between indirect payments and direct payments that involve third parties. Under the Final Rule, however, applicable manufacturers are not obligated to classify payments or transfers of value as either indirect or direct.\(^{29}\)

Therefore, we recommend that Lines 32 and 45 be consolidated and require that applicable manufacturers report either (1) the name of the entity or individual involved in an indirect payment or (2) the name of the entity receiving a payment on behalf of a covered recipient or the term “individual” if an individual receives a payment on behalf of a covered recipient. This consolidated line should not require, however, the applicable manufacturer to identify whether the payment was indirect or direct (i.e., whether the information is being reported under (1) or (2)). We also recommend that Line 44 be removed because the Final Rule does not require applicable manufacturers to distinguish between payments made at the request of a covered recipient versus payments made on behalf of a covered recipient. It is also unclear how to capture such information in an automated, physician-spend system.

Additionally, Line 45 as currently structured, does not sufficiently recognize the nuanced nature of the waiver situation. The Final Rule makes clear that if the covered recipient waives a payment and the manufacturer still donates the payment “on behalf of the covered recipient,” then the payment remains reportable. If the covered recipient waives the payment and the manufacturer donates the payment, but not in the name of the covered recipient, then the payment is not reportable. Therefore, if CMS retains Line 45 separate from Line 32, we recommend that it be clarified to note that the name of the entity that received the payment waived by the covered recipient is only reportable if the payment or other transfer of value was made to the entity in the name of the covered recipient (not simply that the payment was waived and the manufacturer donated the payment to an entity).

III. INPUT ON PUBLIC WEBSITE CONTENT AND OPERATION

The Sunshine Provisions require CMS to establish a clear and understandable website reporting the required information, including background information on industry-physician relationships. As we noted in our comments to the proposed rule, such background ensures the reported data is meaningful and helpful in patient decision-making. Further, the context of reported transfers of value is critical to ensure patients do not form mistaken impressions that all payments to physicians are suspect. In order to ensure that the information posted on the website is clear and understandable, CMS must also ensure that the website it designs and develops is useable for both those reporting information and those reviewing reported information.

\(^{29}\) 78 Fed. Reg. 9,458, 9491 (“Given the unfavorable comments submitted regarding the proposal to classify research payments as direct or indirect, we believe that it would be similarly confusing to classify all payments or other transfers of value as either direct or indirect.”).
The following discussion addresses our recommendations with respect to background information to be included on the public website, as well as the operation of the website to ensure that the website is clear and understandable.

A. Recommendations on Website Context Information

Viewed simply as columns of numbers and “transfer of value” categories, the transparency reports will tell very little in terms of real world impact and are subject to a wide variety of positive and negative interpretations. As patients, caregivers and others review the posted “payment or other transfer of value” data, it will be important to understand the practical nature of these transfers and how they benefit patients, the nation’s health care system and medical advancements.

Given the importance of the background text on industry-covered recipient relationships, in our comments to the proposed rule, we encouraged CMS to publish proposed background text for public review and comment in advance of final promulgation. In addition, we asked that CMS not limit the background information to industry-physician relationships, because teaching hospitals are also covered recipients, and providing the context of transfers of value to teaching hospitals will be equally important.

In the Final Rule, CMS agreed that stakeholder input is essential to the success of the public website and indicated that it planned to engage stakeholders regarding the content of the website. We appreciate CMS’ willingness to engage in an open dialogue regarding this important issue, and we share below additional information and context related to medical device company-physician interactions. This information is consistent with the information we provided in our comments to the proposed rule.

There are numerous ways in which medical innovation companies compensate physicians, academics and health care professionals for their time, expertise and intellectual property, in connection with the development of new medical technologies, the improvement of existing technologies, and training and education of other health care professionals in the safe and effective use of medical technology, among other beneficial services. These arrangements fuel advances in medical technology, and improve medical care and the quality of healthcare available to American patients and consumers. Specific examples are below.

- **Consulting Fees** are both common and essential in the physician-industry innovation-focused relationship. Physician expertise is critical in the development of new medical technologies as well as the refinement and improvement of existing medical devices. Physician input into the device development process assures that an innovation will be of practical use to medical practitioners and will improve patient outcomes. For example, implanted medical devices can sometimes be reshaped to make it easier for physicians to implant. Such an adjustment can save time and prevent
potential complications. An improvement such as this cannot be done without the input of physicians who have real world experience with the device. Consulting fees are also paid for a variety of other activities, including training sales staff and other physicians on safe and effective use of an applicable manufacturer’s products.

- **Honoraria** may be paid when physicians provide their time, preparation and expertise to conferences or medical congresses to share research, provide input on new innovations, and highlight clinical challenges with existing technologies. These discussions are critical to educating physicians, advancing the science of medicine, and ensuring the efficacy of new products. Additionally, honoraria may be paid for instructing company personnel, such as medical science liaisons and research development professionals about the clinical challenges faced in a particular practice area. Physicians deserve compensation for the time taken away from their practice to help with these efforts for the common good. Honoraria therefore may be paid for the same types of activities as consulting fees, although, honoraria are typically used when the physician is expected to provide a limited number of services during a year, and an honoraria agreement may be entered into for each service.

- **Education** is an essential component of the innovative process. When a new device is developed, or an existing technology improved, physicians and other health care professionals often require training on the correct technique, application and usage of the technology. In fact, in many cases, the FDA requires product specific training and education for new devices.

- **Research** is the bedrock of advancing medical progress. To bring a new, beneficial health care innovation from concept to the patient may require years of research and development, at substantial expense. Manufacturer research payments compensate physicians, health care professionals, research institutions, and members of the academic community who bring their unique expertise and perspectives to the research and development process. Research payments and grants offset a variety of other expenses related to research and development, such as institutional review board (“IRB”) preparation and approval, patient informed consents, patient follow-up visits for designated periods of time, reimbursement of certain patient expenses, submission of required data, adverse event reporting, investigator meetings, monitoring visits to confirm compliance, and publication of clinical results.

- **Royalty or license.** In many cases, a new product or an improvement of an existing technology springs from the mind of the health care professional. As practitioners in the field, physicians regularly generate new ideas, designs or prototype technologies. In exchange for the physician’s intellectual property rights and know-how, companies and physician-innovators may enter into agreements that grant the physician innovators royalties or other payments based on sales of products that use the physicians’ intellectual property.
• **Direct compensation for serving as a faculty or a speaker.** Physician-to-physician sharing of medical and scientific knowledge is vital to disseminating information on the most effective uses and applications of new medical innovations, and in training other practitioners on the safe and effective use of technology. Manufacturers typically do not compensate faculty for accredited programs. Instead, they typically compensate physicians serving as faculty for manufacturer programs through consulting or honoraria agreements.

In addition to the above information, it is important to note that industry-physician relationships are also driven by manufacturers’ voluntary compliance with and adoption of codes of conduct, such as AdvaMed’s Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code” or “Code”). AdvaMed developed the Code in 2003 to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making, and strengthened the Code in 2009. A copy of the AdvaMed Code is attached hereto as Exhibit A. Pursuant to the AdvaMed Code, medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program.

In addition to the Code, AdvaMed takes aggressive steps on an ongoing basis to educate the industry and health care professionals about the Code, ethical interactions, and compliance. The AdvaMed Board Ethics and Health Care Compliance Committee has approved a series of Code of Ethics Best Practices guidance documents to assist companies in ensuring that their interactions with health care professionals, including physicians, are ethical and compliant. Specific guidance documents include the following, which are attached hereto as Exhibits B - M, respectively.

- Illustrative Research Grant Funding Best Practices & Considerations
- Illustrative Royalty Best Practices
- Illustrative Plant Tours Best Practices & Considerations
- Illustrative Grand Rounds Best Practices & Considerations
- Illustrative Educational Item or Patient Benefit Item Best Practices
- Illustrative Third Party Educational Conferences Best Practices & Considerations
- Illustrative Demonstration/Evaluation Unit Best Practices
- Illustrative Charitable Donations Best Practices
- Illustrative Meal/Refreshment Provision Best Practices
- Illustrative Best Practices & Considerations for Health Care Professional Travel
- Illustrative Consulting Arrangements Best Practices & Considerations
- Illustrative Fellowship Grant Funding Best Practices & Considerations
In developing website content related to the nature of relationships between physicians and teaching hospitals and the industry, including an explanation of beneficial interactions, we recommend that CMS incorporate existing industry codes of conduct and guidance, including the information referenced above. Such codes and guidance are widely accepted within the industry and have been developed with the intent to differentiate beneficial financial relationships from those that may create improper conflicts of interest.

B. Recommendations on Website Design, Development, and Operation

In addition, and more generally related to the public website, it is our understanding that CMS plans to engage a third party vendor to assist with design and development of the public website on which the information collected will be made publicly available. It is imperative that the website is designed, developed, and operated in a way that ensures that manufacturers can accurately report reportable information and the public can accurately view such information. Given the amount of data expected to be reported and made available, stakeholder input and involvement with this process is essential. Therefore, we recommend that CMS provide to manufacturers and other entities a designated a contact person(s) who is responsible for resolving posting and other technical errors and who can address other questions that may arise. Further, we recommend that within six months (or some other reasonable time) following the first report submission using the website or related terminal, CMS survey manufacturers and other entities to solicit feedback regarding the public reporting process and the website in particular, to evaluate the process and the vendor in charge of operations.

* * *

AdvaMed appreciates the enormous technical and other complexities associated with implementation of the Final Rule. We thank you for considering these comments, and AdvaMed looks forward to actively engaging in continued dialog with CMS as the guidance process proceeds.

Sincerely,

Stephen J. Ubl
President and CEO

cc: Christopher White, Esq.
AdvaMed General Counsel
CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS
ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association (“AdvaMed”) represents 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 (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individually “Company”). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and 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 (“Health Care Professionals”).

Medical Technologies

Medical Technologies are often highly dependent upon “hands on” Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician’s hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- Promote the Advancement of Medical Technologies. Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals. The scope of beneficial interactions includes:...
Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company’s laboratory.

- **Enhance the Safe and Effective Use of Medical Technologies.** The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.

- **Encourage Research and Education.** Companies’ support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.

- **Foster Charitable Donations and Giving.** Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

### The Purpose of the Code of Ethics

AdvaMed recognizes that Health Care Professionals’ first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.\(^1\) To that end, AdvaMed restates and amends its Code of Ethics and Frequently Asked Questions (collectively “Code of Ethics” or “Code”), effective July 1, 2009.

#### II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this 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 Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company’s Chief Executive Officer and Chief Compliance Officer or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

---

\(^1\) The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an “unlawful inducement” to reflect Anti-kickback Statute prohibitions.
Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company’s Compliance Department or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

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.

**Note:** This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General (“OIG”), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies’ interactions with Health Care Professionals 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 engage in any unlawful inducement.

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

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. “Training” means training on the safe and effective use of Medical Technologies. “Education” means 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. Training and Education programs include, but are not limited to, “hands on” training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:
• Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional’s location.

• Programs providing “hands on” training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.

• Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.

• Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

IV.  Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

• Conference Grants. Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for bona fide educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.
• **Conference Meals and Refreshments.** Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Health Care Professional attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

• **Faculty Expenses.** Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.

• **Advertisements and Demonstration.** Companies may purchase advertisements and lease booth space for Company displays at conferences.

V. **Sales, Promotional, and Other Business Meetings**

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional’s place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

VI. **Consulting Arrangements with Health Care Professionals**

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

• Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
• Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.

• Selection of a consultant should be made on the basis of the consultant’s qualifications and expertise to meet the defined need.

• Compensation paid to a consultant should be consistent with fair market value in an arm’s length transaction for the services provided and should not be based on the volume or value of the consultant’s past, present or anticipated business.

• A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.

• The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.

• Company-sponsored meals and refreshments provided 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 should not provide recreation or entertainment in conjunction with these meetings.

• A Company’s sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

**Provisions on Payment of Royalties.** Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the
Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.) Companies are strongly encouraged 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 Health Care Professional and/or members of the Health Care Professional’s practice.

VII. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

A Company’s business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

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

Setting and Location. Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the Health Care Professional’s place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional’s place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional’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. A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where
everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a “dine & dash” program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- Section III: Company-Conducted Product Training and Education.
- Section IV: Supporting Third-Party Educational Conferences.
- Section V: Sales, Promotional, and Other Business Meetings.
- Section VI: Consulting Arrangements with Health Care Professionals.

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than $100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company’s name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

X. Provision of Coverage, Reimbursement and Health Economics Information

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.
Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company’s Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.

- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.

- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company’s Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.

- Providing accurate and objective information about the economically efficient use of the Company’s Medical Technologies, including where and how they can be used within the continuum of care.

- 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, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional’s decision to buy or use the Company’s Medical Technologies.

- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company’s Medical Technologies.

- Facilitating patient access to the Company’s Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company’s Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company’s own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional’s independent clinical decision-
making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

XI. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Company’s sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company’s Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- **Advancement of Medical Education.** A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)

- **Public Education.** A Company may make grants for the purpose of supporting education
of patients or the public about important health care topics.

c. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (*e.g.*, consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when 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.

*Single Use/Consumables/Disposables.* The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

*Multiple Use/Capital.* Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional’s location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

*Demonstration.* Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration
products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.
FREQUENTLY ASKED QUESTIONS REGARDING ADVAMED’S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed’s Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and “hands on” nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 Who are “Health Care Professionals”? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?

The phrase “Health Care Professionals” is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician’s practice managers and management within group purchasing organizations (“GPOs”).

Q3 Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside
the country (such as at a conference or other event). Of course, there are other laws and ethical requirements that may pertain to interactions with Health Care Professionals located both inside and outside the United States.

**Q5 Are combination products covered by the Code?**

Yes, interactions related to combination products (e.g., those that are both biologics and devices or drugs and devices) are covered by the Code. Interactions related to combination products also may be subject to the ethical codes of other trade associations.

**Q6 Does the Code address arrangements between a Company and a Health Care Professional relating to licensing a new product to the Company?**

If these arrangements involve providing services to a Company, they are a type of consulting arrangement addressed in Section VI.

**Q7 What do the terms “modest” and “occasional” mean?**

“Modest” means moderate value, but may differ depending on regional differences. “Occasional” means infrequent.

The provision of meals is subject to the limits discussed in Section VIII. A Company should consider establishing limits on the frequency and costs of meals provided to Health Care Professionals to comply with the requirements that the meals must be “modest” and “occasional.”

**Q8 May a Company’s employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?**

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

**Q9 May a Company offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 units of the Company’s medical technology that the Company has just introduced?**

No. A Company may not provide any item of value to a Health Care Professional that takes into consideration the value or volume of the business that is or may be generated by the Health Care Professional, unless permitted by law (e.g., appropriate discounts).

**Q10 May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?**

No, such support would be inappropriate.
SECTION II:  CODE OF ETHICS COMPLIANCE

Q11  What form should Companies use to make the certification described in Section II, and on what date are such certifications due?

The revised AdvaMed Code of Ethics will take effect on July 1, 2009. Company certifications should be submitted no later than July 1 of each year, beginning in 2010. AdvaMed will publish the certification form that Companies should use. While it may take a period of time for Companies to adopt the revised Code, create and implement policies, procedures and effective compliance programs to comply with the Code, and educate and train employees whose job responsibilities make the information relevant, Companies should endeavor to accomplish these tasks as diligently as reasonably possible.

Q12  Does the AdvaMed Code of Ethics offer legal advice?

No. The Code is intended to facilitate ethical behavior and is not intended to be, nor should it be, construed as legal advice. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations.

Q13  Will AdvaMed staff provide advice on how the Code would apply to specific practices?

No. Companies should address questions about specific practices to their own attorneys or advisors.

Q14  Does the Code govern the actions of Companies’ agents and distributors?

