

INSPIREMD
COMPLIANCE POLICY - ANTI-BRIBERY AND CORRUPTION POLICY

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1. PURPOSE

The purpose of this Policy is to provide guidance and standards for interactions with Healthcare Professionals (HCPs, as defined below), consistent with applicable federal healthcare program laws and regulations and Company's Code of Conduct.

2. SCOPE

This Policy applies to all Company Personnel.

3. DEFINITIONS

Term	Definition
Business Courtesy	Any items, services, benefits or anything of economic value, including meals, gifts and other gratuities, but excluding Educational and Promotional Materials.
Charitable Organization	A non-profit organization with the philanthropic goal of serving the public interest or common good, recognized as federally tax-exempt under Internal Revenue Code Section 501(c)(3) or Section 509.
Compliance Officer	The Compliance Officer is the person responsible for overseeing this Policy and answering questions pursuant to this Policy.
Consultant	An HCP who is engaged to perform consulting services under a Consulting Arrangement.
Consulting Arrangement	An arrangement between Company and an HCP under which the HCP provides consulting services in exchange for compensation.
Educational Grant	A contribution of money to support organizations independent of Company conducting <i>bona fide</i> educational programs that are independent, objective, and provide legitimate medical, health-related education of healthcare professionals and/or the public.
Educational and Promotional Materials	Materials of an educational or promotional nature that focus strictly on providing educational information about or promoting Company products and services, including disease state information, provided these materials provide no independent value to the HCP.

Term	Definition
Fair Market Value (FMV)	Value of compensation based on arm’s-length negotiation between a willing buyer and a willing seller consistent with general market value and not determined in a manner that takes into account the volume or value of any referrals or other business between the parties. “General market value” means compensation that would be included in the agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the agreement.
Healthcare Provider (HCP)	Any healthcare provider and any other person or entity in a position to prescribe, purchase, recommend, refer, or arrange for the purchase or sale of products or services offered by Company or its affiliates, including, but not limited to, executives, physicians, nurses, medical directors, hospitals, insurers, and any individual employed by such entities with responsibility or authority to purchase, prescribe, recommend, influence, or arrange for the purchase or sale of Company products or services.
Company Personnel	All Company officers and directors, full-time, part-time, and temporary personnel.
Sponsorship	Contributions of money, goods, or services such as employee time, office space, equipment, etc. to a third party in return for recognition, acknowledgement or other promotional consideration including exhibitor space, advertising, signage and/or an opportunity to distribute promotional materials.

4. COMPLIANCE WITH LAWS AND REGULATIONS¹

4.1 THE ANTI-KICKBACK STATUTE

- (a) The federal Anti-Kickback Statute and its state counterparts (collectively referred to as the “anti-kickback laws” or the “fraud and abuse laws”) seek to prohibit improper influences on healthcare decisions by making it a felony to knowingly and willfully promise to pay, pay, agree to receive, or receive anything of value (“remuneration”) in order to influence or obtain government healthcare business.
- (b) Specifically, the laws prohibit the giving, accepting, soliciting, or arranging for payments of items of value in any form (cash or in kind), either directly or indirectly, to anyone for the purpose of inducing or rewarding someone for purchasing, prescribing, endorsing, or recommending a product that is reimbursed under federal or state healthcare programs. These laws apply to all arrangements and all sources of referrals.
- (c) For example, the law prohibits such activities as:

¹ The Company’s policy regarding the U.S. Foreign Corrupt Practices Act (FCPA) is contained in a separate Company compliance policy.

