Vyaire Comprehensive Compliance Program and Compliance Declaration

Vyaire is committed to doing business in accordance with the highest standards of business conduct and ethics. Vyaire’s Compliance Program reflects our commitment to compliance with the laws and regulations that apply to our business, including the California Health and Safety Code §§ 119400-119402 (the “California Act”).

I. INTRODUCTION

Our Compliance Program is organized around the seven elements of an effective compliance program as set forth in the voluntary standards “Compliance Program Guidance for Pharmaceutical Manufacturers” published by the Office of Inspector General, U.S. Department of Health and Human Services (“HHS-OIG Guidance”). Our Compliance Program also incorporates voluntary industry guidelines, including the Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”). Our Compliance Program is tailored to Vyaire’s size, organizational structure, available resources, and the nature of our business as a medical device manufacturer.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. The HHS-OIG Guidance recognizes that the implementation of such a program cannot guarantee the complete elimination of improper employee conduct. Vyaire’s expectation, however, is that employees will comply with our Code of Conduct and our policies established in support of such Code. Vyaire will investigate any violation of law or company policy and where appropriate take disciplinary action and institute measures to avoid future violations. The following is a description of Vyaire’s Compliance Program.

II. DESCRIPTION OF COMPLIANCE PROGRAM

A. Leadership and Structure

Our Compliance Program was established by our Board of Directors in conjunction with Vyaire Senior Leadership. The VP, Chief Compliance Officer is responsible for the management and operation of the Compliance and Ethics Department and the development and ongoing enhancement of the compliance program. The VP, Chief Compliance Officer makes regular reports to the Compliance Committee of the Board of Directors.

Vyaire’s executive Compliance and Ethics Committee supports the Compliance Program and assists in preventing, detecting, and reacting to instances of non-compliance.

B. Written Standards

Vyaire’s Code of Conduct and compliance policies provide a guide of individual and collective obligations for responsible business conduct. Our Code of Conduct is a foundational document outlining our policies and providing the ethical framework to guide our business operations in accordance with law and company policies. The Code of Conduct applies to all Vyaire employees and each of our key business partners working on our behalf. It specifically provides a clear and consistent standard to do our jobs in a manner which reflects Vyaire’s values and serves our shared purpose. Among other important topics,
our compliance policies address potential risk areas for medical device organizations to implement our high ethical standards and meet our healthcare compliance obligations under applicable laws and regulations. These policies apply to all employees and compliance with these policies is a condition of employment.

C. Training and Education

Vyaire’s Compliance Program is supported by ongoing education and training of our employees on Vyaire’s Code of Conduct and compliance policies. Training and education programs for employees increase their awareness of our Code’s guidelines and the legal and ethical implications of their actions and behaviors. New employees receive compliance training as part of their initial training, and Vyaire provides ongoing compliance training and updates for its existing employees. Vyaire will regularly review and update its training programs, and identify additional areas of compliance training as appropriate. All employees are required to train on Vyaire’s Code of Conduct annually.

D. Communication

Vyaire is committed to maintaining a work environment where all individuals encourage and embrace open discussion across both geographical and operational boundaries. Employees are encouraged to seek guidance in resolving compliance and ethics questions. They are required to report suspected or actual unethical or non-compliant conduct, violations of law or regulation, and violations of internal company policies. Vyaire maintains a reporting hotline which allows anonymous reporting of suspected or actual noncompliance without retaliation.

E. Auditing and Monitoring

Vyaire self-assesses and will periodically audit its compliance with its policies and procedures to identify and address potential issues and opportunities to enhance its processes and practices.

F. Investigating and Responding to Potential Violations

Our Compliance and Ethics Department monitors company functions and activities for potential violations of law, regulation, the Code of Conduct and company policies. Potential violations are promptly and thoroughly investigated and appropriate corrective action taken.

G. Corrective Action

In determining the appropriate response to an established violation, Vyaire considers various options for corrective action. These options include remediation to evaluate current practices and close any gaps in policies, practices or training that may have led or contributed to the violation, as well as the imposition of disciplinary action up to and including termination.
III. CALIFORNIA ACT DECLARATION

In accordance with the California Act, Vyaire has established a specific annual dollar limit of $1,500, which applies to promotional materials, items, and activities provided by an employee of Vyaire to covered recipients in California. In addition, the following expenses are excluded from the limit: expenses that are directly associated with payments statutorily excluded from the limit (e.g., meals for consultants), items provided to health care professionals that are ultimately intended for patients or consumers, and receptions at third party educational or professional meetings.

To the best of its knowledge and based upon our good faith understanding of the statutory requirements, Vyaire declares that it is in all material respects in compliance with the requirements of the California Act.

A copy of this description of Comprehensive Compliance Program and Compliance Declaration may be obtained by calling 1-833-327-3284.

Last Updated: October 2018