

# OPTI MEDICAL SYSTEMS, INC. COMPREHENSIVE COMPLIANCE PROGRAM

## I. INTRODUCTION

OPTI Medical is committed to establishing and maintaining an effective compliance program in accordance with internal policies and procedures for interactions with health care professionals and a corporation Code of Ethics. OPTI Medical has also adopted the AdvaMed Code of Ethics (as it pertains to interactions with health care providers) found at: <http://advamed.org/res/112/advamed-code-of-ethics-on-interactions-with-health-care-professionals>. The Comprehensive Compliance Program is outlined in the policies and procedures established by OPTI Medical senior management, and is one of the key components of the company 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 Code of Ethics recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, OPTI Medical expects that employees will comply with established policies and procedures, Purpose and Principles statements, and the Code of Ethics. In the event that OPTI Medical 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.

OPTI Medical has described below the fundamental elements of the Comprehensive Compliance Program. In accordance with the voluntary standards established by the AdvaMed Code of Ethics, we have tailored our Compliance Program to fit the unique environment and size of OPTI Medical. 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.

- OPTI Medical follows our parent company's Purpose and Principles statements of ethical and compliance principles that guide our daily operations. The statements establish that we expect management, employees, independent dealers, distributors and agents of the company to act in accordance with law and applicable company policy. The Purpose and Principles articulate our fundamental principles, values and framework for action in our organization.
- The AdvaMed Code of Ethics 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. OPTI Medical's Policies and Procedures for Interactions with Healthcare Professionals speaks to these issues. A specific annual dollar limit has been imposed on promotional materials, items or activities provided by any OPTI Medical employee to covered recipients.

### 2. Leadership and Structure.

**Compliance Officer.** OPTI Medical has designated Theron Gober, Regulatory Affairs Director, as its Compliance Officer. Mr. Gober serves as the focal point for compliance activities. OPTI Medical is committed to ensuring that Mr. Gober, as Compliance Officer, has the ability to effectuate change within the organization as necessary and to exercise independent judgment. Mr. Gober is charged with the responsibility for developing, operating and monitoring the 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. OPTI Medical is committed to effectively communicating our standards and procedures to all affected personnel. Moreover, OPTI Medical 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.** OPTI Medical 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 whom to turn to 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. In order to further encourage open lines of communication regarding potential violations, we have established a toll- free compliance line to allow individuals who want to report anonymously to do so.

**5. Auditing and Monitoring.** OPTI Medical’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 sales force personnel. We note that in accordance with the OPTI Medical policies and procedures, 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.**

OPTI Medical’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, OPTI Medical 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.

**OPTI Medical Systems, Inc. 2015 DECLARATION OF COMPLIANCE**

As part of our continued efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations. Consistent with industry practice and various government guidance documents, we have tailored our Comprehensive Compliance Program to the nature of our business as a medical device manufacturer. The medical device industry has established, and OPTI Medical’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 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, OPTI Medical 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.

OPTI Medical has developed a Comprehensive Compliance Program that we believe meets the compliance goals set forth by the States of California, Connecticut, Massachusetts, and Nevada. 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 1-800-490-6784.

*Last updated: March 04, 2016*

Signed: \_\_\_\_\_



*Theron Gober  
Director Regulatory Affairs*