

# U.S. SALES & MARKETING CODE OF CONDUCT

DO THE RIGHT THING



DJO Global Incorporated requires its sales and marketing personnel to observe high standards of integrity and honesty, and to act with care, diligence and fairness in all business activities. Interactions with all stakeholders and wider society should be conducted in an ethical and legal matter.

To that end, all of us must comply with this code and all supporting policies, the laws and regulations of all countries in which we operate, and all applicable national and international codes.

#### VISION

To be the worldwide leader in providing solutions that promote musculoskeletal health.

#### MISSION

To improve lives by developing medical devices that become the standard of care in the prevention, treatment and rehabilitation of musculoskeletal conditions.

#### WEBSITE

[www.djoglobal.com](http://www.djoglobal.com)

#### ANONYMOUS COMPLIANCE HOTLINE

877.888.0002

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What we do affects the  
reputation and success of DJO Global.

**DO THE RIGHT THING**

**INTRODUCTION**



## WHO MUST COMPLY WITH THIS CODE?

This Sales & Marketing Code of Conduct (“Code”) applies to DJO Global and its subsidiaries (collectively, “DJO Global” or the “Company”) as well as its business associates, which includes our independent sales force. It also applies to full and part-time DJO Global officers, directors, employees and temporary staff worldwide. If you have received a copy of this Code, it means it applies to you! You are expected to read it and comply.

## WHAT ARE YOUR OBLIGATIONS?

Because this Code and our supporting policies cannot cover every situation that may arise, you are expected to exercise good judgment and common sense in deciding the right actions to take. You should ask questions if you are unclear about any aspect of this Code, or if you are not sure how to respond to an issue that the Code does not address. If you are a member of the DJO Global management team (i.e., this includes supervisors, managers, directors, vice presidents, and executives), you are responsible for helping your teams understand the requirements of this Code, the DJO Global policies that support the Code, and how they should best be put into practice.

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*Both DJO Global employees and our independent business associates may be asked to provide assurance of compliance to the DJO Global Executive Team and Board of Directors.*

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## QUICK REFERENCE

- You are responsible for understanding the requirements of this Code, the DJO Global policies that support the Code, and how they should be put into practice.
- DJO Global desires to work only with individuals and entities that demonstrate a commitment to ethical behavior consistent with the standards and principles set forth in this Code.

## WHAT ARE THE CONSEQUENCES OF NON-COMPLIANCE?

Any failure to comply with this Code or its supporting policies will be fully investigated and appropriate action taken. This may include re-training, discipline, or other corrective action, up to and including termination of employment, or termination of a contract or business with DJO Global business associates, depending on the circumstance.

## HOW TO SUBMIT REQUESTS, ASK A QUESTION, OR RAISE A CONCERN

### DJO Global Corporate Compliance Department

You may at some time come across a situation that appears to violate a DJO Global policy. Everyone has a duty to promptly report any suspected violation of this Code. In general, you should first seek to address your concerns with your DJO Global manager or representative. If for some reason you believe this is not possible or appropriate, you may contact the DJO Global Corporate Compliance Department. In all instances, every effort will be made to ensure that information relating to a reported violation is kept confidential and communicated on a need-to-know basis only.

Anyone who raises a concern about a possible compliance breach in good faith will be supported by the Company, and will not be subject to retaliation. Any act or threat of retaliation will be in itself considered a serious violation of this Code.

If you are not comfortable reporting the information directly to your DJO Global manager or representative, or to the Corporate Compliance Department, you may call the **Anonymous Compliance Hotline at 877.888.0002.**

## PROFESSIONAL RELATIONS COMMITTEE (PRC)

If you would like to submit a request for approval for a Company sponsored event, sponsorship of a third party educational event, etc., please submit directly to the **PRC via email: [prc@djoglobal.com](mailto:prc@djoglobal.com) or fax: 760.597.8487.**

All PRC forms are available on **DJOConnect** under **Global Functions/Corporate Compliance/Shared Documents/PRC**. A quick PRC Form reference matrix is provided on the following pages. Independent sales representatives should contact their DJO Global representative for assistance.

## PRC FORMS QUICK REFERENCE<sup>1</sup>

I WANT TO...	I USE FORM	WHEN SHOULD I SUBMIT THE FORM?
Obtain Exhibit Space	• Exhibit Exemption Checklist, or	NA
	• Third Party Conference Support Request Form (If any answer to questions on Exhibit Exemption Checklist is "yes")	6 weeks prior to event
Provide Third Party Conference Support	• Third Party Conference Support Request Form (If any answer to questions on Exhibit Exemption Checklist is "yes")	6 weeks prior to event
Host a DJO Global Sponsored Event Training, Educational, or Business Event (e.g., Educational Lab)	• DJO Global Business Interaction Form D • AdvaMed Statement of Support (provide to attendees at event)	45 days prior to event. However approval should be obtained prior to arrangements being made
	• HCP Tracking Form	After event takes place
Host a DJO Global Educational Breakfast, Lunch or Dinner (estimated costs are equal to or greater than \$1000)	• DJO Global Business Interaction Form D • AdvaMed Statement of Support (provide to attendees at event)	45 days prior to event
	• HCP Tracking Form	After event takes place
Host a DJO Global Educational Breakfast, Lunch or Dinner (estimated costs are less than \$1000)	• AdvaMed Statement of Support (provide to attendees at event) • HCP Tracking Form	After event takes place
Request a Consulting, Product Development or Honorarium Agreement	• HCP Agreement Request Form B	A minimum of 6 weeks prior to need for services. Approval should be obtain prior to the provision of services.
Authorize Consulting Services for an HCP with an established Agreement	• Work Activity Pre-Approval (WAPA)	15 business days prior to the use of the consultant's services

<sup>1</sup>For Grants and Charitable Donations please see the Grants and Charitable Donations section of this Code.