- Providing a HCP with free, or greatly reduced cost, medical equipment or other items or goods;
 - Performing advertising campaigns and other promotional activities on behalf of a HCP;
 - Providing a gift to an HCP to influence his or her prescribing or recommending a product(s);
 - Providing an educational or research grant to a HCP or hospital in order to influence the purchase of a product; and
 - Paying for the services (e.g., consulting services) of an HCP at a fee significantly above the reasonable, fair market value for such services.
- (d) Many states have enacted extended the Anti-Kickback Statute to all payor types, including cash payments and commercial insurance. As such, the Company treats all HCPs in the United States as if they are subject to the anti-kickback laws, even if they do not participate in government healthcare programs.
- (e) The U.S. anti-kickback laws are so broad that, if read literally, they could restrict many perfectly acceptable business arrangements with legitimate purposes and even some non-promotional activities. Recognizing this, the OIG has defined certain "safe harbor" regulations, which address various payment and business practices that are not treated as offenses under the statute. Activities that fall entirely within a safe harbor, such as legitimate service arrangements, will be free of prosecution from the OIG and/or the Department of Justice ("DOJ"). To fit squarely within a safe harbor, the business arrangement must be structured and operated precisely as outlined in the safe harbor regulation.
- (f) A number of safe harbors may be relevant to Company's business activities, including, but not limited to:
- Discount safe harbor: allows Company to discount the price of a product to make it competitive with other products, provided that the discount is properly reported and complies with other safe harbor requirements.
 - Personal Services safe harbor: protects legitimate service arrangements with HCPs, such as consulting or speaking agreements. Compliance with this safe harbor requires, among other things, a written agreement and compensation determined in advance and on a fair market value basis.
 - GPO safe harbor: permits the contracting with group purchasing organizations and the provision of an administrative fee to those organizations for their services.
- (g) The failure to meet all safe harbor criteria does not mean that the activity or arrangement violates the anti-kickback laws or is otherwise per se illegal. Arrangements that do not fit in a safe harbor are analyzed on a case-by-case basis to evaluate the risk of fraud and abuse. The analysis seeks to determine whether the arrangement presents a low, medium/elevated, or high risk for fraud and abuse under the anti-kickback laws. The level of government scrutiny and the potential for enforcement increases commensurate with the increased in the compliance risk.
- (h) Company's policies in this Manual are intended to ensure that Company's business arrangements meet the requirements set forth in these safe harbors, or are otherwise permissible and do not run afoul of the anti-kickback laws.

- (i) If the application of any Policy is unclear, or if you have any uncertainty whether particular actions and/or arrangements are permissible, you should discuss the situation with the Compliance Officer.

4.2 THE FEDERAL FALSE CLAIMS ACT

- (a) In the U.S., the False Claims Act ("FCA") imposes liability on any person who submits or induces someone else to submit a false claim for reimbursement from the federal government. The purpose of the FCA is to indemnify the government through its penalty provisions against losses caused by fraud. The FCA could apply if an HCP falsely seeks reimbursement for medical services he or she did not provide, or if a product manufacturer promotes its product for off-label uses, as well as for violations of the anti-kickback laws. Bootstrapping an anti-kickback action to FCA liability can greatly increase personal liability and a company's financial liability.
- (b) The government, or an individual (known as a whistleblower), may bring a civil action for a violation of the FCA. If an individual brings an action on behalf of the government, then that person may be entitled to a portion of any recovery under the FCA. Whistleblowers could be current or ex-business partners, staff, customers, patients, or competitors.
- (c) Under the FCA, no specific intent to defraud is required. The FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information.
- (d) Most states also have similar false claims acts; however, not all encompass government health claims or contain "qui tam" provisions. These state false claims acts generally prohibit retaliation and discrimination against employees, agents, and contractors because of their initiation of, or participation in a lawful false claims investigation, report, claim, or proceeding.

4.3 PHYSICIAN PAYMENTS SUNSHINE ACT

- (a) The Physician Payments Sunshine Act (the "Sunshine Act") provisions of the PPACA seek to provide increased transparency on interactions between physicians, nurse practitioners, physician assistants, and teaching hospitals and the pharmaceutical, biologics, and medical device industries. Accordingly, certain manufacturers, who engaged in the manufacture of a drug, device, biological, or medical supply in the United States, must submit annual reports that identify payments or other transfers of value to HCPs and teaching hospitals. Such reports must be filed by March 31st each year and reflect all payments and transfers of value to HCPs and teaching hospitals for the previous calendar year. This can include arrangements surrounding investigational products or uses, dependent upon the specific facts and circumstances. Such reported information is made publicly available in a searchable format by the Secretary of Health and Human Services by June 30th of each year.
- (b) Accurate reporting of such payments or transfers of value is extremely important to the Company. While the Commercial Operations department will serve as the data steward and prepare aggregated reporting, the completeness and accuracy of such reported data is the responsibility of all Employees and vendors who are involved in any reportable payments or transfers of value. Manufacturers that fail to report in a timely and accurate manner may be subject to significant civil monetary penalties. As such, the Company requires all payments or transfers of value to a HCP must be reported and documented.

4.4 STATE COMPLIANCE AND DISCLOSURE LAWS

In addition to the federal government, a growing number of states are regulating pharmaceutical and medical device companies' interactions with HCPs. These laws and regulations include restrictions (and sometimes prohibitions) on gifts and meals, and disclosure of payments made to HCPs.

