POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

OraSure Technologies, Inc.

I. Goal and Scope

As stated in the Code of Business Conduct and Ethics (the "Code of Conduct"), the reputation and integrity of OraSure Technologies, Inc. (the "Company") are valuable assets that are vital to the Company's success. Each director, officer and employee of the Company (collectively, "Company personnel") is therefore responsible for conducting the Company's business in a manner that demonstrates a commitment to the highest standards of integrity, honesty and compliance with law.

This Policy on Interactions with Health Care Professionals (this "Policy") covers specific business practices and procedures relating to the Company's interactions with Health Care Professionals (defined below), and is specifically aimed at delineating the types of relationships that are and are not acceptable. The Federal anti-kickback statute contains a criminal prohibition against payments made to induce or reward the referral or generation of Federal health care business. Violators may be subject to civil monetary sanctions and exclusion from Federal health care programs (e.g., Medicare and Medicaid). The anti-kickback law addresses the offer or payment of anything of value in return for purchasing, leasing, ordering, arranging for, or recommending the purchase, lease or ordering of any item or service reimbursable in whole or in part by a Federal health care program. Because the cost of the Company's products is subject to Federal reimbursement, this law applies to the Company and its employees and directors.

Our goal in developing this Policy is to ensure that our collaborative relationships do more than merely comply with applicable laws, regulations and government guidance—we aim to meet the highest ethical standards and achieve appropriate transparency so as to surpass the minimum standards of compliance. As such, we have adopted this Policy, which is modeled on the revised and restated Codes of Ethics issued by the Advanced Medical Technology Association ("AdvaMed") and the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Both are organizations representing companies that develop, produce, manufacture and market medical products, technologies and related services. This Policy also incorporates standards mandated under the laws of Office of the Inspector General ("OIG") and various individual states, several of which are set forth in more detail in Exhibit A hereto. At the federal level in the United States, the Open Payments provisions of the Affordable Care Act (also referred to as the "Sunshine Act") requires specified manufacturers to report certain payments and other transfers of value to certain Health Care Professionals and teaching hospitals. Under these requirements, Company personnel must properly document all payments and transfers of value to Health Care Professionals so that the Company can accurately report them in compliance with disclosure laws.

This Policy sets forth a statement of principles, as well as specific rules and examples, regarding the Company's interactions with Health Care Professionals.

This Policy *does not* cover every type of relationship that may arise, but rather sets out principles to guide Company personnel. Accordingly, questions regarding the application or interpretation of this Policy are inevitable. All Company personnel should feel free to direct questions to the Company's General Counsel, who will act as the Compliance Officer for the implementation, interpretation and administration of this Policy. See Exhibit E, Compliance

Officer. This Policy applies to all employees of Company as well as sales representatives and distributors in the United States who operate under the Company's control or direction.

Knowledge and compliance with this Policy is a requirement of employment with the Company. As such, all Company personnel must complete the Company's training sessions on interactions with Health Care Professionals and compliance with this Policy. See Exhibit B. Statements in this Policy to the effect that certain actions may be taken only with "Company approval" will be interpreted to mean that the Compliance Officer or his or her designee must give prior written approval before the proposed action may be undertaken.

Employees who observe, learn of, or, in good faith, suspect a violation of this Policy, *must* immediately report the violation to the Compliance Officer (who will contact and work with the relevant supervisor). Employees who report violations or suspected violations in good faith will not be subject to retaliation of any kind by the Company. Reported violations will be investigated and addressed promptly, and will be treated confidentially to the extent possible. Additional information regarding the procedures to be followed for reporting and investigating violations is set forth in the Code of Conduct. See also Exhibit C.

All managers and supervisors are required to enforce this Policy and are not permitted to sanction or condone violations. Non-adherence to this Policy may result in serious adverse consequences, up to an including removal from a position as director or officer, and dismissal as a Company employee in accordance the Disciplinary Action section set forth in the Company's Employee Handbook. The Compliance Officer or his or her designee will audit the activities of Company personnel directly involved with interactions with Health Care Professionals on a periodic basis. Such audits could take the form of, for example, review of agreements or purchase orders with Health Care Professionals.

A. General Provisions.

1. The Principle Behind This Policy.

The Company, by and through its personnel, will not offer or give a benefit to a Health Care Professional that is explicitly or implicitly predicated on the Health Care Professional purchasing, leasing, ordering, prescribing, arranging for, or recommending the purchase, lease or ordering of any Company product in the future, or on the Health Care Professional having done so in the past. The Company also will refrain from activities that could give the impression that the Company is attempting to induce or reward the purchase, lease, recommendation, use, prescription or arrangement for the purchase, lease, or order of a Company product.

2. Definition of Health Care Professional(s).

"Health Care Professional(s)" means individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, prescribe or arrange for the purchase or lease of a Company product. This includes existing customers and potential customers. This also includes both clinical and non-clinical individuals who make product-related decisions of the sort listed above concerning a Company product (e.g. hospital purchasing agents, physician practice managers, management in group purchasing organizations ("GPOs"), etc.). A government employee could be a Health Care Professional if he or she makes decisions concerning the purchase, lease, recommendation, use, prescription or arrangement for the purchase or lease of a Company product. Gifts, payments or other benefits given to persons employed by or related to the Health Care Professional likely would be attributed to the Health Care Professional. Similarly, gifts, payments or other benefits given in the name of a Health Care Professional or to an organization with which a Health Care Professional is closely affiliated (e.g., controls the organization, is on the Board of the organization, has an ownership interest in the organization, etc.) will be attributed to the Health Care Professional.

3. Payments by Company Personnel or a Third Party Without Reimbursement from the Company is Equally Prohibited.

This Policy applies to all Company personnel regardless of whether or not the individual seeks reimbursement from the Company for the expenditure. That which the Company cannot do, its personnel also cannot do. Similarly, the Company will promote adherence to this Policy by third parties when the third parties are engaged in marketing, selling

or distributing the Company's products. The Company will not encourage or condone a third party engaging in conduct that is prohibited by this Policy. That which the Company cannot do, third parties working on its behalf also cannot do. If Company personnel become aware of activities by third parties that would violate this Policy, they must report such activities to the Compliance Officer or their supervisor.

