iRhythm Technologies, Inc. California Comprehensive Compliance Program

Introduction

Committed to establishing and maintaining the highest standards of ethical practice, iRhythm, Technologies, Inc. ("iRhythm or "Company") in conjunction with its Board of Directors and Senior Management, has created a Comprehensive Compliance Program ("Program"). For purposes of California Health and Safety Code § 119402, this Program constitutes the iRhythm Comprehensive Compliance Program, which is designed in accordance with the Compliance Program Guidance published by the Office of Inspector General, U.S. Department of Health and Human Services ("HHS-OIG Guidance"). Since iRhythm is a medical device company – not a pharmaceutical company – certain guidance set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Healthcare Professionals" is not applicable to our Program. Accordingly, iRhythm has adopted the "Code of Ethics on Interactions with Healthcare Professionals" issued by the Advanced Medical Technology Association ("AdvaMed Code").

iRhythm makes this declaration available on this website and a written copy of the Company's California Comprehensive Compliance Program and Declaration For California Compliance Law may be obtained by calling 1-888-693-2401.

1. Purpose

The purpose of the Program is to prevent and detect any violations of law or Company policy, which accords with California Health and Safety Code § 119402. Consistent with HHS-OIG Guidance, iRhythm has tailored its business as a medical device manufacturer and implemented the Program to deal with any such violations. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper conduct will be entirely eliminated. Nonetheless, iRhythm expects its employees, officers, and directors, as well as its distributors, agents, and independent contractors[1] to comply with its Code of Ethical Business Conduct (the "Code") and the policies established in support of the Code.

The Code promotes ethical and professional behavior by employees and applicable third parties as described above. In the event that iRhythm becomes aware of potential violations of law or Company policy, iRhythm will, where appropriate, investigate the matter and take disciplinary action and implement corrective measures to prevent future violations.

[1] "Independent contractors" refers to personnel who perform the type of core job function or services on behalf of iRhythm that would otherwise be provided by an employee.

2. Description

iRhythm has provided below a description of its Program. iRhythm regularly reviews and enhances its Program to meet its evolving compliance needs, the voluntary standards established by the HHS-OIG Guidance, and its unique environment and size of the Company.

Overview of the Compliance Program

1. Written Standards

The Code is the statement of ethical and compliance principles that guide daily operations at iRhythm. The Code establishes that iRhythm expects its employees to act in accordance with law and applicable Company policy. The Company's fundamental principles, values, and framework is articulated throughout the Code for within its organization.

The HHS-OIG Guidance has identified several potential risk areas for medical device manufacturers, and called on companies to develop compliance policies in these risk areas. As relevant to medical device manufacturers, these risk areas include: (i) data integrity pertaining to government reimbursement practices and (ii) kickbacks and other illegal remuneration.

Along with the Code, iRhythm has adopted the AdvaMed Code to address these specific risk areas. Furthermore, the Company has established an annual dollar limit of $3,000 for promotional materials, or other transfers of value including items or activities that iRhythm employees may give or otherwise provide to an individual medical or health care professional ("HCP"). This limit represents an annual spending cap and not an average or target. In most instances the amount spent per HCP will be substantially less than this annual limit.

2. Leadership and Structure

The iRhythm Compliance Officer (the "Compliance Officer") shall be the individual to oversee the Program. He or she shall serve as the focal point for compliance activities; however, iRhythm expects every employee to operate with the professional and ethical responsibilities designated within the Code. iRhythm is committed to ensuring that the Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. To assist the Compliance Officer in providing effective leadership and oversight to the Program, iRhythm has created a Corporate Integrity Steering Committee, which is constituted of appropriate executive and management officials.

The Nominating and Corporate Governance Committee and Audit Committee are the Board-designated committees that oversee the development and refinement of the Program and advise the Compliance Officer.

3. Education and Training

A critical element of our Program is the education and training of relevant personnel on their legal and ethical obligations under applicable federal healthcare program requirements. iRhythm is committed to effectively communicating its standards and procedures to all personnel.

4. Communication

iRhythm is committed to fostering dialogue between management and employees. The Company's 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. In order to further encourage open lines of communication regarding potential violations, we have established a toll-free phone line at 1-844-884-0117 and web portal for anonymous reporting at irhythmethics.ethicspoint.com.

5. Auditing and Monitoring

The iRhythm Program includes efforts to monitor and evaluate compliance with the Company's compliance policies and procedures. In accordance with the HHS-OIG Guidance, the nature of the Company's reviews, as well as the extent and frequency of its compliance monitoring and auditing, varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

6. Responding to Past and Potential Violations

iRhythm requires a prompt and diligent response to potential violations of the Company's Program and the Code. Actions in response to detected problems may include improving policies, procedures, training, communications, and monitoring, and may require disciplinary action to prevent 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, the iRhythm 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 the Company's policies, practices, or internal controls, and take action to prevent future violations.

Declaration For California Compliance Law

As part of iRhythm's ongoing efforts in the area of compliance, the Company has developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, iRhythm is in compliance with the Company's Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402.

Last Updated: August 30, 2024