



ARKRAY

CODE OF BUSINESS CONDUCT AND ETHICS





November 2014

Dear Personnel:

Our business is becoming increasingly complex, both in terms of the geographies in which we function and the laws with which we must comply. To help you understand what is required of you and to enable you to carry out your responsibilities, we have created this Code of Business Conduct and Ethics. Additionally, we have designated Chris Koshire as the ARKRAY's Chief Compliance Officer to oversee adherence to the Code.

This Code is not intended to be a comprehensive guide to all of our policies or to all your responsibilities under law or regulation. It provides general parameters to enable you to properly resolve any ethical and legal issues you encounter in conducting our business. Think of this Code as a guideline, or a minimum requirement, that must always be followed. If you have any questions about anything in the Code or appropriate actions in light of the Code, you may contact the Compliance Officer or the Chair of the Compliance Committee.

We expect each of our directors, officers and employees to read and become familiar with the ethical standards described in this Code and to affirm your agreement to adhere to these standards by signing the Code of Conduct Acknowledgement that appears at the end of this Code. Violations of the law, our corporate policies, or this Code may lead to disciplinary action, up to and including immediate termination. We encourage you to ask questions about the Code. If you have any questions, contact information for Mr. Koshire is provided at the end of the Code.

Sincerely,

Jonathan Chapman, President USM

John McCrea, President USF

Dan Sobiech, General Manager, USL

Craig Brosseau, VP, Finance

ARKRAY
CODE OF BUSINESS CONDUCT AND ETHICS

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ARKRAY

PART I: CODE OF BUSINESS CONDUCT AND ETHICS

A. Purpose

ARKRAY, which includes all affiliated United States entities (ARKRAY America, Inc., ARKRAY Factory USA, Inc., U.S. ARKRAY, Inc. and ARKRAY USA, Inc., collectively, “ARKRAY”) is committed to the highest standards of ethical business conduct. ARKRAY adheres to the standards of conduct stated in the AdvaMed Revised and Restated Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code of Ethics”) (July 1, 2009). The AdvaMed Code of Ethics is the standard of practice for device manufacturers in the United States. The ARKRAY Code of Business Conduct and Ethics (the “Code”) summarizes the ethical, legal and regulatory standards that ARKRAY requires and is a guideline for our directors, officers and employees (collectively, “personnel”). It also describes how the AdvaMed Code of Ethics applies to ARKRAY’s structure and business practices. Compliance with this Code is a requirement for all ARKRAY personnel. Non-personnel representatives of ARKRAY, such as distributors, contractors and consultants, are also directed to conduct themselves in a manner consistent with the Code when they are acting on behalf of ARKRAY. ARKRAY reserves the right to amend this Code at any time.

The Code is divided into three sections:

1. The first section describes general Standards of Conduct that are applicable to all aspects of our business practices.
2. The second section describes Sales and Marketing Standards of Conduct that are specific to sales and marketing activities conducted by our personnel and non-personnel representatives.
3. The third section contains state-specific sales and marketing rules and regulations that apply to activities conducted in the specific U.S. states.

If you have questions about the Code or its applicability to particular business conduct or a specific situation, please contact your supervisor or the Chief Compliance Officer. Contact information for the Chief Compliance Officer is provided at the end of the Code.

B. Standards of Conduct

1. Honest and Ethical Conduct

We insist on honest and ethical conduct by all of our personnel and non-personnel representatives. We have built our business based on a commitment to delivering excellence in diabetes products and laboratory equipment. This includes providing quality products for patients and physicians that improve the lives of patients,

and adhering to business practices that demonstrate high standards of honesty, ethics and fairness. We place a high value on the integrity of ARKRAY and its personnel. The following subsections provide guidelines to help personnel understand how this standard of conduct applies to specific situations and job functions.

Serving our customers effectively is our most important goal — in the eyes of our customers, our employees are ARKRAY. This means that we always deal honestly and fairly with our customers, suppliers, competitors and other third parties. In all our business dealings, we market our products fairly and vigorously based on the products quality and reliability, guided by principles of honesty, creativity and ingenuity.

In the course of our business dealings we:

- Prohibit bribes, kickbacks, inducements or any other form of improper payment, direct or indirect, to any representative of government, labor union, customer or supplier in order to obtain a contract or other commercial benefit or government action;
- Prohibit our personnel from accepting any bribe, kickback or improper payment from anyone;
- Prohibit gifts or favors to or from our customers or suppliers that violate ARKRAY policy;
- Limit marketing and client entertainment expenditures to those that are necessary, prudent, job-related and consistent with our policies;
- Require clear, precise and truthful communication in our contracts, our advertising, our literature, our public statements and our statements to government officials and seek to eliminate misstatement of fact or misleading impressions;
- Reflect accurately on all invoices to customers the sale price and terms of sales for products sold;
- Protect all customer or supplier proprietary data, as reflected in our agreements with them, including maintaining the privacy of individually identifiable health information of our customers' patients as required by HIPAA; and
- Prohibit manipulation, concealment, abuse of privileged information or any other unfair-dealing practice with customers, suppliers or other third parties.

2. Compliance with All Applicable Laws, Rules, and Regulations

We will comply with all laws and governmental regulations that are applicable to our activities and expect our personnel to obey the law. Specifically, we are committed to:

- Complying with all applicable state and federal securities laws;
- Complying with all applicable state, federal and international laws concerning the manufacture, distribution and sale of medical devices including those concerning:
 - reporting and investigating complaints and adverse events which may be associated with our products;
 - the design, manufacture and evaluation of our products; and
 - the marketing and sales of our products.
- Complying with all applicable laws designed to protect the confidentiality of patient records and health information;
- Maintaining a safe and healthy work environment;
- Promoting a workplace that is free from discrimination, intimidation or harassment based on race, color, religion, sex, age, national origin or disability;
- Principles of fair competition and laws prohibiting restraints of trade and other unfair trade practices by prohibiting inaccurate or misleading representation of competitors' operations or products or obtaining, through improper means, confidential commercial information concerning our competitors;
- Conducting our activities in full compliance with all applicable environmental laws;
- Keeping the political activities of our personnel separate from our business;
- Prohibiting any illegal payments, gifts or gratuities to any government officials or political party;
- Prohibiting any unlawful inducement to health care professionals or others that violate federal or state law;
- Prohibiting the unauthorized use, reproduction or distribution of any third party's trade secrets, copyrighted information or confidential information; and
- Prohibiting the sale or export, either directly or through our representatives, of our products to countries where our products are not approved for sale.

3. Full, Fair, Accurate, Timely and Understandable Disclosure

We are committed to providing our customers and government agencies and entities with full, fair, accurate, timely and understandable disclosure in the reports that we file with them. To this end, our personnel shall:

- Not make false or misleading entries in our books and records for any reason;
- Prohibit the establishment of any undisclosed or unrecorded bank accounts, funds or assets established for any purpose;
- Comply with generally accepted accounting principles at all times;
- Notify our VP, Finance if there is an unreported transaction;
- Maintain a system of internal accounting controls that will provide reasonable assurances to management that all transactions are properly recorded and all material information is made known to management, particularly during periods when reports are being prepared;
- Maintain books and records that accurately and fairly reflect our transactions;
- Present information in a clear and orderly manner and avoid the use of unnecessary legal and financial language in our periodic reports; and
- Not communicate to the public any nonpublic information except through our VP, Finance and the Legal Department.

4. Confidentiality and Corporate Assets

Our personnel are entrusted with our confidential information and with the confidential information of our suppliers, customers or other business partners. This information may include: (1) technical or scientific information about current and future products, services or research; (2) business or marketing plans or projections; (3) earnings and other internal financial data; (4) personnel information including employee lists and contact information; (5) supplier and customer lists; and (6) other non-public information that, if disclosed, might be of use to our competitors, or harmful to our suppliers, customers or other business partners. This information is the property of ARKRAY, or the property of our suppliers, customers or business partners and in many cases was developed at great expense.

Our personnel shall:

- Not discuss confidential information with or in the presence of any unauthorized persons, including family members and friends;

- Use confidential information only for our legitimate business purposes and not for personal gain;
- Not disclose confidential information to third parties;
- Not use ARKRAY property or resources for any personal benefit or the personal benefit of anyone else. ARKRAY property includes the ARKRAY internet, email, voicemail services, computers, laptops, cell phones, and handheld electronic devices, which should be used only for business related activities and which may be monitored by ARKRAY at any time without notice; and
- Protect the individually identifiable health information of our customer's patients in accordance with U.S. federal HIPAA rules and regulations.

Personnel may be subject to additional responsibilities related to confidentiality and corporate assets, as described in their individual employment and confidentiality agreements.

5. Conflicts of Interest; Corporate Opportunities

Our personnel shall not engage in any activity that creates or gives the appearance of a conflict of interest between their personal interests and the interests of ARKRAY. Directors, officers and employees must notify the Chief Compliance Officer or the Chair of Compliance Committee of the existence of any actual or potential conflict of interest.

The following guidelines are provided to demonstrate the types of activities and relationships that are prohibited without the written permission of the Compliance Committee. If you are unsure whether a particular activity or relationship is a conflict of interest, contact the Chief Compliance Officer.

Personnel shall not:

- Be a consultant to, or a director, officer or employee of, or otherwise operate an outside business that: markets products in competition with our current or potential products; supplies products or services to ARKRAY; or purchases products from ARKRAY;
- Have a significant financial interest, including significant stock ownership, in any entity with which ARKRAY does business that might create or give the appearance of a conflict of interest; provided that an investment position in the stock of a publicly held company which does not exceed 5% of the outstanding stock of that company will not be considered to be a significant stock ownership or significant financial interest;

- Seek or accept any personal loan or services from any entity with which we do business, except from financial institutions or service providers offering similar loans or services to third parties under similar terms in the ordinary course of their respective businesses;
- Be a consultant to, or a director, officer or employee of or otherwise operate an outside business if the demands of the outside business would interfere with the director's, officer's or employee's responsibilities to us (if in doubt, consult the Chief Compliance Officer);
- Accept any personal loan or guarantee of obligations from ARKRAY, except to the extent such arrangements are legally permissible;
- Conduct business on behalf of ARKRAY with immediate family members, which include spouses, children, parents, siblings and persons sharing the same home whether or not legal relatives; or
- Take for their own benefit any business opportunities discovered through their position with ARKRAY or through the use of ARKRAY's property.

C. Compliance with Code

Compliance with this Code of Conduct is the responsibility of every director, officer and employee. We attempt to foster a work environment in which ethical issues and concerns may be raised and discussed with supervisors or with others without the fear of retribution. If you have a question about this Code or a violation of it, contact your supervisor or the Chief Compliance Officer.

Our Executive Management Team and Compliance Committee oversee compliance with this Code. They have also designated the Staff Attorney as the Chief Compliance Officer to administer the Code. While serving in this capacity, the Chief Compliance Officer reports directly to the Executive Management Team.

Training on this Code will be included in the orientation of new personnel and provided to existing personnel on an ongoing basis. On an annual basis, personnel may be asked to read the Code and sign a Code of Business Conduct and Ethics Acknowledgement form to ensure receipt, understanding and familiarity with the Code.

D. Violations of the Code

Directors, officers and employees that violate any laws, governmental regulations or this Code will face appropriate, case-specific disciplinary action, including, and up to, termination.

It is the duty of each director, officer and employee who has knowledge of a violation or suspects a violation of the Code to report it. Note that failure to report a violation can be itself a violation.

E. Reporting and Investigating Violations

All reports of known or suspected violations will be promptly and thoroughly investigated and confirmed violations will be address immediately. The investigation will be conducted by the Chief Compliance Officer with the direction and support of the Compliance Committee and Executive Management Team. The Executive Management Team will have sole authority to direct any investigation and determine and implement any corrective actions. All personnel will cooperate in good faith with compliance investigations.

All reports will be treated confidentially to the extent reasonably possible. To report a suspected violation, contact the Chief Compliance Officer:

Christopher L. Koshire, Chief Compliance Officer
5198 West 76th Street
Edina, MN 55439
Telephone: (952) 646-3292
E-mail: koshirec@arkrayusa.com

You may also report a violation anonymously by contacting the Compliance Hotline at:
1-888-646-3109.

F. Non-Retaliation Policy

We will not allow any retaliation against personnel who acts in good faith to report a known or suspected violation of this Code. All reports will be promptly and thoroughly investigated. Confirmed violations will be promptly and appropriate addressed.

G. Questions

For questions regarding this Code, contact your supervisor or the following individuals:

Chief Compliance Officer:
Christopher L. Koshire
5198 West 76th Street
Edina, MN 55439
Telephone: (952) 646-3292
E-mail: koshirec@arkrayusa.com

Contact information current as of November 2014

ARKRAY

PART II: SALES AND MARKETING STANDARDS OF CONDUCT

ARKRAY adheres to the standards of conduct stated as in the AdvaMed Code of Ethics and the AdvaMed/Eucomed Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary Relationships (December 15, 2011/January 17, 2012). These AdvaMed guidelines are the standard of practice for device manufacturers in the United States. The ARKRAY Sales and Marketing Standards of Conduct describe how the AdvaMed Code of Ethics applies to ARKRAY's structure and business practices.

A. Interactions with U.S. Health Care Professionals

Our employees routinely interact with health care professionals in order to facilitate improvements in patient care and advancement of medical treatments. These interactions should be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. Interactions should be focused on informing health care professionals about our products, providing scientific and educational information and supporting medical education. Promotional materials provided to health care professionals by or on our behalf must:

- Be accurate and not misleading;
- Make claims about a product only when properly substantiated;
- Reflect the balance between risks and benefits; and
- Be consistent with all Food and Drug Administration (FDA) requirements governing such communications.

During interactions with health care professionals, we will engage in ethical business practices and will not unlawfully induce the sale or lease of our products. Specific rules guide our interactions with U.S. health care professionals.

Definition of Health Care Professionals: The term health care professional includes individuals and entities that provide services or items to patients (such as doctors and diabetes educators) and persons and entities that do not provide services directly but who are involved in the decisions to purchase, lease, or recommend our products.

While suppliers and distributors may not be health care professionals in their individual capacity, the general ARKRAY Code of Business Conduct and Ethics and Sales and Marketing Standards of Conduct for Third Party Sales and Marketing Intermediaries apply to our interactions with suppliers and distributors. Also, when suppliers and distributors interact with health care professionals on our behalf, they are expected to adhere to the Sales and Marketing Standards of Conduct for dealings with health care professionals.

All ARKRAY personnel are required to uphold the rules described below when interacting with U.S. health care professionals.

1. Training and education

We have the responsibility to provide training and education to our health care professional customers on the safe and effective use of our products and the advancement of medical procedures connected to the products we develop and sell. Training and educational programs may range from short presentations at the health care institution on our products to multi-day training at a centralized location necessitating out-of-town travel for the participants. Regardless of the setting in which the training or education is provided, we adhere to the following rules:

- Training and educational programs and presentations 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 many cases, it is appropriate to provide training and education at the health professional's office or hospital-based location. The individuals who conduct the training should have the proper qualifications and technical or clinical expertise to conduct such training.
- Payment for attendance or other gifts to attendees at training or educational events is not allowed.
- We may provide health care professional attendees and members of their staff with occasional meals and refreshments in connection with training and educational presentations, provided that the presentations provide scientific or technical training or educational value. The meals or refreshments must be: (a) modest as judged by local standards; (b) not part of an entertainment or recreational event; (c) provided in a manner conducive to informational communication; and (d) subordinate in time and focus to the training or educational purpose of the program.
- When out-of-town travel is necessary to efficiently deliver training or education, we may pay for reasonable travel, modest lodging and meal costs incurred by health care professionals who attend the training or education. All training and educational programs must be focused primarily on providing training and education to the health care professional and be conducted in meeting facilities conducive to the effective transmission of knowledge.
- We may not pay for meals, refreshments, travel, lodging or other expenses for a health care professional's spouse or other guests who does not have a *bona fide* professional interest in the information being shared at the training or education program. Offering "take-out" meals or meals to be eaten without an ARKRAY representative being present is also not appropriate.

2. Evaluation Products

Providing health care professionals with evaluation products at no charge educates health care professionals regarding their use, facilitates the safe and effective use of our products and can assist with improving patient care. If requested, we will provide health care professionals with documentation that the evaluation products were provided at no charge.

- *Single-Use/Consumables/Disposables Products:* We may provide reasonable quantities of our single-use products for evaluation purposes so long as the amount provided does not exceed the amount reasonably necessary to evaluate the products.
- *Multi-Use/Capital Products:* Our multi-use/capital equipment products will be provided only for a period of time that is reasonable under the circumstances to allow for adequate evaluation.

3. Prohibition on Entertainment and Recreation

Our interactions with health care professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, we may not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment or leisure or vacation trips, to any health care professional who is not a salaried employee of ARKRAY. Such entertainment or recreational benefits should not be offered, regardless of the value of the items, whether we engage the health care professional as a speaker or consultant or whether the entertainment or recreation is secondary to an educational purpose.

4. Promotional Items

Promotional items may be educational or non-educational in nature. Different rules apply to each type of promotional item.

- *Educational or patient related items.* We may offer items designed primarily for the education of patients or health care professionals (such as CDs or flash drives containing presentations) if the items are not of substantial value (\$100 or less) and do not have value to health care professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room intended for the education of the patients is appropriate, whereas a DVD or CD player that has value to a health care professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, is not appropriate. Items designed primarily for the education of patients or health care professionals should not be offered on more than an occasional basis even if each

individual item is appropriate. This section is not intended to address the appropriate provision of products for evaluation or demonstration purposes.

- *Non-educational or promotional items.* Non-educational items may not be offered or given to health care professionals or members of their staff even if they are accompanied by patient or physician educational materials. The provision of these items may foster misperceptions that ARKRAY interactions with health care professionals are not based on informing them about medical and scientific issues. Providing items that do not advance training or education, even if they are practice-related items of minimal value, is not appropriate (examples include: pens, note pads, mugs and similar “reminder” items with ARKRAY or product logos). Items intended for the personal benefit of health care professionals likewise may not be offered or given (examples include: floral arrangements, artwork, music CDs or tickets to a sporting event). Payments in cash or cash equivalents may not be offered or given to health care professionals either directly or indirectly, except as compensation for *bona fide* services as provided in this Code (examples include: gift cards, gift certificates).

5. Promotional and Other Business Meetings

We may conduct sales, promotional and other business meetings with health care professionals to discuss our products, sales terms or contracts. Generally these meetings will occur at or close to the health care professional’s place of business. However, when necessary (e.g., for plant tours or demonstrations of non-portable equipment), it is appropriate to pay for reasonable travel costs of health care professionals with a *bona fide* professional interest in the information being shared at the meeting. It is also appropriate to pay for modest meals and refreshments in connection with such meetings, provided that such meals and refreshments meet the requirements described in this Code. It is not appropriate to pay for travel costs or meals and refreshments for anyone who does not have a *bona fide* professional interest in the information shared at the meeting.

6. Continuing Medical Education

Continuing Medical Education (CME) programs help physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care and, therefore, financial support is appropriate. Such financial support is intended to support education on a full range of treatment options and not to promote a particular medicine.

- Responsibility for and control over the selection of content, faculty, educational methods, materials and venue belongs to the organizers of the conference or meeting in accordance with their guidelines. We may not provide any advice or guidance to the program provider, even if asked by the

provider, regarding the content or faculty for a particular program funded by us.

- Any financial support should be given to the program provider, which, in turn, may use the money to reduce the overall registration fee for all participants. Financial support should not be offered for the costs of travel, lodging or other personal expenses of non-faculty health care professionals attending the program, either directly to the individuals participating in the event or indirectly to the event's sponsor. Similarly, funding should not be offered to compensate for the time spent by health care professionals participating in the event. We may not provide meals directly at the event except that the program provider, at its own discretion, may apply the financial support provided by us to provide meals for all participants.
- Financial support will only be provided to programs that meet the Standards for Commercial Support established by the Accreditation Council for Continuing Medical Education or equivalent standards of the relevant continuing education accrediting body.
- All requests for CME financial support must be submitted in writing to the Chief Compliance Officer, and the Chief Compliance Officer shall make all decisions concerning program support. The Chief Compliance Officer shall objectively determine: (a) whether the program is a *bona fide* educational program; and (2) that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.
- Note that CME programs are distinct from ARKRAY-sponsored speaker programs.

7. Medical Meetings and Conferences

Medical meetings and conferences promote medical or scientific knowledge, advancement in medical procedures and the delivery of superior health care. These meetings include conferences sponsored by national, regional or specialty medical associations; conferences sponsored by accredited continuing medical education providers; grand rounds; and medical meetings sponsored by individual health care institutions. All requests for medical meetings and conference support must be submitted in writing to the Chief Compliance Officer, and the Chief Compliance Officer shall make all decisions concerning support. We may support these conferences in the following ways:

- *Conference Grants.* We may provide grants directly to the conference sponsor to reduce conference costs. Grants should be made only to the conference sponsor who should be responsible for and control the section of program content, faculty, educational methods, materials and venue. We may also provide grants to a training institution or the conference sponsor to

allow attendance by medical students, residents, fellows and others who are health care professionals in training (“educational grants”). Educational grants may only be provided if: (1) the meeting or conference is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending health care professionals who are in training. Educational grants shall be paid only to organizations with a genuine education purpose or function, and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organizations.

- *Conference Meals and Refreshments.* We may provide funding to the conference sponsor to support the conference’s meals, refreshments and hospitality. Also, we may directly provide meals and refreshments that are made available to all health care professional attendees, but only if the meals and refreshments are provided in a manner that is consistent with the sponsor’s guidelines. Meals or refreshments may not be provided to fewer than all health care professionals in attendance, unless provided incidental to a *bona fide* scientific, educational, or business information presentation, provided in a manner conducive to the presentation of such information, provided only to health care professionals that attend the presentation and provided while an ARKRAY representative is present. All meals or refreshments must be modest, subordinate to the conference purpose and clearly separate from the continuing education portion of the conference. We may not directly pay health care professionals attending a conference for meals or refreshments.
- *Conference Faculty Expenses.* We may make grants to conference sponsors for reasonable honoraria, travel, lodging and meals for health care professionals who are *bona fide* conference faculty members. We may not make grants or pay directly for conference expenses for non-faculty health care professional attendees.
- *Advertising.* We may purchase advertisements and lease booth space for our displays at conferences and meetings.

8. Grants and Charitable Contributions

We may make research or educational grants or donations for a charitable purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education or the sponsorship of events where proceeds are intended for charitable purposes. Grants or donations must not be provided as unlawful inducements to purchase, lease, recommend, use or arrange for the purchase, lease or use of our products. Grants or donations must not be based up the volume or value of purchases made by or anticipated from the recipient. All requests for grants and charitable

contributions must be submitted in writing to the Chief Compliance Officer and receive approval before a commitment for support is made. All grants and donations must be documented.

- *Research or Educational Grants.* Research grants may be provided to support independent medical research with scientific merit; however, the grants may not be linked to the purchase of ARKRAY products. Educational grants may be given to conference sponsors or training institutions to support advancements of medical education or public education. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows and other health care professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution.
- *Charitable Contributions.* Donations should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in *bona fide* charitable missions for the support of that mission.

9. Provision of Coverage, Reimbursement and Health Care Economics Information

Payor coverage and reimbursement policies for medical technologies are complex. Patient access to such technologies may depend upon health care professionals and patients have timely and complete coverage, reimbursement and health economic information. For this reason, we may provide such information regarding our products, so long as the information provided is accurate and objective. ARKRAY may also collaborate with health care professionals, patients and organizations that advocate for patients' interests to achieve government and commercial payor coverage decisions, guidelines, policies and adequate reimbursement levels that allow access to medical technologies. We may not interfere with a health care professional's clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. We also may not suggest mechanisms for billing for services that are not medically necessary or for engaging in fraudulent practices. Examples of allowable activities include, but are not limited to:

- Including information about the clinical value of our products and the services and procedures in which they are used in the coverage, reimbursement and health economic information and materials provided to health care professionals, professional organizations, patient organizations and payors.
- Collaborating with health care professionals, professional organizations, and patient groups for joint advocacy purposes related to coverage, reimbursement and health economics issues.

- Supporting health care professionals in developing materials or providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to health care professionals about our products, including identifying coverage, codes and billing options that may apply to our products or the services and procedures in which they are used.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes to facilitate a health care professional's decision to buy or use our products.
- Facilitating patient access to our products by providing health care professionals with assistance in obtaining patient coverage decisions from payors. At the request of a health care professional, we may also assist patients by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, or appeals of denied claims. However, such assist may not be provided as an unlawful inducement.

10. Activities with Consultants

We may ask health care professionals to make presentations and draft publications about our products on our behalf at conferences and in journals. It is appropriate to pay health care professionals reasonable compensation for performing these services. All decisions on entering into a consulting arrangement with or payment to a health care professional in conjunction with these services must be made by the ARKRAY Legal Department in advance of the performance of any services. The following factors provide the criteria for selection and support the existence of a *bona fide* consulting arrangement with health care professionals:

- Consulting agreements must be written, signed by the respective parties, specify the term of the agreement, specific services and compensation to be provided and a copy of the agreement must be retained by ARKRAY. When a consultant is engaged to conduct clinical research services, there should also be a written research protocol.
- Before entering into a consulting agreement, a legitimate purpose and tangible benefit must be identified. The number of consultants engaged for the identified purpose should not be greater than the number reasonable necessary to achieve the intended purpose and benefit.
- Compensation paid to consultants should be reasonable and consistent with the fair market value for the services provided, and ARKRAY shall make appropriate use of the services provided. Compensation must not be based on the volume or value of the consultant's past, present or anticipated business.

- Selection of consultants should be based on the consultant's qualifications and expertise to address the identified need and must not be on the basis of volume or value of business generated by the consultant. To avoid the appearance of impropriety, sales personnel may provide input regarding selection of consultants but should not control or unduly influence the decision to engage any particular consultant.
- The location and circumstances for meetings with consultants should be appropriate to the subject matter of the consultation and conducted in settings conducive to the effective exchange of information.
- Modest meals or refreshments may be appropriate to provide during meetings with consultants, so long as they are provided consistent with the terms found in this Code. However, we may not provide recreational or entertainment events in conjunction with these meetings.
- We may pay for the reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement and meeting with us. We may not pay honoraria, travel or lodging expenses to non-consultant health care professional attendees at ARKRAY-sponsored meetings, including attendees who participate in interactive sessions.
- We may engage consultants as speakers to help educate and inform other health care professionals about the benefits, risks and appropriate uses of ARKRAY products during external promotional programs. Selection of health care professionals as speakers should be made based on the professional's expertise and reputation, knowledge and experience regarding the particular medical procedure and communication skills. Speaking arrangements are neither inducements nor rewards for utilizing any ARKRAY product. The speaker arrangement shall meet all requirements for consulting arrangements described in this Code. In addition, compensation and reimbursement should only be offered to speakers if the following conditions are met: (1) the speaker receives extensive training on ARKRAY's products or other specific topic; (2) FDA requirements regarding presentation communication are met; and (3) this training will result in the participants providing a valuable service to ARKRAY. Speakers' materials should clearly identify that the presentation is sponsored by ARKRAY and that the speaker is presenting information that is consistent with FDA guidelines.

11. Payment of Royalties

Developing products that benefit patients by addressing unmet needs health care professionals is key to our business model. In many cases, health care professionals provide us with ideas that are developed into products that we sell. We may enter into royalty agreements with health care professionals if we believe that they have made or

are expected to make a novel, significant or innovative contribution to the development of a new product, technology, process or method. The contribution or expected contribution must be documented, and the royalty agreement shall meet all contracting requirements for consultants described in this Code. Additionally, any agreement for royalties shall not require the health care professional to market the licensed product and will not be conditioned upon a requirement that a health care professional purchase, order or recommend any one of our products. All decisions regarding royalty agreements will be made by our VP, Finance.

B. Dealings with Sales and Marketing Intermediaries

We have entered into relationships with third party intermediaries (such as McKesson) in the United States and countries around the world to assist in the marketing, sale or distribution of ARKRAY products. The form of these relationships varies, but they include distributors, wholesalers, distribution agents, marketing agents, brokers and independent sales representatives (collectively referred to as “Third Party Sales and Marketing Intermediaries” or “SMI”).

ARKRAY’s interactions with Third Party SMI’s, as well as Third Party SMI interactions with health care professionals and government officials, must be conducted pursuant to all applicable legal and ethical principles described in the ARKRAY Code of Business Conduct and Ethics and Sales and Marketing Standards of Conduct. ARKRAY communicates these conduct principles to Third Party SMI’s with the expectation that they will adhere to them.

However, ARKRAY personnel and Third Party SMI’s on our behalf, often interact with non-health care professionals. In these circumstances, ARKRAY bans all forms of bribery by any person or entity acting on our behalf. Bribery includes all transfers of something of value to a government official, health care provider or others that may violate applicable laws, principles or company policies. Specifically:

- 1. Fair Dealing.** ARKRAY requires compliance with all applicable laws and the general principals outlined in the *Fair Dealing* section of the Code.
- 2. Gifts.** ARKRAY generally prohibits all gifts and promotional items, unless the gifts are of nominal value.
- 3. Hospitality.** The provision of modest meals and refreshments is acceptable, provided that the hospitality is necessary, prudent and job-related.
- 4. Grants and Donations.** Some types of grants, such as those for charitable purposes, are appropriate. All requests for grants must be submitted in writing to the Chief Compliance Officer and receive approval before a commitment of support is made. All grants and donations must be documented.
- 5. Travel Expenses.** It is generally appropriate to reimburse individuals for reasonable travel and lodging expenses for travel that is necessary, prudent and related to the appropriate marketing, sale, or training/education of ARKRAY products.

The Legal Department must review all relationships with Third Party SMI’s before entering into any written agreement with the Third Party SMI.

C. International Health Care Professionals

When we interact with international health care professionals, the Sales and Marketing Standards of Conduct are substantially similar to the standards of conduct for interacting with U.S. health care professionals. A health care professional is categorized as a U.S. or international health care professional by where he/she is licensed to work. If a health care professional is licensed both in the U.S. and internationally, the standards of conduct for U.S. health care professionals apply.

Unless specifically modified in this section, the Sales and Marketing Standards of Conduct for interactions with international health care professionals are the same as the standards of conduct for interactions with U.S. health care professionals.

1. Gifts and promotional items. Promotional items may be educational or non-educational in nature. Different rules apply to each type of promotional item.

- *Educational and patient-related items:* Items designed for educational or patient-related purposes may be provided to international health care providers consistent with the rules described in the Promotional Items section of the Code related to U.S. health care professionals.
- *Non-Educational and gift items:* For international health care professionals, the giving of gifts is generally prohibited; however, an exception is made in some countries for gifts which are of nominal value, recognized as a custom of trade and are tasteful and appropriate. This may include modest promotional items, for example: pens, note pads, mugs and similar “reminder” items with ARKRAY or product logos, even if the promotional items do not directly benefit patients or serve a genuine educational function. This allowance is in addition to our ability to offer items designed primarily for the education of patients or health care professionals described in Standards of Conduct for U.S. health care professionals. Any gift or promotional item provided to international health care professionals should have a fair market value of less than \$100. The use of multiple promotional items totaling over \$100 in the aggregate to circumvent this restriction is not permitted. Gifts of cash or cash-equivalent items (e.g., gift cards, gift certificates, etc.) or items intended for the personal benefit (e.g., floral arrangements, artwork, music CDs or tickets to a sporting event) of an international health care professional is prohibited. Gifts or promotional items should not be offered on more than an occasional basis, even if each individual item is appropriate.

2. Prohibition on Entertainment and Recreation. The restrictions in the *Prohibition on Entertainment and Recreation* section of the Code for U.S. health care professionals also apply to international health care professionals.

3. Meals. In addition to the meals permitted in the Code for U.S. Health Care Professionals, we may pay for occasional reasonable meals outside the office,

hospital or educational setting for international health care professionals, so long as the meal is provided in connection with a legitimate business purpose. It is not appropriate to pay for meals of guests of health care professionals, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. This allowance is not intended to prohibit sponsoring meals and receptions at medical meetings, conferences or CME programs.

PART III: State-Specific Supplemental Sales and Marketing Standards of Conduct

A. California

California state law contains compliance requirements for medical device companies (California Health and Safety Code §§ 119400-119402).

The ARKRAY Sales and Marketing Standards of Conduct apply to California. No additional rules apply. However, ARKRAY must annually declare, in writing, that it is in compliance with its Compliance Program and California law.

We must make our Compliance Program and annual written declaration of compliance with the program available to the public on our Web site and provide a toll-free telephone number where a copy or copies of the Compliance Program and written declaration of compliance may be obtained.

In order to facilitate ongoing audits related to compliance with the Sales and Marketing Standards of Conduct and Compliance Program, all sales and marketing representatives who are located in California or who otherwise have interactions with health care professionals who are licensed to practice in California must follow current ARKRAY procedures for routinely tracking activities subject to internal compliance audits.

State-Specific Supplemental Sales and Marketing Standards of Conduct

B. Massachusetts

Massachusetts state law contains a code of conduct for medical device companies (M.G.L. c. 111, § 3 and c. 111N; 105 CMR 970.000).

Standards of Conduct

In addition to the Sales and Marketing Standards of Conduct described in this Code, these additional rules apply to sales and marketing activities conducted in or directed at health care professionals located in Massachusetts.

1. **Provision of Meals:** Any meal or refreshment provided to a health care practitioner must be modest. Additionally, meals and refreshments must be:
 - A. Provided in the health care practitioner's office or hospital setting in connection with informational or educational meetings or presentations; or
 - B. Provided outside of the health care practitioner's office or hospital setting for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to informational communication.

All meals and refreshments are subject to Massachusetts reporting requirements, as described below. For purposes of Massachusetts law, "modest meals and refreshments" means food and/or drinks that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.

2. **CMS, Conferences or Professional Meetings:** We may not provide financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor. This includes grants made either directly to conference sponsors to reduce conference expenses, or to conference sponsors to allow attendance by medical students, residents, fellows and others who are health care professionals in training.

Disclosure/Reports

Massachusetts has state disclosure and reporting requirements that are more broad than the federal Physician Sunshine Payment Act. In Massachusetts, payments to all entities and professionals who are covered recipients must be reported.

Covered recipients include any person authorized to prescribe, dispense, or purchase

prescription drugs or medical devices in Massachusetts, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner.

All sales and marketing representatives who are located in Massachusetts or who otherwise have interactions with health care professionals who are licensed to practice in Massachusetts must follow current ARKRAY procedures for routinely tracking activities subject to disclosure and reporting these activities to the Chief Compliance Officer. The Chief Compliance Officer facilitates the annual disclosure to Massachusetts Department of Health.

Use of Non-Patient Identified Prescriber Data

If we use non-patient identified prescriber data to facilitate communications with health care practitioners, we must:

- maintain the confidential nature of prescriber data;
- follow our policies regarding the use of this data; and
- adhere to consistent disciplinary actions for personnel who misuse this data.

Before using such data for marketing purposes, we must give health care practitioners the opportunity to request that their data be withheld from sales and marketing representatives and not be used for marketing purposes. We must comply with the request of any health care practitioner not to make his/her data available to company sales and marketing representatives.

These requirements do not prohibit the use of prescriber data for delivering safety and risk information, conduct research, comply with FDA mandated prescriber communications, or track adverse events.

State-Specific Supplemental Sales and Marketing Standards of Conduct

C. Nevada

Nevada state law contains compliance requirements for medical device manufacturers (NRS § 639.570; Nevada Administrative Code §§ 639.617-.619)

The ARKRAY Sales and Marketing Standards of Conduct apply to Nevada. No additional rules apply. However, ARKRAY must make an annual report to the State of Nevada that includes information about:

1. The ARKRAY Sales and Marketing Standards of Conduct;
2. The Sales and Marketing Standards of Conduct training program;
3. Annual compliance audits;
4. Policies and procedures for investigating instances of noncompliance; and
5. Identifying the compliance officer responsible for developing, operating and monitoring the Sales and Marketing Standards of Conduct.

In order to facilitate ongoing audits related to compliance with the Sales and Marketing Standards of Conduct and Compliance Program, all sales and marketing representatives who are located in Nevada or who otherwise have interactions with health care professionals who are licensed to practice in Nevada must follow current ARKRAY procedures for routinely tracking activities subject to internal compliance audits. The Chief Compliance Officer facilitates auditing and reporting to the Nevada Board of Pharmacy.

State-Specific Supplemental Sales and Marketing Standards of Conduct

D. Vermont

Vermont state law contains a code of conduct for medical device companies (18 VSA §§ 4631a and 4632).

Standards of Conduct

In addition to the Sales and Marketing Standards of Conduct described in this Code, these additional rules apply to sales and marketing activities conducted in or directed at health care professionals located in Vermont.

1. **Gifts**: We may not offer or give any gift to a health care provider.
 - Gifts include anything of value provided for free; or, any payment, food, entertainment, travel, subscription, advance, service or anything else of value.
 - We are limited in what we may provide to health care professionals licensed in Vermont and their assistants as promotional items. We may only provide: (a) demonstration or evaluation units to assess the appropriate use and function of a device (including a short-term loan of a device); (b) peer-reviewed academic, scientific or clinical articles or journals; (c) samples of devices provided to health care providers for free distribution to patients; and (d) labels approved by the federal Food and Drug Administration.
2. **Provision of Meals/Refreshments**: Meals and refreshments are included within the scope of the Vermont gift prohibition.
 - We are not permitted to provide Vermont health care professionals and members of their staff with meals or refreshments.
 - We may not directly sponsor meals/refreshments at conferences or professional meetings. We are allowed to provide coffee or other snacks or refreshments at a booth at a conference or seminar.
3. **Expense Reimbursement**: We must have a signed contract describing the expenses to be paid on behalf of any Vermont health care professional for related to education or training programs for our medical devices.
 - Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.

- The payment of the reasonable expenses of an individual related to the interview of the individual by a manufacturer in connection with a *bona fide* employment opportunity or for health care services on behalf of an employee of the manufacturer.

4. Medical conference or meeting sponsorship: Vermont has many restrictions regarding conference and meeting sponsorship. Decisions about sponsoring a Vermont conference or conference faculty will be made by the Chief Compliance Officer as described in the Code.

- We may make a payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) the payment is not made directly to a health care professional; (ii) funding is used solely for *bona fide* educational purposes, except that the sponsor may, in the sponsor's discretion, apply some or all of the funding to provide meals and other food for all conference participants; and (iii) all program content is objective, free from industry control and does not promote specific products.
- We may pay honoraria and expenses of a health care professional who serves on the faculty at a *bona fide* significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and (ii) consistent with federal law, the content of the presentation, including slides and written materials, is determined by the health care professional.
- All conferences and seminars must be accredited by the Accreditation Council for Continuing Medical Education or a comparable organization or is present by an approved sponsor of continuing education, provided that the sponsor is not a manufacturer; and offers continuing education credit, features multiple presenters on scientific research or is authorized by the sponsor to recommend or make policy.

5. Research

- For a *bona fide* clinical trial, we may pay only: (i) gross compensation for the Vermont location or locations involved; (ii) direct salary support per principal investigator and other health care professionals per year; and (iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.
- For a research project that constitutes a systematic investigation, it shall be designed to develop or contribute to general knowledge and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry. We may pay only: (i)

gross compensation; (ii) direct salary support per health care professional; and (iii) expenses paid on behalf of each health care professional.

6. Royalties and Licensing Fees: We may pay royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery only if the health care provider holds an ownership right.
7. Educational Grants: We may provide fellowship salary support provided to fellows through grants from manufacturers of prescribed products, provided: such grants are applied for by an academic institution or hospital; the institution or hospital selects the recipient fellows; the manufacturer imposes no further demands or limits on the institution's, hospital's or fellow's use of the funds; and fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.

Disclosure Requirements

In Vermont, Manufacturers must disclose annually the value, nature, purpose and recipient information of allowable expenditures or gifts to any health care provider that are included in the state disclosure requirements. Some reporting requirements are pre-empted by the federal Physician Sunshine Payment Act. However, all sales and marketing representatives who are located in Vermont who otherwise have interactions with health care professionals who are licensed to practice in Vermont must follow current ARKRAY procedures for routinely tracking activities subject to disclosure and reporting these activities to the Chief Compliance Officer. The Chief Compliance Officer facilitates the annual disclosure to the Vermont Office of the Attorney General.

ARKRAY

CODE OF BUSINESS CONDUCT AND ETHICS ACKNOWLEDGEMENT

I have received a copy of ARKRAY's Code of Business Conduct and Ethics (the "Code"). I have read and understand the Code, and I agree to adhere to all standards of business and ethical conduct described in the Code.

I will report any violation of that Code that I discover or suspect. I understand that I will not be retaliated against for reporting a known or suspected violation in good faith. I agree to cooperate with compliance investigations related to the violations that I report.

I also understand and agree that I will report any Conflict of Interest that I may have consistent with the procedures outlined in the Code. If I violate the Code, I understand that I may be subject to appropriate disciplinary action.

I also understand that the Code does not contain all of ARKRAY's policies concerning its business or my employment. I am and continue to be subject to all other ARKRAY policies concerning my position and my employment.

Date: _____

Signature: _____

Name: _____

Title/Position: _____

ARKRAY
CODE OF BUSINESS CONDUCT AND ETHICS

REPORTING FORM

Date of Report: _____

In the space below, please state the nature of your concern and describe the event or circumstance giving rise to this compliance report. Please be as specific as possible and attach extra sheets if more space is required.

This form may be submitted anonymously. While supplying your name may assist in the investigation of your report, you are under no obligation to disclose your identity. It is a violation of the Code to retaliate in any way against an employee or officer who, in good faith, reports any actual or potential violation of the Code of Conduct and Ethics. Please submit the completed form to the Chief Compliance Officer. Contact information for this individual is contained in the Code.

If you wish to provide your name, please do so below:

Name: _____ Phone Number: _____