



CUSTOMER RELATIONSHIP POLICY

I. Preamble: Goal and Scope of Policy

Wright Medical Technology, Inc. ("Wright" or "Company") has always been committed to conducting its business in the most ethical manner. This Customer Relationship Policy ("CRP") applies not only to employees of the Company, but also anyone who acts on the Company's behalf, hereafter referred to as ("Representatives"). Our Code of Business Conduct ("Code") expresses our aspiration not only to comply with the letter of the law, but the spirit of the law as well. Our relationship with customers and consultants is very important to us. Consultants play an important role with Wright in the conduct of clinical studies, providing design input for product improvements, and working together to solve the most challenging orthopaedic problems facing patients today. Many of these consultants are also our customers. They help us be more responsive to meeting our customers' needs.

Our relationships with health care professionals ("HCPs") are governed by professional codes of conduct established by the American Medical Association, the American Academy of Orthopaedic Surgeons, and other professional societies, as well as industry standards, and a variety of laws and regulations which apply both to physicians and medical device manufacturers. It has always been, and continues to be, our policy to comply with these requirements and standards of conduct.

The Office of Inspector General for the U.S. Department of Health and Human Services has published compliance guidelines for the relationship between physicians and the pharmaceutical industry. Many of the principles underlying how pharmaceutical manufacturers should conduct their relationships with physicians to comply with various laws and regulations also apply to relationships between medical device manufacturers and physicians. The Advanced Medical Technology Association ("AdvaMed") also has issued a Code of Ethics on Interactions with Health Care Professionals. AdvaMed is an industry association committed to the advancement of medical science by improving patient care through the use of high quality, cost effective health care technology. AdvaMed adopted its ethics code in recognition that adherence to ethical standards and compliance with applicable laws is critical to the continued collaboration between the medical device industry ("Industry") and physicians. Physicians must make independent decisions about what products are best suited to solve their patients' needs.

Wright closely monitors developments in ethical standards and legal developments as part of its efforts to conduct its business in an ethical manner and to comply with its legal obligations. As guidance is provided by regulators, and as professional organizations discuss the appropriate standards of conduct, we review our policies and procedures to make sure both Wright and its HCP Consultants are in compliance with these requirements. We also regularly review our operating procedures to ensure compliance with the spirit and letter of these obligations. We have incorporated the voluntary AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code") as the basis for how we and our Representatives will comply with our Code and to facilitate our ethical interactions with all HCP Consultants including those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Wright's products in the United States. Consequently, we have adopted this Wright CRP effective as of January 1, 2004 and revised as of April 2009 to accomplish this objective (hereinafter referred to as the "Policy"). In June 2009, this Policy was further revised to include an addendum that incorporates the requirements of the Massachusetts Marketing Code of Conduct (105 C.M.R. 970.000).

There are many forms of interactions between Wright, our Representatives, and Health Care Professionals that advance medical science or improve patient care, including those that:

- *Promote the Advancement of Medical Technologies.* Developing cutting edge medical technology and improving existing products are collaborative processes between Wright and HCPs. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the laboratories of medical device companies. Advanced implants; minimally invasive instrumentation; alternative bearing surfaces; bone graft substitutes; bone conserving implants and instrumentation; time saving

surgical techniques; and advanced biologic solutions are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between HCPs and Industry.

- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated implants, surgical instrumentation, new surgical techniques, and cutting edge biologics and emerging medical technology often requires that HCPs are provided with appropriate instruction, education, training, service, and technical support. Regulators may also require this type of training as a condition of product approval.
- *Encourage Research and Education.* Industry 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.* Providing 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.

Any interpretation of the provisions of this Policy, as well as Representatives' interactions with Health Care Professionals not specifically addressed in this Policy, should be made in light of the following principle: Wright and its Representatives shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, our products.

II. Definitions

The following terms in this Policy shall have the meanings detailed below unless otherwise indicated.

“AAOS” means the American Academy of Orthopaedic Surgeons.

“AdvaMed Code” means the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

“Arrangements” means every arrangement or transaction entered into by Wright that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Wright and any actual or potential source of health care business or referrals of health care business to Wright or any actual or potential recipient of health care business or referrals from Wright. The term “source” shall include any physician, contractor, vendor, or agent; and the term “health care business or referrals” shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

“Arrangements Covered Persons” means Covered Persons involved in the development, approval, management, implementation, use, or review of any of Wright’s Arrangements.

“Charitable Donation” means tax-exempt charitable contributions and/or financial donations that are philanthropic in nature and are provided to not-for-profit foundations or institutions. Charitable contributions may be provided in the form of cash, product donations (e.g., implants), or donations for charitable events (e.g., galas).

“Code” means the Wright Code of Business Conduct.

“Consultant” means any orthopaedic surgeon, Ph.D., Health Care Professional, non-physician practitioner, medical fellow, resident/student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for, or in anticipation of, personal or professional services relating to its products or services. Consultant does not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, or any non-physician engineering or marketing consultants.

“Consulting Agreement” means all contracts with Consultants for services to be performed on behalf of the Company, including, but not limited to, compensation agreements, payments, remuneration, honoraria, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research and professional services agreements.

“Consulting Services” or “Services” means any and all professional services provided by a Consultant to or on behalf of the Company.

“Consultant Qualifications Review Committee” means the committee responsible for reviewing the qualifications of all of Wright’s existing (on an annual basis) and proposed new (on a monthly basis) HCP Consultants and to determine if those qualifications meet specific HCP Consulting needs.

“Contractual Arrangements” means every written Arrangement including all Arrangements related to the provision of goods or services, to or from Wright, including but not limited to, arrangements involving training, education, consulting, research, clinical studies, focus groups, physician advisory boards, intellectual property, grants, and charitable contributions.

“CRP” means the Wright Customer Relationship Policy.

“Education” means communicating information directly concerning, or associated with, the use of Wright’s Medical Technologies, e.g., information about disease states and the benefits of Medical Technologies to certain patient populations.

“Educational Grant” means grants that may be made to support the genuine medical education of HCPs, medical students, residents, and fellows participating in fellowship programs that are affiliated with charitable or academic organizations. Where consistent with the Code, grants may be made for the purpose of supporting education of patients or the public about important health care topics to other medical personnel.

“Fair Market Value” (“FMV”) means the value in "arms-length" transactions, consistent with the general market value; in the context of HCP Consulting Services, FMV means the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties who are not in a position to generate business for one another. FMV may vary by physician specialty and stature in addition to the type of service being performed.

“FDA” means the U.S. Food and Drug Administration.

“Federal Health Care Program” means any plan or program that provides health benefits, whether directly or indirectly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government, including, but not limited to, Medicare, Medicaid, VA, and TRICARE/CHAMPUS.

“Fellowship” means post-residency training programs that allow new physicians to continue their training

and specialize in a specialty or sub-specialty. Sponsoring fellowships is philanthropic in nature but also serves to advance the education and training of new physicians. Grants may only be provided to teaching institutions, an affiliated hospital of that institution, a medical society/association and cooperative group, or an appropriate organization that has a *bona fide* interest in advancing education and research in areas of legitimate interest to Wright.

“GPO” means a group purchasing organization.

“Grants Review Committee” means the committee responsible for reviewing and approving grant requests related to Charitable Contributions, Continuing Medical Education (“CME”) programs, Fellowships, Non-CME Programs, and Residencies.

“Handbook” means this Wright Medical Technology, Inc. Health Care Professional Interaction Policy and Procedure Handbook.

“HCP” means a Health Care Professional.

“Health Care Professionals” means individuals or entities who 1.) are involved in the provision of health care services and/or items to patients; and 2.) 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 is to be interpreted broadly and includes both persons providing services (such as licensed surgeons or consultants) and persons who do not provide services directly, but who are involved in the decision to purchase, lease, or recommend a Medical Technology. Health Care Professionals include, for example, purchasing agents, physician’s practice managers and management within GPOs.

“HHS-OIG” means the U.S. Department of Health and Human Services, Office of Inspector General.

“Hourly Rate” means the Fair Market Value hourly rate.

“Medical Technologies” means medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities in order to enable patients to live longer and healthier lives.

“Modest” means reasonable in terms of cost and venue.

“Needs Assessment Process” means the annual process whereby Wright will reflect our expected, commercially reasonable needs for all Consulting Services to fulfill our medical, clinical, training, educational, and research and development needs for the ensuing year. The Needs Assessment and any modifications shall be used as a basis for Consultant selection and all Consulting Agreements, Services, and Payments.

“Occasional” means infrequent.

“Payment” means any and all compensation or remuneration, direct or indirect, in cash or in kind, paid to, or for the benefit of, Consultants, including, but not limited to, payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, fellowships, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (e.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property.

“Representatives” means any Wright employee, agent, or distributor acting for or on behalf of Wright.

