

## **DECLARATION OF COMPLIANCE AND DESCRIPTION OF COMPLIANCE PROGRAM**

### *Introduction*

*Our goal is to continue as a strong, growing and innovative business long into the future. We are committed to our Culture Pillars: Care; Collaboration; and Courage. We respect the rights of all our stakeholders and seek to build open, honest and constructive relationships. We take into account social, environmental, legal and financial considerations in our planning and business decisions, and are committed to high standards of ethical practice. We aim to be honest and fair in all aspects of our business and we expect the same in our relationships with all those with whom we do business. We do not give or receive improper financial inducements either directly or indirectly, for business or financial gain. As part of our continued efforts in the area of compliance, we have developed a comprehensive Compliance Program that is reasonably designed to prevent, detect and correct violations of our business principles.*

*Our Primary Business is the Design, Manufacture and Sale of Medical Devices.*

*The AdvaMed Code of Ethics on Interactions with Health Care Professionals recognizes that the medical device industry is significantly different than the pharmaceutical industry. Consistent with the "Compliance Program Guidance" published by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance"), we have tailored our Compliance Program to the primary nature of our business as a medical device manufacturer.*

*While the California law makes reference to compliance with the PhRMA Code on Interactions with Healthcare Professionals, we primarily design, manufacture, distribute and sell medical devices rather than pharmaceutical products, and have adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals which is comparable to the PhRMA Code. Smith+Nephew's product portfolio includes some pharmaceutical products due to previous acquisitions. The parts of the business which include pharmaceutical products operate in accordance with the PhRMA Code.*

### *Description of Compliance Program*

*To the best of our knowledge, and based on our good faith understanding of the statutory requirements, we have established a Compliance Program compliant with requirements of Chapter 8 to Part 15 of Division 105 of California's Health and Safety Code. We have developed a Compliance Program tailored to the size, organizational structure and resources of the company, and implemented our Compliance Program to meet the compliance goals set forth by the State of California. The description of our Compliance Program, provided below, reflects the plan we have implemented. To our knowledge, we are, in all material respects, in*

*compliance with our Compliance Program as described, meaning that we have established the elements outlined, and where procedures are described, we have set up programs to initiate these procedures.*

### *Compliance Program Changes and Limitations*

*We regularly reassess the program to improve it, and it is possible that we will make further adjustments aimed at improving the effectiveness of our Compliance Program in the coming year. We recognize that compliance is a dynamic concept that must be adapted to the characteristics of a particular company and emerging risks. Government standards on compliance programs, including the U.S. Sentencing Guidelines and the HHS-OIG Guidance, recognize that no program can completely prevent individual employees or agents from improper conduct. While we are not making a representation that every employee and agent will always fully comply with our business values, our program is reasonably designed to prevent, detect, and correct violations. We are committed to monitoring our conduct and taking action including discipline for any employee or take appropriate action with an agent who violates our Code of Conduct.*

*This declaration is made as of May 1, 2021, and as noted above, it is possible and likely that we will update our program on an ongoing basis.*

## **DESCRIPTION OF COMPREHENSIVE COMPLIANCE PROGRAM**

### **I. Introduction**

Smith+Nephew, Inc. is committed to establishing and maintaining an effective compliance program in accordance with the HHS-OIG Guidance. Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to increase the likelihood of preventing, detecting and correcting violations of law or Company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee or agent conduct will be entirely eliminated. Nonetheless, it is Smith+Nephew's expectation that employees and agents will comply with our Code of Conduct and Business Principles, Global Policies, and other codes, policies and procedures established in support of our Code of Conduct.

In the event that Smith+Nephew becomes aware of violations of law or Company policy, we will investigate the matter and, where appropriate, take

disciplinary action and implement corrective measures to prevent future violations. For purposes of our Compliance Program, the term “agent” means persons under contract to act on behalf of Smith+Nephew as sales representatives or independent distributors to sell, or facilitate the sale of, goods or services that may be reimbursed under US Federal health care programs.

Smith+Nephew has described below the fundamental elements of its Compliance Program. In accordance with the voluntary standards established by the HHS-OIG Guidance and as explicitly recognized in the Guidance, we have tailored our Compliance Program to fit the unique environment, size and product range of our Company. The Compliance Program is dynamic, involving not only multiple policies, procedures, and programmatic activities, but also the commitment of senior management, and the support of employees and agents to make the program effective.

We will regularly review and enhance our Compliance Program to meet our evolving compliance needs. For a written copy of this Declaration of Compliance and Description of Compliance Program, Please send any questions to [the Office of Ethics and Compliance team](#).

