

NeoTract, Inc. (“NeoTract”) has a comprehensive compliance program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. The program is embodied in the principles of our Customer Relationship Policy. As a medical device manufacturer, NeoTract’s compliance policies and procedures address the provisions of the voluntary Medical Device Manufacturers Association (“MDMA”) Code of Conduct on Interactions with Healthcare Providers (“MDMA Code”). The MDMA Code reflects the unique needs of smaller and less diversified independent medical device manufacturers. The MDMA recognizes that adherence to ethical standards and compliance with applicable laws and regulations is critical to ensure that interactions with healthcare providers are responsible and within legal/regulatory requirements.

As of the date of this declaration, NeoTract believes that its United States operations are in material compliance with its comprehensive compliance program and the provisions of Section 119402 of the California Health and Safety Code. This declaration is made solely for the purpose of complying with the California law cited above and should not be read in isolation from the Company’s other discussions of its compliance related activities and information disclosed currently or in the future in its periodic reports, press releases and elsewhere.

NeoTract has implemented and maintains a website [www.neotract.com](http://www.neotract.com) and toll-free number (1-855-648-8840) to facilitate communication and requests for information related to California State requirements. NeoTract’s Customer Relationship Policy is reproduced below.

Last updated: September 30, 2013

## **NeoTract Customer Relationship Policy for Interactions with Healthcare Providers**

### **Introduction**

NeoTract, Inc. (the “Company” or “NeoTract”), is committed to complying with all federal, state, and local laws and regulations, and to maintaining a workplace that is free of retaliation for raising matters of legal compliance. As a medical device company, NeoTract is subject to a number of federal laws governing conflicts of interest, including but not limited to the federal anti-kickback statute (42 U.S.C. § 1320(a)-7(b)), Stark II (Omnibus Budget Reconciliation Act of 1993), the UK Bribery Act, the US Foreign Corrupt Practices Act, the US Physician Payment Sunshine Act, the US False Claims Act, the AUS Code of Practice, and the French Sunshine Act.

Effective February 1, 2010 and updated September 1, 2013, NeoTract has adopted a Customer Relationship Policy (“CRP”), which is based on the MDMA Code of Conduct on Interactions with Healthcare Providers (the “MDMA Code”), and which regulates the Company’s interactions with Healthcare Providers. In some states, state law imposes additional restrictions on interactions

with healthcare providers. In the event a state or federal law applicable to interactions with Health Care Professionals is more stringent than a provision of this document (such as the restrictions outlined in NeoTract's policies governing interactions with health care professionals licensed in particular states, including California, Massachusetts, Nevada, and Vermont), such state or federal law shall take precedence and govern the Company's activities. In addition, in creating this CRP, NeoTract has supplemented the MDMA Code with certain provisions necessary to comply with state laws governing these interactions.

NeoTract employees, consultants and agents are expected to familiarize themselves with NeoTract's legal obligations. In addition, all NeoTract employees, consultants and agents who interact with those individuals or entities involved in the provision of healthcare services and/or items to patients, or who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe NeoTract products are required to complete regular training on this CRP.

At all times, you are required to abide by both the spirit and the letter of the CRP and applicable law. Failure to comply with applicable law can result in serious consequences for both you and the Company, including imprisonment, civil and criminal penalties, and exclusion from participation in federal healthcare programs. Company interactions with Healthcare Providers should conform to ethical business practices and socially responsible conduct. The Company also recognizes the need for Healthcare Providers to make independent and objective decisions regarding product purchases and utilization for the benefit of patients without unlawful inducement.

The Company and MDMA recognize that there are many forms of beneficial interactions between MDMA members and Healthcare Providers that advance medical technology and improve patient care, including:

- *Advancement of Medical Technology.* Developing cutting edge medical technology and improving existing products are collaborative processes between MDMA members and Healthcare Providers. Innovation and creativity, often occurring through "hands on" interactions with Healthcare Providers, are essential to the development and evolution of medical technology. Many of these technologies have been developed through formal and informal research collaborations and relationships between MDMA members and Healthcare Providers.
- *Safe and Effective Use of Medical Technology.* The safe and effective use of medical technology on patients often requires MDMA members to offer Healthcare Providers appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a part of product approval.
- *Research and Education.* MDMA members' support of *bona fide* medical research, education, and enhancement of professional skills serves patient safety, effectiveness of medical care and increases awareness and access to new technology.
- *Encourage Charitable Donations and Giving.* MDMA members support monetary and technology donations for charitable purposes, such as supporting indigent or third world care, as well as patient and public education. This increases access to quality patient care and treatment to patient populations that may not otherwise be reached.

Should you ever have any question as to whether a particular activity violates applicable law or NeoTract's CRP, you are strongly encouraged to contact Human Resources, the Compliance Director, or any member of the Compliance Committee before undertaking such activity.

## **Reporting and Investigation**

The Company is committed to maintaining an atmosphere of open communication and trust between employees, consultants and agents and management. If you reasonably believe that you are aware of conduct that violates the Company's duties under applicable law or the CRP, you should immediately contact your supervisor, Human Resources, the Compliance Director, and/or any member of the Compliance Committee. You can also make a report via NeoTract's compliance hotline number, monitored by Human Resources, which affords the option of making an anonymous complaint. Reports to the hotline number are forwarded to the Company's Compliance Director for investigation.

All complaints under this policy will be promptly and thoroughly investigated, and all information disclosed during the course of the investigation will remain confidential, except as necessary to conduct the investigation and take any remedial action, in accordance with applicable law. All employees, consultants, agents and supervisors have a duty to cooperate in the investigation of reports of any conduct covered by this policy. In addition, an employee, consultant or agent will be subject to disciplinary action, including the termination of employment or engagement, if the employee, consultant or agent fails to cooperate in an investigation or deliberately provides false information during an investigation.

Once the investigation is complete, the specific action taken in any particular case depends on the nature and gravity of the conduct or circumstances reported and the quality of the information provided. If an investigation determines that conduct in violation of the Company's legal duties has occurred, and, if appropriate, the persons responsible will be disciplined.

## **Prohibition on Discrimination, Retaliation or Harassment**

The Company strictly prohibits discrimination, retaliation or harassment of any kind against any employee who, based on the employee's reasonable belief that a violation of the CRP or applicable law have occurred or are occurring, reports that information in accordance with this policy. The Company also strictly prohibits any discrimination, retaliation or harassment against any person who participates in an investigation of such complaints.

Complaints concerning managers, supervisors or employees involved in discrimination, retaliation or harassment related to the reporting or investigation of conduct in violation of the Company's legal duties will be promptly and thoroughly investigated in accordance with the Company's investigation procedures. If a complaint of discrimination, retaliation or harassment is substantiated, appropriate disciplinary action, up to and including termination, will be taken.

The Company may modify this policy as necessary to accommodate organizational changes or to maintain compliance with applicable law and the CRP. This policy is not intended to supersede any other NeoTract's policies relating to whistleblowing, discrimination, harassment or retaliation.

## **Guiding Principle**

Whether or not a particular relationship or situation is specifically addressed in the CRP, the Company's conduct should be guided by the following principle:

**NeoTract encourages ethical business practices and socially responsible conduct and expects that its employees shall not engage in any unlawful inducement. For purposes**

**of the CRP, an “unlawful inducement” shall mean the prohibitions of the U.S. Anti-kickback Statute.**

The anti-kickback law and its implementing regulations provide that anyone who knowingly and willfully offers, gives, solicits, or receives anything of value to influence or reward the ordering, purchase or referral of federal or state health care program business can be charged with a felony.

The anti-kickback law prohibits NeoTract from providing payments, gifts, or other things of value to Healthcare Providers that are intended to induce someone to purchase an NeoTract Product when that product is reimbursable by Medicare, Medicaid, or another federal or state health care program.

The anti-kickback principles apply to the Company’s operations worldwide as “unlawful inducement” is prohibited through various laws, regulations and codes, including, but not limited to the UK Bribery Act, the US Foreign Corrupt Practices Act, the AUS Code of Practice, and the French Sunshine Act.

### **Definitions**

**"NeoTract Personnel"** - Any and all NeoTract employees and other representatives engaged (directly or indirectly) to perform work for NeoTract, such as independent sales representatives and distributor representatives.

**"NeoTract Product"** - Any product that is developed, manufactured, and/or distributed by NeoTract.

**"Entertainment"** - Activities and events that are cultural or recreational in nature that do not involve business being conducted throughout the duration of the activity. This includes, but is not limited to, tickets to the theater, sporting events, concerts, sporting equipment or leisure trips.

**"Fair Market Value"** - The value of an item or service, as bargained for in an arms-length negotiation, consistent with the price that a well informed buyer and seller, neither of whom is otherwise in a position to generate business for the other, would agree to purchase or sell the same item or service, at the same time of the purchase or sale, and in the same geographic region.

**"Healthcare Provider"** - Any person or entity in a position to purchase, lease, recommend, use, or arrange for the purchase or lease of medical technology products. This includes both clinical and non-clinical people who make decisions related to product purchase. It also includes decision-makers within group purchasing organizations. The definition is broad, and is intended to encompass anyone with material influence over purchasing decisions.

### **Elements of the Customer Relationship Policy**

The Company has designed a compliance program incorporating the following seven elements recommended by MDMA, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards

through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

### **Prohibition on Entertainment and Recreation**

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

### **Reasonable Meals Associated with Healthcare Provider Business Interactions**

The Company's business interactions with Healthcare Providers may involve the presentation of scientific, educational, or business information. NeoTract Personnel may conduct sales, promotional and other business meetings with Healthcare Providers to discuss, for example, medical product and technology features, sales terms, or contracts. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, reasonable meals may be provided as an occasional business courtesy consistent with the limitations in this section.

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

**Setting and Location.** Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Healthcare Provider's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Healthcare Provider's place of business, for example, (1) where the medical product or technology cannot easily be transported to the Healthcare Provider's location, (2) when it is necessary to discuss confidential product development or improvement information, (3) where a private space cannot be obtained onsite, or (4) where the demands of a Healthcare Provider's practice dictate limited opportunities for interactions or meetings at other than offsite locations, i.e., during non-business hours or non-work days.

**Participants.** NeoTract Personnel may provide a meal only to Healthcare Providers who actually attend the meeting. NeoTract Personnel may not provide a meal for an entire office staff where everyone does not attend the meeting. NeoTract Personnel also may not provide a meal where its representative is not present (such as a "dine & dash" program). NeoTract Personnel may not invite spouses or guests of Healthcare Providers or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting and is discouraged from providing meals to such persons except, in the rare circumstances, where it is unavoidable as a matter of civility and common courtesy.

**Value.** Business meals should be modest in value. NeoTract Personnel should consult the current version of the Business Travel & Expense Reporting Policy for meal value limits.

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

- Product Training and Education.
- Consulting Arrangements with Healthcare Providers.
- Supporting Third-Party Educational Conferences.

### **Provision of Medically-Relevant Items; Prohibition on Personal Gifts**

The Company occasionally may provide items to Healthcare Providers that benefit patients or serve a genuine medically-relevant function for Healthcare Providers. Other than medical textbooks, anatomical models or other similar medically-relevant items useful to the advancement of medical care, any such item should have a fair market value of less than \$100. NeoTract Personnel may not provide items that are capable of use by the Healthcare Provider (or his or her family members, office staff or friends) for personal purposes, for example, a DVD player, computer or digital music player. NeoTract Personnel also may not provide Healthcare Providers with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

In limited circumstances, it may be appropriate for NeoTract Personnel to recognize major events in the life of a Healthcare Provider. NeoTract Personnel may request that their functional management approve a modest gift with a value less than \$50. It is expected that the value of the gift will be incidental to sympathies or congratulations expressed in an accompanying personal note.

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

### **Product Training and Education**

The Company has a responsibility to make training and education on its medical products and technologies available to Healthcare Providers. The Company may also provide education to Healthcare Providers. "Training" means training on the safe and effective use of NeoTract Products. "Education" means communicating information directly concerning or associated with the use of the Company's medical products or technologies, *e.g.*, information about disease states and the benefits of such products or technologies to certain patient populations. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. The U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical products and technologies.

**Venue.** Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for NeoTract Personnel to provide training and education at the Healthcare Provider's location.

**Hands On Training.** Programs providing "hands on" training on products and technologies should be held at training facilities, medical institutions, laboratories, or other appropriate

facilities. The Company will use training staff with the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees or other agents who have the technical expertise necessary to perform the training.

**Meals, Refreshments, and Expenses.** The Company may provide Healthcare Provider attendees with reasonable meals and refreshments in connection with these programs. Any such meals and refreshments should be reasonable in value and subordinate in time and focus to the training and/or educational purpose of the meeting. Where there are business reasons to support the need for out-of-town travel to efficiently deliver Training and Education on products and technologies, the Company may pay for reasonable travel and lodging costs of the attending Healthcare Providers.

**On-Label.** All training and education programs must be intended to train or educate Healthcare Providers only in a manner consistent with the FDA-approved product labeling

### **Consulting Arrangements with Healthcare Providers**

The Company engages Healthcare Providers to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at NeoTract-sponsored training and other services. The Company may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Company sales and marketing personnel may provide input about the suitability of a proposed consultant, but such personnel will not control or unduly influence the decision to engage a particular Healthcare Provider as a consultant.

Consulting agreements should be written and describe all services to be provided. When a consultant is retained to conduct clinical research services, there should also be a written research protocol.

Consulting arrangements must be evaluated and approved by the NeoTract Compliance Committee. NeoTract Personnel wishing to retain a consultant can contact the Compliance Director for specific guidance on seeking approval for a consulting arrangement. The Compliance Committee considers the following factors, among others: (1) is there a legitimate business need for the services identified in advance and documented; (2) the consultant's qualifications and expertise to meet the defined need; (3) the fair market value of compensation in an arm's length transaction for the services provided; and (4) the compensation is not based on the volume or value of the consultant's past, present or anticipated business.

**Meals, Meetings, and Expenses.** NeoTract may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, meals, and lodging. The venue and circumstances for meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information. Meals and refreshments provided in conjunction with a consultant meeting should be reasonable in value and should be subordinate in time and focus to the primary purpose of the meeting.

## Supporting Third-Party Educational Conferences

NeoTract may support *bona fide* independent, educational, scientific, and policymaking conferences that promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Conference support arrangements must be evaluated and approved by the NeoTract Compliance Committee.

**Conference Grants.** The Company may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Healthcare Providers in training. The Company may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Healthcare Providers who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

**Conference Meals and Refreshments.** The Company may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, The Company may provide meals and refreshments for Healthcare Provider attendees if such meals and refreshments are provided: (1) to all Healthcare Provider attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Healthcare Provider attendees if all other principles related to meals set forth herein are satisfied.

**Faculty Expenses.** The Company may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Healthcare Providers who are *bona fide* conference faculty members.

**Advertisements and Demonstration.** The Company may purchase advertisements and lease booth space for displays at conferences provided that such advertisements and booths serve a legitimate business purpose and that NeoTract pays no more than Fair Market Value for the advertising or booth space.

## Research and Educational Grants and Charitable Donations

The Company may provide research and educational grants and charitable donations, but such grants or donations must not be an unlawful inducement. NeoTract sales and marketing personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but such personnel should not control or unduly influence the decision of whether a particular Healthcare Provider or institution will receive a grant or donation or the amount of such grant or donation. Grants and donations must be evaluated and approved by the NeoTract Compliance Committee.



**Research Grants.** Research grants should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of NeoTract Products.

**Educational Grants.** Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. The Company does not make educational grants to individual Healthcare Providers.

- *Advancement of Medical Education.* Supporting the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel.
- *Public Education.* Supporting education of patients or the public about important healthcare topics.

**Charitable Donations.** The Company may make monetary or product donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in occasional instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission.

### **Provision of Coverage, Reimbursement and Health Economics Information**

The Company may provide coverage, reimbursement and health economics information regarding its medical products and technologies if it is accurate and objective. The Company also may collaborate with Healthcare Providers, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its products and technologies. The Company may not interfere with a Healthcare Provider's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, NeoTract Personnel should not provide free services that eliminate an overhead or other expense that a Healthcare Provider would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further NeoTract Personnel should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of NeoTract Products and technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Healthcare Providers, professional organizations, patient organizations, and payors.
- Collaborating with Healthcare Providers, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Healthcare Providers and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Healthcare Providers regarding NeoTract Products and technologies, including identifying coverage, codes and billing options that may

apply to those products and technologies or the services and procedures in which they are used.

- Providing accurate and objective information about the economically efficient use of NeoTract Products and technologies, including where and how they can be used within the continuum of care.
- Providing information related to NeoTract Products and technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Healthcare Provider's decision to buy or use NeoTract Products or technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of NeoTract Products or technologies.
- Facilitating patient access to NeoTract Products or technologies by providing Healthcare Providers with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Healthcare Provider to facilitate patient access to NeoTract Products or technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a NeoTract Product or technology; however such assistance should not be provided as an unlawful inducement.

### **Evaluation and Demonstration Products**

The Company may provide reasonable quantities of products to Healthcare Providers at no charge for evaluation and demonstration purposes. These products may be provided at no charge to allow Healthcare Providers 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. Products provided for evaluation are typically expected to be used in patient care. The Company will provide Healthcare Providers with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

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

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

***Demonstration.*** Demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Healthcare Provider and patient awareness, education,

and training. Demonstration products are not intended to be used in patient care and are identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies NeoTract Products or technologies.

### **Provisions on Payment of Royalties**

The Company may enter into a royalty arrangement with a Healthcare Provider where the Healthcare Provider is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. Such arrangements will be made in compliance with the CRP and at the approval of senior management.

### **Sunshine Act (Open Payments) Compliance**

The Section 6002 of the Affordable Care Act established a transparency program, now known as the National Physician Payment Transparency Program (Open Payments), and also referred to as the “Sunshine Act.” The final rule published on February 8, 2013 and requires certain manufacturers, including the Company, to report annually to Centers for Medicare & Medicaid Services (“CMS”): (i) payments or other transfers of value made to physicians and teaching hospitals and (ii) ownership or investment interests held by physicians or their immediate family members.

***Company Guidance.*** The purpose of Open Payments is to provide patients with enhanced transparency as to the financial relationships between manufacturers and physicians. Open Payments is not intended to inhibit the Company’s business relationships with physicians, but some physicians may refuse all transfer of value to avoid being on the annual Open Payments report. **NeoTract employees (e.g., sales, marketing, clinical) who interact with healthcare providers will report all transfers of value regardless of value per NeoTract policy. Finance and Legal will ensure NeoTract meets Open Payments reporting requirements.**

***Sunshine Act Tracking & Reporting Categories.*** The final rule of the Sunshine Act lists several different categories under which all transfers of value must be reported. These categories are reproduced below, but it is important to understand that the Company does not necessarily allow for transfers of value in all categories. For example, while the Sunshine Act provides a category for gifts, Company policy generally prohibits giving gifts to healthcare providers. The listed categories are:

- Consulting fees
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honoraria
- Gift
- Food and beverage
- Entertainment
- Travel and lodging (including the specified destinations)
- Education
- Research
- Charitable Contribution

- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant
- Space rental or facility fees (teaching hospital only)

Certain types of transfers of value are excluded from reporting under the Sunshine Act even though they may otherwise fit in a reportable category. For example, educational materials that directly benefit patients or are intended for patient use do not need to be reported. Similarly, product samples and product discounts do not need to be reported. Again, Company employees are obligated to internally report transfers of value to Finance and the Company will ensure compliance.

***Physician Communication.*** The Company believes that it is important to address the transparency requirements of the Sunshine Act with U.S. healthcare providers who may receive transfers of value. Employees are encouraged to raise the topic early in the relationship with U.S. healthcare providers before any transfers of value occur. Employees should consult with their functional management for guidance prior to such communication.