4. Payments to Health Care Professionals Must Come From the Company When Permitted Under This Policy.

Only the Company can make payments to, or on behalf of, or reimburse a Health Care Professional, when such payments are permitted under the provisions of this Policy and only by Company check or wire transfer. Original receipts are necessary for Health Care Professional reimbursement, and attempts should be made to make payments directly to the necessary vendor (e.g., airline, hotel, etc.) whenever possible rather than to the individual Health Care Professional. The Company will not reimburse a Health Care Professional with payment in cash, and Company personnel must not reimburse a Health Care Professional with a personal check. If a situation is anticipated where reimbursement will be necessary, the Health Care Professional should be given per-diem spending guidelines in advance.

5. Limits on Meals and Hospitality.

In connection with product training, conferences, business meetings, and other interactions with Health Care Professionals described herein, the Company may provide modest meals and hospitality to Health Care Professionals as an occasional (infrequent) business courtesy consistent with the limitations in this section (except where prohibited by state law, see Exhibit A). All such meals may not cost more than $150.00 per Health Care Professional per meal.

The meal and hospitality should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The primary purpose of the meal should not be a casual get-together or a general discussion to develop goodwill and a good business relationship. The meal should also not be part of an entertainment or recreational event. In no event may any meal or hospitality be provided for the purpose of inducing a Health Care Professional to purchase, lease, order, prescribe, arrange for, or recommend the purchase, lease or order of any Company product in the future, or for having done so in the past.

Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions, which may include the Health Care Professional's place of

business or an outside location if the place of business is not available for, or conducive to, such scientific, educational, or business discussions.)

Notwithstanding the foregoing, under no circumstances may meals be provided to a Health Care Professional in violation of state law. For example, Massachusetts prohibits companies from providing or paying for meals for a Health Care Professional if such meals are offered or consumed outside of the Health Care Professional's office or a hospital setting, and Vermont prohibits companies from providing meals to Health Care Professionals altogether.

Because state laws vary, you should check this Policy to see if any special rules apply before providing a meal to any Health Care Professional.

The Company may provide a meal only to Health Care Professionals who actually attend the meeting. The Company may not provide a meal for an entire office staff where everyone receiving the meal does not attend the meeting. The Company also may not provide a meal where its representative is not present. The Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

6. Limits on Travel and Lodging.

When appropriate, the Company will reimburse Health Care Professionals for reasonable travel (first class is not considered "reasonable") and lodging costs related to training, sales and other business meetings (including for Consultants). There must be objective, legitimate reasons supporting the need for out-of-town travel. Travel by Company personnel is governed by the Company's Travel Policy.

All lodging provided must be modest and selected based upon program requirements and the convenience of the attendees. No lodging may be provided at a resort or resort location. "Resort locations" are areas, other than major metropolitan areas, known primarily as vacation or recreation destinations (e.g., ski, golf, or beach destinations, such as Aspen, Pebble Beach, or Naples). The lodging should avoid top category or luxury hotels. Company may not pay for or subsidize the travel or lodging of spouses or guests of Health Care Professionals, or for any other person who does not have a bone fide professional interest in the information being shared at the Company's meeting. Company may not pay for a Health Care Professional's personal travel or lodging. In no event may any travel or lodging be provided for the purpose of inducing a Health Care Professional to purchase, lease, order, prescribe, arrange for, or recommend the purchase, lease or order of any Company product in the future, or for having done so in the past.

7. Specific State Law Restrictions.

Several states have enacted laws or regulations that restrict interactions of Health Care Professionals. Certain of these restrictions are summarized in Exhibit A to this Policy. To the extent Company personnel have interactions with Health Care Professionals licensed or located in a state listed in Exhibit A, such personnel are also required to comply with the applicable restrictions set forth in Exhibit A. See also Exhibit D regarding state requirements on tracking and disclosing of certain marketing information/fees.

II. Prohibition on Gifts; Educational Items

Gifts of any type or form are generally prohibited. However, modest items, provided occasionally, that benefit patients or serve a genuine educational purpose (except where prohibited by state law, see Exhibit A) are allowed. Except for medical textbooks or anatomical models used for educational purposes, any gift should have a fair market value of less than $100. The cost to the Company of the item does not matter. The Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, such as a DVD player or MP3 player/I-Pod. Gifts to any particular Health Care Professional should not have a yearly aggregate value over $300. Gifts to Health Care Professionals who work for the same institution must not exceed a per-professional or entity aggregate of $500. No type of gift may be given as a "thank you" for the purchase, lease, recommendation, use, prescription or arrangement for the purchase, lease, or order of a Company product or as an incentive to purchase, lease, recommend, use, prescribe or arrange for the purchase, lease, or order of a Company product.

Gifts can never be in the form of cash or cash equivalents, such as gift cards or gift certificates. Flowers, holiday baskets, candy, wine, or other food items are prohibited, as such items do not benefit patients or serve a genuine educational purpose. Gifts to public employees (e.g., physicians, administrators or other employees of a public university, public hospital, the VA, etc.) are generally prohibited by the rules of the particular institution, and the Company must be careful not to violate such institutional rules. Any item given to a Health Care Professional's staff should be treated as though it is given to the Health Care Professional and is subject to all applicable provisions of the Code. The Company may not raffle or give away an item that it could not otherwise give a Health Care Professional under this policy and applicable law. If a Company director, officer or employee is ever unsure of whether or not a particular item is appropriate in a given situation, he or she should not hesitate to contact the Compliance Officer.

The Company may not give Health Care Professionals any type of complimentary 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/or other items that have a Company name or logo, or the name or logo of a Company product.

III. Evaluation and Demonstration Products

The Company may provide reasonable quantities of products to Health Care Professionals when the Health Care Professional has not recently purchased or used the products (and so is unfamiliar with the product) or the product is marketed for a new indication, at no charge for evaluation and demonstration purposes under the following circumstances:

- These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, or recommend the product in the future. Company products provided for evaluation are typically not expected to be used in patient testing or care.

- The number of single use products provided at no charge may not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

- Products provided without transfer of title for evaluation purposes may 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 products must be set in advance in writing, and the contract must provide that Company will retain title to such products during the evaluation period and that the products must be returned to Company at the conclusion of the evaluation period unless the Health Care Professional chooses to purchase or lease the products.

- Demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to understand how the product is to be operated. Demonstration products are not intended to be used in patient care and should be identified as such by use of designations such as "Sample," "Not for Human Use," or other suitable designation on

the product, the product packaging, and/or documentation that accompanies the product.

- Appropriate documentation and disclosure should be provided to Health Care Professionals regarding the no-charge status of evaluation and demonstration products.

IV. Research and Education Grants and Charitable Donations

A.Charitable Donations

The Company may make donations to support a charitable purpose, but only to a tax-exempt charity. Donations may not result in a personal benefit to a Health Care Professional and may not be made for the purpose of inducing the Health Care Professional to purchase, lease, order, prescribe, arrange for, or recommend the purchase, lease or order of any Company product in the future, or for the organization or related Health Care Professional having done so in the past. Product donations for use outside of the United States may not violate any export control law. Company personnel must consult the Compliance Officer before providing such donations.

Examples of a charitable purpose include supporting (1) indigent care, (2) patient or public education, and (3) sponsorship of events where proceeds are intended for charitable purposes. Donations may be made to support fundraising events, but only where at least a portion of the donation qualifies for a charitable tax deduction. The Company may not sponsor Health Care Professional participation in (e.g., an entrance fee for a charitable golf tournament)or attendance at (e.g., a ticket for a charity dinner) any fundraising events. The Company may not sponsor Health Care Professional Participation in (e.g. an entrance fee for a charitable golf tournament) or attendance at (e.g. a ticket for a charity dinner) any fundraising events. The Company can, however, sponsor the charity event itself (consistent with the guardrails in this section), even if the event organizers have invited HCPs to participate, so long as the HCP's attendance or participation fees are not sponsored by the Company.

All donations (monetary or non-monetary, such as Company products) must be properly documented. Documentation must demonstrate that (1) the recipient is a tax-exempt charity, (2) the donation will be used for an appropriate purpose (described above), (3) the amount of the donation is appropriate for the proposed purpose, and (4) the donation was received by the charity. A transmittal letter clearly explaining the purpose of the donation should be sent by the Company prior to or with the donation.

This letter must be approved by the Compliance Officer or his or her designee. Company personnel involved in sales and marketing may only be involved to the extent that such Company personnel can provide input about the suitability of a proposed charitable donation recipient or program, but such personnel may not approve requests for charitable donations or otherwise attempt to influence Company decision- making with respect to a request for a charitable donation.

B. Research Grants.

The Company supports genuine independent research for the advancement of health care, medical science or medical education that is related to Company products. Such research can provide valuable scientific and clinical information, improve clinical care, lead to the development of new treatments, and improve the delivery of health care.

The Company may provide in-kind or monetary support for independent research with scientific merit. The Company may provide support for research that has defined goals, objectives, and milestones, as outlined in clinical protocols. The Company will evaluate the nature and scope of the research activity, the budget, and the approximate duration of the research before making any determinations.

All grant requests for independent research must be reviewed and approved by the Compliance Officer. Sales personnel may not have control or undue influence over the recipient or amount of support of a research grant, although sales personnel may propose a research program or recipient deserving support. If the requests for research grants is related to Company-sponsored research (i.e. research conducted on behalf of the Company), the proposed grant will be evaluated as a consulting arrangement, and will comply with all applicable guardrails (see Part VIII below).

C. Educational Grants.

Support for education (patient, public, or medical) could include, for example,
(1) support for an endowed chair at an academic institution, (2) subsidizing the education of medical students, residents, or fellows in academic or charitable fellowship programs, and (3) subsidizing medical congresses and conferences. The Company may make educational grants to conference sponsors or training institutions as described in Section VII below. The Company will not make educational grants to individual Health Care Professionals.

V. Sales, Promotional and Other Business Meetings

A business meeting is a meeting between Company personnel and a Health Care Professional for the purpose of (1) negotiating contracts and sales terms, (2) explaining the features, use and other aspects of a Company product, (3) discussing a Health Care Professional's product-related needs or demands, or concerns about a Company product, (4) explaining the services and terms available from the Company; or (5) developing policy/advocacy positions related to the Company's products or a class of products. Unless prohibited by state law (see Exhibit A), the Company occasionally may pay for modest meals and refreshments in connection with business meetings. These meals and refreshments, however, should take place in a location conducive to the exchange of information and consistent with the business purpose of the meeting. Company personnel must be present during the meal or refreshments. If the meal or refreshments does not qualify as a business meeting and/or one or more Company personnel are not present at the meeting the meal or refreshments likely would constitute a gift that is prohibited by this Policy (see Part II, above).

Payment for a Health Care Professional's travel and/or lodging is generally not permitted for a business/policy/advocacy meeting. However, if a business meeting must take place in the Company's offices or another function-appropriate location because of practical considerations (e.g., when there is a genuine need for a centralized location or a business need for the Company to provide a plant tour), and the Health Care Professional must travel to such location, the Company may pay for reasonable travel and/or lodging fees, and meals associated with the trip. Business/policy/advocacy meetings may not occur at a resort or resort location.
Again, the Company may not pay for meals, refreshments, travel or lodging of spouses or guests of a Health Care Professional, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

VI. Company-Sponsored Product Training and Education

The Company has the responsibility to provide instruction, education and training on the safe and effective use of its products to health care providers, and any other individuals who could benefit from such information. Such instruction, education and training includes, for example, "hands on" training sessions, lectures, presentations and

grand rounds. In the case of subsidies to support "grand rounds," as that term is normally understood, there must be a written agreement that specifies the topics to be addressed and the subsidy must not exceed the normal and customary expenses associated with the conduct of grand rounds.