“Research Grant” means grants to support independent medical research with scientific merit.

“Resort Location” means luxury hotels or resorts located on or immediately adjacent to a beach, ski resort, golf course, destination spa, vineyard, or other similar recreational amenities.

“Royalty Review Committee” means the committee responsible for establishing the fair market value royalty percentage based on the expected contribution of design team members and to determine whether or not HCP Consultant contributions to the product development process merit the conditions of a royalty Payment.

“Service Needs Review Committee” means the committee that is responsible for reviewing the service needs requests of the functional areas and to ensure they support *bona fide* business needs and are within all applicable Wright policies and guidelines.

“Training” means training on the safe and effective use of medical technologies.

III. Wright–Sponsored Product Training and Education

Wright has a responsibility to make education and training on our products and medical technologies available to HCPs. Wright may also provide education to HCPs. “Training” means training on the safe and effective use of medical technologies. “Education” means communicating information directly concerning or associated with the use of Wright’s 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 (“FDA”) mandates training and education to facilitate the safe and effective use of certain medical technology. Such programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. With regard to Wright programs focused on the education and training in the safe and effective use of Wright products and medical technologies:

- Programs and events must be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of information. In some cases, it may be appropriate for a Wright Representative to provide training and education at the HCP’s location.
- Programs requiring “hands on” training on medical technologies and/or medical procedures must be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff must have the proper qualifications and expertise to conduct such training.
- HCP attendees may be provided with modest meals and refreshments in connection with these programs. Any such meals and refreshments must be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.
- Wright may pay for reasonable travel and modest lodging costs incurred by attending HCPs where there are objective reasons to support the need for out-of-town travel to efficiently deliver training and education on products and/or medical technologies. It is not appropriate for Wright or its Representatives to pay for the meals, refreshments, travel, or other expenses for spouses and/or 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.

- Participants cannot be compensated for their time related to attending Wright-sponsored training and education programs. Faculty members can only be compensated for services provided and related expenses as provided in this Policy.
- Resort locations are not acceptable locations for training and/or education events, as they are generally not deemed conducive to training, education, or the effective transmission of knowledge and should be avoided as venues for programs and events. The term "Resort location" may include luxury hotels or resorts located on or immediately adjacent to a beach, ski resort, golf course, destination spa, or vineyard. The location and lodging must be selected based upon program requirements such as proximity to a training facility, medical institution, laboratory, or other appropriate facilities, convenience of attendees, and cost savings to Wright.
- Training and/or education programs provided by Wright concerning a Company product must be consistent with the indications for use cleared or approved by the FDA and with the approved labeling of the product. Any Consultants that Wright retains to serve as faculty at a training or education program will be instructed to comply with this requirement.

IV. Supporting Third Party Educational Conferences

Bona fide independent, educational, scientific, or policymaking conferences to promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include continuing medical education (CME) or continuing podiatric medical education (CPME) conferences or events hosted by providers accredited by the Accreditation Council for Continuing Medical Education (“ACCME”), independent, non-accredited scientific or educational programs, grand rounds, and other programs. Each request is evaluated by the Grants Review Committee on the individual program’s merit. Factors considered by the Grants Review Committee include the following:

- *Content.* Wright may only support high quality events that are aligned with strategic objectives. This determination is based on whether the conference has objective and substantive educational value. This may be assessed based on the value of CME or CPME credits and/or the course program or agenda. At a minimum, at least six (6) hours per conference day must be spent engaging in legitimate educational activities such as lectures, labs, or the like. Conferences whereby social events or activities such as golf outings, leisure time, or other recreational activities, take precedence over the educational component, are not considered high quality programs of significant educational value, and sponsorship by the Company may be denied. Wright must not fund any recreational event or activity of the conference.
- *Scope.* Programs that serve a larger audience or which have a greater impact on the medical community may receive greater consideration than those of limited scope. Programs that are duplicative of other programs sponsored by the Company may be denied.
- *Location.* The event’s venue must be appropriate and conducive to achieving its educational objective. Conferences held at ski, beach, spa, vineyards, or golf locations are generally not appropriate venues that are conducive to training or the effective transmission of information, and Wright generally will not provide funding to support programs at such venues. However, fair market value payment for an exhibit booth or advertising may be acceptable at such programs, depending on the circumstances. Wright reserves the right to reject a request if the venue appears inappropriate.
- *Budget.* Wright will assess the reasonableness of the event’s detailed budget provided by the requestor to ensure components are in line with fair market value. The support provided by other sponsors will also be considered. Wright may reject a request or award amount based on the event’s budget or due to internal education grant budget restraints.

All requests for third-party conference funding must be reviewed by Wright’s Grants Review Committee. Voting members of the Grants Review Committee include senior management from Compliance, Medical Education, Regulatory and Clinical Affairs, Finance and Legal. Company associates from Sales and Marketing may provide background information on submitted requests, but do not have a vote in the award decisions. No employee, agent, independent sales representative, or distributor, is authorized to commit grant funding without the approval of the Grants Review Committee. A grant requestor’s history or potential to purchase, prescribe, order, recommend Wright products is not taken into account in evaluating requests for support of educational conferences.

These conferences may be supported in various ways:

- *Conference Grants.* A grant must be provided directly to the conference sponsor to reduce conference costs. No funding may be provided through a conference sponsor or directly to subsidize the costs of non-faculty attendees, except that subsidies may be

provided either to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and other HCPs in training. Conference grants may only be provided 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 HCPs in training to attend. Such grants should be paid only to organizations with a genuine educational purpose or function, and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also must be consistent with relevant standards established by the conference sponsor and any body accrediting the educational activity. Conferences supported by Wright must also meet the following requirements: (1) The conference sponsor should independently control and be responsible for the selection of program content, educational methods, and materials; (2) Wright personnel may not suggest topics, engage in scripting, target points for emphasis, or otherwise attempt to influence program content; (3) Wright may have no role in selecting faculty or attendees; (4) Wright will require the program sponsor to provide meaningful disclosure to the audience of Wright's funding of the program, any significant relationships between Wright and program faculty and moderators, and whether any unapproved uses of products will be discussed; (5) the program must be non-promotional and free from commercial bias; (6) at a live program, there must be opportunities for meaningful discussion or questioning, and no promotional activities may take place in the meeting room. The program sponsor must sign an agreement containing the above requirements.

- *Conference Meals and Refreshments.* Funding may be provided to the a conference sponsor to support the provision of meals and refreshments to conference attendees. Wright may itself provide modest meals and refreshments for HCP attendees if such meals and refreshments are provided to all HCP attendees, and in a manner that is also consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. 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.* Grants may be made to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for HCPs who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Advertisements may be purchased, and booth/exhibit space leased at Fair Market Value, for company displays at conferences.

V. Sales, Promotional, and Other Business Meetings

Wright may conduct sales, promotional, and other business meetings with HCPs to discuss product features, or negotiate contracts or sales terms. Often, these meetings occur close to an HCP's place of business. It is appropriate for Representatives 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. It is not appropriate to pay for meals, refreshments, travel, or lodging of guests and/or spouses of HCPs, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. Guests and/or spouses of HCPs may not be invited, nor may they attend or participate in any sales, promotional, or other business meetings. Unapproved uses of Wright products may not be discussed at such meetings.

VI. Consulting Arrangements with Health Care Professionals

Wright may engage HCPs 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 Wright-sponsored training and other services. Fair market value compensation may be paid to consultants provided the arrangement fulfills a legitimate business need and does not constitute unlawful inducement, as defined by Wright's Needs Assessment process. A signed and executed agreement must be in place before any services are authorized or provided by the Consultant. Proper documentation of work performed as specified in the agreement must be provided before payment for such services will be made. In no event shall a consulting agreement, or any term of an agreement be based on the volume or value of business that a Consultant generates or influences. The following factors support the existence of a *bona fide* consulting arrangement between Wright and Health Care Professionals:

- Wright consulting arrangements must be written, signed by all parties and specify all services to be provided and the compensation to be paid. The signed and fully executed contract must pre-date the activities performed. If Wright contracts with a consultant to conduct clinical research services, a written research protocol is also required.
- Compensation paid to consultants should be consistent with fair market value in an arm's length transaction for services provided and should not be based on the volume or value of the consultant's past, present, or anticipated business.
- Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance and documented as defined by Wright's Needs Assessment process.
- Wright's Consultant Qualifications Review Committee is responsible for reviewing the qualifications of proposed consultants. Selection of consultants should be on the basis of the consultant's qualifications and expertise to meet the defined need, and should not be on the basis of volume or value of business generated by the consultant. Sales and Marketing personnel may provide input about the suitability of a proposed consultant, but Sales and Marketing personnel do not control or have the ability to unduly influence the decision to engage a particular Health Care Professional as a consultant.
- Wright 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 costs incurred by consultants attending meetings with, or on behalf of Representatives. All travel involving consultants must be in compliance with the most current Wright HCP Travel and Expense Policy. In the event of an apparent conflict between this Policy and the HCP Travel and Expense Policy, this Policy shall govern.
- The venue and circumstances for Wright meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other setting, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information. Resort locations are not acceptable locations for training and/or education events, as they are generally not deemed conducive to training, education, or the effective transmission of knowledge and should be avoided as venues for programs and events. The term "Resort location" may include luxury hotels or resorts located on or immediately adjacent to a beach, ski resort, golf course, destination spa, or vineyard. The

location and lodging must be selected based upon program requirements such as proximity to a training facility, medical institution, laboratory, or other appropriate facilities, convenience of attendees, and cost savings to Wright.