4.5 ADVAMED CODE OF ETHICS

- (a) The AdvaMed Code of Ethics (AdvaMed Code) provides medical technology companies with guidance on ethical interactions and relationships with health care professionals, based on the cornerstone values of innovation, education, integrity, respect, responsibility, and transparency.
- (b) The AdvaMed Code is intended to protect patients from undue influences on healthcare decision-making and reaffirms that interactions between company representatives and HCPs should be focused on informing HCPs about the benefits and risks of medical devices to help enhance patient care.
- (c) The tenets of the AdvaMed Code are embedded in the policies throughout this Sales and Marketing Handbook. Company is committed to following all principles of the AdvaMed Code in the states where it is required by law.
- (d) The AdvaMed Code, can be viewed at: <https://www.advamed.org/member-center/resource-library/advamed-code-of-ethics/>

4.6 FDA LAWS AND REGULATIONS

The Food and Drug Administration (FDA) regulates almost every aspect of our business, from research and development to sales and marketing. FDA regulation of product advertising and promotion directly affects our customer relationships. Therefore, all colleagues must understand the basic rules we must follow to ensure compliance with FDA laws and regulations.

Labeling

- (a) The FDA strictly regulates the labeling of all medical device products that Company markets in the United States. Labeling includes all information on a product's package or label, instructions for use, and any other written, printed or graphic material accompanying the product.

Advertising & Promotion

- (b) The FDA also strictly regulates the advertising of all FDA-regulated products that Company markets in the United States. Advertising includes advertisements published in journals, magazines, newspapers, white papers, and other periodicals, as well as broadcast through media such as radio, television, and telephone. Similarly, the FDA strictly restricts the promotion of the use of FDA-regulated products, generally limiting promotion to contents found in the products' labels. In other words, the FDA prohibits the promotion or advertisement of an FDA-regulated product for anything other than its FDA-approved use.
- (c) Any materials (whether in print or electronic form) used to promote our products – including all visual aids, brochures, journal advertising, promotional programs, and other sales aids – may include only claims about the product that are consistent with that product's FDA-approved label. In addition, these materials must contain balanced statements about the product's benefits and risks. All promotional materials must also

include the product's package insert or, for certain advertisements, a brief summary relating to side effects, contraindications, and effectiveness.

5. INTERACTIONS WITH HEALTHCARE PROVIDERS POLICY

5.1 GENERAL

Company may interact with HCPs in a broad range of activities including but not limited to:

- (a) *Technological Development.* Company engages Consultants to improve the utility and application of its services and to develop new medical devices and/or services.
- (b) *Promotional Activities.* Company may promote the sale and use of its services, or services offered by its affiliates, directly and indirectly to HCPs.
- (c) *Training and Product Related Education.* Company may offer education and training on the safe and effective use of its products or services to HCPs.
- (d) *Research and Education.* Company may support bona fide medical research and continuing medical education for HCPs to increase access to new medical devices and to enhance the delivery of safe, efficacious, and cost-effective healthcare.
- (e) *Charitable Services.* Company may provide financial and other support to bona fide charitable organizations with ties to HCPs.

All interactions with HCPs must comply with the requirements of this Policy.

5.2 CONSULTING ARRANGEMENTS

Consulting Arrangements with HCPs may be entered into only if all of the following conditions have been met:

- (a) A legitimate business need for the services that can be met by entering into fee-for-services arrangements with an individual or entity has been clearly identified and documented, in advance.
- (b) There is a written consulting agreement signed by all the parties that has been approved by legal counsel (as necessary) that specifies the nature of all of the services to be provided and the compensation to be paid. The written consulting agreement must satisfy the requirements of section 5.2.1 below.
- (c) The number of Consultants retained is not greater than the number reasonably necessary to achieve the identified purpose.
- (d) The criteria for selecting Consultants, including their education, expertise, knowledge and experience regarding a particular therapeutic area, and competency to perform the required task, are directly related to the identified purpose and not related to the volume or value of Company products or services prescribed, purchased, leased, or recommended by the individual.
- (e) Persons responsible for selecting the Consultants must have the expertise necessary to evaluate whether the Consultant meets the established criteria or have a documented process for validating the satisfaction of the established criteria.

Prior to execution of the consulting agreement and on an annual basis during the term of the arrangement, each Consultant must be screened to determine whether the individual is excluded,

debarred, suspended or otherwise ineligible to participate in any federal healthcare program or in federal procurement or non-procurement programs ("Excluded"), in accordance with Company's [Employment and Screening Policy]. If the individual is Excluded, Company may not enter into the Consulting Arrangement. The exception to this is if the individual is being hired as a subject in a research study.

The Compliance Department will keep a record of all requests for Consulting Arrangements and their dispositions.

5.2.1 WRITTEN CONSULTING AGREEMENTS

(a) All Consulting Arrangements must be memorialized in a written agreement that is signed by all parties prior to the start of any consulting services.

(b) Each new or renewed consulting agreement must:

- Specify the consulting services covered by the arrangement and any deliverables to be provided to Company.
 - If a Consultant also provides services to Company other than consulting services (e.g., if a physician also provides paid speaker services for marketing purposes on behalf of Company or its affiliates), the written consulting agreement must either cover all of the services to be furnished by the Consultant for Company or incorporate each of the separate arrangements between Company and the Consultant.
 - Engagement of Consultants to provide Speaker Services for educational purposes is permissible provided it satisfies the requirements of subsection 5.2.3 below.
- Specify an initial term of not less than one year, unless the consulting services are short-term in nature (e.g., participation in a research study), serve a legitimate business purpose, and the Consultant has not entered into another short-term consulting agreement with Company in the past year. Consulting agreements with a term of less than one year may not be altered within a one-year period.
- Specify compensation that is consistent with the requirements of subsection 5.2.2 below.

(c) The consulting agreement must require Consultants:

- who are members, affiliated with, or employees of educational or not-for-profit institutions, to disclose, if and as required, any proposed arrangements for consulting services in accordance with the policies and procedures of such institution and obtain the prior written approval for the Consulting Arrangement by such institution;
- to disclose any third-party relationships or conflicts of interest during the consulting period;
- who receive equity in Company to disclose all facilities with which they are affiliated and to continue to disclose such facilities for as long as they are equity holders; and who are members of a committee of any entity that develops clinical guidelines to disclose, for the period of the Consulting Arrangement and for the next two year period, the existence and nature of the services contemplated by the Consulting Arrangement and to follow any procedure set forth by such committee relative to services under the consulting agreement.

5.2.2 CONSULTANT COMPENSATION

- (a) Compensation for consulting services must not be determined in a manner that takes into account the value or volume of referrals of patients for items or services furnished by Company or its affiliates.
- (b) Compensation for consulting services must be consistent with Fair Market Value.
- (c) Compensation terms for consulting services must be set in advance over the term of the arrangement.
 - Compensation may be set forth as an hourly rate, flat fee (based on a reasonable estimate of time expected to be spent providing consulting services), or by a fixed methodology.
 - If the compensation is set as a flat fee, the consulting agreement must specify a minimum number of hours, such that the flat fee will be consistent with Fair Market Value for the consulting services to be provided. In addition, the consulting agreement must require detailed and appropriate documentation to support the scheduled work.
 - If the compensation is a fixed methodology, it must not be based on the value or volume of referrals.

5.2.3 ADDITIONAL REQUIREMENTS FOR SPEAKER SERVICES

- (a) In addition to the Consulting Arrangement requirements identified above, speaker services must adhere to requirements of this subsection.
- (b) The consulting agreement must be in place before extending invitations to attendees.
- (c) Consulting agreements for speaker services must specify the length of each speaking engagement and the associated compensation. An addendum to the written agreement is required for each speaking engagement or specified series of engagements.
- (d) Engagement of Consultants to provide speaker services for educational purposes is permissible, so long as it is clear to the audience that the Consultant is receiving compensation from Company.

5.2.4 TRAVEL EXPENSES

- (a) Company may pay for or reimburse documented lodging and meal expenses incurred by Consultants that are necessary in connection with the services being provided and when the commitment to cover such expenses is documented in the consulting agreement. Meals should be modest in nature, and travel should be budget-conscious to the extent practically possible (e.g., UberX instead of Uber XL when available, and coach vs. business class when available).
- (b) Company may not pay for the travel or other expenses (including the cost of meals) of a spouse or other guest of Consultants.
- (c) There must be objective, legitimate reasons that support the need for the travel and lodging for the HCP. All travel expenses incurred on behalf of HCPs, including HCPs who are Company Personnel, must be supported by documentation that is submitted to the Compliance Officer, or entered into the appropriate Compliance records as directed by the Compliance Officer. Documentation must include the business purpose, price, vendor, and any other pertinent details.