The Company may decide, for the sake of efficiency and cost-effectiveness, to hold training and educational meetings at a centralized location for a number of individuals at one time. Such meetings should focus on, for example: (1) training on how to use a Company product; (2) training on indications, testing or therapies for which a Company product may be used; and (3) training on the quality, properties and/or design characteristics of a Company product, provided that such training educates the Health Care Professionals about how to use the product safely and effectively. Company personnel must consult the Compliance Officer or his or her designee before coordinating such training and/or education meetings.

Because at least some Health Care Professionals inevitably will have to travel to this centralized location, the Company may pay for reasonable travel and modest lodging costs incurred by a Health Care Professional traveling to the meeting. The Company may provide modest meals and refreshments in connection with the program, but such meals and refreshments must be subordinate in time and focus to the educational or training purpose of the program.

Again, the Company may not pay for meals, refreshments, travel or lodging of spouses or guests of a Health Care Professional, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Training and education must be the purpose for the program. The Health Care Professional must have a legitimate need to attend a Company-conducted training or education program. The meeting must take place in a clinical, educational, conference or other setting conducive to the effective transmission of knowledge (e.g., a hotel or commercially available meeting facility). If the meeting will provide training on how to use a Company product, the training staff must have the proper qualifications and expertise to conduct the training.

VII. Third Party Educational Conferences

In addition to building awareness and understanding of its own products, the Company has an interest in promoting scientific knowledge, medical advancement and the delivery of effective health care generally. To that end, the Company may support *bona fide*, independent, third party educational, scientific or policymaking conferences. Such conferences typically include: (1) conferences sponsored by national, regional or

specialty medical associations; (2) conferences sponsored by accredited continuing medical education providers; and (3) scientifically valuable roundtables or discussion groups. Company personnel must consult the Compliance Officer or his or her designee before providing support to any educational conferences.

The Company may provide an educational grant to the conference directly to reduce overall conference costs or to support modest meals or refreshments. The Company also may provide a grant to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows or other Health Care Professionals in training. The selection of the attendees, however, must be made by the training institution or conference sponsor and should not be unduly influenced or controlled by Company sales personnel.

Similarly, the conference sponsor must independently control the program content, faculty, educational methods and materials, although Company funds may be used by the conference to support honoraria, travel, lodging and modest meals for *bona fide* conference faculty members. The Company will provide grants only to conferences that are primarily dedicated to promoting objective scientific, medical and educational activities and discussions. The Company will not provide grants to any conference that appears to primarily promote the medical services of a specific provider, such as a particular physician practice group's medical services. The Company may not provide a grant to conferences held in venues that may be considered luxury or 'getaway' locations, unless there are other factors suggesting that the venue is subordinate to the educational nature of the program (e.g. the program has a robust agenda with little built-in time for entertainment, the venue maintains appropriate conference facilities, and/or the audience is composed of mostly local physicians). The grants should also be consistent with the conference sponsor's standards and standards established by the applicable accrediting body.

The Company may directly provide modest meals and refreshments to attendees as part of a conference. The meals and refreshments may only be provided if meals and refreshments are provided (1) to all Health Care Professional attendees (with one exception noted below); and (2) in a manner consistent with sponsor's and the applicable accrediting body's standards. Meals and refreshments can be provided to fewer than all attendees if the Company satisfies all other principles related to meals set forth in Section I.A.5. Again, such events must be subordinate in time and focus to the educational purpose of the conference and clearly separate from the continuing medical education portion of the program. Further, it is important to confirm with the conference sponsor that such events are permitted by the conference and that they conform to all conference guidelines. The Company may also purchase advertisements and lease booth space for Company displays at conferences, provided that the amounts paid for such advertisements and booth space are fair market value.

VIII. Consulting Arrangements with Health Care Professionals

Because many of the Company's Health Care Professionals are some of the leading Health Care Professionals in their respective fields, the Company may desire to engage particular Health Care Professionals as consultants to provide certain services for the Company (e.g., research, clinical testing, participation on advisory boards, presentations at Company-sponsored training programs, etc.). Some such arrangements are acceptable, but there are a number of safeguards that must be in place to limit or eliminate the impression that the arrangement is meant to induce or reward the purchase, lease, recommendation, use, prescription or arrangement for the purchase, lease, or order of a Company product. Consulting arrangements must comply with the personal services safe harbor to the anti-kickback law.

All consulting arrangements must be written, signed by the Company and the consultant, and approved in advance by the Compliance Officer. The agreements must clearly specify all services the consultant will provide, the term of the agreement, the method of payment, and whether or not the Company will be reimbursing documented travel, lodging or other related expenses. In the case of clinical research services, there must be a written research protocol. Finally, the agreement must set forth a mechanism to verify that the consultant, in fact, performs the services for which the contract provides (e.g., periodic progress reports, time sheets, use of invoices, etc.). Arrangements with Health Care Professionals to provide services on an "as needed" basis with payment to the consultant prior to the receipt of services are strictly prohibited.

Selection of consultants will be based on the consultant's qualifications (including the quality of available facilities) and expertise to address the identified purpose. Compensation paid to the consultant for his or her services must be consistent with the fair market value for such services, must be structured on a measurable basis (e.g., daily, hourly or per-project, milestone or deliverable) and should not be based on the volume or value of the consultant's past, present or anticipated business. Company personnel involved in sales must not be involved in the process of selecting consultants (beyond relaying information from the Health Care Professional to the Company about the Health Care Professional's qualifications or interest in a consulting arrangement).

There must be a legitimate Company need for the services to achieve a specific and commercially reasonable objective, which is identified in advance of the services and documented, that the consultant will provide and must not constitute an unlawful inducement. In the case of clinical trials of a Company product (including post- market or outcome studies), there must be a demonstrable need for data (e.g., product approval, reimbursement, etc.). For studies sponsored by a Health Care Professional, the Company

may support such studies if the outcome of the study is likely to be of use to the Company (or if such studies are otherwise consistent with the provisions of this Policy concerning grants and donations to Health Care Professionals (see Part IV, above)). Arrangements with Health Care Professionals intended to generate business or to reward referrals from the contracted Health Care Professional are not legitimate.

