

TITLE: Code of Health Care Compliance

Spineology, Inc. (“Spineology” or the “Company”) is committed to conducting its business with integrity and according to the highest legal and ethical standards, and to providing physicians and patients with high-quality health care products and treatments options. We expect Company Representatives to engage in ethical business practices and socially responsible industry conduct. To assist us in meeting these commitments, we have implemented this Code of Health Care Compliance (the “Code”). This Code sets out the fundamental principles and values that will guide the Company’s operations. The Code is necessarily broad and is not meant to replace more specific guidance that the Company will provide through policies, procedures, or training. Spineology field personnel, including independent distributors and their sales representatives, (collectively, “Company Representatives”) are acting on behalf of the Company and agree to comply with the laws, regulations, and industry standards described in this Code. Contractors and independent distributors conducting business on behalf of Spineology must also comply with this Code.

We operate in a heavily regulated environment, and this Code provides guidance on compliance with the variety of federal, state, and local laws, regulations, and industry standards applicable to the Company in the health care industry. Many practices that are common in other industries are viewed as inappropriate in the health care industry. The laws this Code describes below are broad and are implicated in many common interactions and activities. Company guidance cannot address every situation that may arise, but the principles described in this Code, along with more specific guidance in policies, procedures, and training, should help guide your actions. The absence of specific guidance does not relieve Company Representatives of the responsibility to operate within the highest ethical standards of conduct. If you do not know how to handle a situation, seek guidance from your manager, or Andrew Adams at aadams@spineology.com. In guiding your actions, it is also useful to think about whether a particular program, arrangement or interaction would, if it became public, inspire or diminish the public’s trust in Spineology.

As used in this Code, the term “Customer” means any individual or organization that purchases, recommends, uses, or prescribes products manufactured or distributed by Spineology, or an individual who is in a position to determine whether a Spineology product is purchased, recommended, used, or prescribed. This term can include, but is not limited to, physicians, nurses, office administrators, and purchasing agents.

I. HEALTH CARE LAWS

Spineology is committed to operating in compliance with all applicable health care laws and regulations, which includes the laws summarized below. Legal requirements can vary between jurisdictions. Company Representatives are responsible for complying with the strictest requirements imposed, either by the Code, Company policies and procedures, or the applicable laws, regulations, and other government guidance. Some of the laws applicable to our operations include:

A. Anti-Kickback Laws

In the United States and in many other countries, it is prohibited to offer or pay anything of value to induce or reward the purchasing, prescribing, or recommending a health care item or service.

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The federal anti-kickback statute prohibits offering or soliciting (and giving and receiving) any remuneration to induce or reward the order, purchase, prescription or recommendation of an item or service that may be paid for, directly or indirectly, by a federal health care program like Medicare, Medicaid, the VA, or Tricare. There are also state anti-kickback laws that apply regardless of the payor. Anti-kickback laws aim to ensure a purchase or prescribing decision is based on the best interest of the patient. These laws also aim to prevent a) the over-utilization of goods and services reimbursed by the government, b) increased costs to federal health care programs or beneficiaries, c) inducements that corrupt medical decision-making or pose risks to patient safety, and d) unfair competition practices. Violations of the federal and state anti-kickback laws can result in substantial criminal and/or civil fines, damages or penalties for the Company and its representatives, imprisonment of individuals, and possible exclusion from participation in federal health care programs like Medicare and Medicaid.

These anti-kickback laws are quite broad and are implicated in a variety of business practices and interactions with physicians, patients, payors, and anyone else in a position to order, recommend or influence the use of our products. For example, offering discounts, rebates, or no-charge product implicates the anti-kickback laws, as do referrals or engaging physicians to perform consulting or other services on behalf of the Company. Programs or interactions with customers that involve any transfer of value must be reviewed to ensure compliance with these complex laws.

B. False Claims Act Laws

The federal civil False Claims Act (FCA) prohibits, among other things, knowingly presenting, or causing someone else to present claims for payment of government funds that are false or fraudulent. The FCA also prohibits knowingly making, using, or causing to be made or used a false record or statement that is material to a false or fraudulent claim, or knowingly concealing or improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many states have similar false claims laws. The FCA is violated not only when the person has knowledge that the information is false or fraudulent, but also if the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. In addition, claims for items or services that result from an anti-kickback violation are considered to be false or fraudulent for purposes of the FCA. Violations of these laws can lead to substantial civil and administrative penalties, damages, or exclusion from participation in federal health care programs.

The FCA has been a powerful enforcement tool in the health care industry. FCA cases can be brought by the government or by whistleblowers called “relators” who bring an action on behalf of themselves and the government. The Department of Justice and private whistleblowers have pursued FCA actions against manufacturers for a variety of activities, including providing consulting fees, grants, no-charge product, and other benefits to health care professionals to induce them to use company products; promoting products for “off-label” uses; and providing false or misleading coding and billing information.

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The applicable provisions of the Federal Food Drug and Cosmetics Act, as well as regulations and guidance issued by the Food and Drug Administration (FDA), require the Company to promote and sell its products based solely on the approved labeling, through accurate and truthful communications about the efficacy, quality, and safety of the product. All information provided to health care professionals about Spineology products must be truthful, balanced, fair, objective, not misleading, and supported by data and relevant experience. Advertising or promotion may be unlawful if the Company indirectly or by implication expands the claims made about its products beyond the cleared or approved labeling. All materials created for use in promoting Company products must be reviewed and approved through the proper channels. All statements about Spineology products, whether in written materials and made in verbal communications, must be balanced, truthful, and consistent with the approved label.

D. Privacy Laws

Federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and regulations promulgated thereunder, require individuals with access to patient health information to protect the privacy and security of that information. Company Representatives may learn of, or gain access to, confidential patient health information, and must take care to protect the confidentiality of this information, and refrain from using or disclosing this confidential information other than for a legitimate and appropriate business purpose. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties. Company Representatives must take precautions to prevent unauthorized access to, or uses or disclosures of, confidential information, including by securely storing materials that contain such information. Company Representatives must also take care not to request patient information where not necessary or relevant to a legitimate and appropriate business purpose.

E. Physician Payment Sunshine Act

Spineology is also subject to laws and regulations designed to increase transparency around the financial relationships between physicians and manufacturers of drugs and medical devices, including the Physician Payments Sunshine Act (Sunshine Act). The Sunshine Act requires manufacturers to track and report to the federal government all payments and transfers of value made to certain health care professionals and teaching hospitals in the United States, with certain limited exceptions, along with ownership or investment interests held by physicians or their immediate family members. A manufacturer may be subject to civil monetary penalties for failure to report a payment or transfer of value.

F. Other Applicable Laws

We are also subject to other federal laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. An increasing list of states also have enacted laws that prohibit medical device manufacturers from providing certain economic benefits to health care practitioners, require manufacturers to report certain marketing

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expenditures to state regulatory bodies, and/or require manufacturers to adopt compliance programs consistent with industry guidance.

G. The AdvaMed Code

In addition to the laws and regulations discussed above, the Advanced Medical Technology Association (“AdvaMed”), the trade association representing medical technology companies, has issued a voluntary code of ethics setting out guidelines related to the interactions of medical technology companies and health care professionals. The Company has adopted the principles of the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”), which is available at <https://www.advamed.org/issues/code-ethics/code-ethics>. The AdvaMed Code provides specific guidance about compliant ways to conduct common interactions with health care professionals, such as conducting product training and education sessions, entering into consulting arrangements, providing coverage and reimbursement advice, research and educational grants, and products for evaluation or demonstration purposes.

By adopting the AdvaMed Code, the Company has committed to complying with these guidelines in all interactions with health care professionals. All Company Representatives are expected to be familiar with the principles of the AdvaMed Code, as reflected in the Spineology Compliance policies and procedures.

II. SPECIFIC GUIDANCE

Company Representatives are expected to be familiar with and comply with the Company’s policies and procedures. Company Representatives will adhere to the guidelines described in this Code as well as Spineology’s policies and procedures when interacting with Spineology’s current or potential Customers.

A. General Principles

The following general standards and principles should at all times guide our interactions with Customers:

- Spineology will encourage ethical business practices and socially responsible industry conduct and will not use any unlawful inducement in order to sell, lease, recommend or arrange the sale, lease, or prescription of its products.
- At Spineology, we believe that enduring Customer relationships are based on integrity and trust. We seek to gain advantage over competitors through superior products, research, engineering, manufacturing, marketing, and service, never through improper business practices.
- Spineology’s relationships with Customers are intended to benefit patient care and enhance the practice of medicine. Ethical relationships with health care professionals are key to our goal of helping patients by developing and marketing innovative devices. Interactions should be focused on informing customers and prospective Customers about our products, providing scientific and educational information, supporting medical research and education, and

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obtaining expert input about our products and development plans through appropriate consultation relationships. Our interactions should not, at any time, entice Customers or their representatives to place personal interests above the interests of either the organization they represent, or the interests of the patients who may be treated with our products.

- Spineology will not, directly or indirectly, offer or solicit payments or contributions for the purpose of obtaining, giving, keeping, or rewarding business.

B. Promotional Practices

- Sales and promotion of Company products and services should be based only on the benefit those treatments can offer to patients. Information presented about Company products must be consistent with the approved labeling, must be true and not misleading, comply with any and all specific conditions of clearance or approval, and must present appropriate risk information.
- All promotional activity will be consistent with approved product labeling.
- Company Representatives may only use, and cannot alter, advertising and marketing materials and messages that the Company has approved pursuant to its policies and procedures. Refer to SOP 25.6 Promotional Materials Review for further guidance.
- If Company Representatives receive unsolicited requests for off-label information, the information may only be shared consistent with SOP 25.4 Dissemination of Off-Label Information.

