Healthcare Compliance Program for Philips North America LLC

I. Introduction

Philips is committed to conducting its business ethically and in compliance with all applicable laws, regulations, guidelines, and policies. In keeping with that commitment, its United States affiliates Philips North America LLC and all Business Clusters operating in the U.S. (collectively “Philips U.S.”) have implemented a comprehensive healthcare compliance program for their U.S. operations (“Compliance Program”); this document describes that Compliance Program. The Compliance Program is part of the Royal Philips Legal Compliance Program.

II. Company Background

Philips is a global health and well-being company operating across the health continuum from healthy living and prevention, to diagnosis, treatment, recovery and home care.

- We have a presence in over 100 countries
- A workforce of over 100,000 employees committed to making the world healthier and more sustainable through meaningful innovation
- It is our mission to improve the lives of 3 billion people a year by 2025.

At Philips, we work closely with our customers, clinical partners and opinion leaders from around the world to address the multiple, often conflicting challenges, facing health care today. We combine deep human insights and cutting edge clinical expertise to deliver products, services, software and solutions designed to improve patient outcomes while lowering the cost of care.

Philips’ collaborative business groups put people at the center of everything we do to simplify and improve health care. Modern health care demands integrated solutions across the health continuum and our people focused approach delivers this through multiple digital technologies and connected and wearable devices.

We mine and analyze enormous volumes of health related data to improve clinical decision-making and performance, as well as personal lifestyle choices. Our Health Suite digital platform is further transforming health care by securely democratizing the availability of health care information and solutions.

III. Mission of the Compliance Program

The purpose of the Compliance Program is to:

a) prevent, detect, and correct violations of law and Company policy and procedures;

b) assure the establishment of compliance-related policies and procedures for business operations;
c) assure development of training and other communication programs designed to educate employees regarding applicable regulations, policies, procedures and standards;

d) implement a mechanism to evaluate the effectiveness of essential elements of the Compliance Program;

e) implement a mechanism for internal reporting of questionable or inappropriate activities to enable timely investigation and resolution;

f) assure appropriate corrective action is taken to prevent recurrence of misconduct.

IV. Elements of the Compliance Program

A. North America Compliance Officer

The North America Compliance Officer, or his or her designee, is responsible for overseeing the administration and implementation of the Compliance Program and will report at least quarterly on Compliance Program operations to, among others, the Philips U.S. Compliance Committee and periodically to the North American Executive Team (NEXT).

The North America Compliance Officer is vested with the authority to direct and implement compliance-related change in the organization as necessary and has the authority to exercise independent judgment in assessing compliance-related matters. The North America Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate. The North America Compliance Officer is authorized to report issues of any kind directly to the Company officers and directors.

B. Compliance Committee

The Company has established one or more Compliance Committees, which meet at least quarterly. The mission of the Compliance Committees includes ensuring the implementation and effectiveness of all components of the Compliance Program, which shall include, among other things:

- development and implementation of compliance-related policies, standards, and procedures in all areas of the U.S. business;
- development and implementation of training and other programs designed to educate Company employees regarding applicable laws, rules, regulations, policies, procedures, and standards (collectively, “Requirements”);
- development and implementation of auditing, monitoring, and other controls and processes designed to prevent, detect, and correct violations of applicable Requirements;
- development and implementation of mechanisms for internal reporting of questionable or inappropriate
activities and timely investigation and resolution of such instances; and

- development and implementation of corrective and disciplinary action to address and prevent recurrence of misconduct or non-compliance.

The Compliance Committees also shall provide advice, counsel, and support to the North America Compliance Officer, who shall have day-to-day oversight responsibilities for the North America Compliance Program.

C. Compliance Related Policies

As part of its commitment to the highest ethical standards of business conduct, the Company has implemented corporate standards and requirements that are consistent with that obligation and are specific to the Company’s operations and the evolving business and regulatory environment.

The Company expects employees, including as appropriate contractors, temporary staff and agents, at all levels of the organization to comply with:

- the Compliance Program,
- the standards set forth in the General Business Principles (GBP),
- Simply Right,
- the Code of Conduct for Interactions with U.S. Health Care Providers,
- the Company’s policies and procedures,
- and all applicable laws.

All U.S. employees must annually acknowledge their responsibility and commitment to conduct the Company’s business consistent with these standards and to report to management, Human Resources, Legal, or the North America Compliance Officer or Legal Compliance function knowledge of any violation of these standards. An employee who violates these standards will be subject to appropriate disciplinary action, up to and including termination.

Simply Right expressly prohibits retaliation or retribution against any employee for making any good faith report of suspected misconduct or improper behavior.

A number of policies and procedures are designed to ensure that interactions with healthcare professionals are appropriate,
ethical, and consistent with applicable laws and standards, including (but not limited to):

- Appropriate Compliance Program Guidance issued by the U.S. Department of Health and Human Services Office of Inspector General ("OIG Guidance"),
- the Medical Imaging and Technology Alliance (MITA) “Code of Ethics on Interactions with Health Care Professionals,” revised effective January 2009,
- and the AdvaMed Code of Ethics on Interactions with Health Care Professionals revised effective July 1, 2009 ("AdvaMed Code").

The Company has policies and procedures in place to foster compliance with the MITA Code and AdvaMed Code. For a statement regarding compliance with California Health & Safety Code § 119402, click here.

D. Training and Educational Programs

A critical component of the Compliance Program is the training and education of employees concerning their general ethical obligations and their specific obligations to comply with Company policies and procedures and with all applicable laws and regulations. The Company has implemented training programs to educate employees on the GBP, Simply Right, Code of Conduct on Interactions with U.S. HCPs (HCP Code), on new and existing compliance policies, and on the standards and procedures applicable to their job functions.

New employees receive or will receive compliance training as part of their initial training; employees receive on-going compliance training on a routine and periodic basis. The Company implements additional training for the entire Company or particular departments and/or business units on an as-needed basis.

E. Establishing Effective Lines of Communications

The Company will communicate at regular intervals to the employees about their obligations under the Compliance Program, as well as when material changes are made to guidance, policies or procedures. The Company is committed to fostering an environment in which the open communication regarding questions about the GBP, Simply Right, HCP Code or Company policies and procedures or concerns about suspected improper business practices is encouraged. Any employee who has concerns about a particular activity that the employee feels
may violate policies or the law is required to report such concerns.

Employees are encouraged to ask questions about compliance issues or make reports of potentially problematic conduct to their managers. As an alternative, employees may contact the North America Compliance Officer or use the Philips Ethics Line (1-800-218-1818). The Ethics Line, a toll free number available 24 hours a day and 7 days a week, allows confidential, anonymous reporting. The Ethics Line is administered by an independent outside contractor whose employees are trained to handle such calls. Employees may also submit their concern via the web by clicking here.

Philips expressly prohibits retaliation or retribution against any employee for making any good faith report of suspected misconduct or improper behavior.

F. Monitoring, Auditing, and Investigations

The Compliance Program includes activities designed to monitor and audit compliance with the Company’s policies and procedures. The North America Compliance Officer oversees and/or coordinates systems for periodic monitoring and auditing. On a periodic basis, but not less than annually, the North America Compliance Officer develops a monitoring plan, recognizing that the nature and frequency of reviews depends upon a variety of factors. A variety of internal and external resources may be used to conduct periodic monitoring and auditing. The North America Compliance Officer works with relevant internal experts and management to evaluate findings and ensure the implementation of any corrective action deemed necessary as the result of audits or routine monitoring activities.

The North America Compliance Officer (or designee) reviews and evaluates concerns communicated to the North America Compliance Department to determine whether further investigation is required of activities that may be inconsistent with the GBP, Simply Right, HCP Code, policies or procedures, or any provision of the Compliance Program or applicable law. The North America Compliance Officer may, as required, request assistance from the members of the Compliance Committees or outside experts to conduct an investigation, depending on the nature of the alleged misconduct. Investigations shall be conducted confidentially to the greatest extent possible and with every effort to respect the rights of all concerned.

G. Corrective Action and Discipline
If it is determined, after investigation, that noncompliant conduct occurred, the matter is forwarded to the appropriate parties for corrective and/or disciplinary action. Such response and disciplinary action may include (but is not limited to):

- terminating or otherwise disciplining the employee(s) involved;
- disciplining supervisors in accordance with the facts for failure to supervise adequately and control the behavior of the employee(s);
- revising guidelines, policies, and procedures or any function of the Compliance Program to prevent the reoccurrence of misconduct in the area;
- or increasing auditing and monitoring procedures.

H. Updating the Compliance Program

From time to time, the Company may amend its Compliance Program. The Compliance Committees shall review all changes suggested by the North America Compliance Officer, members of the Compliance Committees, or other Company personnel. The North America Compliance Officer shall be responsible for communicating changes in the Compliance Program to Company employees in a timely manner.

I. References

- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
- Philips Code of Conduct for Interactions with U.S. Licensed HCPs
- Philips Simply Right
- Philips General Business Principles
- Philips Transparency Guide