

# **MEDTRONIC COMPREHENSIVE COMPLIANCE PROGRAM**

## **I. INTRODUCTION**

Medtronic is committed to establishing and maintaining an effective compliance program in accordance with the Compliance Program Guidance published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”). Our Compliance Program, established by our Board of Directors in conjunction with Medtronic senior management, is one of the key components of our commitment to the highest standards of ethical practice.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, Medtronic expects that employees comply with our Code of Conduct (“the Code”), Business Conduct Standards, and the policies established in support of the Code. If Medtronic becomes aware of potential violations of law or company policy, the company will, where appropriate, investigate the matter and take disciplinary action and implement corrective measures to prevent future violations.

Medtronic has described below the fundamental elements of our Comprehensive 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 and size of Medtronic. As a medical device manufacturer and in light of the size of our company, we will rely on existing business units to share responsibility for implementing and maintaining our Compliance Program.

This document is a *description* of our Compliance Program. A Compliance Program is dynamic, involving not only multiple policies, procedures, and programmatic activities, but also the commitment of senior management, and the support of all employees, contractors, and agents to make the program effective.

We regularly review and enhance our Compliance Program to meet our evolving compliance needs.

## **II. OVERVIEW OF COMPLIANCE PROGRAM**

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

- The Medtronic Code of Conduct provides the foundational standards and expectations of behavior for our workplace. The Code establishes that we expect management, employees, independent dealers, distributors, 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.
- The HHS-OIG Guidance has identified several potential risk areas for manufacturers and called on companies to develop compliance policies in these risk areas. As relevant to device manufacturers, these risk areas include (1) data integrity pertaining to government reimbursement practices and (2) kickbacks and other illegal remuneration. Medtronic’s Global Business Conduct Standards Policy and U.S. BCS Playbook speak to these issues.

A specific annual dollar limit has been imposed on promotional materials, items or activities provided by a Medtronic employee to covered recipients in California.

2. **Leadership and Structure.**

- **Compliance Officer.** Medtronic has designated Thomas J. Schumacher, Vice President and Global Chief Ethics & Compliance Officer, as its Compliance Officer. Mr. Schumacher serves as the focal point for compliance activities. We are committed to ensuring that Mr. Schumacher, as Compliance Officer, has the ability to effectuate change within the organization as necessary and to exercise independent judgment. Mr. Schumacher is charged with the responsibility for developing, operating, and monitoring the Compliance Program.
- **Compliance Committee.** Medtronic has established an Executive Compliance Committee to advise the Compliance Officer and assist in the implementation of the Corporate Compliance Program.

3. **Education and Training.** A critical element of our Compliance Program is the education and training of relevant personnel on their legal and ethical obligations under applicable federal health care program requirements. Medtronic is committed to effectively communicating our standards and procedures to all affected personnel. Moreover, Medtronic 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.** Medtronic is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of compliance violations, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted open-door policies, as well as confidentiality and non-retaliation policies. To further encourage open lines of communication regarding potential violations, we established a toll-free and online compliance line to allow individuals to raise concerns of potential misconduct or to ask questions. Reports may also be made anonymously through this service.

5. **Auditing and Monitoring.** Medtronic’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with the company’s compliance policies and procedures, including efforts to monitor the activities of salesforce personnel. 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.**

When allegations of misconduct are raised, they are reviewed and investigated as necessary. Although specific activities associated with an investigation may vary based on the nature and circumstances of the issue, each is conducted using a consistent framework of principles. If a violation is found, Medtronic’s Compliance Program includes clear disciplinary and other policies that set out the consequences for violation of 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.

- 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 act to prevent future violations.

## **MEDTRONIC, INC., 2020 DECLARATION OF COMPLIANCE**

As part of our continued compliance efforts, we have developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations. Consistent with the HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, we tailored our Comprehensive Compliance Program to the nature of our business as a medical device manufacturer. The medical device industry has established, and Medtronic's Comprehensive Compliance Program is designed in accordance with, a voluntary ethical code called the AdvaMed Code of Ethics on Interactions with Health Care Professionals (AdvaMed Code). The AdvaMed Code is substantially equivalent to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code) but reflects the unique interactions between medical technology companies and health care professionals.

Government standards on compliance programs recognize that no program can completely prevent individual employees from improper conduct. Recognizing that compliance is a dynamic concept, Medtronic continuously reviews and updates its Comprehensive Compliance Program to improve it. As a result, the Program periodically incorporates changes in policy and approach that require the subsequent development of new and upgraded systems and processes.

Medtronic has developed a Comprehensive Compliance Program that we believe meets the compliance goals set forth by the State of California. The description of our Comprehensive Compliance Program, provided above, reflects the plan we have implemented. To our knowledge, we are, in all material respects, in compliance with our Comprehensive Compliance Program and applicable law.

A copy of this document may be obtained by calling 1-800-328-2518.

*Last updated: June 9, 2020*

*Signed:*

  
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**Thomas J. Schumacher**  
**Vice President, Global Chief Ethics & Compliance Officer**