Consultants who are Health Care Professionals may not be paid, under any circumstances, to recommend the purchase, lease or use of a Company product. These individuals may be paid only to write, speak, research, train and educate on a Company product and related disease states, and provide technical expertise on the Company's behalf (e.g., involvement with industry policy issues, payers' advocacy efforts for reimbursement of Company products, etc.). These Health Care Professionals must be directed to disclose their affiliation with the Company prior to providing services connected to the Company consulting arrangement or otherwise dealing with a Company product. The Company may invite consultants to meetings of Company personnel to provide *bona fide* consulting services. Again, there must be a written agreement that clearly delineates what services the consultant will provide at the meetings. Copies of the agenda and minutes of the meeting must be appropriately maintained. Company personnel who have a professional interest in, and are in a position to use, the advice to be given by the consultant must be in attendance at the meetings. Although modest meals and refreshments may be provided in connection with the meeting, they must be subordinate in time and focus to the purpose of the meeting. The meeting must take place in a clinical, educational, conference or other setting conducive to the effective exchange of information (e.g., a hotel or commercially available meeting facility). Also, no recreation or entertainment may be provided. Further, the location of the meeting, and the corresponding travel and lodging arrangements, must be consistent with the general provisions of this Policy (see Part I.A.6. above).

If the consultant has developed or contributed to the development or improvement of a product, it may be appropriate to pay the consultant a royalty. Any such royalty arrangement must be in writing, comply with the standards set forth above, and meet the following additional requirements: (1) The contribution by the consultant must be novel, significant and innovative must contribute to the development of a product, technology, process, or method subject to intellectual property protections and must be appropriately documented; and (2) Royalties may not be conditioned on a requirement that the consultant purchase, order or recommend any of Company's products or any product produced as a result of the development project. The Company should base the calculation of royalties payable to a Health Care Professional on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. To the extent practicable, the calculation of royalties should exclude the number of units purchased, used, or ordered by the Health Care Professional and/or the members of the Health Care Professional's practice. Royalties may not be conditioned on a requirement to market the product upon commercialization. However, the Company may elect to

enter into a separate consulting agreement with the consultant for marketing services if such services meet the requirements set forth above.

IX. Prohibition on Entertainment and Recreation

The Company may not pay, directly or indirectly, for any entertainment or recreational event or activity for any Health Care Professional. This prohibition applies regardless of the value of the activity, whether the Company engages the Health Care Professional as a consultant, or whether the entertainment or recreation is secondary to an educational purpose. Moreover, Company personnel or agents may not pay for any such event or activity, even if the Company personnel or agent is not reimbursed by the Company. Such activities divert attention from the legitimate exchange of medical or scientific information between the Company and Health Care Professionals and can create an appearance of impropriety. Examples of prohibited activities include theater, sporting events, golf, skiing, hunting, and leisure or vacation trips. However, Company personnel and agents are permitted to engage in entertainment or recreational events or activities with Health Care Professionals if they have a legitimate outside relationship with the Health Care Professional and they pay their own way without seeking reimbursement and the Health Care Professionals pay their own way.

X. Distribution of Free Samples to Heath Care Professionals

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professionals regarding the use of products and technologies. Under certain circumstances described below, the Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement. Member products that may be provided to Health Care Professional for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment"). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for

evaluation are typically expected to be used in patient care. Such free samples are to be used for evaluation or demonstration purposes only and is not contingent on any future purchase obligation or product sales, or on the value or volume of referrals.

First, the Health Care Professional recipients must be informed in a meaningful manner that free samples may not be sold or billed to any insurance program, including federal health care programs.

Second, if more than a few product units are provided free of charge to a Health Care Professional, such action must conform to the "discount" safe harbor to the federal Anti-Kickback statute (42 C.F.R. § 1001.952(h), which requires, among other things, that:

- The number of single use products provided should not exceed the amount reasonably necessary for the adequate demonstration and evaluation of the products;

- Demonstration products should be marked as "Sample", "Not for Human Use", or other suitable designation on the product, packaging or documentation accompanying the product;

- The discount must be made at the time of the sale of the products or the terms of the discount or rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the products; and

- The Company must fully and accurately report the discount/rebate on the invoice or statement provided to the Health Care Professional and inform the Health Care Professional (in a manner reasonably calculated to give notice to the buyer) of its obligations to report such discount and to provide information upon request by the Secretary of the Department of Health and Human Services or a State Agency.

XI. Provision of Coverage, Reimbursement and Health Economics Information

The Company may provide Health Care Professionals with timely and complete coverage, reimbursement, coding, and health economic information regarding its products if such information is accurate, objective, and readily available. The Company may also collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to

access the Company's products. Further, the Company may identify the clinical value of its products.

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

Questions concerning this Policy should be directed to the Compliance Officer.

Policy Revision Dates:

EXHIBIT A

STATE-SPECIFIC STANDARDS

When interacting with a Health Care Professional located or licensed in these states, Company personnel must adhere to the following standards. For further guidance, please contact the Compliance Officer.

Massachusetts

Limitations on Meals

- No company may provide or pay for meals for Health Care Professionals that are offered, consumed or provided outside of the Health Care Professional's office, a hospital, an academic medical center, or a specialized training facility.
- No meals may be offered without an informational presentation made by a Company representative or without such a representative being present.
- No meals may be offered as "part of an entertainment or recreational event."
- -No meals may be offered that are provided to a "health care practitioner's spouse or other guest."

Gifts Prohibited

- No company may provide direct or indirect payments of any kind including cash, cash equivalents, equity, or other tangible items, to a Health Care Professional, except as compensation for *bona fide* services. In other words, even gifts that benefit patients or serve a genuine educational function are prohibited under Massachusetts law.

Compensation and Expenses by Written Agreement Only

- Companies may provide reasonable compensation for *bona fide* services, or the reimbursement of reasonable out-of-pocket costs incurred by the Health Care Professional directly as a result of the performance of such services, but only where the compensation and reimbursement is specified in, and paid for under, a written agreement.

Educational Conference Limitations

- No company may provide payment for meals directly to a Health Care Professional at any Continuing Medical Education ("CME") event or educational conference, although a CME provider or conference organizer may,

at its own discretion, apply any financial support by the company for the event to provide meals for all participants.
- No company may provide sponsorship or payment for CME that does not meet the standards 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 Professional.

Penalties for Failure to Comply with the Massachusetts Law

- A person who knowingly and willfully violates the Massachusetts marketing code of conduct law may be punished by a fine of up to $5,000 for each transaction, occurrence, or event. The MDPH is required to report to the attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the Massachusetts marketing code of conduct law. The Massachusetts code of conduct is enforced by the attorney general, the district attorney with jurisdiction over a violation, or the MDPH.

Vermont

Definition of Health Care Professional

- Specifically includes a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution a prescribed device in the state of Vermont.

Gifts

- It is unlawful for any company to offer or give any gift to a Health Care Professional. "Gift" is broadly defined as anything of value provided to a Health Care Professional for free. There is no exception for gifts that benefit patients or serve a genuine educational function. Medical device "samples" are not banned but must be reported as described in Exhibit D.
- The gift prohibition does not apply to scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.
- Fellowship salary support may be provided to fellows through grants from manufacturers of prescribed products and is subject to certain limitations.

Meals

- Meals/food may be provided to program participants during a bona fide educational conference sponsored by the medical device manufacturer.
- Food may be provided to healthcare practitioners as part of a fair market value compensation package for service (e.g., service on an advisory board, service, or speaking).
- Provision of coffee or other snacks or refreshments at a booth at a conference or seminar is permitted.
- .

Educational Conferences

- A company may pay an honoraria and/or expenses of a Health Care Professional who serves on the faculty of an educational conference or seminar only if:
    - there is an explicit contract with specific deliverables, which are restricted to medical issues not marketing activities; and
    - the content of the presentation, including slides and written materials, is determined by the Health Care Professional.
- Any conference sponsored by the company must:
    - be accredited by the Accreditation Council for Continuing Medical Education or a comparable organization; and
    - offer continuing medical education credit, feature multiple presenters on scientific research, or be authorized by the sponsoring association to recommend or make policy.

Training

- A company may pay or reimburse for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of Health Care Professionals on the use of a medical device, but only if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the Health Care Professional and the company.

Penalties for Failure to Comply with the Vermont Law

- The Attorney General may bring an action and impose a civil penalty up to $10,000 per violation

EXHIBIT B

TRAINING PROGRAM

I. Training

A. Training. All staff, including agents, who conduct any sales and marketing activities on behalf of the Company shall receive regular training regarding the Company Policy on Interactions with Health Care Professionals (the "Policy"). Training programs will be designed and administered as necessary and appropriate for these individuals to carry out their functions. Such training may take the form of:

- Written training materials to be reviewed by training participant;
- In-person, telephone or webinar training sessions (including group or individual training sessions); or
- Such other format as deemed appropriate by the Company Compliance Officer.

Each new employee or agent who will be involved in sales and marketing activities shall be trained within a reasonable period of time after the individual begins employment.

B. Training Materials. Materials used to train employees/agents will include the Policy and related slides/PowerPoint presentations, as well as any other materials determined to be relevant by the Company and or the Compliance Officer.

C. Effective Lines of Communication. All company training programs/materials will instruct employees and agents to contact the Company Compliance Officer to report potential instances of non-compliance with the Policy and/or applicable law. In addition,

- Employees and agents will be instructed to contact the Compliance Officer to obtain clarification regarding the Policy and related policies and procedures.
- In order to foster effective and open communications, the Company has implemented a post office box so that employees and agents may report non-compliance issues anonymously.

D. Documentation. The Company Compliance Officer or the Human Resources Department shall document that the training described above has taken place. Such documentation may take the form of a training log or file indicating the training date, a

brief description of the training, and the names and titles/positions of each employee who participated in that training session. For written training sessions, this documentation may take the form of a certification from the employee/agent stating that the employee/agent has reviewed the materials and agrees to comply with applicable law and Company policies and procedures.

E. **Massachusetts.** To the extent the Company conducts sales and marketing activities with Massachusetts-licensed physicians, a copy of the training program will be made available upon request to the Massachusetts Department of Public Health ("MDPH").

F. **Nevada**. Nevada law requires device manufacturers to annually provide the Nevada Board of Pharmacy a description of its training program.

EXHIBIT C
AUDITS/INVESTIGATIONS/SANCTIONS

I. Annual Audits

The Compliance Officer or his/her designee will conduct annual audits to monitor compliance with the Policy. Such audits will include but not be limited to the following:

- Determining that all appropriate personnel (including employees and agents who have begun working for the company subsequent to the initial training session) have received training and that such training has been documented;
- Identifying potential areas of compliance vulnerability and risk;
- Ensuring there are adequate corrective action and preventive action programs in effect throughout the Company to remediate policy deviations;
- Confirming that compliance-related reminders have been sent periodically to relevant employees and agents: and
- Confirming that any instances of non-compliance have been investigated and resolved, including implementing sanctions and/or a corrective action plan, if applicable.

To the extent any instances of potential non-compliance are identified during an audit (or at any other time), the Compliance Officer will comply with this Policy regarding investigation, sanctions and reporting of such instances, if required by law. The Compliance Officer will report the compliance issues to senior management on a periodic basis, or as necessary, to ensure appropriate review and support of the findings and remediation.