- Any discussion by Wright personnel of unapproved products or uses should be non-promotional and scientific. It should be made clear to participants that the product or use under discussion is investigational.
- Wright-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. Wright strictly prohibits recreation or entertainment in conjunction with these meetings.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional must meet the contractual standards set forth above. An HCP, acting individually or as part of a group in which he or she is an active participant, often makes valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product development or intellectual property licensing agreement. Wright may enter into a royalty agreement with a Health Care Professional only where the HCP 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, must be appropriately documented. The calculation of royalties payable to a HCP in exchange for Intellectual Property must not be conditioned on: (1) a requirement that the HCP 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.

Wright's Royalty Review Committee is responsible for reviewing the HCP consultant qualifications of design team members, as proposed by Wright Research and Development, to establish a proposed fair market value royalty percentage rate based on the expected contributions of the design team members, and to determine whether or not HCP consultant contributions to the product development process merit a royalty payment upon successful conclusion of the product development process.

VII. Prohibition on Entertainment and Recreation

Wright interactions with Health Care Professionals must 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, Wright or its Representative must not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Such activities and items include, for example, theater, sporting events, golf, skiing, hunting, sports 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 Wright engages the HCP 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

Wright's interactions with HCPs may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described throughout this policy. 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 Wright's limitations regarding the volume and costs for such meals, as defined by Wright's Corporate Travel and

Expense Policy, the HCP Travel and Expense Policy, and the Needs Assessment process. The following requirements must be established:

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

Setting and Location. A modest and occasional meal should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Such meals may occur at the HCP'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 a meal at the HCP's place of business, for example, (1) where the Medical Technology cannot easily be transported to the HCP's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

Participants. Wright or its Representative may provide a meal only to HCPs who actually attend the meeting. Wright may not provide a meal for an entire office staff where everyone does not attend the meeting. Wright also prohibits "dine and dash" meals, where a company representative is not present. Wright may not pay for meals for spouses or 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.

As outlined in Wright's Corporate Travel and Expense Policy, the HCP Travel and Expense Policy, and the Needs Assessment process, meals with Health Care Professionals must be modest and occasional. "Modest" is defined as reasonable in terms of cost and venue. Wright has an established per diem cap on meal expenses not to exceed \$100 per person for dinner, \$25 per person for breakfast, and \$45 for lunch. To accommodate regional differences in prices/cost in such cities as New York, Chicago, Miami, and Los Angeles, or in the case of an international city, a dinner is capped at \$150 per person plus applicable taxes. Breakfasts and lunches in such cities remain capped at the aforementioned limits.

"Occasional" is defined as infrequent. Wright's guideline on the number of meals that a Wright employee or agent may have with any particular Health Care Professional, or group of Health Care Professionals, in general, is no more than two (2) meals per quarter and no more than eight (8) meals per year. This guideline applies to anyone who is employed by, or represents, the Company. Meals that are part of a pre-approved and legitimate training and/or educational event are excluded from this limitation, but are subject to limitations as defined by Wright's annual Needs Assessment process.

Compliance to these guidelines will be monitored and enforced by the Compliance department.

IX. Educational Items; Prohibition on Gifts

Wright may occasionally 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.

Wright 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 or I-Pod.

Wright 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 our Company's name, logo, or the name or logo of one of its Medical

Technologies. Wright may also 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 appropriate sample products and opportunities for product evaluation as outlined 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, Wright may provide such information regarding its Medical Technologies if it is accurate, objective, consistent with FDA approvals, and does not reference or discuss off-label uses. Wright may also collaborate with Health Care Professionals, patients and organizations representing our 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 Wright'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 Wright'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 Wright's Medical Technologies, including where and how they can be used within the continuum of care.
- Providing information related to Wright'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 Wright'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 Wright's Medical Technologies.
- Facilitating patient access to Wright's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decision 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 Wright'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 Wright's own Medical Technology; however, such assistance should not be provided as an unlawful inducement.

Wright 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, Wright shall not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise incur as part of its business operations if doing so would amount to an unlawful inducement. Wright may 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

Wright may provide research and educational grants and charitable donations. However, such grants or donations may not be provided as an unlawful inducement.

Wright's Grants Review Committee is responsible for ensuring that grants and donations and charitable contributions (1) do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (2) are not used as an unlawful inducement; and (3) are appropriately documented. Voting members of the Grants Review Committee include senior management from Compliance, Medical Education, Regulatory and Clinical Affairs, Finance and Legal. Company associates from Sales may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel have no ability to control or unduly influence the decision of whether a particular HCP or institution will receive a grant or donation or the amount of such grant or donation.

The various types of Grant requests may include:

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, Wright 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

Educational Grants. Educational grants may be provided for legitimate purposes including:

- *Advancement of Medical Education.* Grants may be made to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, that are affiliated with charitable or academic organizations. (For additional considerations regarding educational grants, see Section III, Supporting Third Party Educational Conferences.)
- *Public Education.* Grants may be made for the purpose of supporting education of patients or the public about important health care topics.

Wright may make educational grants to conference sponsors or training institutions. Educational grants may not be made to individual Health Care Professionals.

Charitable Donations. Wright may make monetary or Medical Technology donations for charitable purposes, such as providing indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations must 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.

XII. Evaluation and Demonstration Products

Providing products to HCPs 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 HCPs regarding the use of products. Under certain circumstances, Wright may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

Wright products that may be provided to HCPs 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 HCPs 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. Wright 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 and set forth in writing. Wright shall retain title to such multiple use products during the evaluation period and will promptly remove such multiple use products from the HCP's location at the conclusion of the evaluation period unless the HCP 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 HCP 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 are not intended to be used in patient care. Demonstration products are also typically identified as not intended for patient use by use of such designations as "sample-not intended for human use", or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

Wright shall provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

Note: This Policy applies to all persons associated with Wright, including, but not limited to, employees, distributors, and sales representatives. It is expected that they will adhere to this Policy. Wright is committed to making sure its interactions with Health Care Professionals comply with all applicable laws and regulations. This Policy cannot address every situation, but its principles along with the Wright Code of Business Conduct should provide you with a good starting point. However, you should seek guidance on the appropriate course of conduct when you have questions about the Policy or Code of Business Conduct. Because questions do arise regarding ethical decisions or situations, we have a designated Lisa L. Michels, Vice President and Chief Compliance Officer to serve as the Chief Compliance Officer. In her absence, Jason P. Hood, Vice President, General Counsel and Secretary, or Thomas L. McAllister, Senior Corporate Attorney, serve as secondary Ethics Officers. In addition we have set up an Ethics Hotline at (901) 867-4349 or email ethics@wmt.com for confidential assistance or advice. Wright's intent is to provide assistance to everyone in the organization in making the *right* decisions.

FREQUENTLY ASKED QUESTIONS REGARDING WRIGHT'S CUSTOMER RELATIONSHIP POLICY

SECTIONS I and II: PREAMBLE & 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 HCPs because of the complexity and "hand on" nature of Medical Technologies and the importance of having HCPs understand how to use the technologies safely and effectively.

Q2. Who are "Health Care Professionals?" Does the term include non-clinical people who make product 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) who are involved in the provision of health care services and/or items to patients; and (2) who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies. 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 Policy apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Policy 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 Policy.

Q4. Does the Policy 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 Policy applies to interactions with Health Care Professionals to the extent that they provide services or products 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. Compliance with those laws and requirements must be maintained.

Q5. Are combination products covered by the Policy?

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

Q6. Does the Policy address arrangements between Wright and a Health Care Professional relating to licensing a new medical technology to Wright?

Any arrangements that involve providing services to Wright are considered consulting arrangements. Interactions relating to product development and intellectual property are subject to the general principle that Wright shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

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

The Policy seeks to balance an interest in civility with the desire to avoid even the appearance that meals and refreshments may be used as an inducement to purchase or refer for product. Accordingly, the Policy differentiates, depending on the type of meeting, the type of meals and refreshments that may be extended to Health Care Professionals by Representatives. The Policy contemplates that any meals and refreshments should be subordinate in time and focus to the purpose of the meeting.

