

California 2019 Compliance Policy and Declaration

NOTICE: this information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products.

I. INTRODUCTION

QOL Medical, LLC (“QOL”) has established a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, QOL recognizes that adherence to these standards can be furthered through a compliance program that is informed by the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guide”). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of QOL’s program for compliance with the standards regulating the marketing and promotion of its products. In addition, QOL has implemented and maintains a website (www.qolmed.com) and 800 number (866-469-3773 option 6) to facilitate communication and requests for information related to California State requirements.

II. OVERVIEW OF COMPLIANCE PROGRAM

1. Written Policies and Procedures

QOL has written policies to assure substantial compliance with the applicable laws, regulations, and standards governing the marketing and promotion of our products. QOL follows the spirit of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) *“Code on Interactions with Healthcare Professionals.”* QOL has established written policies that govern activities involving communicating with healthcare professionals and patients about the appropriate use of our products, including appropriate instruction and education required for the safe and effective use of our products. QOL also has policies governing activities involving the advancement of scientific and educational activities supporting medical research and education. These policies include:

Policy on Educational Grants and Research Grants

QOL may provide grants for specific educational purposes that benefit patients and healthcare professionals. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners.

Research grants to support physician-initiated research may be provided for programs involving research in areas of legitimate interest to the company. All requests are subject to scientific review prior to funding approval.

Policy on Charitable Contributions and Patient Assistance

QOL will consider charitable contributions and requests for patient assistance for costs associated with the maintenance and care of Congenital Sucrase Isomaltase Deficiency (CSID) for patients meeting reasonable, verifiable, and uniform eligibility requirements.

Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings

QOL may reimburse attendees for their reasonable travel and lodging expenses associated with attendance at training meetings conducted by QOL. Training meetings will be conducted in locations conducive to the exchange of information such as educational or conference settings. Where face-to-face healthcare professionals training is reasonably necessary for the safe and effective use of QOL products is required, QOL may provide training at company facilities, at independent teaching centers such as medical institutions, or in other appropriate clinical settings.

Policy on Business Meals

QOL may occasionally offer a modest meal as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation and attendance by spouses or guests are not permitted.

Policy on the Provision of Educational and Practice-Related Items

On occasion, QOL representatives may provide items that benefit patients or serve a genuine educational function for healthcare professionals.

Total Annual Dollar Limit for Meals, Educational, or Practice-Related Items Training Expenses and Expense Reimbursement for Training Meetings

QOL has established an annual limit of \$3,000 for meals and educational items as the aggregate value of the items or activities that may be provided to California healthcare professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).

Policy Prohibiting Entertainment

It is the policy of QOL not to provide Entertainment (e.g. sporting events, golf outings, concerts, etc.) to healthcare professionals.

2. Assigned Compliance Officer

QOL has a Compliance Officer. Our Compliance Officer is empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management and board of directors.

QOL has a Compliance Committee. The committee is comprised of the company's Compliance Officer and members of the company's management team.

3. Training

QOL has an annual Compliance Training process. New employees receive training at the time of hire and annually thereafter. The training covers applicable guidelines governing our compliance program. Employees are trained on the consequences of failure to comply with the requirements of the company's compliance program.

4. Communication

QOL encourages open and candid discussion between management and employees regarding any compliance concern. QOL employees are encouraged to report their concerns to their manager, the Legal Department, or to the Compliance Officer. Employees also have the option to report potential violations using the QOL Medical Compliance Hotline at (866) 469-3773 x1011.

5. Auditing and Monitoring

QOL self-assesses and periodically audits its compliance with its policies and procedures.

6. Enforcement and Disciplinary Guidelines

QOL may will take disciplinary action, up to and including discharge/termination, in response to violation of the company's compliance policies or procedures. QOL will conduct an investigation of matters that are brought to the company's attention in order to ensure the consistent application of the company's standards.

7. Responses to Detected Problems and Actions to Correct Issues

QOL requires a prompt and diligent response to potential violations of the company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies, procedures, training, communication, and monitoring, or may require disciplinary action to prevent future violations.

I. DECLARATION FOR CALIFORNIA COMPLIANCE LAW

As part of QOL's ongoing efforts in the area of compliance, we have 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, QOL is in compliance with our Comprehensive Compliance program, as described here, and with California Health & Safety Code sections 119400-119402.

Last updated: October 14, 2019