

## **INTRODUCTION**

Zavation is dedicated to upholding the highest ethical, quality and compliance standards as we fulfill our customers' demand for surgical products that satisfy clinical and economic needs. Instead of aiming to merely meet minimum requirements, we have always been committed to exceeding the expectations set forth by applicable policies, standards and laws.

Our organization is guided by the belief that we can have a significant and sustainable impact on healthcare by maintaining an unwavering commitment to transparent business practices. To this end, we conduct business in an open and honest manner and reject business practices that unnecessarily increase the cost of healthcare, compromise patient safety, or stifle innovation.

## **CORPORATE COMPLIANCE OVERVIEW**

Zavation Medical Products, LLC ("Zavation" or the "Company") has adopted a Comprehensive Compliance Program ("Compliance Program"), summarized below and consistent with guidance published by the Office of the Inspector General of the U.S. Department of Health and Human Services (the "OIG"). Zavation's Compliance Program is intended to promote the prevention and resolution of actual or apparent conflicts of interest, appropriate disclosure in Company reports and public communications, compliance with applicable laws and regulations, accountability and prompt reporting of violations of Company policy relating to the sale and marketing of Zavation's products. It is Zavation's expectation that all Team Members, officers, directors, agents, representatives, consultants, and distributors shall comply with Company policies and procedures as well as all of the laws, rules and regulations of the U.S. and other countries, and the states, counties, cities and other jurisdictions, applicable to the Company's sale or marketing of its products.

## **COMPREHENSIVE COMPLIANCE PROGRAM SUMMARY**

The OIG advises that an effective compliance program is comprised of seven elements. Zavation has used these seven elements as a basis for its Compliance Program. Fundamental elements of our Compliance Program are summarized below.

1. *Written Policies and Procedures:* Zavation has adopted the AdvaMed Code of Ethics on Interactions with Healthcare Professionals as the Company's primary statement of policies for assuring compliance with applicable laws, regulations

and standards governing the marketing and promotion of Zavation's products. To the best of its ability and consistent with the OIG's guidance regarding tailoring compliance programs to the nature of Zavation's business as a medical device company, Zavation also has incorporated into its policies and procedures additional requirements of federal and/or state law.

2. *Compliance Leadership:* Elke Carter, Regulatory Affairs Manager, has been designated as the Company's Compliance Officer (the "Compliance Officer") reporting to the CEO. The Compliance Officer is empowered to exercise independent judgment and is responsible for developing, monitoring and otherwise administering the Compliance Program. The Company also has appointed a Compliance Committee comprised of the Compliance Officer and members of the Company's senior management to assist the Compliance Officer with review, revision and implementation of the Compliance Program to meet legal and regulatory requirements applicable to the Company.
3. *Education and Training:* The Company routinely trains appropriate Team Members on their legal and ethical obligations and Zavation's policies and procedures concerning marketing and promotional activities relevant to Zavation's products. Zavation regularly reviews and updates its training programs as needed. The Compliance Officer will work with other Team Members to implement or update appropriate training programs, including specialized training as needed, as well as documenting and maintaining records of such training.
4. *Communication:* Zavation encourages Team Members to talk to supervisors, managers, the Compliance Officer, any member of the Compliance Committee or other appropriate personnel about suspected illegal or unethical conduct or violations of Zavation's policies. Zavation has adopted open-door, confidentiality (to the extent possible) and non-retaliation policies in the event a Team Member is concerned about a potential violation. Team Members may also use the Company's anonymous Hotline at 1-601-292-9042. All reports will be referred to the Compliance Officer for review and for submission, as appropriate, to the Compliance Committee or other appropriate committee.
5. *Auditing and Monitoring:* The Compliance Officer, working in tandem with the Compliance Committee and other members of Zavation's senior staff, is responsible for auditing and monitoring compliance with Company policies and procedures. The Compliance Officer will work with other Team Members to audit and monitor compliance, as well as to document and maintain records of such audits.
6. *Enforcement and Appropriate Disciplinary Action:* All reported potential violations shall be forwarded to the Compliance Officer. The Compliance Officer

or an appointed delegate will, when possible, confirm receipt of the report to the individual making such report unless such report was made anonymously. The Compliance Officer or delegate also will investigate reports of suspected violations brought to the Company's attention and, with input from other members of the Compliance Committee, will take appropriate disciplinary action to address inappropriate conduct and deter future violations by Team Members or third parties with whom the Company does business.

7. *Corrective Action Procedures:* As needed and on an ongoing basis, the Compliance Officer will assess the need to revise policies, procedures, training, communication or other elements of Zavation's Compliance Program to improve its content or address gaps, if any.

### **REPORTING OF VIOLATIONS; NO RETALIATION**

Any Team Member who suspects a violation of the Company policy, financial fraud, accounting irregularities, or auditing issues should promptly contact the Compliance Officer, or the HR manager. Any Team Member wishing to make an anonymous report regarding suspected illegal behavior or financial fraud of any type may do so by calling one of the Company's anonymous hotlines. Team Members may call the following number: 1-601-292-9042.

The anonymous hotlines are intended only for reporting potential financial fraud, concerns regarding accounting controls or irregularities, auditing issues or illegal or unethical behavior in violation of Zavation's policies. For other workplace issues, Team Members should contact their manager or the Personnel Department. The Company will investigate and treat confidentially (to the extent possible) all reported potential violations. All Team Members are expected to cooperate in any internal or external investigations of possible violations of Company policy.

The Company will not permit retaliation of any kind by, or on behalf of, the Company or its Team Members against good faith reports or complaints of potential violations involving financial irregularities, violations of Company policy or other illegal or unethical behavior.