In light of regional differences, “modest” means moderate or low value and “occasional” means infrequent. Meals and hospitality should be ancillary to a legitimate documented purpose. Wright has imposed limits on the frequency and amount of such expenditures. As outlined in Wright’s Corporate Travel and Expense Policy, the HCP Travel and Expense Policy, and the Needs Assessment process, Wright has established modest and occasional limitations on meals with Health Care Professionals. Wright has established a cap on meal expenses not to exceed \$100 per person for dinner, \$25 per person for breakfast, and \$45 for lunch. To accommodate regional differences in prices/cost in such cities as New York, Chicago, Miami, and Los Angeles, or in the case of an international city, a dinner is capped at \$150 per person plus applicable taxes. Breakfasts and lunches in such cities remain capped at the aforementioned limits. “Occasional” means infrequent.

Q8. May a Wright employee or agent pay for meals or refreshments for a Health Care Professional that the Wright could not provide under the policy, if Wright neither pays for the meals or refreshments nor reimburses the employee or agent?

No. The Policy should be viewed as applying to Wright’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 Wright to engage in certain activities with a Health Care Professional if each pays his or her own way.

Q9. May Wright or its Representatives offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 medical devices that Wright has just introduced?

No. It is not appropriate for Wright or its Representatives to provide any item of value to a Health Care Professional that is intended to induce the referral of business, or the recommendation or arranging for the referral of business to Wright. Further, it is not appropriate to provide anything of value to an HCP that, directly or indirectly, 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 Wright or its Representatives provide support for a Health Care Professional-sponsored social event, such as an office party?

No. Such support would be inappropriate.

Q11. Why may it be appropriate under the Policy for Representatives to pay for travel to training and education sessions?

In order to efficiently deliver training at appropriate facilities, the Policy contemplates that Representatives may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section addresses only meetings focused on training and education on Wright products, and only for persons who could legitimately benefit from the training. (Meetings focused on sales, promotional, and other business meetings are discussed under Section V.) Outside of this context, such payments would not be appropriate.

Q12. May Wright pay for travel to a Wright-sponsored general educational program (not specific to Wright's products)?

It may be appropriate for Wright to conduct general educational sessions, but these are not the types of programs for which Wright-supported travel would be appropriate under the Policy. In contrast, paying for Health Care Professionals' travel may be appropriate when Wright is conducting training and education on the safe and effective use of its products.

SECTION IV: SUPPORTING THIRD PARTY EDUCATIONAL CONFERENCES

Q13. May Wright designate attendees or faculty who will speak at third-party educational conferences?

No. The Policy contemplates that an independent third party will select faculty and attendees. The ultimate selection should be made by the conference sponsor and the payment may not be tied to the selection of a particular faculty member.

Q14. Can Wright provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?

The Policy contemplates that grants could be made to the conference sponsor or training institution, which will select the attendees and faculty. Furthermore, the Policy contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training. Wright can provide grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for Health Care Professionals who are *bona fide* conference faculty members. The conference sponsor must be responsible for and control the selection of faculty.

The determination of whether an educational grant to support the attendance of a Health Care Professional at a third-party educational conference is made by Wright's Grants Review Committee and discussed under Section IV.).

Q15. If Wright 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.

Q16. May Wright 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 Policy. Wright must also comply with applicable conference sponsor guidelines. Sales and promotional meetings should be evaluated under Section IV. However, Wright-sponsored product-related educational programs should be evaluated under Section III. In either case, it should be determined whether the conference sponsor has guidelines that cover that type of off-agenda activity, and if so, the sponsor's guidelines should also be honored. If this Policy has rules that are more restrictive, this Policy controls any decisions.

SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

Q17. Why does the Policy not allow business courtesies to be extended to guests/spouses in connection with sales, promotional, or other business meetings?

Wright's Policy is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote Wright's products. It is not appropriate to pay for meals, refreshments, travel, or lodging of spouses or guests of Health Care Professionals or any other person who does not have a *bona fide* interest in the information being shared at the meeting.

Q18. May the 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. Wright should be deliberate in selecting the location and venue for such meetings. Wright should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting in a manner similar to the location and venue selection for training and educational meetings. 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 Sections III and IV, which provide 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 policy provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

Q19. May Wright indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Policy, for example, by reimbursing a distributor who provides these meals while marketing the Company's products or Medical Technologies?

No. Wright shall always promote adherence to the Policy by intermediaries when they are engaged in marketing Wright's products or Medical Technologies. Wright shall not knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Policy. Wright and its Representatives may not do indirectly what they may not do directly.

Q20. May a Representative provide pizza for the staff of a medical office?

Providing pizza for the staff of a medical office would be permissible under the Policy if the Representative provides an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the policy.

Q21. May a Representative invite Health Care Professionals to a meeting at a café bookstore to learn about a new Wright product where coffee and refreshments are served and each attendee is given a gift certificate for books in the amount of \$30?

No. While the presentation may present scientific or educational information and the coffee and

refreshments may be appropriately provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Q22. Is a clinical investigator considered a “consultant” under Section VI?

Yes. If the clinical investigator is providing services to Wright in return for compensation, he or she is considered a consultant.

Q23. Is there a limit to the number of consultants Wright may retain under Section VI?

Only as many consultants as are legitimate and appropriate to provide bona fide services as defined by Wright's Needs Assessment process and determined by Wright's Service Needs Review Committee and Wright's Consultant Qualification Review Committee, may be retained. Moreover, the requirements of Section VI. must be satisfied for each consultant.

Q24. May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section VI. are met.

Q25. What happens if a consultant is engaged but the project is cancelled or modified without using the consultant's services?

The Policy contemplates that if the requirements of Section VI. were met when the consultant was engaged and then unanticipated circumstances prevent performance, 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.

Q26. What factors should Wright consider when evaluating the venues and circumstances for meetings with consultants?

Wright 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 between Wright and consultant; (c) whether the value of any Wright-sponsored lodging is reasonable; (d) whether any ancillary meals and hospitality are modest in value (or alternatively, the fair market value of such meals and hospitality are taken into consideration when determining the fair market value of the compensation to be provided to the consulting Health Care Professional) 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 represent improper inducement of the Health Care Professional.

Q27. 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 Wright where services provided to Wright by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with Section V. 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

agreements and are addressed in Section XI.

Q28. Can the selection of a consultant include his or her experience, usage or familiarity with specific Wright products?

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 may be intended to reward past, or future, usage or constitute and unlawful inducement. Consultant qualification and legitimate and *bona fide* service needs are defined by Wright's Needs Assessment process and evaluated by Wright's Consultant Selection Review Committee and the Service Review Committee.

Q29. How are Clinical Study Agreements treated under the Policy?

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 agreements under the Policy. They should be governed by a written service 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 Wright 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 capacity that is outside the scope of the services covered in the clinical study agreement (e.g., protocol development). In that case, a separate consulting arrangement with that Health Care Professional will be required.

Q30. How can Wright establish "Fair Market Value"?

There are different valuation methods that may be used to establish fair market value. In all instances objective, verifiable criteria should be used and documented. Most often fair market value should be assessed by an independent third-party.

Q31. What is considered a "legitimate need" to engage a Health Care Professional as a consultant?

A legitimate need arises when Wright 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. Such Needs Assessment determinations are made by Wright's Service Need Review Committee, a cross-functional team that is responsible for reviewing service needs requests of the functional areas and to ensure that they support *bona fide* business needs.

SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION

Q32. May Wright or its Representatives invite a group of Health Care Professionals to a suite at a

professional sports game for a 45 minute scientific and educational presentation followed by a buffet and the three-hour game?

No. The provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Policy.

Q33. Under what circumstances would the Policy permit Wright or its Representatives to provide entertainment or recreational activities directly to Health Care Professionals?

Entertainment and recreational activities should not be provided to Health Care Professionals. Health Care Professionals should not be invited to sporting events, concerts, or shows, or be provided with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between Representatives and Health Care Professionals. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

Q34. Could a sales representative invite a Health Care Professional out for a round of golf and lunch where the combined cost of the golf and lunch is \$65 and the Health Care Professional is very busy and difficult to see in her office?

No. It is not consistent with the Policy to provide entertainment or recreational activities such as golf. Health Care Professionals should not be invited to sporting events, concerts, or shows, or be provided with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between Representatives and Health Care Professionals.

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

Q35. Is a general discussion to build good relationships a “business presentation” such that it is appropriate to provide a business meal?

No. A business presentation may include substantial discussions related to a 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 good will and business relationships should not be the primary purpose of a business meal and should not be used for entertainment or recreational purposes.

SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS

Q36. May branded promotional items of minimal value that are “related to a Health Care Professional’s work or for the benefit of patients” be provided to a Health Care Professional?

No non-educational, branded promotional items may be provided, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients (e.g., pens, notepads, mugs, and other items with Wright’s name, logo, or logo of a Wright product).

