

Draeger Medical Compliance Program Policy

Introduction:

Draeger Medical comprised of Draeger Medical, Inc. and Draeger Medical Systems, Inc., is committed to reducing fraud and abuse; enhancing health care provider operation function; improving the quality of health care services; and reducing the cost of health care. We conduct our business practices to assure compliance with applicable statutes, regulations and requirements of federal and state health care programs. The Draeger Medical Compliance Program (Compliance Program) provides the internal controls and procedures to promote adherence to the Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers of April 2003.

The Compliance Program contains the following elements:

- Implementing written policies and procedures;
- Designating a Compliance Officer and Compliance Committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well publicized disciplinary guidelines; and
- Response to detected problems and implementation corrective action
- Internal auditing and monitoring

Policies and Procedures:

The Principles of Business and Conduct in the Dräger Group provides the global code of ethics for Draeger Medical. In addition, Draeger Medical has adopted the AdvaMed Medical Technology Association (AdvaMed) Code of Ethics in Interactions with Health Care Professionals for medical device manufacturers. Internal practices and procedures including the U.S. Sales Guidelines are established to effectively assure the integrity of data used to establish or determine government reimbursement and prevent kickbacks and illegal remuneration.

Compliance Officer and Compliance Committee:

Draeger Medical has established a Compliance Officer and Compliance Committee to effectively manage the Compliance Program for DMI and DMSI. The Compliance Officer and Committee report to the Draeger Medical Systems, Inc. President and CEO.

Members include representatives from:

Processes Quality and Regulatory, DMSI – Compliance Officer
Quality and Regulatory, DMSI - Deputy Compliance Officer
Finance, DMI
Human Resources, DMSI
Legal, DMSI

Training and Education:

Compliance training is required for all employees during orientation training. Refresher training is required for Draeger Medical employees who have regular communications with health care professionals.

Internal Lines of Reporting and Communication:

Employees are encouraged to ask questions and report problems regarding compliance issues. The Draeger Medical management team is trained to serve as a first line of communication with its employee. The Compliance Officer and Compliance Committee provide an open line of communication for the employees. The Compliance Officer/Committee serves as a contact point for reporting problems and initiating appropriate responsive actions. Confidentiality and non-retaliatory policies encourage employees to report issues. A confidential hotline (866-862-5495) to encourage open communication and reporting.

Internal Auditing and Monitoring:

Draeger Medical has established an internal auditing and monitoring program to verify that the Compliance Program is effectively and consistently implemented against its objectives and the applicable statutes, regulations and requirements of the federal and state health care programs. Audit findings are a mechanism to initiate further investigations and define corrective actions to improve the overall program.

Consistent Enforcement of Disciplinary Standards

Appropriate disciplinary actions up to termination will be taken with employees who may violate the law or company policies. For compliance-related violations, the Compliance Committee will review any violations and make the final disciplinary decision to assure that consistent responsive action is taken.

Response to Detected Problems and Corrective Action Initiatives

Reported allegations are investigated to identify the root cause of the problem. Corrective action plans are put into place to address the immediate problem. Preventative actions and process improvements are established to assure that issues are not repeated. Misconduct that may violate criminal, civil, or administrative law will be promptly reviewed by the Compliance Committee for reporting to the appropriate federal or state authority.

Annual Dollar Limit to Health Care Professionals Licensed in California

Draeger Medical has established an annual dollar limit of \$2,000 on specific gifts and promotional materials, or other items or activities per individual.

Summary:

The Draeger Medical Compliance Program is intended to assure proper business conduct with healthcare professionals. The program addresses the key elements identified in the Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers of April 2003.

Change log

Change notes
Rev 01 – Initial release
Rev 02 – revised for 2010 and amended to address requirements from revised & restated AdvaMed Code July 2009
Rev 03 – revised for 2011 <ul style="list-style-type: none">• Add change log and add Hotline phone #• Remove DMSI Finance from Committee and Deputy Compliance Officer