II. Investigations/Corrective Actions

A. **Investigations.** The Compliance Officer will investigate and evaluate any instances of non-compliance with the Policy. The Compliance Officer may learn of instances of non-compliance from an audit or from an employee or agent who reports it to the Compliance Officer. An individual also may report a suspected instance of non-compliance anonymously through the Company post office box. The Training Programs described in Exhibit B will include information regarding such communication mechanisms.

B. **Corrective Actions.** The Compliance Officer will implement and document corrective actions, including any sanctions described below, taken in response to instances of non-compliance.

III. Sanctions for Non-Compliance

If an employee fails to comply with the Policy and/or applicable law, the Human Resources Department will work with the relevant supervisor to implement an appropriate sanction including, but not limited to, the following:

A. Educational discussion regarding the Policy; or

B. Action specified immediately above, plus placing a warning notice in the individual's file (if applicable);

C. Placing the employee or independent contractor on probation;

D. Terminating the employee or independent contractor; or

E. Any other sanction deemed appropriate by the Human Resources Department or under any Company disciplinary policy.

IV. Reporting of Non-Compliance to Appropriate State Authorities.

When required by applicable law, the Company will report instances of non-compliance to the appropriate authorities.

V. Employee/Agent Reporting of Potential Violations; Non-Retaliation.

Any employee/agent who believes he/she may have violated the Policy and/or applicable law, or believes that another employee/agent has done so, should report this to the Company Compliance Officer, the Human Resources Department, or the relevant supervisor. The Company shall not discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse action against any employees, agent, or health care professionals because such person takes or has taken any action in furtherance of the enforcement of the Policy and/or applicable law.

VI. Massachusetts Department of Public Health

A copy of the Policy and procedure will be made available to the MDPH upon request.

VI. Nevada Board of Pharmacy

A copy of the Policy will be made available to the Nevada Board of Pharmacy.

EXHIBIT D

TRACKING AND DISCLOSURE OF CERTAIN MARKETING INFORMATION; FEES

There are several jurisdictions where the Company may be required to make disclosure reports. The exhibit will describe relevant state transparency laws and requirements.

I. Tracking Information

A. **Tracking and Reporting.** When required by law, the Company will track and report information related to payments to health care professionals. In some cases, the Company need only report that it has adopted a marketing code of conduct, but does not have to report on interactions with specific health care professionals.

B. **Responsibility.** The Compliance Officer is responsible for any such tracking and reporting, but may delegate this function while remaining ultimately responsible.

C. **Massachusetts**

1. MDPH states that covered recipients include any person or organization that can prescribe, dispense, recommend, purchase, or influence coverage of a specific drug or device. Massachusetts-licensed practitioners are covered recipients, regardless of whether they are actively practicing or where they practice

2. **Tracking of Information to be Reported.** The Company Compliance Officer will implement a system for tracking the **value, nature, purpose and particular recipient** of any fee, payment, subsidy or other economic benefit with a value of at least $50.00, which the Company provides, directly or through its agents, to any Massachusetts-licensed health care professionals in connection with the Company's sales and marketing activities related to those professionals. The information to be tracked includes payments, subsidies, or other economic benefit with a value of at least **$50.00 or more** to hospitals and health care professionals licensed in Massachusetts.

Examples of fees, payments, subsidies or other economic benefits that must be reported if their value is at least $50.00 include without limitation:

- Expenses in conjunction with a product training;
- Compensation for service as faculty at a CME or participation on a speaker's bureau, and
- Compensation to consultants for Bona Fide Services.

a. **Covered Recipient includes All Massachusetts-licensed Health Care Professionals**. MDPH states that covered recipients include any person or organization that can prescribe, dispense, recommend, purchase, or influence coverage of a specific drug or device. Massachusetts-licensed practitioners are covered recipients, regardless of whether they are actively practicing or where they practice. According to the MDPH website, if a payment, subsidy or other economic benefit is given to a Health Care Practitioner practicing in another state (e.g., Rhode Island) but, who is licensed to practice in Massachusetts and authorized to prescribe in Massachusetts, the payment/subsidy/economic benefit is subject to the Regulation and therefore must be reported if it meets the reporting threshold and is not otherwise exempt from reporting.

b. **$50.00 Threshold**. For the purposes of computing the $50.00 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. Fees, payments, subsidies or other economic benefits to health care professionals may not be structured to circumvent these reporting requirements.

3. **Reporting/Disclosure of Information.**

a. **What is reported?** The information described in Section II.A above shall be reported annually to the Massachusetts Department of Public Health ("MDPH").

- **Note**: The Massachusetts regulation requires that all information reported will be disclosed publicly by MDPH and that such information will be made easily searchable on its website.

b. **What does not have to be reported?** The following activities are **exempt** from disclosure:

- Payments in conjunction with Genuine Research and Clinical Trials;
- The provision of demonstration or evaluation units and in-kind items used for the provision of charity care; and
- Price concessions such as rebates and discounts.

c. **Annual Certification.** The company must certify annually to the MDPH that it has conducted its annual audit and is in compliance with the marketing code of conduct.

d. **To Whom is the information reported?** The disclosure information and related certification, as well as the fee described below, will be sent to the email address of the person designated in the attached Compliance Filing Form For Manufacturers in Accordance with M.G.L. Chapter 111N (the "Filing Form").

e. **Designation of a Compliance Officer to submit the Reports.** The Company Compliance Officer is responsible for reporting in accordance with the Regulation.

f. Time periods Covered in Annual Disclosures. Disclosures shall be made for the previous full calendar year using a standardized reporting format developed the MDPH. Reports are due on July 1 and cover the previous calendar year.

g. Transmission of the Report. The report must be submitted to the MDPH electronically. Each report must certify that to the best of the Company's knowledge, information and belief, the report is true and accurate.

Notwithstanding the provisions of 105 CMR 970.009, no pharmaceutical or medical device manufacturing company is required to disclose information to the Department that has been disclosed to a federal agency pursuant to federal law and that is then provided by the Secretary to the Department in annual reports."

h. Fee. The Fee for submission of disclosure information each year is $2,000.00. Each annual disclosure report must be accompanied by this fee. The fee is to be made payable to the **Commonwealth of Massachusetts** and must be submitted with the report.