Q37. May Wright or its Representatives provide a small (i.e., valued at less than \$100) gift such as flowers or a fruit basket to a Health Care Professional or to a Health Care Professional’s family upon significant life events such as a birth, death, or serious illness?

No. Wright is prohibited from giving flowers, fruit baskets, etc. to recognize Health Care Professional life events (wedding, birth, anniversary, death, etc.)

Q38. May Wright or its Representatives provide a gift valued at less than \$25 (e.g., a box of cookies or bottle of wine) to a Health Care Professional during the holiday season?

No gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents may be provided to a Health Care Professional regardless if the value of such gift is minimal.

Q39. May a Health Care Professional or a Health Care Professional's office or staff be provided a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments?

No. These types of gifts and refreshments are not considered related to the Health Care Professional's work or for the benefit of patients. However, if food is provided in connection with either sales and promotional meetings, conferences, or training and education, see Sections III., IV., and V. to evaluate when meals and receptions may be appropriate.

Q40. Is the \$100 limit determined on a per-gift or per-year basis?

Representatives occasionally may provide modest gifts to Health Care Professionals, but only if the gifts benefit patients or serve a genuine educational function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from Wright should have a fair market value of less than \$100. The \$100 limit is intended to be a per-gift amount; however, consideration should be given to the frequency of providing gifts to any one individual (note the requirement that the gifts only be occasional). Repeated gifts to the same person, each with a value below the \$100 threshold, could violate the spirit of the Policy, the purposes of which are set forth in the Preamble. Similarly, gifts to multiple representatives of a physician practice group or to multiple representatives of a hospital materials management or faculty department could also violate the spirit of the Policy.

Q41. May gifts be given to the staff of a Health Care Professional who are not themselves Health Care Professionals?

No. 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 the provisions of Section VII.

Q42. May Wright or its Representatives 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.

Q43. What types of items are considered to be for the benefit of patients?

Items intended for the benefit of patients could include educational brochures. However, scrubs and office supplies would not be considered an item for the benefit of patients.

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

Q44. Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

It may be appropriate to provide accurate information relating to the costs, savings and revenues associated with the use of a particular product. Without this information, it may be difficult for a Health Care Professional to properly evaluate whether it is economically feasible or desirable to purchase any particular product.

SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Q45. 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 devices to individuals who perform volunteer disaster relief. Supporting disaster relief work may be appropriate under the Policy, notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.

Q46. May grants be given to a for-profit organization, such as a legitimately sponsored research grant to a for-profit hospital? What about a research grant to an individual Health Care Professional?

This section of the Policy addresses charitable giving. Funding a research project at a for-profit institution, or paying an individual researcher, would not qualify as a charitable gift. However, that does not, by itself, mean that the funding would violate the Policy. For example, if the funding constituted payment for a legitimate service, it could be appropriate under Section VI: “Consulting Arrangements with HCPs” (which should be consulted in evaluating proposed arrangements to make payments for the performance of services).

Q47. May a charitable contribution be made to a not-for-profit institution to pay the registration or seminar fees and travel expenses for one or more of its affiliated Health Care Professionals to attend a third-party educational conference?

This contribution should be evaluated under Section IV: “Supporting Third Party Educational Conferences.” Because Section IV. does not permit Wright to pay directly for the registration or seminar fees and travel expenses of a Health Care Professional’s attendance at a third-party educational conference (except for Health Care Professionals in training), this type of support should not be provided indirectly as a charitable contribution to the Health Care Professional’s not-for-profit institution for the purpose of defraying the costs of particular individuals’ attendance. However, it would not be inappropriate to provide funding to a third party conference that the conference sponsor could apply to defray the reasonable travel expenses of faculty selected by the Sponsor, or to reduce the registration or seminar fees for all attendees.

Q48. May a charitable contribution be made to a not-for-profit hospital for construction of a new wing?

Industry has 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 charity; (b) the purpose of the donation is charitable in nature and (c) it is not offered with the intent of providing an inducement to order, sell, lease, recommend, arrange for the sale or lease of, or prescribe Representatives’ products. 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 Wright.

Q49. May Wright make a charitable contribution to pay for a clinical fellow?

Wright 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. Wright may not use the provision of an educational grant as an unlawful inducement.

Q50. May Wright or its Representatives pay for or provide tickets to a Health Care Professional or their spouse or guest to attend charitable events, such as galas and golf outings?

No. Wright or its Representatives 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.

Q51. May Wright give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?

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

Q52. May Wright 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, Wright may not pay for an individual Health Care Professional to attend or participate in the charitable event.

Q53. How can a Company determine whether a charitable organization is a *bona fide* charitable organization?

Wright's Grants Review Committee is responsible for reviewing and approving all grant requests. Various factors that the Grants Review Committee may consider 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

Q54. May Wright provide a recently approved product without charge to a Health Care Professional for evaluation?

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

Q55. A Health Care Professional has requested that Wright provide it with a multiple use product to evaluate. How long can Wright provide the product at no charge to the HCP?

The specific length of time reasonably necessary for a 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. Wright must provide the HCP with documentation and disclosure regarding the no-charge status of evaluation products.

Q56. Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional considered a gift?

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

ADDITIONAL QUESTIONS

Q57. Does the Policy offer legal advice?

No. The Policy is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. You have an independent obligation to ascertain that your interactions with Health Care Professionals comply with all current laws and regulations.

Q58. Will Wright provide advice on how specific provisions of the Policy would apply to specific practices that are being contemplated?

This FAQ is designed to provide information regarding the Policy. Specific questions should be addressed to the Wright Compliance Department.

Q59. Does the Policy govern the actions of Wright's agents and distributors?

Wright expects that its employees, agents, distributors, and sales representatives will adhere to the Policy.

**ADDENDUM TO CUSTOMER RELATIONSHIP POLICY
AS IT RELATES TO INTERACTIONS WITH
HEALTH CARE PRACTITIONERS LICENSED IN MASSACHUSETTS**

The Commonwealth of Massachusetts has enacted “An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.” This law has specific legal requirements related to interactions with health care practitioner who is licensed to provide health care in Massachusetts and who prescribes prescription drugs (a “Massachusetts HCP”). The law sets forth penalties (\$5,000.00 per incident) for failing to comply with the law and related regulations.

The Massachusetts law has three main requirements with regard to medical device manufacturing companies:

- Adopt a marketing code of conduct in compliance with the Massachusetts Department of Public Health Marketing Code of Conduct.
- Implement a corporate compliance program and provide certifications to the state regarding the compliance program and the marketing code of conduct.
- Provide annual disclosures regarding payments, of any type, equal to or greater than \$50 per instance, to a Massachusetts HCP.

Wright’s CRP is consistent with the Massachusetts Department of Public Health Marketing Code of Conduct. However, there are additional requirements mandated by Massachusetts that have been adopted by Wright for interactions by its representatives with a Massachusetts HCP. The following policies apply to interactions by Wright and its representatives with a Massachusetts HCP.

A representative of Wright may not take a Massachusetts HCP out for a meal outside of a hospital setting. This requirement prevents Wright or its representatives from paying for meals at training events outside the hospital setting and prevents any type of meal being provided at a sales or promotional meeting outside the hospital setting. This prohibition does not prevent meals being provided to consultants who are performing *bona fide* services so long as the meal is characterized as compensation in the written consulting agreement.

Wright may not make payments of expenses in conjunction with plant tours and training unless the training is pursuant to a written agreement between the Massachusetts HCP and Wright for the purchase of a medical device. This restriction on training and plant tours requires that all training and plant tours for a Massachusetts HCP outside the hospital setting that would involve payment for travel or expenses by Wright or its representatives and must be approved and coordinated by Wright’s Corporate Compliance Department.

Wright will perform annual audits to monitor compliance with the MA Marketing Code. Non-Compliance following corrective action will be reported to the state of Massachusetts. Penalties under the Massachusetts regulations are significant. Specifically, violations of the regulations are punishable by a fine of up to \$5,000 for each transaction, occurrence, or event. Fines may be issued by the Massachusetts Attorney General, the district attorney with jurisdiction over a violation, or the DPH.

MASSACHUSETTS FAQs

Q1. May a company representative, other than a sales representative or immediate supervisor, take a doctor out for a meal, outside of the hospital setting?

No, unless the doctor is a *bona fide* employee or board member of the company.

Q2. May a PMDMC reimburse a health care practitioner for travel and reasonable expenses associated with plant tour or product evaluation of a medical device?

The regulations prohibit payments to health care practitioners except as compensation for *bona fide* services. Payment of expenses in conjunction with *bona fide* services as defined in the regulations and in connection with product training pursuant to a contract to purchase a medical device is permissible and only after specific approval by Wright's Corporate Compliance Department.

Q3. Is the \$50 threshold for disclosure based upon a singular expense or an annually aggregated basis?

For the purposes of computing the \$50 threshold, the DPH states that "fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual basis and shall not be aggregated." Based on recent guidance, this \$50 threshold would be triggered even if the allocated expense per Covered Recipient is under this amount.

Q4. How is group spend allocated?

Based on DPH guidance, it appears that a manufacturer can either calculate and disclose the per Covered Recipient value or, if the individual Covered Recipients are part of an organization that also is a Covered Recipient (e.g., a physician group practice), determine the amount based on entity level. If a group spend also includes non-HCPs/ Covered Recipients, these participants would be excluded from the allocation. Stated differently, the total spend would be divided among Covered Recipients only.

The example provided by the DPH is as follows:

A \$240 dollar lunch is provided in a hospital setting. In attendance are:

- 5 MDs (Covered Recipients)
- 1 Office Staff (Covered Recipient)
- 1 Manufacturer Rep

In this situation, "because the total cost exceeds the \$50 per instance threshold, it is reportable under Massachusetts law. For purposes of allocation, the manufacturer would divide the total among HCPs only. So, in this instance, a pharmaceutical or medical device manufacturer would disclose its payment of \$240 to the physician practice (as a covered recipient) or divide the \$240 payment by 6, and provide 6 separate disclosures of \$40.00 for each health care practitioner."

Please refer to the following comparison chart outlining the minor differences (highlighted in yellow) between Wright's Customer Relationship Policy and the MA Code of Conduct regulation. Please find the MA Code of Conduct regulation immediately following the comparison chart.

WMT Customer Relationship Policy and MA Marketing Code of Conduct Comparison Chart

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
<p>Company-Conducted Product Training and Education</p>	<p>Wright may pay for reasonable travel and modest lodging costs incurred by attending HCPs where there are objective reasons to support the need for out-of-town travel to efficiently deliver training and education on products and/or medical technologies. It is not appropriate for Wright or its Representatives to pay for the meals, refreshments, travel, or other expenses for spouses and/or guests of Health Care Professionals.</p> <p><i>Section III</i></p>	<p>Nothing in 105 CMR 970.008 shall prohibit payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of health care practitioners on the use of a medical device if the commitment to provide such expenses, and the amounts or categories of reasonable expenses to be paid, are described in the written agreement between the health care practitioner and the device vendor for the purchase of the device</p> <p><i>105 CMR 970.006</i></p>
<p>Provision of Meals</p>	<p>A modest and occasional meal should be incidental to the <i>bona fide</i> presentation of scientific, educational, or business information and provided in a manner that is conducive to the presentation of such information. The meal must not be part of an entertainment or recreational event. Such meals may occur at the HCP'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. Wright or its Representative may provide a meal only to HCPs who actually attend the meeting. Wright may not provide a meal for an entire office staff where everyone does not attend the meeting. Wright also prohibits "dine and dash" meals, where a company representative is not present. Wright may not pay for meals for spouses or guests of Health Care Professionals or for any other person who does not have a <i>bona fide</i> professional interest in the information being shared at the meeting.</p> <p><i>Section VIII</i></p>	<p>Meals must be modest and occasional in nature.</p> <p>Except as otherwise provided in the regulations, NO pharmaceutical or medical device manufacturer may provide or pay for meals for HCPs that:</p> <ul style="list-style-type: none"> • Are part of an entertainment or recreation event; • Are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; • Are offered, consumed, or provided outside of the HCP's office or a hospital setting; or • Are provided to an HCP's spouse or other guest. <p>"Hospital setting" is defined as: (a) a hospital (b) academic medical center or (c) pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.</p> <p><i>See meal restrictions at 105 CMR 970.006</i></p>

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
<p>CME/3rd Party Scientific or Educational Conferences</p>	<p>Wright may only support high quality events that are aligned with strategic objectives. This determination is based on whether the conference has objective and substantive educational value. This may be assessed based on the value of CME or CPME credits and/or the course program or agenda. At a minimum, at least six (6) hours per conference day must be spent engaging in legitimate educational activities such as lectures, labs, or the like. Conferences whereby social events or activities such as golf outings, leisure time, or other recreational activities, take precedence over the educational component, are not considered high quality programs of significant educational value, and sponsorship by the Company may be denied. Wright must not fund any recreational event or activity of the conference.</p> <p>Funding may be provided to a conference sponsor to support the provision of meals and refreshments to conference attendees. Wright may itself provide modest meals and refreshments for HCP attendees if such meals and refreshments are provided to all HCP attendees, and in a manner that is also consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Grants may be made to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for HCPs who are <i>bona fide</i> conference faculty members.</p> <p>Advertisements may be purchased, and booth/exhibit space leased at Fair Market Value, for company displays at conferences.</p> <p><i>Section IV</i></p>	<p>Companies <u>MAY NOT</u> provide:</p> <ul style="list-style-type: none"> • Direct or indirect financial support for the cost of travel, lodging, or personal expenses for any non-faculty HCP attending educational events; • Funding to compensate HCPs for time spent at educational events; • Sponsorship or payment for CME that (1) does not meet the standards established by ACCME or equivalent commercial support standards established by the relevant accrediting body; or (2) provides payment directly to an HCP; • Meals directly to an HCP at educational events (although the organizer may apply financial support provided by a company to provide meals for all participants). <p>The following payments <u>ARE</u> allowed under the regulations:</p> <ul style="list-style-type: none"> • Compensation or reimbursement to HCPs who serve as speakers or provide substantive services as organizers or consultants at CME events, third-party scientific or educational conferences, or professional meetings, provided payment is (1) reasonable, (2) based on fair market value, and (3) complies with the standards of the accrediting body; • Direct payment to organizers of third-party scientific or educational conferences, charitable conferences or meetings, or professional meetings; • Use of hotels, convention centers, or other special events venues for CME events, third-party scientific or educational conferences, or professional meetings. <p>Note: The Massachusetts final regulations do not permit manufacturers to provide financial assistance for medical students, residents, fellows, and other HCPs in training to attend educational conferences. The proposed regulations expressly allowed companies to provide such support, but that express allowance was struck from the final regulations and the Department has indicated that such support is not appropriate.</p> <p style="text-align: right;"><i>105 CMR 970.007</i></p>

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
<p style="text-align: center;">Sales, Promotional and Other Business Meetings</p>	<p>Wright may conduct sales, promotional, and other business meetings with HCPs to discuss product features, or negotiate contracts or sales terms. Often, these meetings occur close to an HCP's place of business. It is appropriate for Representatives 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. It is not appropriate to pay for meals, refreshments, travel, or lodging of guests and/or spouses of HCPs, or any other person who does not have a <i>bona fide</i> professional interest in the information being shared at the meeting. Guests and/or spouses of HCPs may not be invited, nor may they attend or participate in any sales, promotional, or other business meetings. Unapproved uses of Wright products may not be discussed at such meetings.</p> <p style="text-align: center;"><i>Section V</i></p>	<p>Companies may not provide direct or indirect payment of cash, cash equivalents, or items of value to HCPs, except as compensation for bona fide services.</p> <p style="text-align: right;"><i>105 CMR 970.008(1)(b)</i></p> <p>Companies may provide reasonable compensation for bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by the HCP as a result of performing bona fide services, where the reimbursement and compensation are specified in, and paid under, a written agreement.</p> <p style="text-align: right;"><i>105 CMR 970.008(2)(a)</i></p> <p>See also meal restrictions at <i>105 CMR 970.006</i>, specifically:</p> <ul style="list-style-type: none"> • Manufacturers may not offer meals without an informational presentation; and • Manufacturers may not provide meals outside of the HCP's office or a hospital setting.
<p style="text-align: center;">Entertainment or Recreational Items</p>	<p>To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, Wright or its Representative must not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Such activities and items include, for example, theater, sporting events, golf, skiing, hunting, sports 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 Wright engages the HCP as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.</p> <p style="text-align: center;"><i>Section VII</i></p>	<p>Companies may not provide entertainment or recreational items or any value to any HCP who is not a salaried employee of the company (includes theater tickets, tickets to sporting events, concerts, sporting equipment, vacations).</p> <p style="text-align: right;"><i>105 CMR 970.008(1)(a)</i></p>