## **II. Overview of Compliance Program**

### **1. Written standards.**

Smith+Nephew’s Code of Conduct and Business Principles, together with our Global Policies (collectively our “Code”), is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees and agents of the Company to act in accordance with law and applicable Company policy. The Code articulates our fundamental principles, values and framework for action within our organization. Smith+Nephew also has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals. We are committed to train on and comply with the AdvaMed Code’s standards and guidance. In addition, the parts of business which include pharmaceutical products operate in accordance with the PhRMA Code.

To comply with a specific California law, and subject to the provisions of this section, we have established an annual aggregate spending limit of \$2,500 for certain promotional materials, items and/or promotional activities provided to California licensed health care professionals. This amount is an upper limit that represents the most we reasonably anticipate Smith+Nephew would spend on any one licensed health care professional in

a year's time. It is important to note that we expect to spend considerably less, and may never spend the limit on any one licensed health care professional.

The spending limit, consistent with the California statute (California Health and Safety Code Sec. 119402), excludes the value of the following:

- Travel and meal expenses for attendance at company medical education and product training meetings
- Product samples
- Educational materials that directly benefit patients or are intended for patient use
- Short-term loan of a device to permit evaluation
- In-kind items used for the provision of charity care
- Payments for legitimate professional healthcare services provided by a health care professional

Smith+Nephew has established corporate processes to track this limit. However, the Company's systems to support this requirement are limited and we are unable to track all promotional or other items provided to a California health care professional including individual items of a nominal value and approved gifts that may be provided to a California health care professional at a medical or other convention.

## **2. Leadership and Structure.**

**Compliance Officer.** We have a Chief Legal & Compliance Officer for the company, who is supported by regional compliance leaders and a global team. For each business, we have designated a senior level officer to serve as the Compliance Officer. We are committed to ensuring that each Compliance Officer has the ability to affect change within the organization as necessary and to exercise independent judgment. Each Compliance Officer is charged with ensuring an effective compliance program is implemented.

**Compliance Committee.** Smith+Nephew has established a Group Executive Compliance Committee chaired by the CEO and comprised of all members of the Executive Committee, including regional and franchise Presidents, the Chief Legal & Compliance Officer and the Chief Financial Officer. In addition, the Compliance team works closely with Senior Leaders on a regular basis to drive the execution of the Compliance Program within each business, and to regularly assess emerging risk areas and implement actions to address them.

## **3. Education and Training.**

A critical element of our Compliance Program is the education and training of our employees and agents on their legal and ethical obligations under our Code and applicable federal health care program requirements. Smith+Nephew is committed

to taking necessary steps to effectively communicate our standards and procedures to affected personnel. Our training activities include a combination of in-person presentations, on-line web modules, printed materials, and individualized sessions. Smith+Nephew will regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis.

#### **4. Internal Lines of Communication.**

Smith+Nephew is committed to fostering dialogue between management and employees and agents. Our goal is that all employees and agents, when seeking answers to questions or reporting potential instances of misconduct, should know whom to turn to for a meaningful response and should be able to do so without fear of retribution. In order to encourage open lines of communication regarding potential ethical or legal violations, we adopted open-door policies, as well as confidentiality and non-retaliation policies.

To help ensure open lines of communications, Smith+Nephew has implemented an Integrity Line, which is hosted by an independent 3<sup>rd</sup> party known as NavexGlobal, which is comprised of the company EthicsPoint which manages the Smith+Nephew Integrity Line. Anyone with compliance questions, concerns, or anyone who suspects a potential violation of our Code may call Smith+Nephew's Integrity Line at 888-764-3577 or may report on-line at <https://www.smith-nephew.com/compliance/report-a-concern/>. Callers may choose to remain anonymous, and information provided will be treated as confidential as far as possible. We will ensure that no action is taken against anyone who reports, in good faith, actual or suspected misconduct.

#### **5. Auditing and Monitoring.**

Smith+Nephew's Compliance Program includes efforts to monitor, audit, and evaluate compliance with our Code. We note that in accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. We will utilize ongoing assessment of compliance programs to identify new and emerging risk areas and address these risks.

#### **6. Responding to Past and Potential Violations.**

Smith+Nephew's Compliance Program includes clear disciplinary policies that set out the consequences if current employees or agents violate the law or Company

policy. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations. Smith+Nephew's Compliance Program also includes reasonable procedures to screen potential employees, vendors, and agents, and Smith+Nephew will not knowingly do business with persons or organizations that have been excluded, debarred, suspended, or are otherwise ineligible to participate in Federal health care programs.

## **7. Corrective Action Procedures.**

A compliance program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, our Compliance Program requires the Company to 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. To that end we have established procedures to respond to noncompliance and ethics complaints.

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