(d) The setting should be conducive to the exchange of information and should not be the main attraction of the event. For example, the Company should consider the following principles when choosing an accommodation:

- The accommodations should be centrally located and easily accessible (for example, considering proximity to airports and highways) in relation to the place of origin of the invited participants.
- The accommodations should not be selected based on entertainment or recreational facilities (considering, for example, the season or time of year of the event).
- Companies should avoid top category or luxury hotels or resort facilities without an appropriate justification.

5.3 BUSINESS COURTESIES

5.3.1 GENERAL

- (a) Company may not offer or provide Business Courtesies to induce or reward the referral of patients or otherwise influence the independent judgment of any HCP.
- (b) Company may not offer or provide cash or cash equivalents (e.g., checks, coupons, lottery tickets, gift certificates, gift cards, stocks), under any circumstances, to any HCP, as a business courtesy. They may still be given as compensation for services if approved and documented appropriately.
- (c) Company may not provide branded, promotional items or “gifts” to HCPs. Only modest, appropriate educational items or patient benefit items are permitted to provide to HCPs.
- (d) Company may not offer, provide or pay for entertainment or recreational items (e.g., tickets to events, sporting equipment, leisure, or vacation trips) for any HCP.
- (e) Company Personnel may not circumvent this Policy by offering or providing Business Courtesies using their own funds (without seeking reimbursement) or in their personal capacity.

5.3.2 PERMISSIBLE BUSINESS COURTESIES TO HEALTHCARE PROFESSIONALS

(a) Business Meals:

- For all HCPs, a business meal may be provided as a courtesy if:
 - There is a legitimate business purpose.
 - The meal is held in an appropriate and professional setting.
 - The meal is Modest in nature. “Modest” means that the cost of the meal (inclusive of all food, beverage, tax, gratuity, and delivery charges) shall be reasonable based on standards in the relevant geographic area. Alcoholic beverages are permitted, where appropriate, but must be reasonable (i.e., reasonably priced and in reasonable quantities).
 - Such meals are provided only occasionally, although this requirement is not applicable to meals provided to Company employees who are also HCPs.
- Business courtesy meals may not be provided to persons who do not have a bona fide professional interest in the information being presented (e.g., spouses or

other guests of an HCP) or to HCPs (including a physician's office staff) who are not present for the majority of the informational presentation or discussion (e.g., no "dine-and-dash").

- Food and beverage obtained at separate locations (e.g., appetizers at a different restaurant than dinner) count toward the dollar limit per HCP.
- All business courtesy meals provided to HCPs, including HCPs who are Company Personnel, must be supported by documentation that is submitted to the Compliance Officer, or entered into the appropriate Compliance records as directed by the Compliance Officer. Documentation must:
 - record and substantiate the expense of the meal (including itemized receipts);
 - identify the business purpose of the meal;
 - identify the location of the meal; and
- indicates the name of each HCP and all Company Personnel who are provided the meal and the number of any of the HCP's staff who are in attendance.

(b) It may be permissible for Company employees or HCP Consultants who provide services to Company under a Consulting Arrangement may receive branded promotional items (e.g., jackets), if approved by the Compliance Officer.

5.3.3 GOVERNMENT EMPLOYEES

The offer or provision of business courtesies to government employees is prohibited. Company Personnel are prohibited from providing anything of value to any employee of the federal or a state or local government or its fiscal intermediaries, or other official representatives, except for minor refreshments in connection with business discussions.

5.3.4 MANAGER RESPONSIBILITY

When reviewing and approving expense reports, managers are responsible for confirming that expenses incurred in connection with HCPs are consistent with this Policy. Managers are responsible for addressing (including through corrective action plans) and, as appropriate, reporting to the Compliance Officer all expenditures that are inconsistent with this Policy.

5.4 PERMISSIBLE EDUCATIONAL ITEMS TO HCPS

Items designed primarily for the education of patients or healthcare professionals (e.g., disease state related pamphlets or textbooks) may be provided to an HCP upon Company prior approval, if the items:

- (a) Do not have value to an HCP outside of his or her professional responsibilities (e.g., textbooks and anatomic models would be permissible as they don't have value outside of a professional context, while a computer tablet would not be permissible).
- (b) Are of modest value, meaning, other than medical textbooks or anatomical models used for educational purposes, any educational item provided to an HCP should have a fair market value of less than US \$100.
- (c) Are provided only occasionally.

5.5 SPONSORSHIPS

- All Sponsorships must satisfy the requirements of this subsection.

- Company will not offer, pay for, or solicit requests for Sponsorships with the intent to induce or reward referrals of items or services, including those reimbursable by a government healthcare program.
- All Sponsorships must align with Company's vision of social responsibility and core values.
- All Sponsorships must be made at the general request of, and be paid directly to, the organization requesting the Sponsorship.
- Company may consider Sponsorship opportunities at national, state, regional or local events by professional organizations, healthcare institutions (such as hospitals, research institutions or universities), medical societies, trade associations, consumer and patient organizations, and bona fide non-profit organizations that seek to further research, education or benefit patients or public health.
- Company may not fund any Sponsorship opportunities for programs or events organized or conducted by any physicians, physician practices or physician-owned healthcare institutions, except to the extent such an institution is publicly traded on a stock exchange.
- Company may fund a Sponsorship provided that the program or event:
 - (a) Is primarily dedicated in time and effort to promoting objective discourse on one or more clinical, medical, or scientific topics, or is otherwise patient or healthcare related;
 - (b) Includes at least one topic area related to an area of interest to Company;
 - (c) Any time for entertainment or recreational activity is clearly subordinate to the time spent on the educational program;
 - (d) Takes place at a venue that is conducive to an educational exchange among the attendees;
 - (e) Company is not the sole sponsor or exhibitor and other companies or organizations are invited to sponsor at comparable rates;
 - (f) The target attendees of the program are not all from a single healthcare facility or private practice;
 - (g) The fee requested is consistent with fair market value given the size and scope of the audience, duration of the event, the location of the event, sponsorship benefits and entitlements, time allotted for display, and the size and location of exhibit space provided; and
 - (h) The program is not put on by an individual healthcare professional, private physician office, group practice (regardless of size), clinics or other healthcare facility owned by a private physician or group of physicians, patient or caregiver.
- Any promotional materials for use and in connection with the sponsored event must:
 - (a) Meet the specifications established by the event host in solicitation materials;
 - (b) Be broadly, consistently, and widely marketed to the community;
 - (c) Be documented in writing; and

- (d) Be focused on the objective of the event.
- Review of Sponsorship Requests
 - (a) Requests for Sponsorships must be made in writing by, or on behalf of, the potential recipient. Company Personnel who receive a Sponsorship request should forward the request information to the Compliance Officer.
 - (b) Sponsorship requests should provide the following information:
 - Description of the program or event including agenda;
 - Target audience;
 - Expected attendance;
 - The type of Sponsorship opportunity;
 - The applicable fees;
 - A representation that Sponsorship opportunities have been made (or will be made) to other companies or organizations other than Company; and
 - Identification of whether the Sponsorship is requested by, or would benefit or involve HCPs, or organizations controlled or directed by, or whose members are, HCPs.
 - All Sponsorship requests must be approved by the [Compliance Committee].
 - (c) It is the responsibility of the approver to review the circumstances underlying the requested Sponsorship to determine if the Sponsorship involves an HCP and whether the Sponsorship aligns with Company's vision of social responsibility and core values.
 - (d) Company shall maintain a file on each Sponsorship request. At a minimum, each Sponsorship request file shall contain the following:
 - The Sponsorship request.
 - Documentation of the outcome of the Sponsorship request review.
 - Records of all payments made.

5.6 EDUCATIONAL GRANTS

- All Educational Grants must comply with the requirements of this subsection.
- Company will not offer, pay for, or solicit requests for Educational Grants with the intent to induce or reward referrals of items or services, including those reimbursable by a government healthcare program.
- All Educational Grants must align with Company's vision of social responsibility and core values.
- All Educational Grants must be made at the general request of, and be paid directly to, the organization requesting the Educational Grant.

5.6.1 PERMISSIBLE EDUCATIONAL GRANTS

Company may provide grants to support educational programs sponsored by independent third-parties and continuing medical education programs (CME) designed to advance the

understanding of medical, scientific, professional or policy-making issues on topics related to Company's legitimate business interests provided that:

- (a) The program is primarily dedicated in both time and effort to promoting objective discourse on one or more health, medical, scientific, or related topics;
- (b) Any time dedicated to any entertainment or recreational activity organized by the sponsor will be clearly subordinate to the time spent on the educational program;
- (c) The educational program takes place at a venue that is conducive to an educational exchange among the attendees;
- (d) The uses of the grant funds are limited to:
 - Reducing overall conference costs for all conference attendees;
 - Sponsoring modest meals or receptions for all attendees;
 - Compensating the sponsor for the reasonable honoraria, travel, meals, and lodging for bona fide faculty selected and retained at the sole discretion of the educational program sponsor; and
 - Scholarships that are consistent with this Policy; and
- (e) The grant recipient is responsible for all aspects of the educational program and retains control over the program. Company may not:
 - Make suggestions regarding educational program topics;
 - Control or influence the development or planning of educational program content in any way;
 - Script content or provide talking points or reference materials to grant recipients;
 - Review the content of a presentation for accuracy or completeness;
 - Suggest or recommend speakers or faculty to grant recipients; or
 - Meet with speakers prior to the program to discuss the content of their presentations. If the program is accredited CME, it must conform to policies of the Accreditation Council for Continuing Medical Education ("ACCME") or other relevant accrediting organizations for educational programs for healthcare professionals.
- (f) Company may provide an Educational Grant to an educational sponsor or a training institution to reduce the reasonable costs and expenses for medical students, residents, fellows, and other healthcare professionals in training to attend major educational, scientific, or policymaking meetings of national, regional, or specialty medical associations provided that the selection of the scholarship recipients is at the sole discretion of the training institution or educational program sponsor.
- (g) Company may make an Educational Grant to support the education of patients or the public about important health topics.

5.6.2 PROHIBITED EDUCATIONAL GRANTS

- (a) Educational Grants shall not be provided, directly or indirectly: 1) to any individual HCP (including to assist such individual in participating in or to attending a continuing education program); 2) at the request of an HCP to support a favored institution of that HCP; 3) to

defray the expenses of a specific HCP; or 4) to purchase equipment or other items or services for an HCP.

- (b) Educational Grants shall not be conditioned on any explicit or implicit agreement that a program or conference sponsor will use any particular agenda, course materials, faculty input, or other information created or endorsed by Company.
- (c) Educational Grants shall not be provided to or to support educational programs by federal, state, local or other government entities or personnel (including, for example, employees of state, county, or city facilities) without prior approval of the Compliance Department to determine consistency with applicable laws.

Company Personnel may attend third-party educational programs to the extent permitted by the rules or procedures of grant recipient. If the educational program is accredited, Company Personnel shall conform to all rules associated with accreditation of the program, including any rules that prohibit promotional discussion with healthcare professionals in the educational space or place of the medical education program immediately before, during or after a medical education activity. Company representatives shall not participate proactively in program discussions, or ask questions during the program.

5.6.3 EDUCATIONAL GRANT REQUESTS

All Educational Grant requests must be independently initiated, in writing, by the entity that would be conducting the educational program and is independently responsible for and in control of the educational program, including the selection of program content, faculty, educational methods, and materials. Company Personnel who receive requests for an Educational Grant should forward the organization's request letter and materials to the Compliance Officer.

Each Educational Grant request must include:

- A description of the proposed educational program including the subject matter, timing, location, proposed audience, and expected number of attendees;
- A detailed budget showing how the Educational Grant funds, if approved, would be spent;
- The name, address and federal tax identification number of the grant requestor; and
- Identification of whether the Educational Grant is requested by, would benefit, or involve, HCPs or organizations controlled or directed by, or whose members are, HCPs.

5.6.3.1 REVIEW OF EDUCATIONAL GRANT REQUESTS

- (a) All Educational Grant requests must be approved by the [Compliance Committee].
- (b) It is the responsibility of the approver to review the circumstances underlying the requested Educational Grant to determine if the Educational Grant involves an HCP and whether the Educational Grant aligns with Company's vision of social responsibility and core values.
- (c) In evaluating the merits of a particular grant request, the Compliance Officer shall consider the following factors:
 - The purpose to be served by the grant, including the manner in which the grant will be used and the underlying patient care benefit.
 - The quality of the educational program and the qualifications of the requestor to carry out the program (including whether the requestor has access to facilities and

resources adequate to conduct the proposed educational program and whether the requestor has conducted quality educational programs in the past).

- Whether the educational program is consistent with Company's mission and areas of interest.
- Whether the amount of the grant request is reasonable and justified.
- The mix of other educational programs Company currently is funding.
- Any other criteria the Compliance Officer deems appropriate.

5.6.3.2 EDUCATIONAL GRANT AGREEMENT

A grant agreement or letter-agreement, in a form approved in advance by the Compliance Officer, clearly explaining the purpose and limitations of the Educational Grant shall be executed by Company and grant recipient prior to providing any support under an Educational Grant.