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
<p align="center">Prohibited Gifts/Payments to HCPs</p>	<p>Wright 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 or I-Pod.</p> <p>Wright 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 our Company's name, logo, or the name or logo of one of its Medical Technologies. Wright may also not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.</p> <p><i>Section IX</i></p>	<p>Companies may not provide:</p> <ul style="list-style-type: none"> • Any sort of direct or indirect payment in cash, cash equivalent, equity, or "complimentary items" (e.g., pens, coffee mugs), except as compensation for bona fide services; • Any grant, scholarship, subsidy, educational or practice-related item, etc., offered with the intent to encourage or modify prescribing behavior; • Any sort of remuneration or payment, in cash or in kind, directly or indirectly, that is prohibited by federal or state "fraud and abuse" Laws or regulations. <p align="right"><i>105 CMR 970.008</i></p>
<p align="center">Allowable Gifts/Payments to HCPs</p>	<p>Wright may engage HCPs to provide a wide-range of valuable, <i>bona fide</i> 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 Wright-sponsored training and other services.</p> <p><i>Section VI</i></p> <p>Wright may occasionally 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.</p> <p>Wright may provide research and educational grants and charitable donations. However, such grants or donations may not be provided as an unlawful inducement.</p> <p><i>Section XI</i></p> <p>Under certain circumstances, Wright may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.</p> <p><i>Section XII</i></p>	<p>Companies may provide:</p> <ul style="list-style-type: none"> • Reasonable compensation or reimbursement for bona fide services of an HCP, where compensation or reimbursement is specified in, and paid under, a written agreement; • Payment or reimbursement of reasonable expenses necessary for technical training of HCPs on the use of a medical device; • Provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical information; • Advertising in peer-reviewed academic, scientific, or clinical journals; • Medical device demonstration and evaluation units provided to HCPs to assess the use and functionality of the product; • Rebates, discounts, or other price concessions, in the normal course of business; • Product reimbursement information in support of accurate billing to Medicare and other payers, and information designed to offer support for the appropriate use or installation of products; and • Charitable donations provided that the donation: <ul style="list-style-type: none"> <input type="checkbox"/> Is not provided in exchange for prescribing, disbursing, or using prescription drugs, biologics, or devices, or for a commitment to continue prescribing certain products, and <input type="checkbox"/> Does not otherwise violate the provisions of the regulations. <p align="right"><i>105 CMR 970.008</i></p>

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
Consulting Arrangements with HCPs	<p>Wright may engage HCPs to provide a wide-range of valuable, <i>bona fide</i> 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 Wright-sponsored training and other services. Fair market value compensation may be paid to consultants provided the arrangement fulfills a legitimate business need and does not constitute unlawful inducement, as defined by Wright’s Needs Assessment process. A signed and executed agreement must be in place before any services are authorized or provided by the Consultant. Proper documentation of work performed as specified in the agreement must be provided before payment for such services will be made. In no event shall a consulting agreement, or any term of an agreement be based on the volume or value of business that a Consultant generates or influences.</p> <p>Wright consulting arrangements must be written, signed by all parties and specify all services to be provided and the compensation to be paid.</p> <p>Compensation paid to consultants should be consistent with fair market value in an arm’s length transaction for services provided and should not be based on the volume or value of the consultant’s past, present, or anticipated business.</p> <p>Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance and documented as defined by Wright’s Needs Assessment process.</p> <p>Selection of consultants should be on the basis of the consultant’s qualifications and expertise to meet the defined need, and should not be on the basis of volume or value of business generated by the consultant.</p> <p>Wright 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 costs incurred by consultants attending meetings with, or on behalf of Representatives.</p> <p>The venue and circumstances for Wright meetings with consultants should be appropriate to the subject matter of the consultation.</p> <p><i>Section VI</i></p>	<p>Companies may not provide direct or indirect payment of cash, cash equivalents, or items of value to HCPs, except as compensation for bona fide services.</p> <p style="text-align: right;"><i>105 CMR 970.008(1)(b)</i></p> <p>Companies may provide reasonable compensation for bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by the HCP as a result of performing bona fide services, where the reimbursement and compensation are specified in, and paid under, a written agreement.</p> <p style="text-align: right;"><i>105 CMR 970.008(2)(a)</i></p> <p>“Bona fide services,” an arrangement for services including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including U.S. Food and Drug Administration (“FDA”) required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and characterized by the following factors:</p> <ul style="list-style-type: none"> • a legitimate need for the services clearly identified in advance; • a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement; • the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose; • the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner; • the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and • the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company’s sales personnel. <p style="text-align: right;"><i>105 CMR 970.004</i></p> <p>See also meal restrictions at <i>105 CMR 970.006</i>, specifically: Manufacturers may not provide meals outside of the HCP’s office or a hospital setting.</p>

ACTION	Customer Relationship Policy	MA Marketing Code of Conduct
<p>Penalties and Enforcement</p>	<p>The addendum to the Customer Relationship Policy adopts the penalties and enforcements set forth by the Massachusetts Marketing Code of Conduct.</p>	<p>Penalties:</p> <ul style="list-style-type: none"> • Fine of not more than \$5,000 for each transaction, occurrence, or event that is a knowing and willful violation. • Companies may not retaliate or take any adverse action against an individual who has taken any action in furtherance of these regulations. <p style="text-align: right;"><i>105 CMR 970.010</i></p> <p>Enforcement:</p> <ul style="list-style-type: none"> • Fines issued by an authorized entity; • Ten days prior to issuance of any fines, the authorized entity shall provide notice (by mail to person’s place of business or last known address) and an informal opportunity to dispute the fine; • A person aggrieved by the issuance of a fine may seek judicial review in the Superior Court; • An authorized entity may file a civil complaint in Superior Court following the failure of any person to pay a fine. <p style="text-align: right;"><i>105 CMR 970.011</i></p>

105 CMR 970.000: MA PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT

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970.001: Purpose

105 CMR 970.000 is set forth to implement M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care. 105 CMR 970.000 is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners. Pursuant to M.G.L. c. 111N, the regulation seeks to accomplish these objectives without compromising companies' legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

970.002: Regulatory Authority

105 CMR 970.000 is adopted under the authority of M.G.L. c.111, s.3 and M.G.L. c.111N.

970.003: Citation

105 CMR 970.000 shall be known, and may be cited, as The Pharmaceutical and Medical Device Manufacturer Code of Conduct or the Marketing Code of Conduct.

970.004: Definitions

The following terms as used in 105 CMR 970.000 shall have the following meanings, unless the context or subject matter clearly require a different interpretation:

“Authorized entity,” the attorney general, the district attorney with jurisdiction over a violation, or the department of public health.

“Biologic,” a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product, or analogous product, as defined by Section 351 of the Public Health Service Act applicable to the prevention, treatment, or cure of a disease or condition of human beings and regulated as a drug under the Federal Food, Drug, and Cosmetic Act.

“Bona fide services,” an arrangement for services including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including U.S. Food and Drug Administration (“FDA”) required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and characterized by the following factors:

- a legitimate need for the services clearly identified in advance;
- a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement;
- the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner;
- the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and
- the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company’s sales personnel.

“Charitable donation,” the provision of financial support to a 501(c)(3) or the in-kind

provision of drugs, biologics or medical devices for charity care of patients.

“Clinical trial,” a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board (“IRB”) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency.

“Covered recipient,” A person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner. A person who otherwise meets this definition but is a bona fide employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.

“Conference or Meeting,” any convening where responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event’s organizers in accordance with their guidelines, held in a venue that is appropriate and conducive to informational communication and training about medical information, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

“Department,” the department of public health.

“Genuine Research Project,” a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry.

“Health care practitioner,” a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and board members of pharmaceutical or medical device manufacturers are not health care practitioners.

“Hospital Setting,” (a) a hospital (b) academic medical center or (c) pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, such as surgical

equipment, implants, and imaging and clinical laboratory equipment.

“Medical device,” an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (3) intended to affect the structure or function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

“Non-faculty,” a health care practitioner who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education (“CME”) event, third-party scientific or educational conference, or professional meeting.

“Person,” a business, individual, corporation, union, association, firm, partnership, committee or other organization.

“Pharmaceutical or medical device manufacturer agent,” a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices ; provided, however, that “pharmaceutical or medical device manufacturer agent” shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he or she is licensed, a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacist registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

“Pharmaceutical or medical device manufacturing company,” any entity that:
(a) is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (b) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices; provided, however, that “pharmaceutical or medical device manufacturing company” shall not include a health care practitioner, physician practice, home health agency, hospital licensed under M.G.L. c. 111, s. 51, a wholesale drug distributor licensed under M.G.L. c. 112, s. 36A or a retail pharmacist registered under M.G.L. c. 112, s. 37-39C.

“Prescription drugs,” drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: “Caution

federal law prohibits dispensing without prescription.”

“Sales and marketing activities,” for the purposes of disclosure under 105 CMR 970.009, sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose. Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50

to a covered recipient except as follows: Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or “new use” or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan’s formulary.