As stated in Section II, Companies adopting the Code are required to communicate the Code’s provisions to their employees, agents, dealers and distributors with the expectation that they will adhere to them. It is important that these entities are informed that AdvaMed has revised its Code of Ethics and that they are aware of the ethical standards reflected in it.

Q15  What does “appropriately tailored” mean with respect to implementation of the seven elements of an effective compliance program?

“Appropriately tailored” means that each Company’s implementation of the seven elements of an effective compliance program should take into account the Company’s size, resources, particular lines of business, and work-force. AdvaMed recognizes that, given the wide diversity within the medical technology industry, there is no single best compliance program. AdvaMed strongly encourages Companies to develop and implement compliance elements that address the specific types of risks that apply to their operations.
SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Q16 Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?

In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education. (Meetings focused on sales, promotional, and other business meetings are discussed in Section V.)

Q17 May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?

It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional’s travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.

SECTION IV: SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Q18 May a Company designate attendees or faculty who will speak at a third-party educational conference?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor’s guidelines. The ultimate selection should be made by the conference sponsor.

Q19 May a Company provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?

The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

Q20 If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?

Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.
Q21  May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?

Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines.

SECTION V:  SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

Q22  Why does the Code not allow Companies to extend business courtesies to guests/spouses in connection with sales, promotional and other business meetings?

AdvaMed’s Code of Ethics is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Company’s Medical Technologies. On the other hand, Companies may, as a matter of common courtesy and civility, provide occasional modest meals or refreshments for Health Care Professionals in connection with these types of meetings that are conducive to the exchange of information. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a bona fide professional interest in the meeting.

Q23  May a Company conduct a sales, promotional, or other business meeting at a resort location and pay for a Health Care Professional’s travel to the meeting?

Generally, this would not be appropriate. Companies should be deliberate in selecting the location and venue for such meetings. Like location and venue selection for training and education meetings (discussed in Section III), Companies should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Section V, which state that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be “necessary.” Furthermore, the Code provides for limited special circumstances of “plant tours and demonstrations of non-portable equipment” as specific examples of when travel might be necessary.

Q24  May a Company indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Code, for example, by reimbursing a distributor who provides these meals while marketing the Company’s Medical Technologies?

No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company’s Medical Technologies. A Company should never knowingly encourage or condone an intermediary’s engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.
SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Q25 Is a clinical investigator considered a “consultant” under Section VI?

If the clinical investigator is providing services to the Company in return for compensation, he or she is a consultant under Section VI.

Q26 Is there a limit to the number of consultants a Company may retain under Section VI?

Companies may retain only as many consultants as are necessary to fulfill the Company’s requirements for bona fide services; moreover, the requirements of Section VI must be satisfied for each consultant.

Q27 May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section VI are met.

Q28 What happens if a consultant is engaged but the project is cancelled or modified without using the consultant’s services?

The Code contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.

Q29 What factors should a Company consider when evaluating the venues and circumstances for meetings with consultants?

A Company should assess (a) whether there is a bona fide business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information; (c) whether the value of any Company-sponsored lodging is reasonable; (d) whether any ancillary meals and refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not constitute an unlawful inducement.

Q30 Do the restrictions of the AdvaMed Code apply to Company interactions with consultants in the same way as they do to interactions with other Health Care Professionals?

Yes. All interactions with Health Care Professionals must meet the requirements of the Code. These include the requirements of Section VI as well as other applicable sections of the Code.

Q31 When is a Health Care Professional considered a “consultant”? What types of arrangements with consultants are covered under Section VI?
Any relationship between a Health Care Professional and a Company where services provided to the Company by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with Section VI. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, proctoring and preceptorships, reference center or center of excellence arrangements, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting arrangements. They are addressed in Section XI.

Q32 Can the selection of a consultant include his or her experience, usage or familiarity with a specific Company Medical Technology?

Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement.

Q33 How are Clinical Study Agreements treated under the Code?

Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (e.g., protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

Q34 How can a Company establish “fair market value”?

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

Q35 What is considered a “legitimate need” to engage a Health Care Professional as a consultant?

A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly
from such Health Care Professional (or a health care provider that is affiliated with the Health Care Professional) is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. Further, the level of consulting services to be obtained from a Health Care Professional should not exceed the amount that is reasonably necessary to achieve a Company’s proper business objective.

SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION

Q36 May a Company’s employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

SECTION VIII: MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

Q37 Is a general discussion to build good business relationships a “business presentation” such that it is appropriate to provide a business meal?

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS

Q38 May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional’s office or staff?

No. These types of gifts and refreshments are not considered educational items or for the benefit of patients.

Q39 May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to all applicable provisions of the Code.
Q40  May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement even if provided to recognize a significant life event.

Q41  May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section IX.

Q42  What types of items are considered to be for the benefit of patients?

Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, “scrubs” and office supplies would not be considered an item for the benefit of patients. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.

SECTION X:  PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

Q43  Is it appropriate to demonstrate that a Medical Technology can be used in an economically efficient manner?

It may be appropriate for Companies to provide accurate information relating to the costs, savings and revenues associated with the use of its Medical Technologies. Without this information, it may be difficult for a Health Care Professional to properly evaluate their economic feasibility or desirability.

SECTION XI:  RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Q44  What is an example of a grant or donation to “individuals engaged in genuine charitable missions for the support of that mission”?

One example is providing medical technologies to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code, notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.
Q45  May a Company make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for an affiliated Health Care Professional to attend a third-party educational conference?

In general, Section IV does not permit a Company to pay directly for the registration, seminar fees or travel expenses of a Health Care Professional’s attendance at a third-party educational conference. Consequently, the Company should not provide these benefits indirectly as a charitable contribution to a Health Care Professional’s not-for-profit institution for the purpose of defraying the costs of particular individuals’ attendance. However, it can provide grants to sponsors to: 1) pay the expenses of faculty members selected by the conference sponsor; 2) support the participation of Health Care Professionals in training; or 3) reduce the costs of participation by all participants.

Q46  May a Company make a charitable contribution to a not-for-profit hospital for construction of a new wing?

Companies have historically supported the delivery of health care services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if: (a) the recipient of the contribution is a charitable organization; (b) the purpose of the donation is charitable in nature; and (c) it is not an unlawful inducement. Many factors would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Company.

Q47  May a Company make an educational grant to pay for a clinical fellow?

A Company may make an educational grant to an institution to subsidize a clinical fellow if the fellow is in a genuine fellowship program which has a charitable or academic affiliation. A Company may not use the provision of an educational grant as an unlawful inducement.

Q48  May a Company pay for or provide tickets to a Health Care Professional or spouse or guest to attend charitable events, such as galas and golf outings?

No. A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

Q49  May a Company give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?

No. A Company should give research grants only if they are in support of research that has defined goals, objectives, and milestones.

Q50  May a Company make a contribution in support of a Health Care Professional’s charitable event (e.g., golf tournament, outing, gala dinner, and the like), where the proceeds earned from the event will be used for charitable purposes?

Yes, so long as the donation is not an unlawful inducement. However, a Company may not pay for an individual Health Care Professional to attend or participate in the charitable event.
Q51 How can a Company determine whether a charitable organization is a *bona fide* charitable organization?

Companies should exercise diligence to ensure the charitable organization is *bona fide*. Relevant factors to consider may 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, among other factors.

**SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS**

Q52 May a Company provide a recently approved product without charge to a Health Care Professional for evaluation?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately address any obligation to report for reimbursement purposes.

Q53 A Health Care Professional has requested that a Company provide it with a multiple use product to evaluate. How long can the Company provide the product at no charge to the Health Care Professional?

The specific length of time reasonably necessary for a Health Care Professional to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. A Company should provide a Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation products.

Q54 Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional by a Company a gift?

No. Demonstration and evaluation products are not considered gifts under Section IX.
**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.

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.