C. Customer Training and Education

- Company Representatives may provide training and education to Customers regarding the safe and effective use of Company products. Proctorships, defined as hands-on physician training conducted by a Customer on Spineology's behalf, may be offered only in compliance with SOP- 00004 Product Training and pursuant to a written agreement for proctor services in compliance with SOP- 00005 HCP Consulting Services.
- Company Representatives may provide training and education to Customers in the clinical setting at the request and under the supervision of a health care professional. Company Representatives must be transparent that they are acting on behalf of Spineology in a technical support capacity, must not interfere with a health care professional's independent clinical decision-making, must not perform actions as part of the clinical team, and must comply with applicable hospital or facility policies and requirements. Refer to SOP- 00011 Product Support Services and WI- 00019 Representative Presence in the Clinical Setting for further guidance.

D. Business Courtesies

- Company Representatives will not induce or reward business or seek to influence the independent clinical judgment of health care professionals, through improper transfers of value.

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- Any meals, travel or other accommodations must be occasional and modest as judged by local standards; offered only pursuant to a legitimate business purpose; and offered in a venue that is professional, not lavish, and conducive to an effective exchange of information. Refer to SOP- 00002 Business Courtesy Meals for further guidance.
- Any venues for Company-sponsored programs or meetings with Customers must be professional, conducive to an effective exchange of information, and not be lavish.
- Company Representatives will not provide any gifts or entertainment to any health care professional, payer, patient, or other person in a position to influence the prescription, coverage, or use of Company products. Refer to SOP- 00003 Educational Items; No Gifts or Entertainment for permissible educational items.
- Company Representatives shall accurately and timely track and report all expenditures for transfers of value made to health care professionals and teaching hospital customers. Refer to SOP- 00010 National Physician Payment Transparency Program (Open Payments) for additional guidance and specific requirements.

E. Product Support Services and Reimbursement Assistance

- Company Representatives will not provide any services or back-office functions to Customers that the Customer would otherwise have to pay for. Prohibited services include, but are not limited to, completion or submission of Patient Intake Forms; completion or submission of payor forms (CMS 1500 forms, appeals, etc.); or submitting claims.
- Any requests for or materials created for jointly sponsored activities or arrangements with Customers must be reviewed and approved by the Compliance Officer.
- Spineology may provide coverage, coding, billing, and reimbursement information on Company products so long as such information is accurate, objective, and complete and in accordance with SOP- 00011 Product Support Services.
- All coding, coverage, and reimbursement information the Company provides must be consistent with the FDA-cleared or approved uses and directions for use (i.e., on-label) for Spineology's products.
- Company Representatives may only provide Company-approved coverage, coding and reimbursement materials and information.
- Any coverage, coding, billing and reimbursement information or materials provided must include appropriate disclaimers in compliance SOP- 00011 Product Support Services including that it is always the provider's responsibility to determine the appropriateness of filing any particular claim, including determining and submitting appropriate codes, charges, and modifiers.

F. Health Care Professionals as Consultants and Speakers

- Spineology may engage health care professionals to perform certain services for which the Company has identified a legitimate business need that it cannot accomplish without the

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assistance of outside health care professionals. All such engagements must be in accordance with SOP- 00005 HCP Consulting Services and pursuant to a Needs Assessment plan in accordance with SOP-00001 Needs Assessment Policy.

- Spineology may not engage health care professionals to perform services in order to induce or reward the use, prescription, or coverage of Spineology products. Spineology will only compensate health care professionals for legitimate services that are actually performed, and the compensation must be at fair market value rates.
- Spineology will keep accurate books and records that reflect actual payments and transfers of value to health care professionals and will comply with requirements for reporting and disclosing such payments or transfers of value. Company Representatives must track and report any transfers of value to health care professionals and teaching hospitals by submitting the expense and expense detail in Concur or through other means as instructed by the Company.

G. Free and Reduced-Price Product

- Company Representatives may offer product for free or at a reduced price, including Product Samples, Demonstration Product, and Discounts, only in accordance with SOP-00012 on Free and Reduced-Price Product.