- (a) The terms of the Educational Grant agreement or letter-agreement shall include, but are not limited to:
- The total value of all support Company will provide;
 - A description of the educational program or activities to be funded;
 - An authorization for Company to audit the expenditure of Educational Grant funds;
 - An obligation for the grant recipient to comply with all applicable statutory, regulatory and other requirements applicable to the educational activities;
 - An obligation for the grant recipient to ensure meaningful disclosure to the audience at the time of the program of (i) Company's Educational Grant; and (ii) any other significant financial relationship between Company and the grant recipient and/or the individual speakers; and
 - A provision ensuring that live presentations include an opportunity for scientific debate or questioning.

5.6.3.3 DOCUMENTATION.

Company shall maintain a file on each Educational Grant request. At a minimum, each Educational Grant file shall contain the following:

- (a) The Educational Grant request.
- (b) Documentation of the outcome of the review of the grant request.
- (c) Grant agreement (for all approved grants).
- (d) Records of all payments made to the grant requestor.

5.7 CHARITABLE CONTRIBUTIONS

Upon receipt of a request that meets the requirements of this subsection, Company may, on occasion, make contributions to a charitable organization for a bona fide charitable purpose.

5.7.1 ACCEPTABLE CHARITABLE CONTRIBUTIONS

Charitable contributions may be acceptable if granted in accordance with this Policy to advance a bona fide charitable purpose, such as supporting indigent care, patient education, public education, public health, or sponsoring an event for which the proceeds are intended for charitable purposes.

The contribution must be made in response to a broadly-disseminated solicitation to fund a specific effort or specific fundraising event. Examples of permissible charitable contributions include, but are not limited to:

- (a) Sponsorship of a benefit fundraiser for charitable purpose;
- (b) Sponsorship of a participant in a charity fundraiser (such as a walk-a-thon), if the contribution is made payable to the organization and not to the participant;
- (c) Support for a community service project; and
- (d) General support for patient support groups.

5.7.2 IMPERMISSIBLE CHARITABLE CONTRIBUTIONS

Charitable contributions cannot be made directly or indirectly to an individual in a position to prescribe or recommend a product or service provided by Company or a Company affiliate, or to a charitable organization on behalf of, or in the name of, a specific individual in a position to prescribe or recommend a product or service provided by Company or a Company affiliate. That is, Company will not contribute to the "favorite charity" of an HCP at the individual's request.

Charitable contributions must never be tied in any way to the past, present, or future purchase, prescribing, recommendation, or formulary placement of any Company product or service (or that of a Company affiliate), or as a reward for any such past behavior. Any benefit that Company obtains must be minimal and incidental to the main purpose of the charitable contribution.

5.7.3 CHARITABLE CONTRIBUTION REQUESTS

Requests for charitable contributions must be made in writing by, or on behalf of, the potential recipient on its letterhead. Company Personnel who receive the request for a charitable contribution should forward the organization's request letter to the Compliance Officer. An organization's request letter must provide the following information:

- (a) Description of the requesting organization and its mission or purpose;
- (b) Description of the activity for which contribution is requested;
- (c) The charitable organization's tax-exempt identification number and proof of its section 501(c)(3) designation; and
- (d) Explanation of what part of the requested contribution (if any) will represent value given to Company (e.g., meal at a fundraising dinner).

5.7.3.1 REVIEW OF CHARITABLE CONTRIBUTION REQUESTS

The Compliance Officer, shall be responsible for assessing, and approving or rejecting, all requests. In evaluating the merits of a particular request for a charitable contribution the following factors will be considered:

- (a) The purpose to be served by the contribution;
- (b) The reputation and expertise of the charitable organization;
- (c) Whether the purpose of the charitable contribution is consistent with Company's areas of giving and corporate mission;
- (d) Whether the amount of the contribution is reasonable and justified;

- (e) Whether any benefit to Company is minimal and incidental to the main purpose of the charitable contribution; and
- (f) Whether the charitable contribution is unrelated to and not contingent upon the referral or generation of business generally, or federal healthcare program business specifically.

If tickets or invitations offered to Company in return for sponsoring a charity event, Company may not invite HCPs to attend the event or activity. Company Personnel and their guests who are not healthcare professionals may attend. If some allotment will go unused, Company may return the unused portion to the organization for use as it sees fit. Company must not suggest to the organization in any way, either directly or indirectly, any particular individuals who should be invited to use the unused allotment.

6. DOCUMENT REVISION HISTORY

Revision	Description	Author	Date
01	Initial Release		