# Vapotherm Code of Conduct

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# **Key Definitions**

The terms defined below are used throughout this Code of Conduct. Capitalized terms used in this Policy that are not defined below are defined in throughout the Code of Conduct.

- "Attendee" means an HCP attending a Medical Education Event.
- "Agent" means those individuals, including but not limited to Independent Sales Contractors (ISCs) and distributors, authorized to act on behalf of Vapotherm.
- "Charitable Grants" means all grants, donations, contributions or payments, financial or in kind, made by Vapotherm, for a charitable purpose, and made to a Qualified Recipient.
- "Compliance Committee" means Vapotherm's Compliance Committee, which shall include, at a minimum, the Vice President of Legal Affairs & Compliance, representation from the Senior Leadership Team, and other cross functional Vapotherm Personnel (e.g. finance, human resources, U.S. & international sales, quality & regulatory, marketing, science & innovation, and clinical affairs).
- "Compliance Occurrence" means an event or series of events which a Vapotherm Personnel suspects in good faith to be Improper Conduct.
- "Compliance Policy" or "Compliance Policies" or "Policy/Policies" when used individually, means the applicable compliance policy from Vapotherm's Code of Conduct, and when used collectively, means Vapotherm's Code of Conduct, Vapotherm's Professional Conduct Principles, the AdvaMed Code of Ethics and Vapotherm's standard operating procedures, accounting practices, internal accounting controls and auditing practices.
- "Covered Contractor" means a Vapotherm contractor or a proposed Vapotherm contractor who is in a position to influence the volume or value of referrals of business between Vapotherm and its customers. The definition of a Covered Contractor includes, without limitation, sales contractors, marketing contractors, clinical contractors, and HCPs that Vapotherm has arrangements with in accordance with Vapotherm's Policy entitled "Arrangements with Healthcare Professionals" (but not including HCPs who enter into a Primary Market Research contract).

- "Employee" means a Vapotherm full time employee or an applicant for a position as a Vapotherm full time employee.
- "Event" or "Events" means any event at which one of the business purposes set forth in Section IIIA of this Policy occurs.
- "Exclusion Screen" means a screen of an Employee or Covered Contractor
  against the Restricted Party Screening Authorities, including Export-related
  Restricted, Denied, and Blocked Persons List; Sanction Programs-related Blocked
  Persons Lists; GSA Lists and OIG Lists; International Terrorist, Blocked Person,
  Wanted and Entity; and Politically Exposed Persons Lists to determine whether the
  Employee or Covered Contractor is an Ineligible Person.
- "Federal Health Care Programs" means Medicare, Medicaid and all other Federal health care programs as defined in 42 U.S.C. §1320aa-7b(f).
- "Fair Market Value" or "FMV" Means the value in arm's length transactions, consistent with general market value.

The following are indicators of Fair Market Value and may be taken into consideration for purposes of determining compensation:

- The price for similar services in the industry as a whole.
- The price of similar services in the same geographic area.
- The amount that ordinarily would be paid for like services by other comparable medical device companies, in the absence of any desire to influence referrals.

The following may <u>not</u> be taken into consideration in determining Fair Market Value:

- The added value of obtaining the HCP Services from a customer.
- The purchases expected to be made for Vapotherm products by a customer.
- Whether a customer or others under his/her direction or control, has influenced or could influence a purchasing decision with respect to Vapotherm products.

- The volume or value of business generated between Vapotherm and the contracting party or others under his/her direction or control.
- "Fair Market Value Analysis Tool" means the reference tool(s) obtained from an objective third party that uses accumulated data to provide a fair market value analysis either by way of a reference table, online platform, software product, or otherwise, that permits the user to calculate a fair market value for services by an HCP when considering the curriculum vitae of the HCP.
- "GSA Lists" means the "Excluded Parties List System" and the "System for Award Management" lists maintained by the General Services Administration. Both lists are available at https://www.sam.gov/. Vapotherm subscribes to a third-party compliance screening service that incorporates the GSA List in its review criteria.
- "Government Investigations" means any formal investigation of, or legal proceeding against Vapotherm undertaken or brought by a governmental body or agent thereof. For the purposes of this Policy, the term Government Investigation does not encompass a routine FDA, distributor, or supplier audit.
- "HCP Services" Means (1) general consultant or advisory board member bona fide services performed by an HCP, or (2) market research participant *bona fide* services performed by an HCP.
- "HCP Arrangements" Means a written agreement for the provision of HCP Services.
- "HCP Consultant" Means an HCP who is engaged to perform HCP Services under an HCP Arrangement.
- "Health Care Professional" or "HCP" means those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe a Vapotherm product. HCPs include both clinical and non-clinical individuals who make or influence product related decisions of the sort listed here.
- "Improper Conduct" means conduct that is inconsistent with Vapotherm's Compliance Policies and/or illegal, unethical and otherwise inappropriate conduct.
- "Ineligible Person" means an individual or entity who or which (i) is currently excluded, debarred, suspended or otherwise ineligible to participate in the Federal Health Care Programs, (ii) has been convicted of a criminal offense related to the

provision of health care items or services covered by a Federal Health Care Program, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible; or (iii) otherwise is properly included in the TWS List, the GSA List, or the OIG List.

- "Interview Request" means a request by a government agent to participate in a voluntary interview.
- "Investigator initiated Research Grants" Refers to grants and/or equipment loans
  provided to a Qualified Recipient in connection with a third-party investigatorinitiated research agreement for scientific or clinical studies that are developed,
  approved, and executed independently of Vapotherm.
- "Medical Education Event" means a Vapotherm-sponsored medical education event designed to provide formal education and training to HCPs on Vapotherm products or related technology, benefits, risks, appropriate uses of devices, diseases, disease states and other medical conditions and their treatment in furtherance of improved clinical and/or economic outcomes. A Medical Education Event can be national or local. Medical Education Events may, but do not need to offer continuing education unit or CEU credits for respiratory therapists. Medical Education Events may not offer continuing medical education or CME credits for physicians. Medical Education Events are typically conducted directly by HCP Consultants and/or Vapotherm Employees with clinical or technical knowledge.
- "Meals" Includes any food or beverages provided by or on behalf of Vapotherm to HCPs.
- **"On Label"** means any promotion consistent with a Vapotherm product's applicable clearance or authorization documentation and the product's instructions for use.
- "OIG List" means the "List of Excluded Individuals/Entities" maintained by the Office of the Inspector General of the Department of Health and Human Services ("OIG") at <a href="http://www.oig.hhs.gov">http://www.oig.hhs.gov</a> (or any successor governmental database). If Vapotherm payroll provider offers a background screen service that includes the OIG List in its review criteria or Vapotherm otherwise subscribes to a third party compliance screening service that incorporates the OIG list in its review criteria, that service may also be used.

- "Off Label" means any promotion inconsistent with a Vapotherm product's applicable clearance or authorization documentation and the product's instructions for use.
- "Personnel" or "Vapotherm Personnel" means any Employee, officer, member of the Board of Directors or Agent of Vapotherm, including without limitation any contractor of Vapotherm involved in sales and marketing activities relating to Vapotherm's products.
- "Professional Conduct Hotline" means the anonymous, toll-free telephone Professional Conduct Hotline (US: 1-844-308-2530 or UK: +44 330 027 2187), website (www.intouchwebsite.com/VapothermProfessionalConduct) or e-mail address (VapothermProfessionalConduct@GetInTouch.com).
- "Promotional Review" means Vapotherm's Policy on Product Promotion and its promotional review processes as set out in Vapotherm's Review and External Distribution of Promotional Material policy and Social Media policy.
- "Qualified Recipients" Qualified Recipients of Grants made by Vapotherm include the following categories of recipients: (i) hospitals, community health centers or other similar health care facilities (not including physician group practices); (ii) academic medical centers and universities; (iii) patient groups; (iv) organizations exempt from federal income tax under Internal Revenue Code Sections 501(c)(3) (non-profit organizations), 501(c)(4) (social welfare organizations), and 501(c)(6) (trade and professional associations); and (v) educational conferences and training institutions.
- "Requesting Employee" refers to the Vapotherm employee (manager level or above) who identifies a need for HCP Services and submits a formal request to the Vice President of Legal Affairs & Compliance. Sales and clinical specialist personnel may supply information about HCP qualifications and HCP interest in performing HCP Services to a Requesting Employee, but absent approval from the Vice President of Legal Affairs & Compliance, may not serve as a Requesting Employee themselves. The Vice President of Legal Affairs & Compliance ensures that the requested HCP Services and corresponding contract are aligned with Vapotherm Policy.
- "Search Warrant" means a legal authorization in connection with a Government Investigation or other government inquiry for a government agent to conduct a

search subject to the parameters of the warrant and to confiscate any evidence they find.

- "Senior Leadership Team" means the Chief Executive Officer, the Chief Financial Officer and the Vice Presidents and/or Directors that report to the Chief Executive Officer. Senior Leadership Team members may appoint designees from time to time for specific matters and this term includes such designees where applicable.
- "Site Visit" means a Vapotherm-supported, pre-planned visit to Vapotherm corporate offices by an HCP with a bona fide business purpose, for which the HCP's travel expenses may be reimbursed in accordance with Vapotherm's "HCP Travel and Related Expenses Policy", but for which the HCP's service and travel time will not be compensated.
- "Subpoena" means an order issued in connection with a Government Investigation directing a person to appear and testify at a given place and time, and/or requiring a person to produce documents within the person's possession, custody, and control.
- "Terrorist Watch Screen" means a screen of an Employee or Covered Contractor
  against the terrorist watch screen list maintained by the International Trade
  Association. The list is available at http://apps.export.gov/csl-search#/csl-search If
  Vapotherm payroll provider offers a background screen service that includes the
  TWS List in its review criteria or Vapotherm otherwise subscribes to a third-party
  background screen service that incorporates the TWS List in its review criteria that
  service may also be used.
- "Vapotherm" means Vapotherm, Inc. and its subsidiaries.
- "Vice President of Legal Affairs & Compliance" means Vapotherm's Vice President of Legal Affairs & Compliance or his/her designee.

# **Introduction to Vapotherm's Compliance Program**

#### **MISSION STATEMENT**

Vapotherm is committed to building a robust, understandable, and culturally embraced compliance program through frequent training & education, monitoring, and enforcement. As Vapotherm pursues this mission, Vapotherm is committed to conducting all of its business in a law-abiding and principled fashion and Vapotherm will exercise due diligence to prevent and detect conduct that is inconsistent with Vapotherm's Compliance Policies.

Without limitation, the compliance program encompasses:

- Written Compliance Policies in the form of a Code of Conduct;
- Education and training regarding Vapotherm's Compliance Policies;
- Monitoring and auditing to ensure Vapotherm is adhering to its Compliance Policies;
- Open lines of communication and a retaliation-free work environment for reporting Compliance Occurrences; and
- Corrective and disciplinary action for Improper Conduct.

#### **COMPLIANCE ORGANIZATION AND OVERSIGHT**

The compliance organization includes a Vice President of Legal Affairs & Compliance whose responsibilities include developing, operating and monitoring the compliance program, and who is supported by a Compliance Committee. Compliance oversight is provided by Vapotherm's Board of Directors and the Senior Leadership Team as discussed in greater detail below.

#### **Vice President of Legal Affairs & Compliance:**

The Vice President of Legal Affairs & Compliance has day-to-day operational responsibility for the compliance program, and functions independently and objectively in reviewing and evaluating compliance matters as well as other compliance activities of Vapotherm. The Vice President of Legal Affairs & Compliance is responsible for developing and implementing the Compliance Policies.

The Vice President of Legal Affairs & Compliance reports directly to the Chief Financial Officer, has direct access to the Chief Executive Officer, the Senior

Leadership Team, and the Board of Directors, and may engage independent legal counsel and advisors concerning compliance activities of Vapotherm. The Vice President of Legal Affairs & Compliance reports periodically to the Chief Executive Officer, the Senior Leadership Team, and the Audit Committee of the Board of Directors on compliance activities, including the implementation and effectiveness of the compliance program.

The Vice President of Legal Affairs & Compliance has authority and resources necessary to conduct all necessary actions to meet the objectives of the compliance program. This includes the authority to review all documents and other information relevant to compliance activities.

#### **Compliance Committee:**

The Compliance Committee supports the Vice President of Legal Affairs & Compliance in fulfilling his/her responsibilities and advise the Vice President of Legal Affairs & Compliance concerning the compliance activities of Vapotherm. The Vice President of Legal Affairs & Compliance chairs the Compliance Committee, which meets on a regular basis throughout each calendar year.

#### **Compliance Oversight:**

In addition to the involvement of the Chief Executive Officer and the Senior Leadership Team, the Audit Committee of Vapotherm's Board of Directors remain informed about the content and operation of the compliance program and exercise reasonable oversight with respect to compliance activities, including the implementation and effectiveness of the compliance program.

#### WRITTEN STANDARDS OF CONDUCT, POLICIES AND PROCEDURES

Vapotherm has developed and implemented a compliance program as set forth in this Code of Conduct and formalized standard compliance operating procedures to guide the conduct of Personnel in day-to-day operations, and otherwise to prevent and detect Improper Conduct. The Code of Conduct is intended to establish a framework to ensure compliance but is not to be considered all-inclusive.