H. Requests for Funding

- Spineology may agree to provide funding to a third party subject to the limitations and requirements in Spineology compliance policies, and in accordance with SOP- 00001 Needs Assessment Policy.
- Company Representatives should refer questions about potential funding requests as follows:
 - Requests for commercial support of a third-party conference or event (e.g., conference sponsorship, trade show exhibit booth) for which Spineology receives a direct and tangible business benefit may be submitted through Medical Education, in accordance with SOP- 00008 Sponsorships.
 - Requests for funding to support bona fide scientifically rigorous, independent clinical and/or preclinical research should be referred to the Grant Committee, in accordance with SOP- 00006 Research Grants. Marketing and Sales personnel shall not be involved in the solicitation of research grant applications or otherwise assist in the preparation, review, or evaluation of applications for research grant support.
 - Requests for funding to promote scientific knowledge, medical advancement, and the delivery of effective health care through grants to fund educational programs, including conferences sponsored by an accredited continuing medical education provider, should be referred to the Grant Committee, in accordance with SOP- 00009 Educational Grants.
 - Requests for non-promotional contributions to charitable entities in the form of financial or in-kind donations should be referred to the Grant Committee, in accordance with SOP- 00007 Charitable Contributions.

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- Spineology will protect the privacy and security of personal information, and Company Representatives will not access, obtain, use, or disclose personal information other than for a legitimate and appropriate business activity.
- Protected Health Information (“PHI”) will be accessed, used, and disclosed in compliance with applicable laws.
- Company Representatives will take care to secure and protect personal information from improper access, use, and disclosure.
- Company Representatives will promptly and without delay report to Andrew Adams at aadams@spineology.com any impermissible access to, or use or disclosure of, personal information, or actual or suspected security incident potentially affecting personal information.
- Spineology is not a Covered Entity or Business Associate, each as defined under HIPAA. Company Representatives must not sign Business Associate Agreements (BAAs) on behalf of Spineology. Refer requests for BAAs to the Compliance Officer by email or phone.

III. COMPLIANCE WITH THE CODE

All Company Representatives are responsible for knowing and complying with the provisions of this Code, Company policies and procedures, and applicable laws and regulations and prevailing industry standards of ethical business conduct. All Company Representatives must acknowledge that they have received, reviewed, and understand this Code and will carry out their responsibilities in accordance with this Code. The most up-to-date version of this Code is always available on Showpad and www.spineology.com.

We expect managers to be role models for corporate ethics and compliance. All managers should make consistent and reasonable attempts to identify misconduct by Company Representatives that they supervise. Managers may be sanctioned for failing to instruct their subordinates adequately or for failing to identify noncompliance with applicable policies or legal requirements where reasonable diligence on their part could have identified the problem.

A. Monitoring Compliance and Disciplinary Action

Spineology will monitor compliance with this Code and Spineology policies and procedures, and, when appropriate, impose and enforce appropriate disciplinary actions. Disciplinary measures for violations of applicable law, regulation, the Code, or Spineology policies and procedures may include, but are not limited to, counseling, oral or written reprimands, warnings, probation or suspension, demotions, and termination of employment or service. The precise discipline imposed will depend on the nature, severity, and frequency of the violation. The following individuals may be subject to such disciplinary action:

- Company Representatives who violate any law or regulation, the Code, or Spineology policies and procedures;

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- Company Representatives who purposefully withhold or fail to report information concerning violation of law, regulation, the Code, Spineology policies and procedures; and
- Company Representatives who refuse to cooperate with or obstruct an investigation into violations of law, regulation, the Code, or Spineology policies and procedures.

B. Reporting Violations and Non-Retaliation

All Company Representatives are encouraged to act proactively by asking questions, seeking guidance, and reporting suspected violations of the Code and other Spineology policies and procedures, as well as any violation or suspected violation of applicable law or regulation. If any Company Representative believes that actions have taken place, may be taking place, or are about to take place that violate or would violate a law, regulation, the Code, or Spineology policy or procedure, s/he is obligated to bring the matter to the Company's attention. Company Representative are encouraged to consult with their manager, a supervisor, compliance@spineology.com, or the Compliance Officer with compliance questions or to report violations or suspected violations.

If you would like to submit an anonymous report, you may fill out the online Compliance Reporting Form located on our website (www.spineology.com) or via this link ([Compliance Reporting Form](#)). Spineology will use reasonable efforts to protect the confidentiality of the reporting person subject to applicable law, rule, or regulation or to any applicable legal proceedings. In the event the report is made anonymously, however, the Company may not have sufficient information to look into or otherwise investigate or evaluate the allegations. Accordingly, persons who make reports anonymously should provide as much detail as is reasonably necessary to permit Spineology to evaluate the matter(s) set forth in the anonymous report and, if appropriate, to commence and conduct an appropriate investigation.

The ability to discuss ethical and legal issues without fear of retribution is vital to the effectiveness of Spineology's compliance program. We expressly forbid any retaliation against any person who, acting in good faith, reports suspected misconduct. Any person who participates in any such retaliation is subject to disciplinary action up to and including termination. If you believe you have faced retaliation of any kind related to reporting of a compliance issue, please report it so that the Company can investigate.