## CORPORATE COMPLIANCE & PRC CONTACT INFORMATION

CORPORATE COMPLIANCE DEPARTMENT	
Corporate Compliance Email:	corporate.compliance@djoglobal.com
DJO Global Compliance Officer Phone:	760.734.4742
DJO Global Compliance Officer Email:	dale.hammer@DJOglobal.com
Corporate Compliance Mailing Address:	1430 Decision Street, Vista, CA 92081-8553
Anonymous Compliance Hotline:	877.888.0002
PROFESSIONAL RELATIONS COMMITTEE	
PRC Phone:	760.597.3925
PRC Email:	PRC@DJOglobal.com
PRC Fax:	760.597.8487

## POLICY STATEMENT

The successful business operation and reputation of DJO Global is built upon the principles of fair business practices and ethical conduct of its employees and business associates, including the DJO Global independent sales force.

Such practices and conduct extend, but are not limited, to:

- A. Accurate reporting, maintenance and confidentiality of all business and patient records;
- B. Respect and care for the Company, including the Company's name, property and ideas;
- C. Avoidance of conflict of interest situations, or outside influences which could interfere with an individual's ability to represent the Company appropriately or perform his or her job responsibilities fully;
- D. Protection of confidential or proprietary information, which must be safeguarded from unauthorized and/or inappropriate disclosure outside the organization;
- F. Relationships and dealings with customers and suppliers that are conducted on a fair and equitable basis;
- G. Dealings with competitors that comply with antitrust rules related to pricing and business tactics.



## FRAUD & ABUSE

### Anti-Kickback Statute

The Federal Anti-Kickback Statute ("AKS") establishes criminal as well as civil penalties for offering, paying, soliciting, or accepting a kickback, bribe, rebate or any other form of remuneration for ordering or purchasing a product or any service reimbursable by federal or state health care programs, including Medicare. Because many DJO Global products are reimbursable by Medicare, the AKS is applicable to the Company's sales and marketing practices.

***In addition to corporate penalties, the AKS provides that violators may be fined in their individual capacity and may receive jail terms if they are found guilty of any violations.***

To avoid violating the AKS, it is important to remember that no program or practice involving remuneration to customers may have, as part of its purpose, the securing of referrals for products or services reimbursed by a federal or state program.

## FALSE CLAIMS ACT

The False Claims Act (FCA) prohibits the knowing submission of false or fraudulent claims to the federal government. Many states have also adopted FCAs or other laws that are similar to those found in the federal FCA. Examples of a False Claim include, but are not limited to: filing a claim for services that were not rendered at all or were not rendered as described on the claim form; filing a claim for services that were rendered, but were not medically necessary; submitting a claim containing information one knows to be false; or assisting a customer in submitting a false or fraudulent claim.

A person or entity found liable under the FCA is subject to a civil monetary penalty of between \$5,550 and \$11,000 per False Claim, plus three times the amount that the government paid for each False Claim.

***In addition to fines and penalties, the courts can impose criminal penalties against individuals and organizations for willful violations of the FCA. States that have adopted False Claims laws can also impose significant fines and penalties.***

## QUICK REFERENCE

- The Anti-Kickback Statute prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business.
- Many states have adopted state anti-kickback statutes that have the same penalties as the Federal Anti-Kickback Statute.



## WHISTLEBLOWER STATUTE

The FCA allows anyone to bring a *qui tam* (whistleblower) action under the FCA. Anyone initiating a *qui tam* case will not be discriminated or retaliated against by the Company. The employee is authorized under the FCA to initiate court proceedings to make themselves whole for any job related losses resulting from any such discrimination or retaliation.

# LEGISLATION OVERVIEW



## MASSACHUSETTS AND VERMONT

On July 1, 2009, stringent new requirements relating to the sales and marketing of medical devices became effective in Massachusetts and Vermont. Both laws include gifts bans and reporting requirements and impose penalties for non-compliance.

The ability to track, consolidate, and report all covered payments by individual HCP requires medical device companies to have the appropriate systems in place to capture and consolidate information by HCP name, the nature and purpose of each reportable expenditure, the amount of the payment, and any other remuneration provided. Such laws also impose new administrative requirements on medical device companies. By way of example, the Massachusetts law requires:

- The adoption of a marketing code of conduct that is in compliance with the new regulations
- Adoption of a training program based on the marketing code of conduct
- Certification to the state that, to the best of its knowledge, the company is in compliance with the new regulations
- Adoption of policies and procedures for investigation of non-compliance with the new regulations

## QUICK REFERENCE

- The laws in Massachusetts and Vermont extend beyond and are more restrictive than the AdvaMed Code in a number of areas
- Vermont – Charitable contributions to HCPs and hospitals (including fellowships) are banned
- Massachusetts – Monetary donations are permitted to a 501(c)(3) entity only
- Physician Payment Sunshine Provision – requires all payments to US licensed physicians and teaching hospitals to be tracked and reported if a single expense is greater than \$10 or total spend is equal to greater than \$100

# EXHIBIT SPACE/THIRD PARTY CONFERENCE SUPPORT



CONTINUING MEDICAL EDUCATION ("CME"), THIRD-PARTY SCIENTIFIC OR EDUCATIONAL CONFERENCES, OR PROFESSIONAL MEETINGS			
REQUIREMENT	ADVAMED CODE	MASSACHUSETTS	VERMONT
The conference must be a legitimate independent educational, scientific, and policy making conference	✓	✓	✓
Conferences must promote knowledge, medical advancement or the delivery of effective health care	✓	✓	✓
Only the conference sponsor may select the HCP attendees	✓	✓	✓
Meals and refreshments must be modest in value and subordinate in time and focus to the purpose of the conference	✓	✓	✓
Booth/exhibit/advertisement space may be purchased	✓	✓	✓
The conference sponsor must independently control and remain responsible for the selection of program content, faculty, educational methods, and materials	✓	✓	✓
Any DJO Global support provided must be consistent with standards established by the conference sponsor and any body accrediting the educational activity	✓	✓	✓
Grants for Non-CME conferences (i.e., an independent medical education or professional meeting that are <u>not</u> accredited by the Accreditation Council for Continuing Medical Education ["ACCME"] or equivalent accreditation body.)	Yes if the above listed requirements are met	Yes as long as the conference meets ACCME or accrediting body standards	No
DJO Global <u>may not</u> reimburse faculty directly for time, travel or any expenses associated with the conference	True	True	True
DJO Global <u>may not</u> reimburse any HCP attendees for time, travel, registration or any other expense associated with the conference	True	True	True

## GRANTS AND CHARITABLE CONTRIBUTIONS



GRANTS AND CHARITABLE CONTRIBUTIONS				
CHARITABLE CONTRIBUTIONS & GRANTS	TAX-EXEMPT STATUS	CAN DJO GLOBAL MAKE CONTRIBUTIONS TO INDIVIDUALS?	APPLICATION PROCESS	ROLE OF SALES PERSONNEL
Charitable Contributions	Required	No. Charitable contributions will only be made to state or federally recognized non-profit entities	Requesting organization applies directly to PRC	Direct customer to DJO Global's public website and/or provide DJO Global's customer with letter
Research Grants	Not required	Yes	Requesting organization applies directly to PRC	Direct customer to DJO Global's public website and/or provide DJO Global's customer with letter
Education Grants	Not required	No. Educational grants will only be awarded to organizations or entities	Requesting organization applies directly to PRC	Direct customer to DJO Global's public website and/or provide DJO Global's customer with letter

DJO will not make a Charitable Contribution or a Research or Educational Grant that implicitly or explicitly rewards a Customer for past or future purchases, uses, orders, or recommendations of DJO products. Any evidence that a Charitable Contribution or Research or Educational Grant request is tied in any way to the

past, present, or future use, order, recommendation or purchase of DJO's products will result in denial, and may exclude the organization from consideration for future funding.

## EDUCATIONAL ITEMS

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## EDUCATIONAL ITEMS

### GENERAL PRINCIPLES

To avoid the appearance of impropriety, DJO Global prohibits giving health care professionals gifts or other incentives, including all non-educational logoed items. DJO Global may occasionally provide items that benefit

patients or serve a genuine educational function for health care professionals. In each case, the value of these items, other than medical textbooks or anatomical models used for educational purposes, must be less than \$100.

EDUCATIONAL ITEMS AND OTHER PAYMENTS TO HEALTH CARE PROFESSIONALS		
REQUIREMENT	ADVAMED CODE	MASSACHUSETTS/ VERMONT
DJO Global <u>may not</u> pay for entertainment or recreational items or events	True	True
DJO Global <u>may not</u> provide "complimentary" items (e.g., pens, notepads, coffee mugs, gift cards, cookies, treats etc.	True	True
DJO Global <u>may not</u> provide items that are capable of use by the HCP, office staff, or family members (e.g., iPods, DVD players)	True	True
DJO Global <u>may not</u> provide an item for a "life event" (e.g., wedding, new baby, death)	True	True
DJO Global <u>may not</u> provide an item in a raffle or as give-aways at a trade show that could not otherwise be given to an HCP or ancillary office staff	True	True
Occasional educational items may be given to HCPs. It is DJO Global policy that the PRC review and approve all proposed educational items to HCPs before any such item is provided. (See following page for educational items guidelines)	True	True

## EDUCATIONAL ITEM GUIDELINES

TYPE OF ITEM	EXAMPLES	PERMISSIBLE UNDER ADVAMED AND DJO GLOBAL POLICY?	PERMISSIBLE FOR MASSACHUSETTS AND VERMONT HCPS?
Non-Educational	Flowers, cookies, wine, tickets, gift certificates, scrubs, iPod	No	No
Branded and Non-Branded Items	Pens, notepads, clipboards, hand sanitizer, post-it notes, general office supplies	No	No
Educational Items with Value of \$100 or Less (may contain DJO Global brand/logo)	Patient educational brochures, patient self-assessment tools, patient instructional videos	Yes with PRC approval	Yes with PRC approval
Educational Items with Value of \$100 or More (may contain DJO Global brand/logo)	Textbooks, anatomical models	Yes with PRC approval	Yes with PRC approval

MEALS



### DJO GLOBAL MEAL LIMITS

Meals may not exceed the per-head amounts listed above. These ceilings are inclusive of all charges including, without limitation, tax, tip, service charges and alcohol. DJO Global will not provide reimbursement above these amounts. All DJO Global employees and agents, including the DJO Global independent sales force, must make a good faith effort to keep meals with HCPs modest by remaining within these limits.

*Employees or agents who show a pattern of exceeding these limits may be subject to disciplinary action, up to and including termination of employment for DJO Global employees, or termination of the Company's business relationship with the sales agents.*

DJO MEAL LIMITS	
MEAL	DOLLAR LIMIT PER HEAD
Breakfast	\$30 per head, includes tax, service charges, tip and alcohol
Lunch	\$50 per head, includes tax, service charges, tip and alcohol
Dinner	\$150 per head, includes tax, service charges, tip and alcohol

<sup>1</sup> Meals in restaurants are not permissible for Massachusetts licensed HCPs.

MEALS		
REQUIREMENT	ADVAMED CODE	MASSACHUSETTS
Occasional and modest	✓	✓
<u>May not</u> be part of an entertainment or recreational event	True	True
<u>Must</u> be provided in conjunction with education/product training	True	True
Only those with a legitimate professional interest in the information being provided may attend	✓	✓
May not pay for spouses or other guests	True	True
<u>Must</u> be at a location conducive to the education/training/business that is being conducted	Yes	Yes
Meals may be provided <u>outside</u> an HCP's office or hospital setting or in another setting conducive to a business meeting	Yes	No Meals may be provided only in a clinical setting (e.g., HCP office or hospital) <sup>1</sup>

NOTE: Vermont Statute prohibits the provision of food to Vermont HCPs for free. This prohibition includes food during in-services as well as meals in restaurants.

## DJO GLOBAL-SPONSORED TRAINING/EDUCATION



### DJO GLOBAL-SPONSORED TRAINING/EDUCATION

REQUIREMENT	ADVAMED CODE	MASSACHUSETTS	VERMONT
Programs should be conducted in locations that are conducive to the training/education	✓	✓	✓
Training staff should have the proper qualifications and expertise to conduct such training	✓	✓	✓
Meals and refreshments should be modest in value and subordinate in time and focus to the training and education	✓	Special rules apply. Please contact the PRC	Special rules apply. Please contact the PRC
DJO Global may pay for reasonable travel and modest lodging costs for program attendees	✓	Only with a written agreement established through the PRC	Only with a written agreement established through the PRC
DJO Global may pay for meals, refreshments, travel, or other expenses for guests of HCPs	No	No	No
Attendees must have a bona fide professional interest in the information being shared at the meeting	Yes	Yes	Yes

## OTHER BUSINESS INTERACTIONS



It's what you do – your actions –  
which people will remember.

**DO THE RIGHT THING**

**SAMPLE FORMS/  
GENERAL INFORMATION**

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## SAMPLE FORMS/GENERAL INFORMATION

### FORM DESCRIPTIONS

FORM NAME	WHEN USED	DOCUMENTS TO SUBMIT
<b>EXHIBIT EXEMPTION CHECKLIST</b>	Use this form when you are requesting payment for exhibit/booth space. If all of the questions are answered "NO" on the Checklist, PRC review and approval are not required. Please submit the completed checklist with the registration forms for payment through your normal departmental procedures.	<ul style="list-style-type: none"> <li>Nothing to submit to PRC</li> <li>Completed Forms with all "NO" responses must be included with the registration documents</li> </ul>
<b>THIRD PARTY CONFERENCE SUPPORT REQUEST</b>	<p>Use this form to request exhibit/booth space or for financial support of a third party educational conference or when the Exhibit Exemption Checklist has a "YES" box checked. (see "Third Party Conference Support" section of this Code for additional information)</p> <p>Please be sure to complete all information requested on the form and to submit all supporting documentation as requested to avoid any delays in your request.</p>	<p><b>For Educational Meeting Sponsorships: (CME/CEU and Non CME/CEU):</b></p> <ul style="list-style-type: none"> <li>Registration documentation, Letter of Request (on institutions letterhead), or other documentation to show the PRC how the funding amount was determined</li> <li>Tax-Exempt Status Determination Letter</li> <li>Detailed Program Brochure/Agenda (all content/times must be included)</li> <li>W-9</li> <li>Event Budget</li> <li>Evidence of CME/CEU</li> <li>Composition of Target Audience</li> <li>SVP Approval</li> </ul>
<b>HCP AGREEMENT REQUEST FORM B</b>	Use this form when you would like to contract with an HCP.	<ul style="list-style-type: none"> <li>Completed HCP Agreement Request Form B and the KOL/Consultants CV (resume) with SVP Approval</li> </ul>
<b>WAPA (WORK ACTIVITY PRE-APPROVAL)</b>	Use this form when you plan to use a consultant (that is already contracted with DJO Global) for services, such as a faculty for a DJO Global educational event meeting	<ul style="list-style-type: none"> <li>WAPA (completed in its entirety and submitted to the PRC before the date services will be provided by the consultant, (including manager approval)</li> </ul>
<b>DJO GLOBAL BUSINESS INTERACTION FORM D</b>	Use this form when you are planning a DJO Global Training, Educational, Business Event, In-service or Meal (e.g., cadaver lab, dinner, lunch, etc.) where the estimated costs for the event are equal to or greater than \$1,000.	<ul style="list-style-type: none"> <li>Completed Form D with SVP approval</li> <li>Invitation, meeting brochure, agenda, announcement</li> <li>List of prospective attendees/invitees</li> </ul>
<b>ADVAMED STATEMENT OF SUPPORT</b>	Provide this statement to all HCPs when food is included at a DJO Global Training, Education, or other business interaction.	<ul style="list-style-type: none"> <li>Nothing to submit</li> </ul>
<b>HCP TRACKING FORM</b>	Page 1 of this form must be completed by the DJO Global employee or agent. Page 2 is a sign-in sheet for all DJO Global employees and agents in attendance. Page 3 is completed by the DJO Global employee or agent or the attending HCPs. Every HCP in attendance must have his/her information included on this form.	<ul style="list-style-type: none"> <li>All pages (including additional page 3s if necessary) are submitted to the PRC after the meeting. Reimbursement will be held until such time as the forms are submitted and approved by the PRC.</li> </ul>

## WHERE TO FIND THE FORMS

For DJO Global employees:

DJO Connect/Global Functions Corporate Compliance/  
Shared Documents/PRC.

For DJO Global independent agents:

Please contact your DJO Global representative.

## WHERE TO SUBMIT THE FORMS AND SUPPORTING DOCUMENTS

Via Email: [PRC@DJOglobal.com](mailto:PRC@DJOglobal.com)

Via Fax: 760.597.8487

All PRC requests must be approved by the appropriate member of the DJO Global management team.



## Exhibit Exemption Checklist

**DJO GLOBAL** Exhibit Exemption Checklist

Reset Form Print Form

Event Dates From \_\_\_\_\_ to \_\_\_\_\_

Meeting Event Title \_\_\_\_\_

DJO Requestor Name \_\_\_\_\_ Phone Number \_\_\_\_\_

Check the appropriate **Yes** or **No** Box in response to the below:

Is this a non-EMC/CEU event? (i.e., check "YES" if there is *NO* CME or CEU offered for this event; check "NO" if CME or CEU will be offered for the event)  Yes  No

Is the TOTAL dollar amount request OVER \$10,000?  Yes  No

Does the word or words **GRANT** or **SPONSORSHIP** appear anywhere in the registration information?  Yes  No

Are there any extracurricular activities included in the registration fee? (i.e., meal(s), entertainment, etc.)  Yes  No

Will this event be held in the State of Massachusetts?  Yes  No

**If all boxes checked are NO, proceed with check request and proper department financial approvals and submit to AP for payment with a copy of this completed checklist.**  
(This checklist MUST be attached to the check request or the request will be returned to you by AP)

If any box is checked **YES**, complete and submit the *Grant Request Form C* to the PRC for further consideration

Signature of Person Completing Checklist \_\_\_\_\_  
If not submitting electronically please print you name below.

Date Signed \_\_\_\_\_

Additional Comments \_\_\_\_\_

Version 5.2.010 DJO, LLC 1430 Decision Street, Vista CA 92081 PRC Phone: 760.597.3925 PRC Fax: 760.597.8487 PRC@DJOglobal.com

## DJO Global Third Party Conference Support Request Form

**DJO GLOBAL** DJO Third Party Conference Support Request Form

Page 1 of 2

Print Form  
Reset Form

DJO prefers that all information is typed to ensure readability. If requests are received that are illegible, the request will be returned to you.

Date Submitted 3/16/11 Requested Funding Amount \_\_\_\_\_ Support Due Date \_\_\_\_\_  
Payment Terms and Currency Type if not US dollars \_\_\_\_\_

**I. DJO Requestor Information**

DJO Requestor Name \_\_\_\_\_  
DJO Requestor Phone \_\_\_\_\_ DJO Division/DP Name \_\_\_\_\_

**II. Recipient/Payee Information** *Please note: checks must be made payable to the education conference provider as listed on the W-9*

**Due to changes in Vermont law effective July 1, 2009 For Vermont organizations All educational events or professional meetings for health care providers must be ACCME accredited to receive grant funding from DJO**

Please check if Recipient is located in Massachusetts or Vermont  Contact Information (Please include email address to facilitate communication)

Recipient Name \_\_\_\_\_ Contact Name \_\_\_\_\_  
Name 2 \_\_\_\_\_  
Recipient Address \_\_\_\_\_ Email \_\_\_\_\_  
Address 2 \_\_\_\_\_ Phone \_\_\_\_\_  
Address 3 \_\_\_\_\_ Fax \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Recipient is a for-profit entity  
 Recipient is IRS Tax Exempt  
Recipient's Tax-Exempt Status \_\_\_\_\_ For Example: 501c3, 501c4, 501c6

If not in US, City/Country \_\_\_\_\_

Recipient Website Address \_\_\_\_\_

**III. Conference Information**

Conference Name \_\_\_\_\_  
Dates(s) \_\_\_\_\_ Through \_\_\_\_\_ Is conference accredited?  Yes  No If yes, please address educational credit questions below  
Location City \_\_\_\_\_ State \_\_\_\_\_  
Type of Educational Credits Provided \_\_\_\_\_  
Number of Educational Credits Applied for/Approved \_\_\_\_\_ If other, please describe \_\_\_\_\_

Additional Support Requested (e.g., samples, supplies, raffle items or door prizes) \_\_\_\_\_

Please List Items Included with Grant (e.g., exhibit space, advertisements) \_\_\_\_\_  
If this is a Re-Occuring Event, Please List Previous Support Provided by DJO (monetary and non-monetary) \_\_\_\_\_

Version 5.2.010 DJO, LLC 1430 Decision Street, Vista CA 92081 USA Phone: 760.597.3925 Fax: 760.597.8487 PRC@DJOglobal.com

## HCP Agreement Request Form

**Health Care Professional Agreement Request Form B** Reset Form Print Form

Date Form Completed \_\_\_\_\_

Key Items to Include with Request  
 SVP Approval  Previous Contract  
 HCP CV  Only if previous contract was not completed by the PRC

**1. DJO Requestor Information**

DJO Requestor Name: \_\_\_\_\_ DJO Division: Corporate  
 DJO Requestor Phone: \_\_\_\_\_ Email: \_\_\_\_\_

**2. Contract Information** New/Renewal: \_\_\_\_\_ Type of Agreement: \_\_\_\_\_  
 Agreement Start Date: \_\_\_\_\_ Agreement Duration (number of years): \_\_\_\_\_  
 Please check if one time engagement please enter the name of the event below in the description

**3. Consultant Information**

Please check if the HCP is licensed or works in the State of Massachusetts or Vermont

**Official Contract Information**

Contract Party Name: \_\_\_\_\_ Best Way to Contact: \_\_\_\_\_  
 Street Address: \_\_\_\_\_ Phone Type: \_\_\_\_\_ Number: \_\_\_\_\_  
 No PO Boxes \_\_\_\_\_ Fax: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ Email: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Payment/Correspondence Address: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
 Fax: \_\_\_\_\_  
 Email: \_\_\_\_\_

**4. Services Information**

Describe, with specificity, the input and services that the Consultant will provide or perform \_\_\_\_\_

Justification for engaging the Consultant to provide the services and work product (what benefits or results are anticipated as a result of engaging with this Consultant) \_\_\_\_\_

Are the services to be provided by this Consultant included in the current Needs Assessment?  
 Yes If yes, where in the assessment can these hours be found? \_\_\_\_\_  
 No If no, explain \_\_\_\_\_

Time Requirement (Please provide an estimated of time requirement to complete the services by the Consultant on an annual basis)

A) Types of Consultant Activities: \_\_\_\_\_ Number of Hours: \_\_\_\_\_  
 B) Types of Consultant Activities: \_\_\_\_\_ Number of Hours: \_\_\_\_\_  
 C) Types of Consultant Activities: \_\_\_\_\_ Number of Hours: \_\_\_\_\_  
 D) Types of Consultant Activities: \_\_\_\_\_ Number of Hours: \_\_\_\_\_ If Other, explain \_\_\_\_\_

Please Enter Additional Activities Here: \_\_\_\_\_ Number of Hours: \_\_\_\_\_ Total Annual Hours: \_\_\_\_\_

**5. Approvals**

DJO Requestor Signature: \_\_\_\_\_ SVP Signature: \_\_\_\_\_  
 If submitting electronically, please click in the space above and follow the prompts to electronically sign document. Unsigned documents will not be accepted.

V3.13.2011 DJO, LLC 1430 Decision Street, Vista CA 92081 PRC Phone: 760.597.3925 PRC Fax: 760.597.8487 PRC@djoglobal.com

## WAPA

**DJO GLOBAL** Reset Form Print Form

**DJO KOL WORK ACTIVITY PRE-APPROVAL FORM (WAPA)**

Date Submitted: 2011-03-16 19:49:22

HCP Name: \_\_\_\_\_

**Instructions:**

1. Date should be the date the activity is scheduled to occur.
2. Product or Project examples: 3DKnee, New Hip Fracture System, Bone Stimulation, Brace Enhancement training, etc)
3. Activity should reflect the nature of the services provided (i.e., product evaluation, presentation preparation, sales representative training, etc)
4. DJO Requestor should reflect the DJO employee(s) that requested the activity.
5. Hours should reflect the ANTICIPATED TIME TO BE SPENT on the activity and associated preparation time.
6. Estimated travel time, if applicable.
7. Comments should include any additional information supporting the description of the services provided (i.e., name(s) of visiting physician(s), title of presentation, paper or abstract, etc.).
8. DJO Notes column is for Corporate Compliance personnel use only

**Please also submit any existing supporting documentation at the time of request form submission**

Is activity included in current Needs Assessment?  
 Yes  No If no, explain \_\_\_\_\_

Date	Product/Project	Activity	DJO Requestor	Anticipated Hours	Anticipated Hours Travel Time	DJO Notes

Comments: \_\_\_\_\_

Requestor Signature: \_\_\_\_\_ Department Head Signature: \_\_\_\_\_

V1/2008 DJO, LLC 1430 Decision Street, Vista CA 92081 PRC Phone: 760.597.3925 PRC Fax: 760.597.8487 professionalrelationscommittee@djoglobal.com

## AdvaMed Statement of Support

**DJO GLOBAL** AdvaMed Code of Ethics DJO Statement of Support 

*This Statement must be distributed at all business interactions with HCPs where meals are provided.<sup>1</sup>*

*DJO Complies with the AdvaMed Code of Ethics. A Company's<sup>2</sup> business interactions with Health Care Professionals ("HCP") may involve the presentation of scientific, educational, or business information. Such exchanges may be productive and efficient when conducted in conjunction with meals. Occasional and modest meals may be provided as an occasional business courtesy, as follows:*

- The meal must be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner and location conducive to the presentation of such information.
- 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.
- The meal may not be part of an entertainment or recreational event.
- Meals may occur outside of the HCP's place of business where that location may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions or may be impractical or inappropriate. In such instances it is acceptable to provide meals outside of the HCP's place of business as long as all other conditions are met.
- Meals may be provided only to HCPs who actually attend the meeting and who have a bona fide reason for attending.
- Meals may not be provided to spouses, guests, an entire office staff, or any other person who does not have a bona fide professional interest in the information being shared at the meeting.

If you have questions about the AdvaMed Code of Ethics (for the full code please go to <http://www.advamed.org/MemberPortal/About/code>) or DJO's policies, please feel free to email the DJO Corporate Compliance Department at [corporatecompliance@djoglobal.com](mailto:corporatecompliance@djoglobal.com)

<sup>1</sup> Please note that in accordance with the "Pharmaceutical and Medical Device Manufacturer Conduct" in the State of Massachusetts and the federal "Physician Payment Sunshine Act" any cash or "in-kind" payments, such as the cost of your meals, may be reportable to the respective state or federal government agency and be available for public review (such as on a website). Reportable information may include your name, business address, type of payment, amount of payment, and relationship with DJO.  
<sup>2</sup> For the purpose of this communication, the term "Company" refers to DJO, its employees, its agents, distributors, contractors, consultants and sales representatives.  
 V2.2.11.2009

## HCP Tracking Form

**DJO GLOBAL**  HCP Tracking Form

**BUSINESS PURPOSE**

Date: \_\_\_\_\_  
 Location (including address, street, city, state and zip): \_\_\_\_\_  
 Type of Meal/Refreshments (Breakfast, Lunch, etc.): \_\_\_\_\_  
 Actual Meal/Refreshment Cost: \_\_\_\_\_  
 Total Number of Participants: \_\_\_\_\_  
 Cost per Head\*: \_\_\_\_\_  
 Total Cost: \_\_\_\_\_

Did the meeting take place in the State of Massachusetts or Vermont? **Y N**  
 If yes, please confirm that this event took place in the HCP's clinical setting/office:  Initial Here: \_\_\_\_\_

\*Meals (including refreshments or "treats") may not exceed the following per person limits: Breakfast \$30, Lunch \$50, and Dinner \$150. These ceilings are all inclusive (tax, tip, alcohol, dessert, service charges, etc.)

**EDUCATIONAL FOCUS/AGENDA**

Please specify the DJO products that were the focus of this training/education: \_\_\_\_\_

Describe the educational focus of this meeting: \_\_\_\_\_

What new knowledge should the meeting participants gain as a result of this meeting? \_\_\_\_\_

Provide a detailed list of the educational materials/handouts that were provided (please include a copy if you are not able to provide a detailed description): \_\_\_\_\_

Initial Here:  **No HCPs that work or are licensed in the State of Vermont attended this event.**

I declare under penalty of perjury, under the laws of the State of California, that all statements contained in this attestation form are true and correct, with full knowledge that all statements made are subject to investigation and that any false or dishonest answer to any question may be grounds for further disciplinary action up to and including termination from my employment at DJO, or, for independent sales persons, my right to sell DJO products.

Printed Name of Person Completing Form (PLEASE PRINT LEGIBLY) \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

This page should be completed by the appropriate DJO employee in its entirety. Upon completion please submit with your expense report receipts. If you have any questions please contact the PRC Phone 760.597.3925, Fax 760.597.8487 or email PRC@djoglobal.com

V5.10.2010 Page 1 HCP Tracking Form

DJO Global Business Interaction Form D



**DJO Business Interaction Request Form D**  
(HCP Meeting, Education and Training Programs)  
*Please complete this form in its entirety*

Requestor and Event Information  
Page 1 of 2

Reset Form    Print Form



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Date Submitted \_\_\_\_\_ Total Estimated Costs \_\_\_\_\_

**I. Requestor/Co-Sponsor Information**

Requestor Name \_\_\_\_\_ DJO Division \_\_\_\_\_  
 DJO Requestor Phone \_\_\_\_\_ Department \_\_\_\_\_

Co-Sponsor(s), if any \_\_\_\_\_ Co-sponsor Contact Name \_\_\_\_\_  
 (e.g., Distributor, Agent) \_\_\_\_\_  
 Co-Sponsor Phone \_\_\_\_\_ Co-Sponsor Email \_\_\_\_\_

**II. Event Information**

Event Name \_\_\_\_\_  
 Type of Event \_\_\_\_\_  
 (if event type is not listed please describe) \_\_\_\_\_

Date(s) Held \_\_\_\_\_ To \_\_\_\_\_  Please Check this box if the Event will take place in Massachusetts or Vermont

**Event Location**

Name of Facility \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_  
 If not in U.S. please add City/Country: \_\_\_\_\_  
 Type of Facility \_\_\_\_\_  
 (if facility type is not listed please describe) \_\_\_\_\_  
 Rationale for Selecting Location and Facilities \_\_\_\_\_

**Event Purpose/Objectives**

Rationale for Selecting Invited HCPs \_\_\_\_\_  
 Program Objectives \_\_\_\_\_  
 (describe the overall focus and objective of the presentation and expected outcomes)

**Event Resources** Please specify DJO resources necessary to meet the objectives of this program

Proposed Faculty/Course Directors (please indicate if DJO KOL) \_\_\_\_\_  
 DJO KOLs (include copies of WAPAs) if applicable     Instrumentation/Products     Training Models  
 Other    if other, please describe in detail \_\_\_\_\_

**IV. Attendees**

Provide names and credentials of all attendees (Please indicate if DJO KOL) \_\_\_\_\_  
 A separate list of attendees may be attached. Please indicate as such if applicable.

**V. Supporting Documentation** **REQUIRED FOR PRC CONSIDERATION**

- Detailed Agenda - must include all educational/training program content and travel information (such as arrival and departure date(s)/time(s)) and lodging information (i.e., name of hotel)
- List of Attendees (if attendees not available please provide invitees)
- Proposed Invitation (if applicable)

- Detailed Description of All Costs of Event - including costs paid by another entity (e.g., distributor/agent) and those not specifically addressed on this form.
- Notification to PRC if MA or VT licensed HCPs are invitees

Please Note: DJO's Advamed Statement of Support should be provided to all attendees and the HCP tracking Form must be completed and its entirety and submitted per DJO policy.

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VL13.09    DJO, LLC    1430 Decision Street, Vista CA 92081    PRC Phone: 760.597.3925    PRC Fax: 760.597.8487    PRC@djoglobal.com

# ADVAMED FREQUENTLY ASKED QUESTIONS



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**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.?

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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.

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

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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.

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

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

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

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“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.”

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**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?

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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.

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**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?

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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).

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

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No, such support would be inappropriate.

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## SECTION II: CODE OF ETHICS COMPLIANCE

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

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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.

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**Q12** Does the AdvaMed Code of Ethics offer legal advice?

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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.

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

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

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

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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.

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

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"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.

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## SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

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

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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.)

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

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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.

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#### **SECTION IV: SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES**

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

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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.

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

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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.

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**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?

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Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.

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**Q21** May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?

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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.

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#### **SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS**

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

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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.

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**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?

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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.

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**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?

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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.

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## SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

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

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

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

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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.

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

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Yes, provided the requirements of Section VI are met.

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

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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.

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

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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.

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**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?**

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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.

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**Q31 When is a Health Care Professional considered a “consultant”? What types of arrangements with consultants are covered under Section VI?**

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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.

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

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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.

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**Q33 How are Clinical Study Agreements treated under the Code?**

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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.

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

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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.

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

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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.

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#### **SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION**

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**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?

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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.

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

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

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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.

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#### **SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS**

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**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?

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

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

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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.

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**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?

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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.

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**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?

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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.

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

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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.

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

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

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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.

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#### **SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS**

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

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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.

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**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?

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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

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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.

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

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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.

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

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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.

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**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?**

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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.

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

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

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**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?**

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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.

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**Q51 How can a Company determine whether a charitable organization is a bona fide charitable organization?**

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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.

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**SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS**

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

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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.

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**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?**

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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

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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.

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

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

**ONE COMPANY, ONE VISION**

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**CMF**

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#### **AIRCAST**

Aircast's trusted product lines include orthopedic bracing, cold therapy and vascular systems that provide solutions for post-operative deep vein thrombosis.

#### **CHATTANOOGA**

Chattanooga's over 300 products include hot and cold therapy, treatment platforms, clinical electrotherapy, ultrasound and laser devices, traction systems and CPMs.

#### **CMF**

CMF's SpinaLogic® and OL1000® bone growth stimulators offer clinically proven nonunion fracture and spinal fusion healing in a simple 30-minute-a-day treatment program.

#### **DJO SURGICAL**

DJO Surgical's comprehensive suite of unique reconstructive products for the hip, knee and shoulder help patients regain their motion.

#### **DONJOY**

DonJoy offers a complete line of rigid and soft bracing solutions for nearly every joint in the body as well as advanced cold therapy products.

#### **EMPI**

Empi markets a wide range of rehabilitation products including electrical muscle stimulation devices, trans-dermal drug delivery and traction.

#### **IOMED**

Iomed is a pioneer in the active drug delivery system, with innovative products for the physical and occupational therapy and sports medicine markets.

#### **PROCARE**

ProCare provides advanced orthopedic bracing and soft goods for individuals of all ages, abilities and levels of fitness.

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Saunders offers the popular 3D ActiveTrac® treatment table as well as trusted home cervical traction devices.





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