This Code of Conduct provides a general statement of the expectations of Vapotherm regarding the ethical standards that each director, officer and employee should adhere to while acting on Vapotherm's behalf. This Code of Conduct has been adopted in order to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and understandable disclosure in reports and documents that Vapotherm files with, or submits to, the Securities and Exchange Commission, and in other public communications made by Vapotherm;
- Compliance with applicable governmental laws, rules and regulations;
- The prompt internal reporting of violations of this Code of Conduct to an appropriate person or persons identified herein; and
- Accountability for adherence to this Code of Conduct.

A request for a waiver under a provision of this Code of Conduct may be made to the Vice President of Legal Affairs & Compliance must obtain the approval of Vapotherm's Chief Executive Officer to grant a waiver hereunder. In addition, a majority of the Board of Directors must approve a waiver for any director or executive officer. Vapotherm shall disclose any such waiver within four business days by either (i) filing a Current Report on Form 8-K with the Securities and Exchange Commission or, in cases where a Form 8-K is not required, by distributing a press release, or (ii) disclosing such waiver on Vapotherm's website in a manner that satisfies the requirements of the Securities and Exchange Commission.

Vapotherm's Compliance Policies are made available as applicable to all relevant Personnel at the time of hiring, following any updates, and periodically as determined by the Vice President of Legal Affairs & Compliance.

The Board of Directors reserves the right to amend any provision of this Code of Conduct at any time.

#### **INFORMATION, EDUCATION AND TRAINING**

Vapotherm has implemented a process for providing Personnel with education and training regarding the compliance program and the Compliance Policies.

#### Information:

Information relevant to the compliance program may be periodically disseminated in Vapotherm e-mail, newsletters or other publications.

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**Education and Training:** 

Vapotherm education and training includes general training sessions regarding the

Compliance Policies as are relevant to all Vapotherm's Personnel.

Beyond general training, more specific training sessions include additional information for

those Personnel members whose job requirements and responsibilities make the

additional information necessary, including, for example, Personnel who interact with

Vapotherm customers or HCPs on a regular basis.

Successful completion of required compliance education and training is required of all

Personnel. This education and training must be successfully completed within a reasonable period of time after a Personnel member begins his/her employment with or service to

Vapotherm, and periodically thereafter as required by Vapotherm.

**Records:** 

Education and training records detailing compliance training activities for all Personnel are

maintained by Vapotherm. These records must include attendance logs, descriptions of the training sessions, and copies of the material distributed at training sessions, except as

otherwise approved by the Vice President of Legal Affairs & Compliance.

PERSONNEL RESPONSIBILITIES

**All Personnel:** All Personnel have the following responsibilities under the compliance

program:

• Compliance with Vapotherm's Compliance Policies.

• Promptly reporting Compliance Occurrences.

Adherence to the compliance program, including satisfying all education and

training requirements.

Failure to adhere to the compliance program by Vapotherm Personnel, including satisfying

all education and training requirements, may result in disciplinary action and other

consequences, up to and including termination of employment.

**Leaders:** All Vapotherm leaders have the following responsibilities under the compliance

program:

- Monitoring the activities of Personnel reporting to them to ensure compliance with Vapotherm's Compliance Policies.
- Monitoring the education and training needs of Personnel reporting to them for their specific job responsibilities and ensuring that all education and training needs are fulfilled.
- Informing Personnel reporting to them of:
  - > Education and training requirements.
  - Cooperation and adherence to the compliance program responsibility.
  - Disciplinary action, up to and including termination, for Improper Conduct or failure to adhere to the compliance program.
- Preventing and detecting Improper Conduct involving Personnel reporting to them or otherwise involving their departments.

In addition to the foregoing responsibilities, all leaders will be knowledgeable about the content and operation of the compliance program, perform their assigned duties consistent with the exercise of due diligence and promote a culture that encourages ethical conduct and a commitment to compliance.

#### REPORTING PROGRAM AND NON-RETALIATION

Vapotherm has developed and implemented a reporting program that provides Personnel as well as customers, vendors and other business associates a process to report any concerns or complaints regarding the adherence of Vapotherm and its Personnel to Vapotherm's Compliance Policies. The reporting program provides avenues for both direct and indirect reporting, including a Professional Conduct Hotline for anonymous reporting. The reporting program includes without limitation procedures for confidential, anonymous submission of concerns regarding questionable accounting, internal accounting controls or auditing matters. Concerns will be directed to the applicable department for resolution, and in the case of accounting, internal accounting controls or auditing matters, to the Chairman of Vapotherm's Audit Committee of the Board of Directors.

Anonymous reporting using Vapotherm's Professional Conduct hotline is available 24 hours by phone at 1-844-308-2530 for U.S.-based employees or +44 330 027 2187 for U.K.-based employees or by email at <a href="mailto:VapothermProfessionalConduct@getintouch.com">VapothermProfessionalConduct@getintouch.com</a> for all Vapotherm employees, consultants, and distributors.

It is the responsibility of all Personnel to promptly report Compliance Occurrences by any Personnel conducting business on behalf of Vapotherm.

Vapotherm has developed and adheres to non-retribution, non-retaliation policy for all good faith reports of Compliance Occurrences. Any individual who (i) believes that he/she is being penalized in any way for reporting a Compliance Occurrence in good faith, (ii) believes that there has been cover up of the action disclosed, or (iii) does not believe that he/she has had a satisfactory response to his/her disclosure should communicate the same to the Vice President of Legal Affairs & Compliance or the Professional Conduct Hotline.

For more on Vapotherm's Reporting and Non-Retaliation policy, please refer to Vapotherm's Policy on "Reporting, Internal Investigations, Corrective Actions, and Non-Retaliation".

#### **INTERNAL INVESTIGATIONS**

Upon receipt of reasonable indications of possible Improper Conduct, the Vice President of Legal Affairs & Compliance will conduct a prompt internal investigation. Alternatively, the Vice President of Legal Affairs & Compliance may have an investigation conducted by external auditors, lawyers or some other external entity.

While the exact nature and level of thoroughness of the internal investigation will vary according to the circumstances, the investigation and any subsequent report will focus on factual findings concerning the veracity of the possible Improper Conduct and, when such Improper Conduct is determined to exist, determining the scope and underlying cause of the Improper Conduct.

Once an internal investigation is complete, the Vice President of Legal Affairs & Compliance will inform the appropriate parties of the investigation outcome and any corrective actions to be taken.

For more on Vapotherm's Internal Investigation policy, please refer to the "Vapotherm Policy on Reporting, Internal Investigations, and Corrective Actions, and Non-Retaliation".

#### **CORRECTIVE AND DISCIPLINARY ACTIONS**

The Vice President of Legal Affairs & Compliance will make a recommendation to Human Resources as to whether corrective action is warranted from reports on investigations, and the form such corrective action will take. Corrective actions may include, but are not limited to, the following: new or modified standards of conduct, policies or procedures, education and training, changes to monitoring and auditing, or disciplinary action.

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For more on Vapotherm's Corrective and Disciplinary Actions policy, please refer to the

"Vapotherm Policy on Reporting, Internal Investigations, and Corrective Actions".

**HUMAN RESOURCES PRACTICES** 

Vapotherm seeks to hire and promote individuals who will perform their assigned duties consistent with the exercise of due diligence and the promotion of a culture that

encourages ethical conduct and a commitment to compliance. Vapotherm has implemented policies and procedures to screen potential employees to the extent required

by law and to review with departing employees their employment experience (i.e., exit

interviews).

Vapotherm precludes the hiring of any Ineligible Person as is set forth in Vapotherm's

policy entitled "Exclusion Screening".

Vapotherm is committed to following all applicable wage and hour laws and regulations.

To help ensure that all work performed for the Vapotherm is compensated correctly, employees compensated on the basis of hours worked must report and record time

accurately in accordance with established local procedure.

**MONITORING AND AUDITS** 

Vapotherm will conduct periodic monitoring and audits of aspects of the compliance

program.

**EXCLUSION SCREENING** 

Vapotherm will screen Employee applicants and proposed Covered Contractors against

the Restricted Party Screening Authorities.

All new Vapotherm Employees and Covered Contractors will be required to affirm in writing that the Employee or Covered Contractor is not an Ineligible Person, and that the

Employee or Covered Contractor will notify the Vice President of Legal Affairs &

Compliance immediately if the Employee or Covered Contractor learns during the course of its employment or arrangement with Vapotherm if the Employee or Covered Contractor

becomes an Ineligible Person or is otherwise subjected to an investigation that might result

in the Employee or Covered Contractor becoming an Ineligible Person.

Vapotherm shall conduct periodic reviews of the Restricted Party Screening Authorities to verify that no current Employee or Covered Contractor is an Ineligible Person.

Upon notice that a Vapotherm Employee or Covered Contractor is an Ineligible Person or subject to an investigation that might result in the Employee or Covered Contractor becoming an Ineligible Person, the Vice President of Legal Affairs & Compliance will investigate the circumstances of the situation in conjunction with the applicable Employee or Covered Contractor, the supervisor of the Employee or the Covered Contractor, the Director of Human Resources, and the Chief Financial Officer. Based on the results of the investigation, the Vice President of Legal Affairs & Compliance will make a recommendation to the Director of Human Resources (for Employees) or the Chief Financial Officer (for Covered Contractors) regarding corrective action in accordance with Vapotherm's Policy on "Reporting, Internal Investigations, Corrective Actions & Non-Retaliation".

# REPORTING, INTERNAL INVESTIGATIONS, CORRECTIVE ACTIONS AND NON RELATIATION

Vapotherm Personnel must report Compliance Occurrences by (1) calling the Professional Conduct Hotline; (2) notifying the Vice President of Legal Affairs & Compliance directly; or (3) notifying their direct manager and requesting their manager notify the Vice President of Legal Affairs & Compliance directly. Concerns will be directed to the applicable department for resolution. Personnel may choose to report Compliance Occurrences through the Professional Conduct Hotline anonymously (i.e., without providing their name or otherwise identifying themselves) to report information, including accounting, internal accounting controls and auditing matters, seek guidance, or for any other reason. In situations where the Vice President of Legal Affairs & Compliance is made aware of the reporting individual's identity, the Vice President of Legal Affairs & Compliance will take reasonable steps to maintain the confidentiality of such individual's identity. This means that such individual's identity will be disclosed to other persons only when there is an overriding reason for disclosure, such as, for example, in order to conduct a fair investigation, or in response to legal process or as otherwise required by law.

Complaints regarding accounting, internal accounting controls or auditing matters deemed creditable by the Vice President of Legal Affairs & Compliance will be promptly forwarded to the Chairperson of the Audit Committee of the Board of Directors. Complaints that are not deemed creditable will be communicated to the Chairperson of the Audit Committee of the Board of Directors no less frequently than quarterly.

Vapotherm will not tolerate any form of retaliation against Vapotherm Personnel who report a Compliance Occurrence in good faith. Retaliation is prohibited even if it is determined that the allegedly improper conduct was proper or did not occur, provided that the report was made in good faith. Prohibited retaliation includes, but is not limited to, terminating, suspending, demoting, failing to consider for promotion, harassing or reducing the compensation of any Personnel. Notwithstanding the foregoing:

This Policy shall not be interpreted in a manner that prevents, limits, or delays Vapotherm from taking disciplinary action, up to and including termination, against any Personnel who abuse this procedure, for example, by reporting a matter as a Compliance Occurrence without the requisite good faith basis for making a report or making a report as a means of avoiding problems with the individual's overall performance, conduct, attitude or demeanor.

No assurances will be made to Personnel who report a Compliance Occurrence regarding his/her liability for any underlying conduct involving the individual or what steps will be taken in response to the report, other than the assurance that Vapotherm will not take any type of retaliatory action against the individual for having made the report in good faith.

#### **REVISIONS TO THE COMPLIANCE PROGRAM**

This compliance program is flexible and readily adaptable to the changing needs of Vapotherm, changes in applicable laws regulations and industry standards, and identified weaknesses in the compliance program. The Vice President of Legal Affairs & Compliance will review the compliance program at least annually to ensure that it remains current and effective.

#### **HEALTHCARE LAWS AND REGULATIONS**

Vapotherm adheres to all applicable healthcare laws and regulations, including without limitation those applying to the design, testing, production, promotion, registration, clearance or approval, distribution, or sale of our products in all countries in which Vapotherm conducts business. An illustrative list of applicable health care laws can be found in the Appendix B of this Code of Conduct.

#### **POLITICAL CONTRIBUTIONS**

Federal law regulates a company's ability to make political contributions and to engage in political activities, including lobbying. Except as otherwise approved by the Vice President of Legal Affairs & Compliance, Employees shall not make any contribution of the

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Vapotherm funds, property, or services to any political party or committee, domestic or foreign, or to any candidate for or holder of any office of any government - national, state, local or foreign. This policy does not preclude, where lawful, the operation of political action committee company contributions and political contributions that have been reviewed and approved in advance by the Chief Executive Officer.

# **Our Professional Conduct Principles**

#### **VAPOTHERM'S PROFESSIONAL CONDUCT PRINCIPLES**

Vapotherm is committed to maintaining a professional culture. We also understand that guidance is most impactful when teams have ownership in its creation. To that end, Vapotherm's employees came together to establish our Professional Conduct Principles, three bedrock principles that are universally applicable and guide decision-making in their professional capacities. Vapotherm's Professional Conduct Principles are:

- 1) We are accountable to ourselves and to others for acting with integrity, respect, and empathy.
- 2) We seek continuous improvement by operating transparently and embracing open discussion.
- 3) We are engaged global citizens who value diversity, inclusion, and social responsibility.

Vapotherm's Professional Conduct Principles and this Code of Conduct may not address every situation Vapotherm employees may encounter. Many resources exist to assist Vapotherm employees in their decision-making, including Vapotherm's Senior Leadership Team, Human Resources, the Legal and Compliance department, and Vapotherm's Professional Conduct hotline. Vapotherm employees are expected to practice good judgment and ask questions when in need of guidance or clarification.

### **Our Relationships with Customers and Patients**

#### PRODUCT ARRANGEMENTS WITH CUSTOMERS POLICY

Vapotherm offers its customers numerous ways to purchase, lease, finance, rent, or otherwise use Vapotherm products. The purpose of this Policy is to set forth guidelines for all product arrangements offered and provided by Vapotherm to any HCP. Product arrangements between Vapotherm and HCPs are subject to complex laws and regulations, therefore, all such arrangements offered and provided by Vapotherm must comply with the terms of this Policy.

#### **Ouestion & Answer**

#### What is a Sales Program?

A sales program is a business arrangement relating to the sale of Vapotherm products to a distributor or an end-user customer. The definition of a Sales Program is limited to the business and/or legal details of the offer or arrangement itself, not the promotional statements, materials, or other activities associated with the deal.

This Policy applies to all Vapotherm Personnel who are involved in discussing, negotiating and/or entering into Sales Programs with distributors and end-user customers on behalf of Vapotherm. This Policy does not apply to promotional materials relating to a Sales Program. Product Promotion is addressed separately in Vapotherm's Policy on "Product Promotion".

The Vice President of Marketing or his/her designee will distribute to all appropriate Vapotherm
Personnel information about Sales Programs offered by Vapotherm that have been approved by the Vice

President of Legal Affairs & Compliance and, as applicable, the Vice President of Marketing, the Chief Financial Officer, the Vice President of US Sales and/or the Vice President of International Sales. Absent approval from the Vice President of Legal Affairs & Compliance:

- No Vapotherm Personnel may permit a distributor or end-user customer to purchase a Vapotherm product outside of an approved Sales Program.
- All Vapotherm Personnel must use the most current form agreement for each Sales Programs.

 All Sales Program contracts must be signed by the Chief Executive Officer, the Chief Financial Officer, or their designee.

#### PRODUCT PROMOTION POLICY

The purpose of this Policy is to set forth guidelines for promoting products of Vapotherm to persons outside the company. Promoting Vapotherm medical device products requires operating in compliance with the

#### **Ouestion & Answer**

#### What is Promotion?

Promotion is any action that encourages the purchase, lease, recommendation, use, arrangement for the purchase or lease of, or prescription of a Vapotherm product. The definition of the term "Promotion" does not include the business or legal terms or a particular arrangement itself.

Food, Drug and Cosmetic Act ("FDCA"), its international equivalents, and all related regulations. The United States Food and Drug Administration ("FDA") and its international equivalents have cleared each Vapotherm product on the market for use only as described in the applicable clearance or authorization documentation and incorporated into each product's instructions for use. Although HCPs may use a product Off Label in accordance with their independent, professional judgment, Vapotherm may not solicit, encourage, or promote Off Label uses of its products.

This Policy governs <u>all</u> activities designed to promote Vapotherm products, including <u>without limitation</u>, sales calls, in-office programs, speaker programs, and exhibits/displays at trade shows or third-party educational conferences. All Vapotherm Personnel must comply with this Policy and Vapotherm's Review and External Distribution of Promotional Material policy and Social Media policy in the performance of all promotional activities.

This Policy does not govern the distribution by Vapotherm of truthful and non-misleading Off Label information in scientific articles, reference texts, or clinical practice guidelines in accordance with applicable laws, rules, and regulations. The distribution of such materials is governed by Vapotherm's Review and External Distribution of Clinical Material policy. Nor does this Policy govern the details of an arrangement for the sale of Vapotherm products. Sales Programs are addressed separately in Vapotherm's Policy on "Product Arrangements with Customers".

**Promotion Requirements:** All Vapotherm Personnel are prohibited from initiating discussion of, soliciting, or promoting unapproved uses of Vapotherm products and must comply with the requirements listed below. For Vapotherm Personnel in the field, including those designated as sales and clinical Personnel, this Policy is particularly important, because they are the segment of Vapotherm employees who most frequently

interact with Vapotherm customers and are therefore likely to have their communications viewed by others as having a promotional purpose. Absent approval from the Vice President of Legal Affairs & Compliance and/or the Vice President of Quality and Regulatory, Vapotherm Personnel must always remember to:

- Promote only to HCPs who treat an On-Label patient population.
- Use only promotional materials that are reviewed and approved in accordance with Vapotherm's Promotional Review process, are consistent with the current product label/indications for use, and promote a validated use of our products. Vapotherm Personnel may not:
  - **1.** Use or distribute homemade materials or information about a Vapotherm product obtained from another source that has not been reviewed and approved in accordance with Vapotherm's Promotional Review policies; or
  - 2. Alter any promotional materials reviewed and approved in accordance with Vapotherm's Promotional Review policies, including underlining or highlighting. This requirement is intended to preclude Vapotherm Personnel from altering the content and appearance of approved promotional materials. It is not intended to prevent Personnel from combining two approved slide presentations or removing or reordering slides from approved presentations.
- Forward requests for publications or information on unapproved uses to Vapotherm's Vice President of Science and Innovation or Vapotherm's Director of Scientific and Clinical Affairs or anyone in Vapotherm's Scientific and Innovation department.
- Ensure references to the efficacy (e.g. clinical and physiological outcomes) of a competitor's products must be supported by reliable data and analysis and be approved in accordance with Vapotherm's Promotional Review process.
- Never initiate discussion of, solicit, or prompt questions about Off-Label uses of Vapotherm products. Generally, a Vapotherm Representative may only respond to unsolicited (meaning not prompted) Off-Label questions only by stating and/or doing the following. This approach applies regardless of the forum in which the Off-Label question is raised.

- 1. "I can't answer questions that relate to the Off-Label use of Vapotherm products" or "Vapotherm has not validated equipment, collected data, or submitted to the applicable regulatory agency for that use so I cannot speak to the benefits/risks."
- 2. If the inquirer persists with questions, Vapotherm Personnel must direct the inquirer to Vapotherm's Vice President of Science and Innovation or Vapotherm's Director of Clinical and Scientific Affairs if he/she has further questions.
- **3.** If appropriate, and if directed privately to the inquirer, Vapotherm Personnel may also offer to provide the inquirer with in-servicing or training in accordance with the On-Label use of Vapotherm's products and/or provide the inquirer with promotional materials reviewed and approved in accordance with Vapotherm's Promotional Review SOPs.

Notwithstanding the foregoing, however, Vapotherm makes patient safety its highest priority. In the interest of patient safety, when a physician has decided to use a Vapotherm product for an unapproved use (or decided to use a Vapotherm product in a manner inconsistent with the approved use or labeling), Vapotherm Personnel may provide routine technical support <u>during</u> such procedures or <u>in</u> such environments. Any response to a question regarding an unapproved use in such a situation must be oral, narrowly tailored to the question asked, and may not be promotional in nature. Where a question regarding an unapproved use is raised <u>before</u> such a situation arises, Vapotherm Personnel must reply as set forth in bullets #1, #2, and #3 immediately above.

- When Vapotherm Personnel refer unsolicited Off Label inquiries to Vapotherm's Vice President of Science and Innovation or Vapotherm's Director of Scientific and Clinical Affairs or provides an in-service or training in accordance with the On-Label use of Vapotherm's products to an inquirer, the Vapotherm Personnel should record summary information detailing Off Label inquiries, including the following information, as applicable:
  - 1. The On-Label Promotion that prompted the Off Label inquiry (if applicable);
  - 2. The unsolicited Off Label inquiry and the response provided;
  - **3.** Identification of any On Label promotional materials that were left behind.

This summary information should then be promptly submitted to the Compliance Administrator at complianceadmin@vtherm.com.

#### **NOTE:**

**Suggested Documents:** If a Vapotherm Representative has a suggestion for new promotional materials or changes to existing promotional materials, the proposed suggestion shall be submitted for review in accordance with Vapotherm's Promotional Review process.

#### POLICY ON VAPOTHERM-SPONSORED MEDICAL EDUCATION EVENTS

Vapotherm has a responsibility to provide information, education, and training to Healthcare Professionals regarding the safe and effective use of Vapotherm products. The purpose of this Policy is to set forth guidelines for Medical Education Events sponsored by Vapotherm and presented by HCP Consultants.

#### **Ouestion & Answer**

#### What is a Medical Education Event?

A Medical Education Event is a Vapotherm-sponsored medical education event designed to provide formal education and training to HCPs on Vapotherm products or related technology, benefits, risks, appropriate uses of devices, diseases, disease states and other medical conditions and their treatment in furtherance of improved clinical and/or economic outcomes. A Medical Education Event can be national or local. Medical Education Events may, but do not need to offer continuing education unit or CEU credits for respiratory therapists. Medical Education Events may not offer continuing medical education or CME credits for physicians. Medical Education Events are typically conducted directly by HCP Consultants and/or Vapotherm Employees with clinical or technical knowledge.

#### What is an Attendee?

An Attendee means an HCP attending a Medical Education Event.

**Faculty:** HCP Consultant faculty must have the proper qualifications and expertise to conduct the Medical Education Event and must have a currently effective Consulting Agreement with the faculty member, as required by Vapotherm's Policy on "Arrangements with Healthcare Professionals". HCP Consultant faculty must be selected by Vapotherm's Medical Education, Marketing, or Science and Innovation teams. Sales personnel may

request a medical education event, but do not control HCP Consultant faculty selection for the event.

**Faculty Compensation:** All compensation to HCP Consultants serving as faculty must be provided in accordance with the faculty member's Consulting Agreement and the procedures set forth in Vapotherm's Policy on "Arrangements with Healthcare Professionals". HCP faculty members may not be provided any compensation for time spent performing clinical procedures in connection with a Medical Education Event, as the faculty member is likely receiving reimbursement from a third party payer for his/her professional services. The HCP Consultant expenses associated with Medical Education Events must be paid out of a corporate, non-sales budget.

**HCP Disclosure:** Vapotherm's contracts with HCP Consultants serving as faculty for a Medical Education Event will require the HCP to affirmatively and effectively disclose their affiliation with Vapotherm when interacting with third parties on behalf of Vapotherm during a Medical Education Event. The scope of such disclosure is described in the procedures portion of Vapotherm's Policy on "Arrangements with Healthcare Professionals".

#### **Attendees:**

- Only Attendees who have a bona fide professional interest in the content of a
  Medical Education Event may be invited to attend a Medical Education Event.
  Attendance at Medical Education Events by guests of Attendees (or any other
  persons) who do not have a professional interest in the information shared at
  the event is inappropriate.
- Medical Education Event content must be based on an On Label use of Vapotherm's products.
- Attendees, as a general rule, should not be affiliated with the HCP Consultant faculty for the event (e.g., in the same group practice, employed by the same office or institution, or working in the same hospital).
- Attendees may not receive an honorarium or other compensation for their time spent attending a Medical Education Event.

**Hospitality and Travel:** Vapotherm may provide faculty and Attendees with modest and reasonable meals/hospitality, travel, and lodging in connection with a Medical Education Event, consistent with Vapotherm's policies entitled "HCP Meals" and "HCP Travel and

Related Expenses". Hospitality must always be modest in value and subordinate in time and focus to the primary purpose of the Medical Education Event. Vapotherm will not pay (and no Vapotherm employee may pay) for the meals, hospitality, travel or other expenses of guests of attendees (or for any other person) who do not have a *bona fide* professional interest in the information presented at the Medical Education Event.

**Location:** Medical Education Events should be conducted in settings conducive to the effective exchange of information. A restaurant setting that is consistent with Vapotherm's Policy on "HCP Meals" may be appropriate for a Medical Education Event if the content of the Medical Education Event does not include a hands-on technique presentation. If the Medical Education Event will include a hands-on technique presentation, the Medical Education Event should be conducted in training facilities, medical institutions, laboratories, or other appropriate facilities, private rooms or conference rooms. Effort should be made to host Medical Education Events in a central location based on where the Attendees will be traveling from or an appropriate location in conjunction with a meeting or event where Attendees are known to be independently traveling to, provided such location is consistent with the foregoing requirements.

**Content of Medical Education Event:** All content and material presented in connection with a Medical Education Event must be consistent with the approved/cleared label for Vapotherm's products. All faculty must comply with Vapotherm Policies in that regard, including, without limitation, the requirement to submit all content and material to for prior approval in accordance with Vapotherm's Promotional Review process.

**Attendance by Vapotherm Employees:** The number of Vapotherm attendees shall be limited to any Vapotherm employees necessary to oversee the Medical Education Event. At least one (1) Vapotherm employee must attend each Medical Education Event to ensure that the requirements set forth in this Policy are met and that the faculty members are effectively and appropriately presenting the necessary information.

#### **POLICY ON ARRANGEMENTS WITH HCPs**

The purpose of this Policy is to set forth guidelines for Vapotherm's engagement of HCPs for the provision of services in furtherance of a legitimate, predetermined business purpose. While fair market value payments based on an arm's length negotiation for bona fide services are permissible, improper payments may raise serious legal issues, including criminal penalties and fines.

#### **Question & Answer**

#### What is an HCP?

HCP stands for healthcare professional and means any individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe a Vapotherm product. HCPs include both clinical and non-clinical individuals who make or influence product related decisions of the sort listed here.

All HCP Services within the scope of this Policy must be conducted consistent with Vapotherm's policies and procedures, including without limitation Vapotherm's Policies on "HCP Meals", the "HCP Travel and Related Expenses", and "HCP Gifts and Entertainment".

#### **Prohibited Arrangements:**

- **1.** HCP Arrangements may not be entered into as a reward to an HCP for using, purchasing, or recommending Vapotherm products or as an inducement to do so.
- **2.** HCP Arrangements may not be offered in connection with discussions, negotiations or decisions involving product pricing or purchasing.
- **3.** HCP Arrangements must not be unnecessarily duplicative of services or feedback already obtained.
- **4.** HCP Arrangements must not be entered into in a quantity that exceeds the number reasonably necessary to accomplish the *bona fide* business/scientific purpose for the arrangement.

**Meetings with HCPs:** The venue and circumstances of all meetings with HCPs must be conducive to the services being provided. Where possible, meetings should be conducted in clinical, educational, conference settings, Vapotherm offices, or other settings, including hotel or other commercially available meeting facilities (such as restaurants) that are conducive to the effective exchange of information.

**Exchange of Information:** The following guidelines will govern the exchange of information between HCP Consultants and Vapotherm:

- 1. Vapotherm should only provide information to HCP Consultants, if necessary, for the HCP Consultants to perform their services properly.
- 2. Any information provided should be tailored to the purpose of the HCP Arrangement and the desired feedback. For example, if the HCP Consultant is engaged to provide feedback on a new marketing message in a visual aid, it would be appropriate to provide the HCP Consultant with the visual aid and any sales message that would be delivered with the visual aid.
- 3. Any information and materials provided to or shared with HCP Consultants must be On Label unless there is a legitimate business need to obtain feedback on off label information (e.g., in preparation for the launch of a new cleared indication).

**Feedback:** When appropriate for the service rendered (e.g., advice regarding a Vapotherm product or disease state), the process for collecting, analyzing, and incorporating the HCP Consultant's feedback must be documented prior to obtaining the HCP Consultant's feedback.

**Compensation of HCP Consultants:** All HCP Consultants shall be paid FMV based on objective review of the HCP's qualifications to perform the services as determined via the Fair Market Value Analysis Tool then currently available. Any deviation from the FMV payment determination resulting from the aforementioned processes must be approved by the Vice President of Legal Affairs & Compliance.

**Meals, Travel, and Related Expenses:** All meals, travel, and accommodation provided to HCPs must be modest (being of moderate value, but may differ depending on regional differences) and consistent with Vapotherm's policies entitled "HCP Meals" and "HCP Travel and Related Expenses." Hospitality must always be modest in value and subordinate in time and focus to the primary purpose of the meeting. All allowable expenses must be documented and entered into Concur in accordance with applicable Vapotherm Policy.

**Prohibition of Entertainment, Recreation, and Gifts.** As set forth in Vapotherm's "Policy on HCP Gifts and Entertainment", Vapotherm will not pay for pure entertainment or recreational events for HCPs or HCP Consultants, even if provided in connection with an otherwise permissible educational event. Vapotherm also prohibits giving healthcare professionals gifts or other incentives, including all non-educational logo items.

Vapotherm may occasionally provide items that benefit patients or serve a genuine educational function for healthcare professionals, but the value of these items must be less than \$100. Any allowable educational items must be documented and submitted in accordance with Vapotherm Policy.

Promotional Review and Disclosure: If any HCP Consultant makes presentations on behalf of Vapotherm during the term of the HCP Arrangement, the presentations must be approved through Vapotherm's Promotional Review process. Additionally, unless otherwise approved by the Vice President of Legal Affairs & Compliance, the HCP consulting agreement entered into between the HCP Consultant and Vapotherm must provide that if the HCP Consultant makes presentations that address Vapotherm products during the term of the HCP Arrangement, whether or not such presentations are directly sponsored or funded by Vapotherm, the HCP Consultant must disclose that he/she is a Vapotherm HCP Consultant and receives compensation from Vapotherm for such services. As may be necessary or advisable to comply with any conflict of interest or other similar institutional policies applicable to the HCP Consultant, the HCP Consultant must make a similar disclosure to all hospitals or other health care facilities where the HCP Consultant practices medicine using Vapotherm's products, and when possible and reasonable in the course of providing treatment, to all patients (or the patient's guardian(s)) prior to using a Vapotherm product on such patient.

**Past Experience with HCPs:** Absent approval from the Vice President of Legal Affairs & Compliance, Requesting Employees shall not engage an HCP for HCP Services if the HCP was previously engaged by Vapotherm and prior services were documented as unsatisfactory in the HCP's Request for Payment.

**Clinical Trial Agreements:** Arrangements that involve clinical research services by an HCP in return for compensation are also type of consulting agreement, subject to the principles of this Code of Conduct. The clinical program for which the services are being provided should fulfill a legitimate research purpose. A written agreement should govern these arrangements.

A clinical trial agreement typically is entered between Vapotherm and an HCP that is a facility, institution, or practice group, and compensation for research services is paid to that entity. An individual HCP may act as a study investigator but also provide related services in his her or individual capacity that is outside of the scope of the services covered in the clinical trial agreement (i.e. protocol development, delivering education and presentations on Vapotherm's behalf, etc.) In that case, it may appropriate to enter a separate consulting agreement with that individual HCP.

#### **HCP MEALS POLICY**

The purpose of this Policy is to ensure that the primary focus of interactions between Vapotherm Personnel and HCPs is the communication of accurate, complete, balanced scientific and relevant product information in furtherance of a legitimate, pre-determined business purpose.

This Policy applies to all Vapotherm Personnel, and provides guidelines for their interactions with HCPs.

All Meals provided by Vapotherm to HCPs must meet the following standards.

**Legitimate Business Purpose:** The Meal is provided in connection with a legitimate business purpose and is subordinate in time and focus to the business purpose of the gathering. Examples of legitimate business purposes include, but are not limited to, the following:

- 1. Promotional activities, such as in-office visits, performed in accordance with Vapotherm's Policy on "Product Promotion."
- 2. HCP Services performed in accordance with Vapotherm's Policy on "Arrangements with Healthcare Professionals."
- 3. Training and education programs provided in accordance with Vapotherm's Policy on "Vapotherm-Sponsored Product Training and Education."
- 4. Facilitating HCP gatherings during third party educational conferences or medical congresses in accordance with Vapotherm's Policy on "Vapotherm Support of Third Party Educational Conferences."

The Vice President of Legal Affairs & Compliance must approve any HCP Meals for a purpose other than those set forth in this section.

**Time Period:** The Meal should be secondary to the legitimate business purpose and occur immediately before, during, or immediately after the applicable business event.

**Modest:** The Meal provided must be modest.

1. A Meal is modest if the cost of the Meal is both reasonable by local standards and does not exceed the applicable Vapotherm limits described below.

2. In many geographic areas, a modest Meal may be considerably less than the Vapotherm upper limit.

#### **Question & Answer**

#### What cities are deemed high-cost cities?

For the purposes of this Policy, the list of High Cost Cities includes the following: Boston, Chicago, District of Columbia, Las Vegas, Los Angeles, Miami, New York City, San Diego, San Francisco, Paris, Singapore, and Tokyo.

**Limits:** The cost of the Meal should not exceed the per person limits in the table below.

Meal	United States *tax inclusive	United Kingdom *VAT inclusive
In-Office (Breakfast/Lunch/Dinner)	\$35.00	£30.00
Out of Office Breakfast/Lunch	\$50.00	£45.00
Out of Office Dinner	\$125.00	£90.00
Out of Office Dinner (High Cost City)	\$150.00	N/A

Locations outside of the U.S. and U.K. shall adhere to Vapotherm's U.S. meal limits unless otherwise prohibited by local governing authorities or applicable codes of conduct.

These limits include all costs associated with the food and beverage provided and associated private room charges, gratuities, tax and/or delivery charges. The limits do not include the costs associated with renting audio/visual equipment for the presentation.

**Payment:** The Meal is paid for directly by the Vapotherm employee to the restaurant, caterer, or other Meal provider, on Vapotherm's behalf. Payments may not be made to an HCP, HCP's office, or healthcare institution.

**Target audience:** The Meal is provided to an appropriate target audience.

- 1. An appropriate target audience for an event facilitated by a modest Meal include those HCPs and staff necessary to achieve the legitimate business purpose (e.g. those directly involved in the clinical area related to the approved use of the Vapotherm product or related disease state being discussed).
- 2. Guests, including spouses, should not attend Meal events unless the guest/spouse would be an appropriate individual to invite to the program or

meeting independently. In no event may a Vapotherm employee pay for the guest, including a spouse, of an HCP unless the guest/spouse would be an appropriate individual to invite to the program or meeting independently.

With the exception of events where continuing medical education credits are offered, there should be an appropriate ratio between Vapotherm Personnel and HCPs at out-of-office events that take place during a meal so as to allow for meaningful discussion with all attendees.

**Venue:** The Meal is provided in an appropriate venue.

- 1. A proper venue for a Meal with HCPs is a location that allows for the presentation of information and related discussion. The venue may be a restaurant or other public eating establishment if the location allows for the presentation of information and related discussion.
- 2. Venues should be modest. Sites that are primarily for recreational activities or other entertainment are not appropriate (e.g., private boxes at sporting arenas, live musical performances, etc.)

Occasional Basis: Meals are provided on an occasional basis only.

1. An occasional basis means that Vapotherm may not provide Meals on a routine or regular basis, such as on a weekly basis for an HCP, HCP practice or institution. This includes sponsoring informational programs or presentations for the same HCPs every week or every month at different venues.

**No Entertainment:** As set forth in Vapotherm's Policy on "HCP Gifts and Entertainment", pure entertainment and recreational events may not be offered in connection with Meals. Alcohol should be consumed in moderation.

**In-Office Promotional Programs:** If a Meal or other hospitality is being provided during a promotional program that takes place in an HCP's office, the Vapotherm employee hosting the event should ask the appropriate contact person whether Meals/hospitality may be provided. Some health care facilities have instituted strict standards regarding industry-sponsored Meals and hospitality, which Vapotherm must respect.

**Meals Offered by HCPs to Vapotherm Personnel:** Vapotherm Personnel will not accept offers from HCPs to pay for their Meals.

#### **PROHIBITED MEALS**

All Meals that do not meet the requirements in the section above are prohibited unless they receive the approval of the Vice President of Legal Affairs & Compliance. For the purposes of illustration, this Policy specifically prohibits the following:

- No Meals may be provided in cash or in cash equivalents (e.g., restaurant gift certificates).
- No Meals may be provided when Vapotherm Personnel are not present (no drop and dash). Additionally, the number of meals ordered (or for catered events, the quantity of food ordered) should be proportional to the expected target audience as that term is used above.
- Only Vapotherm Employees may provide and expense Meals for HCPs. This requirement does not apply to Vapotherm's distributors; provided any such Meal is provided in accordance with the entity's distribution contract with Vapotherm.
- Vapotherm employees may not provide Meals with his/her own funds, even if the employee does not intend to seek reimbursement from Vapotherm. All expenses must be documented and submitted in accordance with Vapotherm's Compliance Policies.
- No Meals may be provided to HCPs who regularly practice in Vermont unless that Meal is a component of the HCP's FMV compensation under an HCP Arrangement.
   The Vapotherm employee planning the meal is responsible for determining if the HCP they are meeting with regularly practices in Vermont.

#### **HCP TRAVEL AND RELATED EXPENSES POLICY**

The purpose of this Policy is to ensure that the primary focus of interactions between Vapotherm Personnel and HCPs is the communication of accurate, complete, balanced scientific and relevant product information in furtherance of a legitimate, pre-determined business purpose.

This Policy applies to all Vapotherm Personnel and provides guidelines for their interactions with HCPs.

Absent approval from the Vice President of Legal Affairs & Compliance, all reimbursement and/or direct payments for travel and related expenses provided by Vapotherm to HCPs must be authorized in advance, , and must meet the following standards.

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**Legitimate Business Purpose:** Vapotherm will reimburse HCPs or pay directly for reasonable travel, and lodging expenses incurred in connection with the following legitimate business purposes:

- 1. Attendees at training events provided in accordance with Vapotherm's Compliance Policies, including the Policy on "Vapotherm-Sponsored Product Training and Education".
- 2. HCP Services performed in accordance with Vapotherm's Policy on "Arrangements with Healthcare Professionals".
- 3. HCP Services performed under a clinical trial agreement and in furtherance of the clinical research being performed.

If an employee desires to arrange for travel and lodging expenses for an Event that does not relate to a business purpose described in this section, such travel and lodging must receive the approval of the Vice President of Legal Affairs & Compliance.

**Airline Travel:** If approved by the Vice President of Legal Affairs & Compliance, Vapotherm may cover and/or arrange for an HCP's modest airline travel costs incurred in connection with an Event as follows:

- 1. For travel within North America and Central America:
  - Least expensive, unrestricted coach-class fare for the given route.
- 2. For travel outside North America and Central America -
  - For travel that has a flight time less than six hours: Least expensive, unrestricted coach-class fare.
  - For travel that has a flight time exceeding six hours: Business class or equivalent. Absent approval from the Vice President of Legal Affairs & Compliance, Vapotherm will not pay for an HCP to fly first class.

**Trains, Buses, and Rental Cars**: If approved by the Vice President of Legal Affairs & Compliance, Vapotherm may cover and/or arrange an HCP's reasonable train, bus, and rental car travel costs incurred in connection with an Event.

**Lodging:** If approved by the Vice President of Legal Affairs & Compliance, Vapotherm may cover and/or arrange an HCP's modest lodging expenses at a business class hotel incurred in connection with an Event. Lodging must be reasonable in price for the geographic location and conveniently located in relation to the Event.

**Personal Vehicles:** If approved by the Vice President of Legal Affairs & Compliance, Vapotherm may cover and/or arrange an HCP's modest car travel costs incurred in connection with an Event where an HCP travels by personal vehicle in accordance with the following standards:

- 1. Vapotherm will reimburse HCPs pursuant to the standard mileage reimbursement rate as published by the IRS (or other local taxing authority as applicable for Events outside of the US) for actual driving distance by direct route and will reimburse for parking and tolls. Notwithstanding the foregoing, Vapotherm will not reimburse for commuting mileage which consists of travel between home and HCP's regular place of work, unless otherwise approved by the Vice President of Finance.
- 2. If an HCP chooses to drive rather than fly to a business destination, mileage reimbursement may not exceed the lowest reasonable airfare between the HCP's local airport and the location of the Event. In such case, Vapotherm will determine the lowest reasonable airfare from Vapotherm's corporate travel agency or via Vapotherm Personnel internal research.
- 3. Vapotherm does not reimburse for gas, oil, services and parts, car washes, towing charges, insurance, or repairs to a personal vehicle.

**Other Transportation:** If approved by the Vice President of Legal Affairs & Compliance, Vapotherm will reimburse HCPs for reasonable transportation expenses incurred in traveling to and from the Event and the HCP's accommodations, including taxis, Uber, subways, and similar transportation.

#### **PROHIBITED EXPENSES**

All travel and lodging expenses that do not meet the requirements outlined in this Policy are prohibited unless they receive the approval of the Vice President of Legal Affairs & Compliance. For the purposes of illustration, examples of travel and lodging expenses that do not meet the requirements in this policy include:

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Additional costs for transportation, meals, and lodging incurred when personal

travel is combined with a business trip.

• Car rental costs over standard vehicle model or level.

Personal entertainment or recreational activities.

• Costs of guests not separately participating in the Event.

• Excess baggage charges (e.g. charge for a second checked bag absent a

predetermined business need).

Loss of or damage to personal property during travel.

Additional hotel charges, such as telephone calls and movies.

• Fines for traffic violations, parking tickets, and towing charges.

Travel insurance premiums.

Dry cleaning or laundry costs.

HCP GIFTS AND ENTERTAINMENT POLICY

The purpose of this Policy is to ensure that the primary focus of interactions between Vapotherm Personnel and HCPs is the communication of accurate, complete and balanced scientific and relevant product information in furtherance of a legitimate, pre-determined

business purpose.

This Policy applies to all Vapotherm Personnel and provides guidelines for their

interactions with HCPs.

**GIFTS POLICY** 

**Scope of Policy:** This Policy addresses Gifts between Vapotherm Personnel and HCPs only. This Policy is not intended to address the legitimate practice of

providing appropriate sample products and opportunities for product evaluation.

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#### **Question & Answer**

## What is the difference between a gift and an educational item?

An **Educational Item** for use by an HCP that directly relates to Vapotherm's technology and serves a genuine educational function. Examples of Educational Items include anatomical models or medical textbooks for use in an HCP's office that can be used for educational purposes to enhance patient care.

A **Gift** is anything of value given or received by Vapotherm Personnel, without payment or without an even exchange of services from the other party.

Permissible Gifts: Only Educational Items are permissible as gifts. All Educational Items must be through the applicable Promotional Review process and must have a retail value of \$100 or less. No HCP may receive more than \$300 worth of Educational Items per year from Vapotherm.

**Prohibited Gifts:** All gifts that do not meet the requirements in this section above are prohibited unless specifically approved by the Vice President of Legal Affairs &

Compliance. Gifts may not in any circumstance be provided or received that directly or indirectly influence or reward the purchasing, leasing, recommending, using or arranging for the purchase or lease of, a Vapotherm product. For purposes of illustration, this Policy specifically prohibits the following:

- Cash or cash equivalents (e.g., gift certificates)
- Gifts provided to an HCP, in a manner inconsistent with this Policy, and purchased with the Vapotherm employee's or agent's own funds, even if the employee or agent does not intend to seek reimbursement from Vapotherm.
- Gifts for the personal benefit of a HCP or HCP's family member (e.g., flowers, gift baskets), even when they bear a company or product logo (e.g., clothing, golf balls, pens, stress balls, and other low-dollar Vapotherm promotional material).
- Gifts of tickets to recreation or entertainment events.
- Meals, travel, or other hospitality provided without a legitimate business purpose (as described in Vapotherm's Compliance Policies entitled "HCP Meals" and "HCP Travel and Related Expenses".
- Gifts received by Vapotherm Personnel from HCPs.

#### NO ENTERTAINMENT POLICY

Paying for pure entertainment and recreational events for HCPs is strictly prohibited because Vapotherm-sponsored entertainment may be viewed as inappropriately influencing the decisions of HCPs. Examples of prohibited entertainment include, but are not limited to, attendance at sporting events, golf outings, concerts, theatre events or festivals.

### POLICY ON SUPPORT OF THIRD PARTY EDUCATIONAL CONFERENCES

Vapotherm may support legitimate independent educational, scientific, or policymaking conferences and trade shows that promote scientific knowledge, medical advancement and the delivery of effective health care (e.g. educational grants, meals and hospitality, faculty expenses, advertisements, and demonstration).

#### **Ouestion & Answer**

## What are Third Party Educational Conferences (TPECSs)?

**TPECs** are legitimate independent, educational, scientific, or policymaking conferences and trade shows that promotes scientific knowledge, medical advancement, and/or the delivery of effective healthcare. **Attendees** are HCPs attending a TPEC.

# STANDARDS FOR THIRD PARTY EDUCATIONAL CONFERENCES

The TPEC provider must be responsible for and retain complete control over the event, including program structure, content, speakers, and invitation lists. Examples of TPECs generally include:

- 1. Conferences sponsored by national, regional, or specialty medical associations; and
- 2. Conferences sponsored by hospitals or universities

#### TPECs do not include:

- 1. Programs focused on business topics, such as running a practice;
- 2. Routine staff meetings that do not involve a presentation by an outside speaker;
- 3. Vapotherm-Sponsored Product Training and Education as set forth in Vapotherm's Policy on "Vapotherm-Sponsored Product Training and Education".

#### SUPPORT OF THIRD PARTY EDUCATIONAL CONFERENCES BY VAPOTHERM

Vapotherm may support TPECs only in the following ways:

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**Conference Grants:** Grants may be provided to TPECs to reduce the costs of the conference. Grants may also be provided to TPECs (or training institutions) to allow attendance by medical students, residents, fellows, and others who are HCPs in training; provided, however, the TPEC (or training institution) selects the attending HCPs who are in training.

**Modest Meals and Refreshments:** Vapotherm may provide funding to TPECs to provide attending HCPs with items of value permissible under Vapotherm's Code of Conduct, such as meals, refreshments, and Educational Items, but only if the meals, refreshments or Educational Items are modest in value, subordinate in time and focus to the purpose of the conference and are provided in a manner consistent with the TPEC's guidelines and Vapotherm's Policies on "HCP Meals" and "HCP Gifts and Entertainment". Any meals or refreshments provided by Vapotherm directly to Attendees in connection with a TPEC must also meet each the above requirements.

**Faculty & Non-Faculty Attendee Expenses:** Vapotherm may make grants to TPECs for reasonable honoraria, travel, lodging, and meals for HCPs who are *bona fide* faculty members. Vapotherm may not make any direct payments to HCPs who are faculty at TPECs for participating in or attending the conference unless in connection with a "product theater" arrangement whereby Vapotherm purchases a time-slot and is free to present content of its choosing or otherwise permissible by TPEC policies and procedures. In either case faculty must be under contract with Vapotherm in accordance with Vapotherm's Policy on "Arrangements with Healthcare Professionals."

Vapotherm may not pay honoraria, travel, or other expenses of non-faculty Attendees unless in connection with a bona fide consulting arrangement in which HCP is performing legitimate consulting services at the TPEC on behalf of Vapotherm. In this case, the HCP must be under contract with Vapotherm in accordance with Vapotherm's Policy on "Arrangements with Healthcare Professionals."

**Advertisements and Demonstration:** Vapotherm may purchase advertisements and lease booth space for company displays at TPECs. Such displays must comply with any applicable TPEC requirements as well as the requirements set forth in Vapotherm's Policy on "Product Promotion".

Vapotherm will support TPECs only in the ways set forth in this Policy and only if the TPEC satisfies all of the following standards:

**Basis for Decision:** The decision to support a TPEC should be made on the basis of the program topic and content. It should not be made on the basis of, for example, the TPEC

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speakers, moderators, attending HCPs, or location. Vapotherm generally supports TPECs that relate to a disease state or condition of interest to Vapotherm. The title of the program should not mention an off-label use of a Vapotherm product.

- 1. **Program Content:** The program content must remain in the control of the TPEC provider and independent from Vapotherm influence unless in connection with a "product theater" arrangement whereby Vapotherm purchases a time-slot and is free to present content of its choosing or otherwise in accordance with the TPEC's policies and procedures. Unless in connection with a "product theater" event or otherwise in accordance with the TPEC's policies and procedures, Vapotherm may not suggest speakers for a TPEC unless the TPEC provider makes an unsolicited request for speaker suggestions, in which case Vapotherm may provide a recommendation for a speaker in response (including one of Vapotherm's own employees). If Vapotherm recommends a HCP, Vapotherm should provide at least two (2) HCP recommendations when reasonably possible. Any recommendations must be based on the clinical skill of the persons selected; it may not be based upon product usage or other arrangements between Vapotherm and the persons suggested. If Vapotherm suggests a person who has an employment or a contractual arrangement with Vapotherm, this affiliation must be disclosed to the TPEC provider. The TPEC provider must make the ultimate selection decision(s). To the extent Vapotherm purchases a "product theater" event or the TPEC policies otherwise allow Vapotherm to make recommendations for and/or directly pay HCP speaker(s) that is attending to speak on Vapotherm's behalf, Vapotherm may select HCP faculty and directly pay honoraria, travel and other expenses related to the HCP's participation as TPEC faculty. The HCP speaker must have an active consulting agreement and meet requirements as set forth in Vapotherm's Policy on "Arrangements with Healthcare Professionals".
- 2. Vapotherm Personnel may not control any aspect of program planning or development. Vapotherm Personnel may not attend planning meetings, and they may not make final content determinations with regard to program materials. If the TPEC provider selects Vapotherm Personnel to speak at the TPEC, then Vapotherm Personnel may develop a draft presentation, but the TPEC must retain sole control over the final content of the presentation.
- 3. The TPEC provider must be primarily responsible for promoting its program. If the program provider requests guidance on which audiences might benefit from the program, Vapotherm may supply broad categories of professionals that might be interested. Vapotherm may also distribute promotional content developed by the

TPEC. Under no circumstances should Vapotherm develop its own promotional content for the program.

**Conflicts of Interest:** Vapotherm should generally refrain from supporting TPEC providers that have legal, business, or other relationships with Vapotherm that could place Vapotherm in a position to exert influence over the content of the TPEC. Similarly, Vapotherm should refrain from supporting TPEC providers that employ individuals who have been involved in the marketing of Vapotherm's products. Any arrangements to support TPEC providers with such conflicts must be approved by the Vice President of Legal Affairs & Compliance.

**Agreement:** Any support provided by Vapotherm to a TPEC provider must be documented in a written agreement. The agreement should make clear that the TPEC provider is solely responsible for the content, development, and delivery of the conference. The TPEC provider must commit to disclosing the following information to the Attendees: (1) Vapotherm's support for the TPEC; (2) any significant relationship between the provider presenters or moderators, and Vapotherm; and (3) any Off-Label uses of Vapotherm products that will be discussed.

Attendance by Vapotherm employees at Live Vapotherm-Sponsored TPEC Events: Vapotherm Personnel may attend live TPEC presentations; however, they may not participate in audience discussions, or ask questions of the presenter. In addition, Vapotherm Representatives may not engage in any promotional activities during the actual delivery of TPEC programs.

**Evaluations:** It is appropriate for Vapotherm to evaluate TPECs it has funded for purposes such as vendor compliance, assessing program quality and educational reach. It is <u>not</u> appropriate to conduct a return on investment ("ROI") analysis to assess a TPEC's effect on the future product usage of specific Attendees. Vapotherm should not continue to support TPECs with a history of conducting programs that fail to promote scientific knowledge, medical advancement, and/or the delivery of effective healthcare as required under this Policy.

### RESEARCH, EDUCATIONAL, AND OTHER CHARITABLE GRANTS POLICY

Vapotherm is committed to supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education and the sponsorship of charitable events. It is not appropriate for Vapotherm to make donations for the purpose of unlawfully inducing HCPs to purchase, lease,

recommend, use or arrange for the purchase, lease or prescription of Vapotherm's products.

**Permissible Grant Categories:** Vapotherm will consider making Grants to qualified Recipients in support of the following purposes and activities:

- Independent medical education or Third Party Educational Conferences in accordance with Vapotherm's Policy on "Vapotherm Support of Third Party Education Conferences";
- Genuine independent medical research with scientific merit;
- Disease-awareness programs or events;
- Patient education activities or materials;
- Indigent care; and
- Other genuine philanthropic and charitable activities that demonstrate good corporate citizenship and represent a benefit to society.

**Prohibited Grants:** Absent approval from the Vice President of Legal Affairs & Compliance, Vapotherm will not make Grants to:

- 1. Individuals; or
- 2. Qualified Recipients that are predominately owned and/or operated by an HCP or a group of HCPs (unless the Grant is a directed payment in exchange for services performed by the HCP in accordance with Vapotherm's Policy on "Arrangements with Healthcare Professionals").

**Criteria:** Absent approval from the Vice President of Legal Affairs & Compliance, all Vapotherm Grants must meet the following criteria:

- Grants must not be linked, directly or indirectly, to an agreement to use, purchase, recommend, or refer Vapotherm products, or be used to reward past, present, or future business.
- Grants must not fund expenses already incurred by the Qualified Recipient (Grants must be funded prospectively).
- Grants may not be used to fund payments for items or services rendered to Vapotherm.
- Grants must primarily benefit the Qualified Recipient and not result in more than an incidental personal benefit to an individual HCP or another private individual.

- Grants may be made to the charitable subsidiary of a customer of Vapotherm, but only in response to a general fundraising effort by the customer, rather than a request directed only to Vapotherm.
- If a Grant is made to a charitable organization, the Grant must be intended and used to further the organization's charitable purpose.
- Grants may not be hand-delivered by Vapotherm sales representatives or area clinical specialists.
- Under no circumstances may Grants or other charitable contributions be made in cash.

Vapotherm-initiated or directed research involving Vapotherm's products or technologies, such as a clinical trial, is addressed separately in Vapotherm's Policy on "Arrangements with Healthcare Professionals."

**Written Agreements & Approval:** Education and Investigator-Initiated Research Grants must be documented in a written agreement, and certain Charitable Grants, at the discretion of the Vice President of Legal Affairs & Compliance, must also be documented in a written agreement. Absent approval from the Vice President of Legal Affairs & Compliance of the written agreement and/or the applicable Vapotherm grant request form, as applicable, no Vapotherm Personnel may make a commitment that Vapotherm will fund a grant request or make any other charitable contribution.

#### Additional Considerations for Charitable Contributions:

- 1. Charitable organizations that request support from Vapotherm will be required to provide the following information:
  - The tax identification number of the charitable organization;
  - A statement of its charitable, tax-exempt status;
  - A description of the charitable organization and its charitable mission or purpose;
  - If a specific fundraising event is not involved, a description of the fundraising efforts and purpose and a statement whether the request is part of a broad solicitation for support.

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- If the charitable donation is requested in connection with a fundraising event, the following additional information is required:
  - A description of the fundraising activity for which the contribution is requested;
  - The location where the fundraising activity will be held; and
  - The date of the fundraising activity.
- 2. Vapotherm may support fundraising events of charitable organizations if the following requirements are satisfied:
  - The event is widely publicized;
  - The organization has a process for soliciting contributions from a broad range of potential donors and not merely Vapotherm;
  - The Grants qualifies for a charitable tax deduction; and
  - Absent approval from the Vice President of Legal Affairs & Compliance, Vapotherm does not pay for HCP attendance at, or participation in, the event unless the organization selects the attendees or participants without Vapotherm input into the selection process.

#### ANTI – CORRUPTION AND BRIBERY POLICY

Corrupt practices and bribery undermine Vapotherm's commitment to transparency and our goal to preserve our business's integrity. Vapotherm does not permit employees and/or affiliated entities, agents, or individuals (including distributors, suppliers, contractors, subcontractors, consultants and other business partners) to offer or provide illegal payments or kickbacks to further our business. We strictly prohibit the offer or provision of items of value to reward or induce customers, suppliers, partners

## **Question & Answer**

#### What is Bribery?

Bribery is the act of offering or giving, a financial or other type of advantage with the intention of influencing the recipient or provider in some way favorable to our business.

Bribery also includes requesting or agreeing to receive a financial or other type of advantage from another party where that advantage is intended to induce that party to perform a particular function improperly or where the acceptance of that advantage is in itself improper, or where that party acts improperly in anticipation of such advantage.

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or government officials in order to influence decisions, business or to obtain an unfair advantage.

A facilitation payment is defined as a small payment made to officials in order to ensure or speed up the performance of routine or necessary functions.

Facilitation payments constitute bribes and may not be made at any time irrespective of prevailing business customs in certain territories.

In the event that a Vapotherm employee or affiliate becomes aware of corrupt practices or should a Vapotherm employee or affiliate have any questions or doubts, the individual should immediately consult the Vice President of Legal Affairs & Compliance.

## **Due Diligence and Risks**

The following issues should be considered with care in any and all transactions, dealings with officials, and other business matters concerning third parties:

- Territorial risks, particularly the prevalence of bribery and corruption in a particular country.
- Cross-border payments, particularly those involving territories falling under the previous section above.
- Requests for cash payment, payment through intermediaries or other unusual methods of payment.
- Activities requiring the Company and / or any associated party to obtain permits or other forms of official authorization.
- Transactions involving the import or export of goods.

### **POLICY ON PRIVACY AND PERSONAL INFORMATION**

#### **Question & Answer**

#### What is identifiable information?

A person is considered identifiable if they can be identified by reference to factors including but not limited to, an individual's name, address, telephone numbers, e-mail addresses, social security number, driver's license number, bank account number, credit card number, PIN number, credit records, billing records, service records, payment and deposit history, online identifier, location data, genetic information, health information, and race or ethnicity.

Vapotherm recognizes the importance privacy protections with respect to the collection, use, and disclosure of personal information. Personal information may include any information relating to an identified or identifiable natural person.

Every employee is responsible for protection of personal information that they come into contact with during their work, and may only use such information for the proper conduct of such work in accordance with Vapotherm policies and applicable laws. If any employee receives

personal information in error, the employee should immediately contact the Vapotherm's Vice President of Legal Affairs & Compliance, and fully cooperate with any instructions provided to the employee, which may, at Vapotherm's direction, include notifying the sender, returning the information, and/or destroying the information.

## **Our Relationships with Regulators and Other Third Parties**

## **COOPERATION WITH STATE DISCLOSURE REQUIREMENTS**

Vapotherm complies with all state and federal disclosure requirements. Vapotherm is obligated to report any transfer of value to Covered Recipients as defined by the Physician Payment Sunshine Act (Sunshine Act) and some individual State Laws and/or certify code of ethics with various states. Examples of state disclosure requirements include:

- Massachusetts: Massachusetts state law defines Covered Recipients more broadly than the federal Sunshine Act as "anyone in a position to decide which prescription drug or medical device is used."
- Vermont: Vermont state law more broadly defines transfer of values to include anything of value transferred to a Covered Recipient, outside of a commercial arrangement, including loan equipment, and research or clinical trials.
- California: The state of California requires certain medical device manufactures to adopt and publicly certify annual audits of a Comprehensive Compliance Program for Sales and Marketing activities.

### **ENGAGING WITH THE MEDIA**

Only authorized Vapotherm personnel may take part in press releases or other interactions with news media. Vapotherm personnel should not comment on, confirm or deny any information relating to our business, unless you have been previously authorized to do so. If approached by a member of the news media approaches you, they should be referred to the appropriate Vapotherm authorized personnel.

#### **ANTITRUST**

The purpose of competition (or antitrust) laws is preserve the competitive free market and create an equal playing field or all businesses allow them to generate a fair profit. The laws prohibit agreements or business practices that may inhibit markets for goods and services to operate competitively and efficiently for buyers and sellers, including price fixes, market division or allocations or decisions to boycott competitors, regardless of the size or market power of the companies involved.

Violations of these laws are not limited to written agreements between competitors, but also include individual employees sharing confidential information or strategies with competitors such as:

Prices, discounts, or terms or conditions of sale

- Profits, profit margins or cost data
- Market share, sales territories or markets
- Allocation of customers or territories
- Restricting the territory or markets in which a company may resell products
- Restricting the customer to whom a company may sell

Violations of the antitrust laws can result in civil and criminal monetary penalties, imprisonment, and court orders to stop the prohibited activity. In order to protect Vapotherm and yourself do not share confidential information with competitors. If you are approached by a competitor requesting confidential information or asking for your cooperation in illegal competitive activities you should notify the Vice President of Legal Affairs & Compliance as soon as possible. It should be noted that these laws vary by country. Any questions regarding antitrust laws in your country should be forwarded to the Vice President of Legal Affairs & Compliance.

#### **Question & Answer**

## What is considered Confidential Information?

Confidential Information includes but is not limited to patents, trade names, trade secrets, trademarks, copyrights, product designs and development plans, financial data and projects, business development plans, strategic plans, customer lists, sales and marketing data, customer or supplier contracts and other intangible industrial or commercial property.

#### INTELLECTUAL PROPERTY AND CONFIDENTIALITY

Vapotherm vigorously protects our intellectual property by obtaining patents, trademarks, copyrights, and trade secret protections and taking measures to avoid inappropriate disclosure, loss, or use of this information. We must ensure that we do not disclose Vapotherm's intellectual property or confidential information with any third-party outside of the Company unless a legitimate business purpose exists prior authorization is granted via the approval of a confidentiality and non-disclosure agreement. Each Vapotherm employee is responsible for knowing what is considered confidential information and following all policies and procedures in place to protect it.

## **Safeguarding Confidential Information:**

Safeguarding confidential information is imperative to maintaining Vapotherm's competitive advantage. Disclosure of such information could seriously harm our Company's interest. When protecting our confidential information, Vapotherm employees should:

1. Protect mobile or handheld devices from theft or loss:

- 2. Pick an appropriate venue for business meetings and ensure conversations related
  - to confidential information cannot be overhead; and
  - 3. Secure sensitive records and documents.

In order for Vapotherm to conduct daily business we may partner with third parties such as vendors, suppliers, distributors or other business partners. These partnerships may require us receive confidential information from third parties. Vapotherm requires that all employees properly safeguard this information in order to protect the intellectual property, inventions, and confidential information of our partners from disclosure, loss, theft or misuse.

#### INTERNATIONAL TRADE

Vapotherm recognizes that we must understand and remain compliant with all U.S. import and export laws, regardless of where in the world we conduct business. Vapotherm also understands that we are expected to know and remain in compliance with all applicable laws and regulations of the countries to/from which we import or export products.

Vapotherm understands that U.S. laws prohibit trade with certain sanctioned countries as well as participation in boycotts imposed by some countries on to others. Vapotherm employees should notify the VP of Legal Affairs & Compliance should they receive a request to export to any sanctioned country or cooperate with prohibited boycotts. For questions regarding applicable trade laws or Vapotherm's policies you may reach out to Vapotherm's VP of Legal Affairs & Compliance.

#### **CONFLICT OF INTEREST**

Personal activities, interests, or relationships – or those of someone close to us – must not conflict with the best interests of our company. Vapotherm employees shall work to avoid perceived or actual conflicts of interest by addressing such concerns with a member of Vapotherm's Senior Leadership team and/or discussing with the Vice President of Legal Affairs

## **Ouestion & Answer**

#### What is a Conflict of Interest?

A perceived or real Conflict of Interest may exist when our personal relationships, activities, outside opportunities hinder or appear to hinder with our judgement to act in the best interest of Vapotherm.

& Compliance if necessary. Vapotherm employees are responsible for disclosing any possible conflict of interest with the Director of Legal Affairs & Compliance. Examples of

#### conflict of interest include:

- Vapotherm employees maintaining a financial or professional relationship in supplier, vendor, customer, competitor or distributor with which Vapotherm conducts contracts or conducts business with (i.e. a competitor, supplier, vendor etc.),
- Creating side businesses related to Vapotherm technologies,
- Involvement in personnel decisions based in which you have friendship, family, or romantic relationship interests or involving Vapotherm in business relationships based on the above-mentioned interests
- Receiving personal or professional gain or benefit from commercial opportunities identified during the time in which you are employed by Vapotherm.

Exchanging Business Courtesies: Vapotherm must not provide gifts, regardless of value to any supplier, distributor, consultant or vendor with which we conduct business without the approval of the Vice President of Legal Affairs & Compliance. Vapotherm employees may accept occasional gifts with managerial approval so long as they are of nominal value and are not intended to improperly influence business decisions. In some jurisdictions, any gifts or hospitality may require registration or may trigger separate reporting obligations; see the Vice President of Legal Affairs and Compliance with questions. Cash should never be given or nor received as a gift under any circumstances. The exchange of business courtesies should be avoided at the in which contacts are being negotiated or finalized.

#### FINANCIAL INTEGRITY

Honesty and integrity are essential to providing our shareholders with accurate information regarding Vapotherm's financial performance. Our honesty and integrity as a corporation is reflected in the accuracy of our records. Therefore, it is critical that our financial activities satisfy all domestic and global legal, accounting, and financial standards, including the maintenance of accurate, complete, non-misleading financial information, records, and accounts. Additionally, Vapotherm senior leadership and/or financial officers involved in the preparation or communication of our public disclosures must understand and comply with all such requirements.

#### PROPER USE OF CORPORATE ASSETS

Vapotherm's assets shall be used for their intended business purposes. Personal use of Vapotherm's funds or property, including charging personal expenses as business expenses, inappropriate reporting or overstatement of business or travel expenses and

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inappropriate usage of Vapotherm equipment or the personal use of suppliers or facilities without advance approval from an appropriate officer of Vapotherm shall be considered a breach of this Code of Conduct.

#### **CORPORATE OPPORTUNITIES**

Except as otherwise set forth in Vapotherm's certificate of incorporation and applicable law, directors, officers and employees are prohibited from (a) taking opportunities for themselves that are discovered through the use of Vapotherm property, information or position, (b) using Vapotherm property, information or position for personal gain and (c) competing with Vapotherm. Each director, officer and employee owes a duty to Vapotherm to advance Vapotherm's legitimate interests when the opportunity to do so arises.

#### **FAIR DEALING**

Directors, officers and employees should endeavor to deal fairly with Vapotherm's customers, suppliers, competitors and employees. Directors, officers and employees should not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practices. Directors, officers and employees may not engage in activities that:

- Are designed to reach an understanding with competitors concerning prices, production methods or division of customers;
- Are designed to reach an understanding with vendors regarding reciprocal buying and selling; or
- Result in other prohibited activity such as illegal price discrimination or trade restraints.

Additionally, directors, officers and employees should not talk to Vapotherm's competitors about prices, marketing practices, other competitors, vendors, geographic regions or market allocation.

#### **RESPONDING TO GOVERNMENT INVESTIGATIONS**

Vapotherm expects its Personnel to deal in an honest, fair, and ethical manner with government representatives and to avoid circumstances that could be considered deceitful, wasteful, fraudulent, or that create the appearance of an impropriety or a conflict of interest.

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Personnel who receive notice or otherwise learn of a Government Investigation, or Subpoena, or are served with a Search Warrant or Interview Request will immediately notify the Vice President of Legal Affairs & Compliance and provide a list of all relevant documents and information requested by the Government and an explanation regarding the facts and circumstances surrounding the Government Investigation, Subpoena, Search Warrant, or Interview Request.

Without the written consent of the Vice President of Legal Affairs & Compliance, no Vapotherm Personnel is to respond in any way to a Government Investigation or Subpoena, including providing documents or responses to verbal or written questions or contacting a government agent involved in the Government Investigation. Notwithstanding the foregoing, if Vapotherm Personnel are served with a Search Warrant or Interview Request, Vapotherm Personnel may respond as set forth in the Responding to Search Warrants and Interview Requests Procedure set forth below.

Upon notice of a Government Investigation, Subpoena, Search Warrant, or Interview Request, the Vice President of Legal Affairs & Compliance shall work with Vapotherm's senior leadership team to develop an action plan for handling and responding to the government, including whether to initiate an internal investigation in accordance with Vapotherm's Policy on "Reporting, Internal Investigations, Corrective Actions, and Non-Retaliation" and whether outside counsel should be retained to lead the investigation.

## APPENDIX A: COMPLIANCE WITH THE LAW AND OVERVIEW OF KEY HEALTHCARE LAWS

Vapotherm is committed to conducting their business in compliance with all applicable laws, rules and regulations governing its operations.

This overview summarizes the key health care laws and regulations that apply to Vapotherm's business. This overview is not intended to be a detailed recitation of every aspect of the laws and regulations discussed. Accordingly, Vapotherm Personnel should consult the Vice President of Legal Affairs & Compliance for direction when questions arise about these laws, rules or regulations or the related compliance policies and procedures.

#### **INSIDER TRADING**

While at Vapotherm you may come into contact with information that requires special handling and discretion. Inside information is material, non-public information about Vapotherm or another company that, if made public, would affect the price of a company's securities. Directors, officers and employees must never use inside information to obtain any type of personal advantage. For further discussion on our policy with respect to inside information, please review Vapotherm's Insider Trading Policy which is deemed part of this Code of Conduct.

#### **PUBLIC COMPANY DISCLOSURE OBLIGATION**

Vapotherm's business affairs are subject to certain internal and external disclosure obligations and recordkeeping procedures. As a public company, we are committed to abiding by our disclosure obligations in a full, fair, accurate, timely and understandable manner. Only with reliable records and clear disclosure procedures can we make informed and responsible business decisions. When disclosing information to the public, it is Vapotherm's policy to provide consistent and accurate information. To maintain consistency and accuracy, specific company spokespersons are designated to respond to questions from the public. Only these individuals are authorized to release information to the public at appropriate times. All inquiries from the media or investors should be forwarded immediately to the Vice President of Legal Affairs & Compliance or his or her designee. The Vice President of Legal Affairs & Compliance or his or her designee must approve all press releases, speeches, publications or other official Vapotherm disclosures.

Our internal control procedures are further regulated by the Sarbanes-Oxley Act of 2002. Sarbanes-Oxley was a U.S. legislative response to events at public companies involving pervasive breakdowns in corporate ethics and internal controls over financial reporting. It was designed to rebuild confidence in the capital markets by ensuring that public

companies are operated in a transparent and honest manner. Ensuring proper and effective internal controls is among Vapotherm's highest priorities.

We take seriously the reliance our investors place on us to provide accurate and timely information about our business. In support of our disclosure obligations, it is our policy to always:

- comply with generally accepted accounting principles;
- maintain a system of internal accounting and disclosure controls and procedures that provides management with reasonable assurances that transactions are properly recorded and that material information is made known to management;
- maintain books and records that accurately and fairly reflect transactions; and
- prohibit establishment of material undisclosed or unrecorded funds or assets.

#### **ANTI-KICKBACK LAW**

The federal anti-kickback law broadly prohibits anyone (including Vapotherm and its personnel, and healthcare professionals) from knowingly and willfully offering, paying, asking for, or receiving anything of value to influence referrals or generate business reimbursable under federal health care programs, such as Medicare and Medicaid. Even if only one purpose of a payment arrangement is to influence referrals or generate business, the payment may be found to be unlawful. Notably, with the enactment of the Patient Protection and Affordable Care Act of 2010 ("ACA"), actual knowledge of an anti-kickback statute violation or the specific intent to commit a violation of the anti-kickback law is no longer necessary for conviction under the statute. It is enough that a defendant knew, or should have known that the conduct was generally unlawful.

The federal anti-kickback law is intended to prevent corruption in healthcare choice and inappropriate utilization. Healthcare choices should be made based on what is best for the patient and on appropriate price competition, not on incentives offered to the healthcare professional or decision-maker.

The anti-kickback law is very broad, and it effectively prohibits many types of business arrangements that would be lawful in other industries. It applies to Vapotherm's relationships with physicians, hospitals, and other third parties in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Vapotherm products for a beneficiary of the federal health care programs.

The government agency with responsibility for interpreting and enforcing the anti-kickback law, the Department of Health and Human Services' Office of Inspector General ("OIG"), has established a number of "safe harbors". These safe harbors are government-recognized guidelines for legitimate business activities that the OIG has determined are unlikely to be abusive (e.g. unlikely to result in overutilization or adversely affect the quality of patient care). Arrangements that fall within the safe harbors will not be subject to prosecution.

The primary safe harbors that relate to the business activities of Vapotherm are:

- <u>Discount safe harbor:</u> The discount safe harbor permits certain discounts on items and services if the buyer and seller comply with the requirements of the safe harbor, including reporting the discount to the government. Discounts are protected because the government recognizes that public policy generally favors open and legitimate price competition in the health care industry because that competition can benefit federal health care programs. The term "discount" is defined as a reduction in the amount a buyer is charged for an item or service based on an armslength transaction. The discount must be in the form of a reduction in price given at the time of sale or set at the time of sale and must meet certain specific disclosure requirements. Any value that is meant to function as a discount should be clearly identified and consistently treated as a discount.
- <u>Personal services safe harbor:</u> The personal services safe harbor protects legitimate service arrangements, such as consulting arrangements, between Vapotherm and health care professionals and other individuals, so long as the safe harbor's requirements are satisfied. These requirements include but are not limited to the following:
  - The arrangement is in writing and for a term of not less than one year;
  - The contract covers all of the services the agent provides to Vapotherm and specifies the services;
  - o The total compensation is set in advance;
  - The compensation does not vary based on volume or value of referrals or business generated between the parties; and
  - The compensation is consistent with fair market value.

Discount, payment, and other compensation arrangements that do not meet all of the safe harbor requirements are not necessarily illegal, but they may be subject to government scrutiny. The analysis of a payment practice under the anti-kickback law and the safe harbors is based upon the specific facts and circumstances of each arrangement and is very complex. Vapotherm personnel should not make independent judgments about

whether a safe harbor applies to any payment practice, discount, or other arrangement. Arrangements that could trigger the anti-kickback law must be brought to the attention of the Vice President of Legal Affairs & Compliance for review.

Violations of the anti-kickback law are criminal and are punishable by fines and/or imprisonment. Civil penalties may also be imposed. Violations also expose a company to exclusion from federal healthcare programs. That is, programs such as Medicare and Medicaid would not provide reimbursement for use of the company's products.

### STATE FRAUD AND ABUSE LAWS

Many states also have laws that are similar to the federal anti-kickback law discussed above. In some cases, the law is not limited to financial relationships between providers and physicians who provide services to beneficiaries of governmental health care programs (such as Medicaid), but also extend to services provided to patients covered by commercial health plans or even self-pay patients.

#### **FALSE CLAIMS ACT**

The False Claims Act ("FCA") protects the federal government from false or fraudulent claims for payment. Through programs such as Medicare and Medicaid, the federal government purchases or reimburses purchases of healthcare-related products and services. Vast amounts of money are spent on federal healthcare programs and therefore the government is rightly concerned about getting the best price and value for our taxpayer dollars.

Under the FCA, it is an offense to submit a false or fraudulent claim to the United States government. This might include falsifying records or making false statements to obtain payment from the government. It is also an offense to cause a third party to submit a false claim to the government.

In recent years, the government has used the FCA to prosecute pharmaceutical and medical device companies for encouraging doctors to prescribe or order their products for off-label uses that may not be reimbursable under Medicare or Medicaid. Cases have also been brought against manufacturers under the FCA for providing inaccurate billing or reimbursement advice to healthcare professionals leading improper reimbursement from federal healthcare programs. Notably, under the ACA, anti-kickback claims now constitute a violation of the False Claims Act.

Damages under the False Claims Act are severe. Violators must pay the government three times the amount of damages suffered plus a mandatory civil penalty that is assessed on a per-claim basis.

The FCA has provisions that encourage whistle-blowing when there is evidence that companies are defrauding or abusing government programs. The FCA prohibits employers from retaliating against employees who bring such matters to the government's attention. Vapotherm has policies and procedures that encourage and facilitate the reporting of concerns about non-compliance with healthcare laws and policies through the Vice President of Legal Affairs & Compliance or anonymously though the Professional Conduct Hotline. Vapotherm's Compliance Policies protects employees from any retaliation for reporting such concerns.

#### **FOREIGN CORRUPT PRACTICES ACT (AND INTERNATIONAL EQUIVALENTS)**

The Foreign Corrupt Practices Act ("FCPA") was enacted for the purpose of making it unlawful to make payments to foreign government officials to assist in obtaining or retaining business. Specifically, the anti-bribery provisions of the FCPA prohibit the corrupt offer, payment, promise to pay, or authorization of payment of money or anything of value to any person, while knowing that all or a portion of such payment will be offered, given, or promised, directly or indirectly, to a foreign official to influence the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist in obtaining or retaining business. The FCPA also includes certain accounting provisions, but their applicability is limited to publicly traded companies.

Because many countries around the world have state run health systems, it is not uncommon for physicians, nurses, respiratory therapists, and purchasing managers at foreign hospitals to be classified as foreign government officials under the law. As a result, many actions that would violate the Anti-kickback statute domestically would also violate the FCPA if taken in an international jurisdiction.

Violations of the FCPA are criminal and are punishable by fines and/or imprisonment. Civil penalties may also be imposed. Violations also expose a company to exclusion from federal healthcare programs.

Beyond the FCPA, it is important to understand that many countries have adopted their own anti-bribery statutes over the past twenty-five years, and while these statutes typically are intended to prohibit the same conduct that is prohibited under the FCPA, they can vary dramatically in terms of scope and penalty.

### **THE UK BRIBERY ACT 2010**

The UK Bribery Act 2010 ("the Act") was enacted to ensure that no bribes or other corrupt payments, inducements or other similar gestures are made, offered, sought or obtained by an entity or individual or by anyone working on behalf of that entity, including government officials.

The Act defines bribery as giving someone a financial or other advantage to encourage the person to perform their functions or activities improperly or to reward that person for having already done so. This includes, seeking to influence a decision maker by offering or providing a benefit to that party rather than what can legitimately be offered in the course of normal business conduct.

Violations of the Act are criminal and punishable by fines and/or imprisonment for up to 10 years. An individual or an organization found guilty of bribery under the Act may face individual fines and/or prison terms.

#### FEDERAL FOOD, DRUG AND COSMETIC ACT

The Food and Drug Administration ("FDA") approves new drugs and approves or clears medical devices (depending on device classification) and regulates how they are designed, manufactured, marketed and distributed. FDA, through the Federal Food, Drug and Cosmetic Act ("FD&C Act"), regulates the labeling and promotion of all medical devices that are marketed for sale in the United States. The FDA regulates the labeling that accompanies a medical device, which includes information on the medical device packaging and other materials providing information about the device.

The FDA approves or clears a medical device for use only as described in the indications for use stated in the labeling. Any other use is considered "off-label". Although physicians and other providers can use products "off-label" in the exercise of their professional judgment, manufacturers may not solicit, encourage, or promote unapproved uses of a product. Any advertising and promotion materials for a medical device must be consistent with its indications for use.

The FD&C Act has broad application and carries a range of criminal and civil penalties including imprisonment and exclusion.

TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS ACT (AKA THE "SUNSHINE ACT")

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The Sunshine Act, a component of the ACA, requires applicable manufacturers of drugs and devices covered by a federal healthcare program (e.g. Medicare, Medicaid, etc.) to collect and report annually payments and other transfers of value (e.g. meals, travel, lodging, etc.) to physicians and teaching hospitals. Additionally, although the federal Sunshine Act preempts any state reporting obligation regarding payments or other transfers of value to physicians and teaching hospitals, certain states including Massachusetts, Vermont, Connecticut, California and Nevada can and do impose more stringent collection and reporting obligations on manufacturers of drugs and devices (including, for example, payments or other transfers of value made to non-physician healthcare professionals and/or certification of code of ethics for interactions with healthcare professionals). These reporting requirements are outlined in greater detail in Appendix B of this Code of Conduct.

#### MEDICARE AND MEDICAID BILLING RULES

The Medicare and Medicaid programs impose numerous standards on the coding and billing practices of organization, such as physicians, hospital, and other providers, who submit claims for items or services to the federal government.

Claims submitted to Medicare or Medicaid must be for items or services that are covered by the program. Accurate and complete documentation in the patient record of the provision of the items or services is required. The claims that are submitted must be accurate and complete and must follow coding standards. Additional Medicare and Medicaid rules apply to billing the federal government for reimbursement of specific items and services.

These rules must be strictly followed to avoid overpayments, which must be refunded to the government, and to avoid civil and criminal penalties for improper coding and billing practices.

### **HIPAA AND PATIENT PRIVACY LAWS**

Many federal and state laws and regulations protect the personal information of individuals who are consumers of health care items or services. At the federal level, the regulations issued under the Health Insurance Portability and Accountability Act ("HIPAA") imposes standards for protecting the privacy and security of individuals' health information (called "protected health information" or "PHI").

Under HIPAA, doctors and healthcare institutions are required to keep PHI confidential within the patient treatment team. Vapotherm employees are not part of a patient treatment team. Therefore, the disclosure of patient information in interactions between

providers and Vapotherm field personnel may or may not be permitted depending on the circumstances.

## **UNFAIR BUSINESS PRACTICES AND CONSUMER FRAUD**

In addition to the antitrust laws, other federal and state laws regulate market competition in general. The Federal Trade Commission Act and the laws of almost all states prohibit the use of "unfair" or "deceptive" acts practices, including the distribution of advertising and marketing materials that are false or misleading.

## APPENDIX B: OVERVIEW OF KEY HEALTHCARE TRANSPARENCY AND REPORTING LAWS

#### I. FEDERAL PHYSICIAN PAYMENTS SUNSHINE ACT

- A. The Physician Payment Sunshine Act (PPSA) of the Affordable Care Act of 2010 requires medical device and pharmaceutical manufacturers to disclose annual data on payments and transfers of values made to certain healthcare professionals via the Center for Medicare and Medicaid Services (CMS) in order to increase transparency around the financial relationships between physicians, teaching hospitals and manufactures.
  - PPSA requires medical device manufacturers covered by Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS any general payments or "transfers of value" under a number of categories, including the following:
    - i. General payments or "transfers of values" such as meals, travel reimbursements, and consulting fees.
    - ii. Ownership and investment interests in manufacturers held by physicians as well as their immediate family members.
    - iii. Any payment made for participation in preclinical research, clinical trials, or other development activities.
  - 2. The types of healthcare professionals considered to be "covered recipients" under the PPSA are:
    - Doctor of Medicine
    - ii. Doctor of Osteopathy
    - iii. Doctor of Dentistry
    - iv. Doctor of Dental Surgery
    - v. Doctor of Podiatry
    - vi. Doctor of Optometry
    - vii. Doctor of Chiropractic Medicine
    - viii. Teaching hospitals
    - ix. Covered recipients do not include:
      - 1. Medical residents
      - 2. Nurse practitioners
      - 3. Office staff
  - 3. Records of payments are available via the Center for Medicare and Medicaid Services online portal: Open Payments.

4. Reporting is not required for payments or transfers of value that are under "de minimus" threshold meet certain other requirements in the PPSA.

# II. LAWS WITH SPECIFIC STATE MARKETING DISCLOSURE REQUIREMENT AND/OR PUBLIC DISCLOSURE OF TRANSFERS OF PAYMENT<sup>1</sup>

States under this category require the submission of disclosure reports noting transfers of value between a manufacturer and certain delineated healthcare professionals.

#### **CONNECTICUT**

- A. Pursuant to the Connecticut Comprehensive Compliance Program/Code of Conduct Law (Connecticut General Statutes Sec. 21a-70d-f), certain medical device companies are required to adopt a Code that includes policies that comply with the Advanced Code of Ethics. Additionally, Connecticut Public Act 15-4 requires pharmaceuticals and medical device companies to submit annually report of payments or other transfers of value to advanced practice registered nurses (APRNs), not practicing in collaboration with a physician.
  - 1. The types of healthcare professionals considered to be covered recipients under Connecticut law are:
    - i. Nurse practitioners
    - ii. Certified registered nurse anesthetist
    - iii. Clinical nurse specialist
    - iv. Certified nurse midwife
  - 2. Reportable activities include:
    - i. All reportable activities under PPSA.
    - ii. Exemptions include:
      - 1. Samples distributed free of charge
      - 2. Certain indirect payments where the company does not know or intend that the payment or transfer of value will be made to a healthcare professional

#### **MASSACHUSETTS**

A. Pursuant to the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Law (Mass. Gen. Laws ch. 111N; 105 MASS. CODE REGS. 970.000), certain Medical Device companies are required to register and certify the following, annually:

- Implementation of a marketing Code of Conduct in compliance with the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct.
- 2. Adoption of routine training programs of employees.
- 3. Implementation of policies and procedures for conducting investigations into any and all non-compliance with the Code of Conduct
- 4. Completion of annual audit to ensure compliance with Code of Conduct
- B. The types of healthcare professionals considered to be covered recipients under Massachusetts law are:
  - 1. All covered recipients under PPSA; and
  - 2. Residents
  - 3. Physician assistants
  - 4. Nurse practitioners
  - 5. Pharmacists
  - 6. Employees of prescribers
  - 7. Non-teaching hospitals/clinics
  - 8. Nursing homes
- C. Reportable activities in the state of Massachusetts include:
  - 1. All reportable activities under PPSA<sup>i</sup>; and
    - i. Accredited CMEs
    - ii. Anatomical models and charts (educational gifts)
- D. The Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Law prohibits the following:
  - 1. Meals that are part of entertainment or recreational events or offered without an informational presentation made by a marketing agent, or meals that are provided to a healthcare professional's guest or spouse.
  - 2. Certain financial support for Continuing Medical Education, third party scientific or educational conferences, and professional meetings as well as compensation for healthcare professional attendance at these events, or direct payment for meals at these events. These regulations require a separation of Marketing and Sales in grant-making functions.
  - 3. Entertainment, cash or other transfers of value/complimentary items that are not for services as well as payments or transfers of values in exchange for prescribing, disbursing, and using prescription products, or any other kind of kickbacks.

- 4. Entertainment or recreational items of any value to healthcare professionals who are not a salaried employee of the pharmaceutical or medical device manufacturing company.
- 5. Payments of any kind, such as cash or cash equivalents, tangible items, or complimentary items (gifts) except as compensation for bona fide services.
- 6. Grants, scholarships, or any such support or transfer of value in exchange for prescribing, disbursing, or using prescription drugs, biological or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices.
- 7. Rebates or kickbacks prohibited under federal or state fraud and abuse laws.
- E. Reporting not required for payments or transfers of value that are under the "de minimis" threshold of \$50.00 per covered recipient event and meet certain other requirements in the Massachusetts law.

## **VERMONT**

- A. Pursuant to the Vermont Prescribed Products Gift Ban and Disclosure Law (VT. STAT. ANN. Tit. 18, § 4631a; VT. STAT. ANN. Tit. 18, § 4632), certain medical device companies are required to disclose the value, nature, purpose, and recipient of any allowable expenditure or permitted gift to certain healthcare professionals once annually.
  - a. Reportable activities include:
    - i. All reportable activities under PPSA
    - ii. Discount program allowances (coupons, vouchers etc.)
    - iii. Samples
    - iv. Sponsorship of an educational program offered by a medical device manufacturer at a national or regional professional society meeting at which Continuing Medical Education credits are offered
    - v. Demo units
    - vi. Patient starter kits
    - vii. Patient education and disease management materials
  - b. The types of healthcare professionals considered to be covered recipients under Vermont law are:
    - i. All covered recipients under the PPSA; and
    - ii. Residents
    - iii. Physician Assistants
    - iv. Nurse Practitioners

- v. Pharmacists
- vi. Employees of prescribers
- vii. Non-teach hospitals/clinics
- viii. Health plans
- ix. Pharmacies
- x. Universities
- xi. Non-profit foundations
- xii. Patient advocacy associations
- xiii. Professional associations
- c. The Vermont Prescribed Products Gift Ban and Disclosure Law prohibits the following:
  - i. Offering or giving any gift, defined as anything of value provided for free, to certain healthcare professionals licensed in Vermont
  - ii. Meals provided to certain healthcare professionals in Vermont, except meals associated with advisory boards, provided that the meal is subtracted from the healthcare professional's honorarium.
  - **iii.** Participation of a healthcare professional in a meal if they are not paid as a speaker or consultant with the manufacturer.

# III. LAWS WITH MARKETING DISLCOURE REQUIREMENTS BUT NO SPECIFIC TRANSFER OF VALUE DISCLOSURE REQUIREMENTS

The following states require the manufacturer to certify a code of ethics but do not require the submission of payment disclosure reports to certain healthcare professionals.

#### **CALIFORNIA**

- A. Pursuant to the California Health and Safety Code (Cal. Health & Safety Code § 119400 119402), certain pharmaceutical and medical device manufacturers are required to adopt a "Comprehensive Compliance Program" (CCP) for Sales and Marketing activities.
  - The CCP must include explicit dollar amount limitations on gifts, promotional materials, items or activities that the manufacturer may give to healthcare professionals. In addition, the CCP must include policies enforcing compliance with the Advanced Medical Technology Association Code of Ethics on Interactions with Healthcare Professionals (Advamed Code of Ethics).

B. Manufacturer is required to declare its CCP and provide a written certification of compliance with California's Health and Safety code on its website as well as provide a toll-free number where a copy of the CCP and written certification of compliance can be obtained. Manufacturer is expected to conduct an annual audit of its compliance with its policies and spending limits. The state of California does not provide a specific date by which to complete the above-mentioned requirements.

#### **NEVADA**

- A. Pursuant to the Nevada Pharmaceutical Code of Conduct Law (Nev. Rev. Stat. Ch. 639), any manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in Nevada must adopt a written Marketing Code of Conduct that establishes the practices and standards that govern the marketing or sale of their products.
  - 1. The Nevada Pharmaceutical Code of Conduct Law requires that these manufacturers must:
    - i. Identify a compliance officer
    - ii. Adopt policies for the investigation of non-compliance with the Code of Conduct
    - iii. Annual audits to monitor compliance with Code of Conduct
    - iv. Adopt a written training program to provide regular training to employees on Code of Conduct
    - v. Adopt a Code of Conduct that establishes practices and standards that govern marketing and sales of product, basis of interactions, informational presentations, third-party educational conferences, the use of consultants, scholarships and educational funds, and adherence to the Code of Conduct
  - 2. Manufacturer is required to submit the following:
    - i. A copy of Code of Conduct
    - ii. Description of its training program
    - iii. Description of investigation policies
    - iv. Name, title, address, telephone number and electronic mail address of its compliance officer
    - v. Certification of the completion of annual audit with favorable results

## Vapotherm Code of Conduct

<sup>&</sup>lt;sup>1</sup> State disclosure reports do not require manufacturers to include activities reported under the Physician Payment Sunshine Act of the Affordable Care Act due to federal preemption.