MDPH website materials indicate that an initial $2000 registration fee is required, in addition to the reporting fee for the first year a device manufacturer submits a disclosure report to the MDPH.

This initial registration and each disclosure report must be accompanied by a completed Filing Form certifying that the Company:

- is in compliance with the Regulation;
- has adopted a program to routinely train appropriate employees;
- has policies and procedures in place for conducting investigations into any and all non-compliance with the Regulation, taking corrective actions in response to all non-compliance, and reporting instances of non-compliance to the appropriate state authority.

D. Vermont

1. **Disclosure of Compliance Officer**. No later than January 1, on an annual basis, medical device manufacturers must disclose to the Vermont Office of Attorney General the name and address of the person responsible for the Company's compliance with the Vermont's Prescribed Products Law Disclosure provisions. This disclosure is done via an online Compliance Officer form.

2. **Fee**. Companies with expenditures to report must pay an annual $500.00 registration fee. The fee is paid by sending a check for $500.00 made out to **State of Vermont** and mailed to:

Vermont Office of Attorney General Public Protection Division

109 State Street
Montpelier, VT 05609-1001

3. **Reporting Deadline**: Annually on or before April 1 of each year, every manufacturer of prescribed products shall disclose to the Office of the Attorney General for the preceding calendar year the information described below regarding marketing expenditures.

4. **Information to be Disclosed**: The Company must disclose the "value, nature, and purpose, and recipient information" of most permitted gifts or allowable expenditures to any health care provider who regularly practices in Vermont or otherwise lawfully providing health care in Vermont must be disclosed, as well as the prescribed product or products being marketed, if any. All payments to active Vermont health care providers or to Vermont health care institutions which are not exempt must be reported. Unlike Massachusetts, there is no dollar amount threshold – all allowable expenses must be reported.

5. **Exemptions from Disclosure:** Free samples, rebates and discounts and royalties and licensing fees are exempt from disclosure.

6. **Reporting Mechanisms**: Information may be reported by entering data through a form on the Attorney General's website or by downloading an Access-based database from the website, entering the data, and returning the data base to the Attorney General's office. The Attorney General's office has strict rules regarding how to report the value, nature and purpose of allowable expenditures, as well as recipient and product information. Special rules apply to information regarding clinical trials. All disclosed information will be made available and searchable on an internet website.1

E. Nevada

1. **Disclosure of Code of Conduct and Related Materials.** Device manufacturers who market their devices in Nevada must adopt a marketing code of conduct that addresses specified interactions with health care professionals Manufacturers must submit to the Nevada Board of Pharmacy their codes of conduct, and descriptions of training program and investigation policies. Manufacturers also must certify that they have conducted their annual audit and are in compliance with their marketing codes of conduct.2 In lieu of submitting its own marketing code of conduct, a manufacturer may adopt without modification the current version of the PhRMA Code of Interactions with Healthcare Professionals or the AdvaMed Code of Ethics on Interactions with Health Care Professionals.3

F. California.

1. Manufacturers must establish a comprehensive compliance program in accordance with OIG Guidelines and the PhRMA Code. Manufacturers must post the compliance program and an annual declaration of compliance on their website

G. Connecticut

1. Device manufacturers are required to annually report payments and transfers of value to advance practice registered nurses who practice independently (i.e., not in collaboration with a physician).

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1 Guide To Vermont's Prescribed Products Law for FY10 Disclosures, published by the Vermont Office of the Attorney General (8/25/09) at http://www.atg.state.vt.us/assets/files/FY10%20Pharmaceutical%20Marketing%20Disclosure%2 0Law%20Guide.pdf.

2 Nev. Rev. Stat. Ann. § 639.570 (2009).

3 *Id*. The statute mentions the PhRMA Code, but the regulations adopted by the Nevada Board of Pharmacy and forms for disclosure available on the Board's website indicate that manufacturers also may avoid submitting a code of conduct if they state that they have adopted the AdvaMed Code. Nev. Admin. Code 639.610 and 615 (Sections 3.2 and 12); https://bop.nv.gov/uploadedfiles/bopnvgov/content/resources/all/ab_128_compliancepacket.pdf

EXHIBIT E
COMPLIANCE OFFICER

I. Company Compliance Officer.

The General Counsel hereby is designated as the Company Compliance Officer.

II. Duties and Responsibilities

The Compliance Officer's responsibilities include, without limitation:

- Overseeing and monitoring implementation of the compliance program, including the Policy;

- Reporting on a regular basis to the Chief Executive Officer and Audit Committee of the Board of Directors regarding compliance matters;

- Periodic review and revision of the compliance program, as appropriate, to respond to changes in the Company's needs and applicable federal and state health care program requirements, identified weakness in the compliance program, or identified systemic patters of noncompliance;

- Developing, coordinating and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeing to ensure that all affected employees and management understand and comply with pertinent federal and state standards;

- Ensuring that independent contractors and agents, particularly those who are involved in sales and marketing activities, are aware of the requirements of the Policy;

- Developing and maintaining effective lines of communication regarding compliance, including issuing periodic compliance reminders, encouraging employees and agents to contact the Compliance Officer regarding potential instances of noncompliance with the Policy, and developing mechanisms for anonymous reporting of such instances;

- Coordinating personnel issues with the Company's Human Resources/Personnel departments to make sure that the List of Excluded Individuals/Entities has been checked with respect to all employees and independent contractors (the list is accessible through http://oig.hhs.gov);

- Reviewing and, where appropriate, acting in response to reports of noncompliance received anonymously through the post office box or otherwise brought to the Compliance Officer's attention;

- Independently investigating and acting on matters relating to compliance, including developing corrective action plans, applying sanctions for noncompliance with the Policy (see Exhibit D), and other appropriate actions; and
- Working with outside counsel, as needed, regarding any suspected violations of federal or state health care program requirements.
- Complying with applicable federal and state transparency reporting requirements for payments and transfers of value to Healthcare Professionals.