970.005: General Requirements

1. By July 1, 2009, each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall:
 - a. adopt a marketing code of conduct in compliance with the requirements of 105 C.M.R. 970.000.
 - b. adopt and submit to the Department a description of a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct. The training program must:
 - i. ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of:
 1. the marketing code of conduct,
 2. general science, and
 3. product-specific information to provide accurate, up-to-date information, consistent with state law and FDA requirements; and

ii. provide for regular assessments of persons who are employed by or acting on behalf of the companies to ensure that they comply with the requirements of 105 C.M.R 970.000 and other relevant company policies.

c. certify to the Department to the best of the company's knowledge, information and belief that it is in compliance with 105 C.M.R. 970.000;

d. adopt and submit to the Department policies and procedures for investigating non-compliance with 105 C.M.R. 970.000, taking corrective action in response to noncompliance and reporting instances of non-compliance to the appropriate state authorities; and

e. submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for certifying compliance with 105 C.M.R. 970.000 and implementing, monitoring, and enforcing the company's marketing code of conduct.

2. Each pharmaceutical manufacturing company that uses non-patient identified prescriber data to facilitate communications with health care practitioners shall:

a. maintain the confidential nature of prescriber data;

b. develop policies regarding the use of the data;

c. educate employees and agents about these policies;

d. designate an internal contact person to handle inquiries regarding the use of the data;

e. identify appropriate disciplinary actions for misuse of the data; and

f. comply with the request of any health care practitioner not to make his or her prescriber data available to company sales representatives.

g. Before utilizing health care practitioner prescriber data for marketing purposes, manufacturers must give health care practitioners the opportunity to request that their prescriber data :

i. be withheld from company sales representatives, and

ii. not be used for marketing purposes.

h. Nothing in this section shall prohibit pharmaceutical manufacturing companies from using prescriber data to:

i. impart important safety and risk information to prescribers of a particular drug or device;

ii. conduct research;

iii. comply with FDA mandated risk management plans that require manufacturers to identify and interact with health care practitioners who prescribe certain drugs or devices; or

iv. track adverse events of marketed drugs, biologics or devices.

3. In all speaker and commercial consultant contracts, pharmaceutical manufacturing companies shall require any health care practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.
4. Beginning on July 1, 2010, and annually on or before July 1 of each year thereafter, each pharmaceutical and medical device manufacturing company must certify to the Department that it has conducted annual audits to monitor compliance with 105 C.M.R. 970.000.

970.006: Provision of Meals

1. Except as otherwise provided in 105 CMR 970.000, no pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide or pay for meals for health care practitioners that:
 - a. are part of an entertainment or recreational event;
 - b. are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present;
 - c. are offered, consumed, or provided outside of the health care practitioner's office or a hospital setting; or
 - d. are provided to a healthcare practitioner's spouse or other guest.
2. Meals provided to health care practitioners in compliance with 105 CMR 970.006 must be modest and occasional in nature.

970.007: CME, Third-Party Scientific or Educational Conferences, or

Professional Meetings

1. No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:
 - a. financial support for the costs of travel, lodging, or other personal expenses of nonfaculty health care practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor.
 - b. funding to compensate for the time spent by health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;
 - c. payment for meals directly to a health care practitioner at any CME event, thirdparty scientific or educational conferences, or professional meetings, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants;

d. sponsorship or payment for CME, also known as independent medical education, that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education (“ACCME”) or equivalent commercial support standards of the relevant continuing education accrediting body, or that provides payment directly to a health care practitioner.

2. A pharmaceutical manufacturing company shall separate its CME grant-making functions from its sales and marketing departments.

3. A pharmaceutical manufacturing company shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company.

4. Nothing in these regulations shall prohibit:

a. compensation or reimbursement made to a health care practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, provided that the payment:

1. is reasonable;

2. is based on fair market value; and

3. complies with the standards for commercial support as established by the relevant accreditation entity.

b. sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers.

c. the use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences.

970.008: Other Payments to Health Care Practitioners

1. No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:

a. entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing company;

b. payments of any kind including cash or cash equivalents, equity, “in kind” or tangible items including any “complimentary” items such as pens, coffee mugs, gift cards, etc. to health care practitioners either directly or indirectly, except as compensation for bona fide services;

c. any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices;

d. any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under applicable federal or state "fraud and abuse" laws or regulations including the federal "Anti-Kickback Statute" (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws such as M.G.L. c. 118E, s. 41 and M.G.L. c. 175H, s. 3.

2. Nothing in these regulations shall prohibit the following:

a. Reasonable compensation for bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by the health care practitioner directly as a result of the performance of such services, where the compensation and reimbursement is specified in, and paid for under, a written agreement;

b. Payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of health care practitioners on the use of a medical device if the commitment to provide such expenses, and the amounts or categories of reasonable expenses to be paid, are described in the written agreement between the health care practitioner and the device vendor for the purchase of the device;

c. The provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;

d. The purchase of advertising in peer reviewed academic, scientific or clinical journals;

e. The provision of prescription drugs to a health care practitioner solely and exclusively for use by the health care practitioner's patients;

f. The provision of reasonable quantities of medical device demonstration and evaluation units provided to a health care practitioner to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future.

g. The provision of price concessions, such as rebates or discounts, in the normal course of business;

h. Provision of reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products, or of procedures using those products and information, in support of accurate and responsible billing to Medicare and other payors and provision of information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products, provided, however, that this technical or other support shall not be offered or provided for the purpose of inducing health care practitioners to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of products; or

i. The provision of payments, or the provision of free outpatient prescription drugs, to health care practitioners for the benefit of low income individuals, through established "patient assistance programs" ("PAPs"), provided the program meets the criterion for a permissible

program in accordance with the relevant published guidance available from the U.S. Department of Health and Human Services Office of the Inspector General, or is otherwise permitted under applicable federal laws and regulations including the "Anti-Kickback Statute" (42 USC 1320a-7b).

j. The provision of charitable donations provided that the donation:

1. is not provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices, and

2. does not otherwise violate the provisions of 105 C.M.R. 970.000.

970.009 Disclosure of Payments

1. Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall disclose to the Department the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.

2. Each annual disclosure report shall be accompanied by a fee of \$2,000. The first annual payment of \$2,000 shall be due to the Department on July 1, 2009.

3. Disclosures shall be made for the previous calendar year using a standardized reporting format developed by the Department. The first required disclosure report shall cover the period from July 1, 2009 through December 31, 2009. Each annual disclosure report may be submitted to the Department electronically.

4. Pharmaceutical or medical device manufacturing companies shall certify that to the best of the company's knowledge, information and belief, the report is true and accurate.

5. For the purposes of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements of M.G.L. c. 111N, §6 and 105 C.M.R. 970.009.

970.010 Penalties

1. A person who knowingly and willfully violates 105 CMR 970.000 shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event.

2. No pharmaceutical or medical device manufacturing company, shall discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse action against any employee, applicant, health care practitioner or covered recipient because such employee, applicant, health care practitioner, or covered recipient takes or has taken any action in furtherance of the enforcement of 105 CMR 970.000.

970.011 Enforcement

1. Fines pursuant to 105 CMR 970.000 shall be issued by an authorized entity.
2. Ten days prior to the issuance of any fine pursuant to 105 C.M.R. 970.000, the authorized entity shall provide notice and an informal opportunity to dispute the issuance of the fine in person or by counsel or other representative as to the proposed action.
3. Notice shall be provided by mail, postage prepaid, to the person's usual place of business or, if unavailable, to the person's last known address.
4. A person aggrieved by the issuance of a fine by an authorized entity pursuant to 105 CMR 970.000 may seek judicial review in the Superior Court.
5. An authorized entity may file a civil complaint in Superior Court following the failure of any person to pay a fine issued by the authorized entity.



**ACKNOWLEDGMENT AND RECEIPT
OF
CUSTOMER RELATIONSHIP POLICY (USA)**

I hereby acknowledge that I have received a copy of the Wright Medical Technology, Inc. ("Wright") Customer Relationship Policy (USA) (the "Policy") and that I have read the Policy. I agree to comply with the Policy (and related policies and procedures adopted by Wright), and understand that compliance with these standards, policies and procedures is a condition of my continued employment or association with Wright. I understand that these documents serve only as guides to possible conflicts of interest and problems of compliance with law and business ethics, and that all conflicts, violations of law or failures to adhere to business ethics are required to be reported to Wright whether or not they are of the type discussed in the Policy or the Wright Code of Business Conduct ("Code").

I understand that I am to give immediate notice to Wright if any situation should arise involving a possible, direct or indirect, conflict of interest, violation of law, the Code or the Policy or unethical action involving myself or others in the corporation.

At this time I have no personal interests and, to the best of my knowledge and belief, no member of my family has any personal interests, that conflict with the aforesaid Code and Policy and I have not engaged in any activity prohibited by either document, except as set forth below.

I acknowledge that the Code and Policy is a statement of policies for individual and business conduct and does not, in any way, constitute an employment contract or an assurance of continued employment or employment other than at-will or any other contractual relationship, or an assurance of a continued contractual relationship.

Sign and Print Name after Signature

Date

Position or Relationship with Wright/Subsidiary

Disclosures required under Wright policy described above:

