Marketing Code of Conduct

This code of conduct is in compliance with Massachusetts law 105 C.M.R. 970.000

1. Code of Conduct

1.1. Purpose

The Code is intended to ensure that the relationship between Paradigm BioDevices, Inc. (Paradigm) and health care practitioners does not interfere with the independent judgment of health care practitioners.

1.2. Definitions

The following terms have the following meanings, unless the context or subject matter clearly require a different interpretation

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

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

"Charitable donation," the provision of financial support to a 501(c)(3) or the in-kind provision of drugs, biologics or medical devices for charity care of patients.

"Clinical trial," a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the

FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency.

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

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

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

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

"Hospital Setting," (a) a hospital (b) academic medical center or (c) pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide

medical training on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.

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

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

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

"Pharmaceutical or medical device manufacturing company," any entity that:
(a) is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or
(b) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices;

provided, however, that "pharmaceutical or medical device manufacturing company" shall not include a health care practitioner, physician practice, home health agency, hospital licensed under M.G.L. c. 111, s. 51, a wholesale drug distributor licensed under M.G.L. c. 112, s. 36A or a retail pharmacy registered under M.G.L. c. 112, s. 37-39C.

"Prescription drugs," drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription."

"Sales and marketing activities," for the purposes of disclosure under 105 CMR 970.009, sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug , biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose. Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least $50 to a covered recipient except as follows: Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan's formulary.

1.3. Provision of Meals

No employee may provide or pay for meals for health care practitioners that:

(a) are part of an entertainment or recreational event; or
(b) are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; and
  i. are not less than $50 per presentation;
  ii. are offered, consumed, or provided outside of the health care practitioner's office or a hospital setting; or
  iii. are provided to a healthcare practitioner's spouse or other guest.

Meals provided to health care practitioners in compliance with the above must be occasional in nature.

1.4. CME, Third-Party Scientific or Educational Conferences, or Professional Meetings

(1) No employee may provide:

(a) 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.
(b) funding to compensate for the time spent by health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;
(c) payment for meals directly to a health care practitioner at any CME event, third-party scientific or educational conferences, or professional meetings, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants
(d) sponsorship or payment for CME, also known as independent medical education, that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education ("ACCME") or equivalent commercial support standards of the relevant continuing education accrediting body, or that provides payment directly to a health care practitioner.

(2) No employee may provide any advice or guidance to a CME provider regarding the content or faculty for a particular CME program funded by Paradigm.

1.5. Other Payments to Health Care Practitioners

No Employee may provide:

(a) entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips to any health care practitioner who is not a salaried employee of Paradigm;

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

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

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

1.6. Penalties

An employee who knowingly violates this code of conduct may be punished by a fine of not more than $5000 for each occurrence and subject to termination of employment.

Prior to the issuance of any penalty an informal opportunity to dispute the penalty with the Ethics and Governance Committee will be granted if requested by the employee. The decision of the Committee is binding.

1.7. Enforcement

Violations of the Code cannot and will not be tolerated. Employees, regardless of their level within the Company, who are found to have violated the Code, as well as those who may have knowingly failed to report a known violation, will be subject to Penalties herein.

Paradigm employees who violate laws and government regulations also may be exposed to criminal fines, prison terms, and civil damages.

Each Paradigm employee is responsible for his/her own conduct. An illegal or unethical act cannot be justified by the individual committing it claiming that he/she was acting under the order of another individual, including that individual's supervisor or a member of senior management.

Failure to read and/or acknowledge the Code does not exempt an employee from his/her responsibility to comply with the Code, all applicable laws, rules, and regulations,

2. Compliance Program Administration

2.1. Compliance Officer

Paradigm's Marketing Code of Conduct is administered by the Payroll and Benefits Administrator, who is responsible for overseeing Paradigm's compliance and the day-to-day administration of the Code, for applying the Code to specific situations in which questions may arise, and interpreting the Code in particular situations.

2.2. Ethics and Governance Committee

The Ethics and Governance Committee ("Ethics Committee") has been created to broaden the reach of the Compliance Officer. The Ethics Committee is comprised of the Compliance Officer, the President and CEO, and the Sales Manager. The Ethics Committee will meet quarterly to review the Code of Conduct and Compliance Program and to monitor compliance activities. The members oversee Paradigm's compliance strategy and system.

3. Open Door Policy: Resources for Obtaining Guidance and Reporting Questionable Behavior and Possible Violations

The foundation of Paradigm's compliance effort is openness, accessibility, and discussion within the company. Paradigm encourages employees to present ideas, raise concerns, and ask questions — especially those of a legal or ethical nature, but also those relating to quality of work. All managers are responsible for supporting this policy by maintaining an "open door" for their direct reports and other employees who may reach out to them. While we hope that employees feel comfortable discussing any matter with their supervisors, there may be times when a supervisor cannot help.

To obtain guidance about a business ethics or compliance concern or to report a questionable behavior and/or a suspected, planned, or actual violation, you may speak with your supervisor, the Compliance Officer or any member of management.

Reporting is protected and encouraged. Paradigm will make every effort to protect the confidentiality of any employee who makes a report or requests guidance on an issue.

There will be no retaliation against any employee who, in good faith, reports a suspected, planned, or actual violation. However, if a Paradigm employee knowingly makes a false report of a violation with the intent of harming another individual, that employee will be subject to disciplinary action.
All reports of actual or potential violations will be taken seriously, investigated promptly, and resolved appropriately. Paradigm employees are expected to cooperate fully in any Company investigation. Paradigm will maintain the confidentiality of reports and investigations to the fullest extent allowable by law.