---

### Support of this research grant is not permitted by the Code.

- **Is the research grant provided as an unlawful inducement?** [Section XI, FAQ 47]
  - Yes
  - No

- **Was this research grant request and/or dollar award amount controlled or unduly influenced by sales personnel?** [Section XI]
  - No
  - Yes

- **Is the research grant appropriately documented?** [Section XI]
  - No
  - Yes

- **Does the research activity in question have well-defined objectives and milestones?** [Section XI]
  - No
  - Yes

---

**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
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
      - This royalty arrangement is permitted by the Code.
    - No
      - 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
          - 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
              - This royalty arrangement is not permitted by the Code.
            - No
              - Is the contribution by the HCP appropriately documented? [Section VI]
                - Yes
                  - Is the payment consistent with fair market value? [Section VI]
                    - Yes
                      - This royalty arrangement is permitted by the Code.
                    - No
                      - No
                - No
                  - No

- No
  - Is the Company have a bona fide business need to license the intellectual property? [Section VI]
    - Yes
      - This royalty arrangement is not 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
          - Note: Arrangements involving the payment of royalties to an HCP should meet the contractual standards set forth in Section VI of the Code.
        - No
          - 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 practice.

Is the Company have a bona fide business need to enter into an agreement with the HCP to develop a Medical Technology?

- 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
      - 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
          - This royalty arrangement is not permitted by the Code.
        - No
          - Is the contribution by the HCP appropriately documented? [Section VI]
            - Yes
              - Is the payment consistent with fair market value? [Section VI]
                - Yes
                  - This royalty arrangement is permitted by the Code.
                - No
                  - No
            - No
              - No

- No
  - Is the royalty payment conditioned on a requirement that the HCP market the product or medical technology upon commercialization? [Section VI]
    - Yes
      - Note: Companies may elect to enter into separate consulting agreements with HCPs for marketing services consistent with Section VI.
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.

**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

**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 tours [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
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:

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]
   - Yes: Review grand rounds request as 3rd party educational conference support
   - No: Review grand rounds request as company conducted training

2. 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]
   - Yes: Does the training staff have proper qualifications and expertise to conduct the training? [Section III]
     - Yes: 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]
       - Yes: This grand rounds activity is permitted by the Code.
       - No: This grand rounds activity is not permitted by the Code.
     - No: This grand rounds activity is not permitted by the Code.
   - No: This grand rounds activity is not permitted by the Code.

[Diagram of flowchart]

[Diagram of flowchart]

[Diagram of flowchart]
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.

**Illustrative Educational Item or Patient Benefit Item Best Practices**

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

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

- **Yes**: Does providing the item to the HCP serve a genuine educational function for the HCP? [Section IX]
  - **Yes**: Is the item capable of a non-educational, non-patient related purpose of the HCP? [Section IX]
    - **Yes**: Is the item offered as an unlawful inducement? [FAQ 42]
      - **Yes**: The item is prohibited by the Code. Do not provide.
      - **No**: The item is permitted and may be provided.
    - **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**: The item is prohibited by the Code. Do not provide.
          - **No**: Is the item a permitted educational item and may be provided.
        - **No**: Is the item offered as an unlawful inducement? [FAQ 42]
          - **Yes**: The item is prohibited by the Code. Do not provide.
          - **No**: Is the item a permitted educational item and may be provided.
      - **No**: Is the item offered as an unlawful inducement? [FAQ 42]
        - **Yes**: The item is prohibited by the Code. Do not provide.
        - **No**: Is the item a permitted educational item and may be provided.
  - **No**: Is the item a permitted patient benefit item and may be provided.

- **No**: Is the item intended for the patient (e.g., starter kit, educational brochures)? [Section IX, FAQ 42]

**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, non-patient-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]
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.

---

**Is the event primarily dedicated to objective scientific and educational activities? [Section IV]**

*Note: A Company may want to consider establishing a threshold for minimum number of hours dedicated to education.*

- **Yes**
- **No**

**Does the training institution or conference sponsor select attending HCPs? [Section IV; FAQ 18, 19, 20]**

- **Yes**
- **No**

**Is the grant recipient (payee) an organization with a genuine educational function? [Section IV]**

- **Yes**
- **No**

**Does the conference sponsor have independent control and responsibility for the selection of program content, faculty, educational methods, and materials? [Section IV; FAQ 18]**

- **Yes**
- **No**

**Is the venue conducive to the educational program? [Section IV]**

- **Yes**
- **No**

**Is the grant consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity (e.g., ACCME)? [Section IV]**

- **Yes**
- **No**

---

**Support of this 3rd party educational conference is not permitted by the Code.**

---

**Key Terms**

<table>
<thead>
<tr>
<th>Terms</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?

**Agenda**

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

**Conference Topic**

- (disease state/therapeutic area)
- Is the topic relevant to the business & supportive of business objectives?

**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?

**Note:** Many companies request the total budget figures from the conference organizers.

- Are multiple companies providing support, or is my company the sole supporter?
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.

Is the item a demonstration unit or an evaluation unit?

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].

Does the Company retain title to the evaluation product during the evaluation period? [Section XII]

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]

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

This item is prohibited by the Code. Do not provide.

This item is permitted and may be provided.

This item is permitted and may be provided.

This item is permitted and may be provided.

This item is permitted and may be provided.

This item is permitted and may be provided.
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

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.

This charitable donation is permitted by the Code

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.
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.

### Purpose (Q1): Is the meal being provided in conjunction with an HCP interaction with a bona fide business purpose?
- Yes
- No

### 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?
- Yes
- No

### Purpose (Q3): Is the meal part of an entertainment or recreational event?
- Yes
- No

### Value (Q1): Is the business meal modest and occasional?
- Yes
- No

### Setting & Location (Q1): Is the venue/setting conducive to bona fide scientific, educational, or business discussions?
- Yes
- No

### Participants (Q1): Is the meal for an individual who has a bona fide professional interest in the information being shared at the meeting?
- Yes
- No

### Participants (Q2): Is the meal for only individuals in attendance at the event?
- Yes
- No

**Footnotes:**
All references to “meals” in the decision tree above refer to both “meals” and “refreshments.”
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]

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.

This Consulting Agreement 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.

The AdvaMed Code permits a Company to pay for an HCP’s travel expenses in the following situations:

- **Company Conducted Training and Education** [Section III]
- **Sales, Promotional, and Other Business Meetings** [Section V]
- **Consulting Arrangements** [Section VI]

**A Company may consider the following factors, among others, when determining whether payment for travel is appropriate:**

- 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) [Section III, FAQ 16]?
  
  *Note: It is not appropriate for Companies to pay for travel or other expenses for guests of HCPs without a bona fide professional interest in the information being shared at the meeting [Section III]. It is also inappropriate to provide travel to HCPs for a general education session [FAQ 17].*

- For meetings with consultants, is the travel necessary to carry out the consulting arrangement, and are the venue and circumstances of the meeting appropriate to the subject matter of the consultation [Section IV]?

- The AdvaMed Code contemplates that travel will be reasonable in nature.
  
  *Note: factors to consider may include the duration of travel, how travel dates and times align with the planned meeting or consultation, class of travel, and cost.*

- Is HCP traveling to a sales, promotional, or other business meeting necessary (e.g., for plant tours or demonstrations of non-portable equipment) [Section V]?

- Is the travel being provided to the HCP as an unlawful inducement?

**A Company may also wish to take into account the following additional factors when determining whether payment for international travel is appropriate:**

*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 the travel provided reasonable in nature [Section III]?

- Has the Company identified an objective need for the travel [Section III] or is the travel necessary to conduct a business meeting (e.g., a plant tour or a demonstration of non-portable equipment) [Section V]?

- Is the travel location appropriate for, and conducive to, accomplishing the purpose of the meeting or training [FAQ 23]?
  
  *Note: Generally, conducting a sales, promotional, or other business meeting at a resort location would not be appropriate [FAQ 23].*
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.

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

- 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]

- No

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

- Yes

**Is the fellowship grant appropriately documented?** [Section XI]

- No

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

- Yes

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

- Yes

**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]

**Other Considerations - Fellowship Grant Funding**

- 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

Support of this fellowship grant is not permitted by the Code.

This fellowship grant is permitted by the Code.