

Vertiflex Comprehensive Compliance Program

NOTICE: This information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765), should it apply to Vertiflex, which requires certain pharmaceutical and medical device companies doing business in California to make available their policy for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products to California health care professionals.

I. INTRODUCTION

Vertiflex (“Vertiflex”) has established a program designed to ensure; (1) ethical interactions with health care providers; and (2) promotion and marketing practices that are in compliance in all material respects with applicable federal and state laws and industry standards. An overview of Vertiflex’s Compliance Program follows.

II. Overview of Compliance Program

1. Written Policies and Procedures

Vertiflex has developed and implemented written policies governing the ethical marketing and promotion of our products and interactions with health care providers. Our policies are intended to ensure compliance with applicable federal, state and industry standards, including the *Code of Ethics on Interactions with Health Care Professionals*, published by the Advanced Medical Technology Association (“AdvaMed”). Our policies address activities involving communicating with customers about the appropriate use of our products including appropriate instruction, education, training, service and technical support required for the safe and effective use of our products. Vertiflex also has developed and implemented policies governing the advancement of scientific and educational activities, and supporting medical research and education. These policies include:

Policy on Educational Grants and Research Grants

Vertiflex may provide grants for specific educational purposes that benefit patients and customers. These may include, but are not limited to, certified continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners.

Research grants to support customer-initiated research may be provided for programs involving bona fide scientific research in areas of legitimate interest to the company. All grant requests are subject to scientific or clinical review prior to funding approval.

Policy on Travel Expense Reimbursement for Product Training and Education and Sales and Promotion Meetings

Vertiflex will, with limited exceptions that are in accordance with nationally recognized standards, not reimburse for travel and lodging expenses of attendees at third party educational conferences.

Vertiflex may reimburse attendees for their reasonable travel and lodging expenses, and provide modest hospitality, associated with attendance at meetings focused on the education and training in the safe and effective use of Vertiflex products. These meetings are conducted in locations intended to be conducive to the exchange of information such as conference settings or company facilities. Vertiflex will not pay for lodging or travel for guests or spouses of attendees.

Policy on Business Meals

Vertiflex may occasionally offer a modest meal and/or reception, typically as part of an educational or product training meeting.

Policy on the Provision of Educational and Promotional Items

On occasion, Vertiflex representatives may provide patient or practice-related items. These items will be of reasonable value (less than \$100 retail value per item).

Promotional or “reminder” items of nominal value (less than \$25) such as coffee cups, pens, and notepads are not permitted under Vertiflex’s policy.

Total Annual Dollar Limit for Gifts, Promotional Materials and other Items or Activities

Vertiflex has established an annual limit of \$2,000 for gifts, promotional materials (described above) and other items or activities as the aggregate value of the items or activities that may be provided to California health care professionals pursuant to the requirements of Cal. Health & Safety Code § 119402. This limit excludes business or consulting arrangements and educational grants. Spending limits are the maximum boundaries for spending, and do not represent a spending “goal” or “average.” In many cases, Vertiflex spends significantly less per California physician than the listed limit.

2. Acting Compliance Officer

Our Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

3. Employee Training

A critical element of Vertiflex's Compliance Program is the education and training of our employees on their legal and ethical obligations under applicable healthcare programs. Vertiflex is committed to taking necessary steps to effectively communicate our standards and procedures to all affected personnel. Additionally, Vertiflex will regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis. Vertiflex also provides targeted training in key risk areas to those employees whose job functions are affected by those risk areas, such as employees in marketing, sales, and the like.

4. Communication

Vertiflex encourages dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of legal violations, should know whom to turn for a meaningful response and should be able to do so without fear of retaliation. Employees are expected to report suspected violations of company policy by contacting the Director of Compliance. Employees may also report potential violations through their chains of command, to Human Resources.

5. Auditing and Monitoring

Vertiflex's Compliance Program includes ongoing efforts to monitor, audit, and evaluate adherence to its compliance activities. The nature of our reviews as well as the extent and frequency of our compliance monitoring, auditing, and evaluation varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

6. Enforcement and Investigation

Vertiflex's Compliance Program strives to ensure that the consequences of violating the law or company policy are clearly understood by its employees and agents and that appropriate, consistent disciplinary action is enforced. Our Compliance Program requires the company to evaluate each case and respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations.