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Introduction

This Compliance and Ethics Manual (referred to hereinafter as "the Manual") contains an overview of the global laws and compliance policies, as well as some procedures, to which all employees and Third-Party Affiliates at Aerocrine, AB and its Subsidiaries and Affiliates (collectively “Aerocrine” or the “Company”), including Aerocrine, Inc. must adhere. Certain policies and procedures contained herein may only apply to a limited subset of employees, agents, and other Third-Party Affiliates. However, all are required to have a good understanding of the entire Manual and especially to study the portions of the Manual that are relevant to their jobs. In addition, all employees and Third-Party Affiliates must complete general compliance training. This is not merely a requirement as an Aerocrine employee or Affiliated Third Party; it is your obligation as a good steward of the work we all do every day in a highly regulated environment to improve patients’ lives and to assist the healthcare professionals (“HCPs”) who treat those patients.

The Manual is an expression of Aerocrine’s commitment to conduct business appropriately and with integrity, globally in the United States ("U.S.") and around the world. The Manual does not limit, but rather supplements, all other Aerocrine policies, including the Code of Business Conduct. You should refer to the Manual in addition to the Code of Business Conduct as necessary to ensure your actions comply with the relevant law and policies. The Global Policy on Interactions with Healthcare Professionals in this Manual provides the minimum standards for common practices. However, all interactions with HCPs must meet the requirements of the local laws, regulations, industry codes, or other applicable guiding principles, which may have more strict standards or requirements. There may be some territories or jurisdictions where local policies may supplement or alter the guidance provided in this Manual, so all employees and Third-Party Affiliates must ensure that they are familiar with any such local laws and policies. If you believe there are any such local policies that are in conflict with the guidance set forth in this Manual, you should consult with your manager or the Compliance Officer. Anyone who has any questions or concerns about a contemplated or proposed or conducted activity must consult with their manager or the Compliance Officer.

Unless specifically stated, the U.S. guidelines and standards apply to all activities.

Integrity

Aerocrine is committed to performing and conducting its business with the highest standards of corporate integrity. Aerocrine's commitment to integrity is demonstrated by its compliance with all applicable global and territory healthcare laws, regulations, pertinent industry standards, and Aerocrine's business policies, particularly those governing its interactions with customers. Healthcare compliant behavior builds trust with patients, HCPs, institutions, purchasers, and the government.
In addition to the guidance provided in this Manual, Aerocrine management is committed to training each person on the most important, relevant elements of these laws, codes, guidelines and the associated company policies. All employees and Third-Party Affiliates are expected to have a general understanding of the healthcare laws, regulations, and applicable industry standards that apply to Aerocrine’s business, including but not limited to:

- Anti-Kickback Laws
- ACCME Guidelines/EACCME
- Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code")
- Eucomed Guidelines
- False Claims Act
- FDA Laws and Regulations (or the territory analogue, including the EU Directives)
- Federal Sunshine provisions, and various state and ex-U.S. disclosure and marketing laws (discussed in the Transparency Laws chapter and throughout this Manual)
- International Anti-Bribery Statutes/Laws
- Office of Inspector General of the U.S. Health and Human Services ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance")
- Privacy Laws
- Consumer Protection Laws for each country in which we do business

Improper activities can violate several of these laws and regulations and may result in criminal and civil penalties for you and the Company.

**Anti-Kickback Statute**

The federal Anti-Kickback Statute and its state and foreign analogues (collectively referred to as the “anti-kickback laws” or the “fraud and abuse laws”) seek to prohibit improper influences on healthcare decisions by making it a felony to knowingly and willfully promise to pay, pay, agree to receive, or receive anything of value ("remuneration") in order to influence or obtain government healthcare business. Specifically, the laws prohibit the giving, accepting, soliciting, or arranging for payments of items of value in any form (cash or in kind), either directly or indirectly, to an HCP for the purpose of inducing or rewarding someone for purchasing, prescribing, endorsing, or recommending a device that is reimbursed under federal or state healthcare programs. These laws aim to ensure that HCPs’ decisions about the treatment of their patients are not tainted by motives of personal gain or enrichment.

For example, the law prohibits such activities as:
• Providing a gift (e.g., a free NIOX MINO Sensor, etc.) to an HCP to influence his/her prescribing or recommending or purchasing a MINO or other Company device
• Providing an educational or research grant to a hospital in order to influence the purchase of a medical device
• Paying for the services (e.g., consulting services) of an HCP at a fee significantly above the reasonable, fair market value for such services

Aerocrine treats all HCPs in the U.S. as if they are subject to the anti-kickback laws, even if they do not participate in government healthcare programs. For information on foreign anti-bribery laws, see the section on International Anti-Bribery Laws.

Safe Harbors
The U.S. anti-kickback laws are so broad that, if read literally, they could restrict many perfectly acceptable business arrangements with legitimate purposes and even some non-promotional activities. Recognizing this, the OIG has defined certain “safe harbor” regulations, which address various payment and business practices that are not treated as offenses under the statute. Activities that fall entirely within a safe harbor, such as legitimate service arrangements, will be free of prosecution from the OIG and/or the Department of Justice (“DOJ”). To fit squarely within a safe harbor, the business arrangement must be structured and operated precisely as outlined in the safe harbor regulation.

A number of safe harbors may be relevant to Aerocrine’s business activities, including, but not limited to:

• Discount safe harbor: allows Aerocrine to discount the price of a device to make it competitive with other devices, provided that the discount is properly reported and complies with other safe harbor requirements.
• Personal Services safe harbor: protects legitimate service arrangements with HCPs, such as consulting or speaking agreements. Compliance with this safe harbor requires, among other things, a written agreement and compensation determined in advance and on a fair market value basis.
• GPO safe harbor: permits the contracting with group purchasing organizations and the provision of an administrative fee to those organizations for their services.

Aerocrine’s policies in this Manual are intended to ensure that Aerocrine’s business arrangements meet the requirements set forth in these safe harbors, or are otherwise permissible and do not run afoul of the anti-kickback laws. If the application of any policy is unclear, or if you have any uncertainty whether particular actions and/or arrangements are permissible, you should discuss the situation with the Compliance Officer.
False Claims Act

In the U.S., the False Claims Act ("FCA") imposes liability on any person who submits or induces someone else to submit a false claim for reimbursement from the federal government. This could apply if an HCP falsely seeks reimbursement for medical services he or she did not provide, or if a device manufacturer promotes its device for off-label procedures. In addition, the passage of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, "PPACA") recently expanded FCA liability. Now, the federal government can bootstrap a violation of the anti-kickback laws into the FCA on grounds that a violation of the anti-kickback laws constitutes a false or fraudulent claim that is a sufficient basis for FCA liability. Bootstrapping an anti-kickback action to FCA liability can greatly increase personal liability and a company's financial liability. In addition, PPACA also decreased the evidence needed to demonstrate a “knowing” violation of the FCA. Whereas previously a person had to act "knowingly and willfully" to be held liable under the FCA, actual knowledge or specific intent is no longer required. A person who recklessly disregards or deliberately ignores whether particular information is true or false can be found liable under the FCA. Significantly, the FCA is the primary means by which the federal government and state Attorneys General prosecute biotech and device manufacturers and their employees (both civilly and criminally)—for example most fraudulent marketing and sales initiatives are prosecuted under the FCA even though the sale representative does not “submit” the claim, they induce it.

AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents U.S. companies that develop, produce, manufacture, and market medical devices, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. AdvaMed has adopted a voluntary code for interactions with HCPs, namely the Code of Ethics on Interactions with Healthcare Professionals (the "AdvaMed Code"). The AdvaMed Code sets forth various activities that are prohibited and those that are permitted.

Both the AdvaMed Code and the anti-kickback laws are intended to protect patients from the undue/improper influence of remuneration on quality healthcare decisions. The AdvaMed Code builds on the anti-kickback laws by focusing on specific relationships between device manufacturers and HCPs. Aerocrine has adopted the AdvaMed Code, and the principles set forth in the AdvaMed Code are embedded in the policies throughout this Manual.
Eucomed

Eucomed represents medical device and technology companies in Europe that design, manufacture and supply medical technology used in the diagnosis, prevention, treatment, and amelioration of disease and disability. Eucomed's Code of Ethical business Practice and Guidelines on Interactions with HCPs (the "Eucomed Code") is intended to provide guidance and set forth the appropriate standards regarding the various relationships and interactions between device manufacturers and HCPs. The Eucomed Code is based on the principles of separation, transparency, equivalence and documentation, and sets forth various activities that are prohibited and those that are permitted.

The Eucomed Code is committed to high ethical standards for its members and works to ensure that they act according to the highest ethical and professional standards when working with HCPs. The Euomed Code is not intended to supplement or supersede national laws or regulations. In that regard, Aerocrine will also evaluate and comply with all current national and ex-U.S. laws, regulations, and professional codes when interacting with HCPs.

Although Aerocrine is not a member of Eucomed and has not adopted the Eucomed Code, Aerocrine expects all employees to adhere to the principles set forth in the Eucomed Code and accompanying guidelines.

FDA and Other Regulatory Agency Laws and Regulations

The Federal Drug Administration ("FDA"), China Food and Drug Administration ("CFDA"), National Sanitary Surveillance Agency ("ANVISA"), or the regulatory agency in the jurisdiction in which you conduct business, regulates almost every aspect of Aerocrine's business, from Research and Development to Sales and Marketing. FDA, CFDA, ANVISA, or the applicable regulatory agency, regulation of device advertising and promotion directly affects Aerocrine's customer relationships. Therefore, all Aerocrine employees and Third-Party Affiliates must understand the basic rules they must follow to help ensure compliance with applicable laws and regulations.

Labeling

The FDA, CFDA, ANVISA, or the applicable regulatory agency, strictly regulates the labeling of all devices that Aerocrine markets in the U.S. and around the world. Please refer to local territory rules to the extent that they differ from the guidance set forth in this Manual.

In the U.S., the FDA takes action against regulated devices via the Federal Food, Drug and Cosmetic Act (FFDCA). The FFDCA definition of "labeling" is broad and includes the following:

- All information on the device's package/User Manual
• The information contained in the Package insert or Prescribing Information and Instructions for Use (collectively referred to herein as "User Manual") and
• Any other written, verbal statements from Company employees, and printed or graphic materials provided by the Company about the device (this includes any medium utilized to promote an Aerocrine device, including the web, blogs, etc., where Aerocrine controls the content or produces the content).

Promotion

Any proactive statements by any Aerocrine employee, or materials used to promote its approved devices—including all smartphone/tablet applications, blogs, social media, visual aids, brochures, journal advertising, promotional programs, and other sales aids—must be consistent with that device’s labeling. In addition, regulatory agency in the jurisdiction in which you conduct business may impose additional requirements on promotional statements and materials. For example, the FDA requires that all promotional materials balance statements about the benefits of the device with information on the safety risks—otherwise known as Fair Balance. All promotional materials should meet the standard of being balanced, accurate, non-misleading, and truthful. All promotional materials that make claims about Aerocrine’s devices must include the device’s User Manual or, for certain advertisements, a Brief Summary. Before dissemination, all promotional materials must be reviewed and approved internally consistent with the associated Aerocrine policies and procedures. Promotion conducted outside of the U.S. must adhere to the standards and guidelines provided by the regulatory agency in the jurisdiction in which you conduct business.

Federal Sunshine Provisions (U.S. Transparency)

Sections 6002 and 6004 of PPACA are known as the Sunshine Provisions or Sunshine Act. Those provisions in PPACA and the implementing regulations require all device manufacturers to disclose certain payments or transfers of value (spend) with physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (“CMS”) on an annual basis. Some states also have transparency laws and disclosure obligations for HCPs with licenses from their states. For more information, please see the chapter on Transparency Laws. It is important that Aerocrine fulfills its reporting obligations to CMS and various state laws with accurate information.

In addition, it is equally important to adhere to the various state law obligations imposed on device manufacturers like Aerocrine (e.g., no meals in Vermont), which are set forth in the Transparency Laws chapter. In both the state and federal context, Aerocrine may be subject to civil and possibly criminal penalties pursuant to the Federal Sunshine Act and/or State Consumer Protection Laws (discussed below) if these laws are violated. Although beyond the scope of the Manual, some countries, including France, have enacted similar transparency laws. Please review the International Transparency heading in the Transparency chapter for a brief discussion.
French Sunshine (ex-U.S. Transparency)

LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé is known as the French Sunshine Act. Like the U.S. Sunshine Act, the French Sunshine Act requires broad disclosure by pharmaceutical and medical device companies. Specifically, the French Sunshine Act and its implementing final decree impose two main types of disclosure requirements on pharmaceutical and medical device companies: 1) all agreements, except for commercial sales agreements of goods and services, that they have with specified individuals, including HCPs, and entities; and 2) certain benefits given to those individuals and entities.

Companies must report the pertinent information on agreements to the public authority within fifteen days of the signing of the agreement. In contrast, for benefits, the relevant information must only be submitted bi-annually. Similar to the U.S., the information that companies report to the French government is made publicly available in France.

France is the most well-known European country to take a legislative approach to transparency, but it is not the only one. For example, Portugal, Slovakia, and Romania also have disclosure laws. It is important that Aerocrine fulfills all U.S. and ex-U.S. reporting obligations, if applicable. Please consult with the Compliance Officer for more information on Aerocrine's reporting requirements.

Japanese Federation of Medical Devices Association (ex-U.S. Transparency)

In Japan, disclosure requirements have been implemented by the Japanese Federation of Medical Devices Association ("JFMDA") via its "Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations." Notably, the JFMDA is an outlier compared to other medical device industry groups around the world, like Eucomed and Mecomed, the Middle East Medical Devices and Diagnostics Trade Association, because it imposed reporting requirements on its members while other similar groups have not.

Under the JFMDA, members must do two things. First, they must establish a transparency policy to govern activities in accordance with the Guidelines. Second, they must publicly disclose payments to medical institutions and healthcare professionals by uploading data on their websites annually for the preceding fiscal year. Under both sets of Guidelines, there are five categories of payments that must be disclosed: 1) research and development expenses; 2) academic research support expenses; 3) manuscript writing, consulting, speaking services; 4) provision of information related expenses; and 5) other expenses, including hospitality provided to healthcare professionals.
Although Aerocrine is not a member of JFMDA and has not adopted any of their codes. Aerocrine expects all employees conducting business in Japan to adhere to the principles set forth in the JFMDA Code and accompanying guidelines.

### Privacy Laws

Both Aerocrine and those working on behalf of Aerocrine (e.g., speaker bureau agents/vendors, etc.) collect and process various types of personal healthcare data—through demo devices, research, etc. Aerocrine is responsible for ensuring that such data is handled carefully and in compliance with applicable federal and state privacy laws and regulations—including, but not limited to, the Health Insurance Portability and Accountability Act (“HIPAA”), the EU Privacy Directive, Brazil’s Marco Civil da Internet and various state laws that prohibit the use of clinician data. If, in the normal course of doing your job, you come into contact with patient information of any sort, the patient’s privacy must be protected—this means that information about a patient may not be emailed to the US-based servers. When and where protected health information (“PHI”) is collected or stored, Aerocrine is committed in complying with the various privacy laws across the globe. If you have any questions, you should speak with the Aerocrine Legal Department or Compliance Officer. For further information on patient privacy and protection of PHI, please refer to the chapter on Patient-Identifiable Data.

### Anti-Trust Obligations

Most countries, including the U.S., Brazil and China, prohibit deceptive or unfair commercial practices. Aerocrine is committed to complying with these trade and anti-trust obligations. In addition to federal law, many states have laws that seek to protect consumers from inappropriate marketing and sales practices. All Aerocrine employees and Third-Party Affiliates are subject to the laws of the various states in which work is performed/provided. Accordingly, Aerocrine employees and Third-Party Affiliates must be cognizant of the state laws and act in accordance with them. For example, virtually all states have broad laws prohibiting “unfair” or “deceptive” trade practices. Some state Attorneys General have utilized the state consumer protection laws to prosecute kickbacks and off-label promotion (any promotion of items or services outside of the User Manual/IFU/Labeling summary). Similar to the state enforcement, Aerocrine competitors are under the same obligations as it relates to claims made about their devices or efficacy. You should direct any questions regarding state laws, antitrust laws, and their impact on your activities to the Legal Department or the Compliance Officer.

### ACCME Guidance

The Accrediting Council for Continuing Medical Education (“ACCME”) and its European counterpart, the European Accrediting Council for Continuing Medical Education (“EACCME”), identifies, develops,
and promotes standards for quality of CME used by physicians to maintain competence and incorporate new knowledge to improve medical care for patients.

Device manufacturers commonly support CME programs conducted by an independent third-party authorized to provide CME (i.e., an ACCME accredited provider), such as a hospital, medical society, or educational vendor. Such “commercial support” for CME programs from a device company must comply with ACCME’s Standards for Commercial Support. Key provisions of these ACCME Guidelines are described below:

- **Independence.** A CME provider must select and control the program’s educational objectives, content, faculty, and educational methods.
- **Financial Disclosures.** Faculty must disclose any relevant financial relationships with the financial supporter of the CME program.
- **Appropriate Use of Commercial Support.** The terms, conditions and purposes of the commercial support must be set out in a written contract between the CME provider and the manufacturer. The CME provider must be responsible for paying faculty as well as reimbursing appropriate faculty expenses in compliance with the provider’s own written policies and procedures. Unless permitted by local law, the provider may not use commercial support to pay or reimburse expenses for attendees. Social events or meals at CME activities cannot compete with or take precedence over educational events. Please see the Sponsoring Non-U.S.-Based Doctors to Attend Medical Congress, CME Events, or Meetings or Informational Sessions section for additional information.
- **Exhibits and Displays.** Device-promotion material or device-specific advertisement of any type is prohibited in or during CME activities. This would allow for promotional booths that are separate and apart from the CME activity location, typically in a room separate from the CME educational sessions. While at the CME event, sales and marketing representatives, and all other company employees, should engage in promotional discussions/activities only where company promotional booths are located and in other areas away from the CME educational sessions. Please see the Grants chapter for further information on whether and how a sales employee may attend a company-funded CME event.
- **No Commercial Bias.** The content or format of a CME activity and its related materials must not promote a particular company or device. This includes any and all communication between the CME vendor/provider and Aerocrine (even a review for medical accuracy). Presentations must be objective and balanced. The source of all support from commercial interests must be disclosed to attendees.
The Grants Review Committee (“GRC”) is the review and approval committee charged with the implementation of the ACCME Guidelines at the Company. The GRC will endeavor to ensure compliance with the above standards in any and all requests for CME support.

With respect to the EU, the good CME (gCME) practice contains similar obligations and strictures. Please consult with the Compliance Officer regarding EU differences.

International Anti-Bribery Laws

The U.S., China, and other countries have statutes or laws that prohibit the promising, authorization, offering, or furnishing with a corrupt or other illegal intent of money or anything of value to influence (or attempt to influence) an HCP, Government Official, or any other person. The payment of a Bribe (or any payment with the intent to influence) to Government Officials is illegal in every country in which Aerocrine does business. In all instances, it is Aerocrine policy that Bribes are prohibited. Aerocrine also forbids all employees, agents, or Third-party Affiliates from requesting, seeking, or accepting Bribes in relation to the Company. All of the above prohibitions apply irrespective of whether the offer, provision, request, or acceptance of the Bribe occurs directly by the employee or through some third-party.

The Global Government-Employed HCP, Physician, and Government and Public Official Interactions Policy and International Anti-Corruption chapter provide specific guidance on how to avoid corruption risks and adhere to Company ethical standards in circumstances that may arise in the conduct of Aerocrine's business outside of the U.S. These sections highlight certain activities that, when performed or employed internationally with HCPs, may inadvertently implicate various anti-corruption laws outside of the U.S.
Aerocrine

Your Duty to Act and Report; The Company’s Open Door, Non-Retaliation and Confidentiality Commitment

The OIG, the DOJ, their foreign regulator analogues, and the state Attorneys General aggressively enforce the anti-kickback laws, the False Claims Act, and other laws and regulations discussed in this Introduction chapter. Any violation of law is subject to prosecution and potentially punishable by a fine and/or imprisonment, as well as civil monetary penalties. Conviction of a company under these laws can also result in its exclusion from participation in federal and state healthcare programs, as well as imprisonment of officers and/or employees responsible for each violation. Increasingly, the OIG and DOJ have sought to impose individual liability on employees pursuant to the Park Doctrine (a theory of law that holds responsible corporate citizens liable for the wrong-doings of the Company).

FDA laws and regulations are also enforced through both the civil and the criminal context. Failure to adhere to the FDA strictures surrounding promotion of an Aerocrine device, in particular, can result in a requirement to run corrective advertising or “pre-clear” future promotional materials. Aerocrine takes compliance with these laws and regulations very seriously and expects every one of its employees to do the same. Any employee who is found to have lied, cheated, or perpetrated a fraud against Aerocrine or any government agency will be subject to disciplinary action, up to and including termination. Taking compliance seriously includes taking prompt action to disclose potential violations (set forth below is the means to do such) and cooperating with investigations of possible violations.

Each employee has a Duty to Act—meaning, if you see, hear, or know about a potential violation of the above-mentioned laws and regulations, you have a duty to report the information pursuant to the means provided herein—by reporting suspected compliance violations to the Compliance Officer, or via one of the methods listed below:

- The Aerocrine compliance email: kathy.rickard@aerocrine.com (non-anonymous); or

Aerocrine follows a strict non-retaliation policy as part of its Code of Business Conduct. Aerocrine adheres to an "Open Door Policy," and encourages Aerocrine personnel to discuss with their manager, Corporate Compliance, Legal, or Human Resources Departments any compliance issues, concerns, problems and/or suggestions without fear of retaliation and with the assurance that the matter will be kept as confidential as possible.

It is important to note that Aerocrine prohibits its employees who are participating in investigations from discussing that investigation with anyone other than the investigator unless specifically advised
to discuss the matter with others within the Company. This maintains the integrity of the process and assures fairness to all Aerocrine employees. Failure to maintain confidentiality and/or failure to act may result in disciplinary action, up to and including termination.

If you ever have a question about whether a particular activity is compliant, always check with the Compliance Officer before engaging in it.
Promotion Policy

This Promotion Policy applies to all employees, distributors or agents of the Company that promote an Aerocrine device to HCPs or to any entities that can influence the use or reimbursement of Aerocrine devices, including GPOs, payers, or any other managed care entities.

This Policy does not apply to those disclosures or activities made pursuant to Aerocrine's SEC reporting obligations, nor does it typically apply to clinical research and R&D activities.

Pre-Approval Activities

Pre-approval or pre-authorization activities may be appropriate in certain situations following local law. These activities may not promote a product in advance of its approval or authorization. Any materials used in support of these activities must be approved before use through the PRC (Promotional Review Committee).

Use Only Promotional Review Committee (“PRC”) Approved Items

Generally, marketing will create any and all promotional pieces for use by sales personnel. Prior to use, the PRC, which is global in scope, must approve those pieces for use for specified promotional purposes for all jurisdictions in which the Company conducts business. Aerocrine maintains a multi-disciplinary PRC that reviews and approves all promotional materials relevant to Aerocrine devices. The PRC is made up of different functional areas including, Medical Affairs, Regulatory and Legal/Compliance (may be outside counsel and may be on an ad hoc basis). The purpose of the PRC is to ensure that each claim related to a device is consistent with FDA, CFDA, ANVISA, or applicable regulatory agency approved labeling, and each claim is substantiated with appropriate scientific or other relevant evidence. The PRC must also ensure that there is sufficient balance between the benefits and the safety risks of a device. To the extent that the Company uses distributors in certain territories, any and all promotional pieces provided to the distributor must be PRC-approved.

Promotional materials directed to patients may only be used or provided when permitted by local laws (e.g., prohibited in the EU) and approved by the PRC. In addition to being accurate, fair and balanced, and not misleading, patient-directed promotional materials must take into account varying levels of education and sophistication of a population.

It is for these reasons that Aerocrine employees may only use pre-approved materials with HCPs, patients or persons that can influence the purchase of our device(s) or use thereof. When meeting with an HCP, Aerocrine employees may never alter, change or delete any portion of approved piece.
By way of example (this is not an exhaustive list), the following practices are allowed or permitted:

- E-mails for inside sales, so long as any product-specific content is approved by the PRC.
- Marking or altering any internal sales training piece for your own information or studying purposes during training classes. Those altered pieces may never be used/discussed/employed with customers/HCPs or externally.
- Note cards with the NIOX logo that have been approved by the PRC.
- Leaving a personal note behind or sending an e-mail to an HCP that is not affixed to a promotional piece, reprint or other disease state material, and does not contain any device information or make a claim. Essentially, professional courtesy notes (“sorry I missed you,” “when can I make an appointment,” or “I would like to schedule a time to discuss exhaled nitric oxide testing with Nixon”) are completely permissible without any device claims.

Conversely, the following practices are not permitted or allowed:

- The creation and use of any “homemade” piece in connection with device discussions external to the Company;
- Marking or highlighting any approved promotional material or any other PRC-approved item that you use with HCPs;
- Sending approved materials by email or other electronic means with personal messages that make any claims about Aerocrine’s devices;
- Marking or highlighting certain sections within the User Manual or reprints unless the marks or highlights where approved by the PRC (the PRC may approve certain reprint carriers that have approved call-outs);
- Providing a press release that has not been approved by the PRC for use with HCPs; or
- Leaving behind published or unpublished data or otherwise (abstracts or posters) that have not been approved for use with HCPs by the PRC.

If you have a suggestion about any marketing materials or other promotional pieces, please do not hesitate to contact the members of the Marketing Department.

All Statements and Activities Must Be Consistent with the Device’s User Manual

All promotional statements and activities MUST be consistent with the User Manual or PRC-approved promotional piece and may not be used or occur before Aerocrine or an Affiliate has received the proper approval, clearance, or authorization in the country in which the activity will occur or the materials will be used. If an HCP asks you an unsolicited off-label question, you must

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1 Press Releases are created pursuant to the Company’s Stockholm Stock Exchange obligations. Unless instructed otherwise and approved by the PRC, a Press Release may not be disseminated promotionally, nor used by the Field. For further discussion see Press Release Policy.
refer it to CSL (Aerocrine Sales persons may not respond to any question or inquiry that requires information or data that is outside of, or inconsistent with, the device’s approved labeling and PRC-approved sales materials). The unsolicited question must be referred to your regional CSL. If no CSL is present in a particular area or country, the question should be referred to the country’s medical director. This question (and call) must either come from the HCP or be written and signed by the HCP. If the CSL is unable to answer the question, the question may be referred to Aerocrine’s Medical or Clinical staff by the CSL.

Questions submitted to Aerocrine’s CSL team must be unsolicited. That means you are not permitted to drive, bait, prompt or solicit questions about the off-label use of Aerocrine devices.

It is important to note that the Field or Aerocrine Commercial may contact the appropriate CSL to follow-up based upon an unsolicited request from an entity or HCP about an Aerocrine device(s), but may not discuss the request with the entity or HCP. In all cases, the CSL will complete the HCP Tracker Form for tracking purposes.

To be clear, Aerocrine employees, other than designated Scientific/Medical Affairs and Clinical staff, are not permitted to answer unsolicited questions about off-label use of Aerocrine devices from an HCP.

Social Media

If you are engaged in any form of social media on behalf of the Company, any and all device-related posts, tweets, updates or otherwise must be approved by the PRC prior to dissemination. The simple mention of an Aerocrine device implicates the legal framework discussed in the Introduction. In addition, and as stated in the Aerocrine SOP 000369 Vigilance System all content posted on the corporate site is Aerocrine’s responsibility. Social media includes all forms of public, Web-based communication.

With respect to internet or social media platforms that have character space limitations (e.g., Twitter, and Google and Yahoo sponsored links), any post or message that presents the benefits of an Aerocrine device must present risk information as well, and conform with the standard requirements pertaining to promotional labeling. To this end, any and all company-sponsored social media that proactively discusses an Aerocrine device, or corrects misinformation online, irrespective of medium, must be PRC-approved.

For a more robust discussion of the use of social media, please consult the Social Media Policy or the Compliance Officer.
Washington Legal Foundation

Aerocrine adheres to the principles set forth in the Washington Legal Foundation (“WLF”) case and related rulings in the U.S. courts with respect to the usage and dissemination of truthful and accurate scientific medical information. For more information, please see Dissemination of Medical and Scientific Information to HCPs. By way of refresher, WLF stands for the proposition that Aerocrine may disseminate truthful, non-misleading, accurate information to HCPs even though it may not be in the User Manual. Prior to any dissemination, the PRC must approve any and all reprints, promotional pieces and means by which the information is disseminated.

Discuss Only Approved Devices and Indications

In a promotional context (excluding investigational use devices), Aerocrine employees may only discuss those things that are consistent with the current approved User Manual and/or approved by the PRC.

Prior to agency approval or clearance of a device or the approval/clearance of a new indication for a device, any claim that the device is efficacious and safe for such use by the manufacturer (or its representatives or agents) is illegal as it is deemed “pre-approval promotion”. During the pre-approval period, there may be some activities and discussions about the disease state in general. These types of activities and discussions are appropriate non-branded discussions. Pre-approval branded promotion (claims about the safety, efficacy or device features prior an approval) can jeopardize a new indication, approval, and/or result in severe remedial penalties. Therefore, it is Aerocrine policy that Aerocrine employees who proactively promote its devices may only discuss approved devices and the approved indication(s).

Prior to an approval, and from time-to-time, payers and other managed care payers/customers may inquire about all uses of a device. If a payer, GPO, or other managed care entity requests information about our device(s), new or potential new indications, the request must be documented preferably via a MIR, but it can be documented in the form of an email which must be kept by the Medical Affairs team. To the extent that the dissemination of the requested information will disclose embargoed or non-public data (data that is material to the Aerocrine and not publicly disclosed), there must be a Confidential Non-Disclosure Agreement (“CDA” or “NDA”) executed prior to any disclosure between Aerocrine and the entity. In that instance, a Medical Affairs employee should disseminate the requested information after receiving the final executed CDA or NDA.
Other Promotional Considerations

Providing a Fair and Balanced Presentation

All presentations regarding Aerocrine devices must include a summary of the relevant safety information in order to “balance” the statements on the device’s efficacy. The FDA requires such “fair balance” and it is necessary to make certain that such disclosures comply with FDA regulations, ensure patient safety, and maintain our scientific credibility. The more robust the efficacy discussion (not defined by the weight of the data, but on the length and prominence of the discussion), the more robust the risk information provided must be in order to balance the efficacy information. This means providing material information, such as relevant clinical trial exclusion criteria, that is necessary for an HCP to make an informed decision about whether and how to employ the device. Balanced presentations demonstrate Aerocrine’s commitment to improving patient care, in addition to being required under the law.

Admittedly, sales interactions are usually limited in duration due to the time pressures on HCPs. However, the Field or other employees that promote Aerocrine devices are still required to make balanced presentations that include relevant device safety information. It is not necessary to use the approved core visual aid or other approved materials on every call. When you do use a promotional piece, you must cite the fair balance as provided in that piece. It also is advisable that the Aerocrine employee provide and leave behind a copy of the Intended Use section of the IFU with the HCP, especially if there is any data discussion about an Aerocrine device.

Making Comparative Claims

The FDA considers promotional materials to be false and misleading if they state or suggest that the safety and/or effectiveness of an approved device is comparable or superior to another without “substantial evidence” to support the claim. Accordingly, no comparative claims may ever be made, suggested or intimated, directly or indirectly, by an Aerocrine employee without PRC-approval.

Except as noted below, it is not appropriate to make comparative claims based on the data included in another device’s User Manual. Similarly, because of the differences in trial designs, inclusion/eligibility criteria and other factors, it is not permissible to compare results from two non-comparative trials. Moreover, it is equally impermissible from making comparisons along a class of devices, or class-type effect.

Local Exhibits and Displays

Aerocrine is often given the opportunity to promote Aerocrine devices and provide approved information and materials to entities and organizations by paying a fee for an exhibit or display table.
It is important to note that this discussion does not include corporate exhibit booths or promotional exhibit booths at large national and international medical congresses/conferences. For more discussion on that topic, please see the discussion on [Conventions and Symposia Exhibits (non-CME)](#) set forth below.

A local exhibit or display opportunity can occur at a variety of venues and programs, but the key principle is that Aerocrine is paying a fee for the space to promote its devices. Aerocrine employees must not pay more than fair market value for the display opportunity.

**Regional Exhibitor/Booth Registration Process:**

1. Get Written (email) approval manager
2. Complete registration paperwork – include date when needed
3. Get W9 from the hosting organization. Check will be sent to address on W9 form.
4. Email paperwork, W9 and managers approval to tradeshow.us@aerocrine.com.
5. If paperwork incomplete, finance will send back to project initiator (sales)
6. Processing of checks is approximately 7-10 business days.
7. Request marketing/sales materials using online form: [https://www.surveymonkey.com/s/jNLHH7B](https://www.surveymonkey.com/s/jNLHH7B)
8. Email will be sent to project initiator when invoice is paid.
9. For expedited requests, please highlight on original request. NOTE: Expedited requests should occur infrequently.

Aerocrine employees may never utilize the CME grant approval process to fund promotional or commercial exhibit opportunities. Promotional and non-promotional funding must always be separated and easily identifiable and able to be tracked for auditing purposes. When determining the appropriate exhibit and display fee, the following variables are a helpful guide and should be considered (this is to be used as a guide and is not exhaustive):

- The opportunity the exhibit and display provides for promotion to a large number of people, or to HCPs that are difficult to see outside of the display opportunity;
- The size of the table/booth and number of Aerocrine employees that can work the table or booth;
- The length of time given to Aerocrine to exhibit and display;
- The physical location of the table or booth in relation to those attending an event;
- Whether setup and cleanup are provided with the exhibit and display fee.

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2 Exhibits and displays may include but are not limited to table-top displays at a hospital event, an advisory board, a regional HCP meeting, a local chapter of a medical association meeting, a large community practices’ meeting, or a local charitable event (e.g., asthma awareness) where exhibits have been requested.
Exhibit and displays are never appropriate in a private practice or local community medical practice, or a foundation that is directly linked to a private practice/community practice.

**Meals Associated with Promotional Activities**

In the promotional context, subject to the requirements set forth below, meals and/or snacks may be provided during promotional activities provided by Aerocrine employees or while promotional speakers (those HCPs speaking on behalf of Aerocrine) are providing a device-focused discussion/review. It is important to note that there is a **total ban** on meals in **Vermont** (absolute prohibition). In certain jurisdictions, the value of a meal must be disclosed, specifically Massachusetts and Federal Sunshine. For more information, please see the discussion in the **Transparency** chapter. When and where possible, this Manual provides clarity about certain state, AdvaMed Code, and Eucomed limitations or requirements.

If permissible by local law, wherever and whenever Aerocrine provides a meal (either via an office visit or “call” with an Aerocrine employee or via a promotional speaker program) the following criteria must be satisfied:

- there must be a significant and substantive discussion of Aerocrine device(s);
- the venue must be conducive to the type of medical and educational exchange;
- there must be an Aerocrine employee or agent (third-party speaker) speaking on behalf of Aerocrine present; and
- the event must be primarily dedicated to the provision of information about the Aerocrine device(s); and
- only HCPs may receive meals (in a restaurant venue but office staff may receive meals in-office).

Aerocrine has determined that, globally, the cost for the meal/food per HCP should be judged as “modest.” In the U.S., Aerocrine has determined that “modest” is:

- A Maximum of $125 per HCP per restaurant meal unless it is a high-cost city
- A Maximum of $150 per HCP in the following high-cost cities: San Francisco, CA; Los Angeles, CA; Chicago, IL; Boston, MA; New York, NY; Washington, DC; Dallas, TX; Miami, FL; all of Hawaii; and Las Vegas, NV
- A Maximum of $30 per HCP per in-office/in-hospital meal if there is no third-party speaker (applies irrespective of the meal—breakfast, lunch or dinner)
• A maximum of $60 per HCP per in-office/in-hospital meal if there is a third-party speaker performing a formal promotional speaker talk (see the Promotional Speaker Programs Policy).

Outside of the US, please consult with the Compliance Officer for the definition of “modest” and “reasonable”.

The restaurant cost per HCP does not include venue/room charges (and any tax on the room charge), but includes food, beverage, gratuity and associated tax. The nature and location of the office visit, or speaker program and attendant meal must facilitate the dissemination of the substantive medical and scientific information about the Aerocrine device(s). To the extent that the purpose of the meeting is more than the visit/call (standing or existing meetings of HCPs), the portion of the meeting in which the Aerocrine device information is provided must be primarily dedicated to providing Aerocrine device information.

Aerocrine employees may not provide food/ meals for existing HCP meetings when the purpose of the meeting is purely social.

In addition, the venue for the meal may not provide independent value, e.g., sporting events, theater, and boat cruises or other venues that are not conducive to informational exchange/dissemination of medical and scientific information. Consequently, no entertainment or recreational events are permitted. It is important to note that some countries (i.e. Italy) may regulate other aspects such as type of airfare (no business class) (if provided). Please check your local country regulations and ensure that you comply with such restrictions.

Meals in the Sales Territory: If the office setting is impractical or not conducive to the exchange, a meal may be provided at a restaurant venue in the territory of the Sales person. However, the following restrictions must be satisfied:

• At least two HCPs have been invited (in good faith), to the program. Generally, the sales representative should, if possible, target an entire practice or office to provide the device discussion (office staff may not attend dinner programs)
• None of the attendees are licensed in the state of Vermont (if s/he maintains an active license and is practicing in the state of Vermont, the attendee may not receive any meal or other “gift” as discussed the Vermont section of Transparency Laws chapter)
• The Salesperson has a significant substantive conversation about Aerocrine’s devices during the meal
• All attendees must remain for the entire meal and device discussion
• Non-HCP guests and HCPs who do not have a legitimate clinical/medical interest in the company’s device being discussed may not attend these discussions or partake in the meal provided (this includes spouses), unless they independently qualify as an HCP who could attend a particular meal
• The meal is modest as consistent with the guidance above
• The venue is conducive for an exchange of information
• At all times, the interaction between parties is promotional and all other policies in this Manual are satisfied, including, but not limited to, on-label discussions
• An CSL or Medical Affairs employee should not attend the meal, but if they do they may not answer any off-label questions (if the CSL is requested, the CSL may alternatively host a meal without the Sales rep in attendance).

Meals at National/International Congresses: Sales personnel may attend and/or host meals with HCPs at national or international congresses if all of the following conditions are satisfied:

• The meal with the HCP occurs during a national or international medical congress or conference, and
• The meal satisfies all other policies set forth in this Manual.

Meals Associated with a Promotional Speaker Program: Sales Personnel may attend promotional program events in a restaurant whereby Aerocrine has procured the services of an HCP to speak on behalf of the Company—this would include the infrequent use of an CSL as the presenter. See the Promotional Speaker Programs Policy, and the underlying Personal Service Arrangements Policy for more information.

Educational-Related Items; Prohibition on Gifts

Aerocrine employees are prohibited from providing gifts to any HCP. Subject to the conditions set forth below, the provision of gifts, in cash or in kind, either directly or indirectly, to induce or with the intent to induce an HCP to prescribe or recommend an Aerocrine device is never appropriate, nor permissible. Unless permitted by local law, an Aerocrine employee may never provide any item or thing of value to an HCP that is intended for the HCP’s personal use, including gift cards or memory sticks whereby there is a value in the unused memory. If permitted by local law, local Affiliates may set their own limitation on value or types of items that may be provided, which will take into account local customs and practice, and will comply with any governing local law, regulation, or industry code. In all cases, gifts must be modest and may be provided infrequently. Further, gifts may never include cash, even if common in the culture or permitted by local law or industry code.
Items primarily for the education of patients and/or HCPs ("Education-Related Items") may be provided if each of the following conditions is satisfied (assuming the PRC has approved the item for dissemination):

- The value of the item is $100.00 or less per item;
- The primary purpose of the item is to advance the disease or education of the patient or the HCP
- The HCP receives the item on an infrequent (occasional) basis and
- The HCP does not “reside” (depending upon the state this could mean licensed and actively works in the state) in a state that would prohibit such Education-Related Item, including the state of Vermont.

Education-Related Items may include (this list is not all inclusive, so consult the Compliance Officer if you have any questions about what is appropriate or are providing items outside of the U.S.):

- Medical text books (see below)
- Anatomical models
- Patient self-assessment and tracking tools
- Other medical tools that an HCP may use directly to educate his/her patients or for the education of the HCP him/herself.

It is important to note that there are only two exceptions to the $100 value for Education-Related Items; specifically, medical textbooks and anatomical models may exceed the $100 threshold only if the following are satisfied:

- The provision of the medical textbook or anatomical model is not promoted by Aerocrine
- The medical textbook or anatomical model is either provided to a practice group (more than one HCP in the group), or the medical textbook or anatomical model is provided to an individual HCP who has not received a medical textbook or an anatomical model from Aerocrine within the past 36 months; and
- If provided to an individual HCP, the HCP is not active and licensed in the state of Vermont.

It is important to note that non-educational materials may not be commingled with Education-Related Items.

**Important Note:** There may be an absolute ban on meals/gifts, or there may be disclosure obligations (even though the provision of the educational item is permitted the value may still be disclosed to a State or Federal Government). Aerocrine employees in certain states, including, but
not limited to the state of Vermont, must consult with the Compliance Officer to determine whether the provision of any Education-Related Item is permissible. Although permissible at the federal level, or in the Manual, some states are more restrictive (there is an absolute ban in the state of Vermont).

Please review the Transparency Laws chapter to determine whether state law prohibits certain gifts or further defines a “modest meal” or requires disclosure of the value of such.

Coverage and Reimbursement Discussions

The payment and reimbursement landscape is ever changing. Aerocrine may partner with HCPs, patients and patient organizations to represent Aerocrine’s interests and/or to achieve government and commercial payer coverage decisions, guidelines, policies and adequate reimbursement. Accordingly, permissible activities may include:

- Identifying the clinical value of Aerocrine’s devices and technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to HCPs, professional organizations, patient organizations, and payers.
- Collaborating with HCPs, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting HCPs and their professional organizations in developing materials and otherwise providing direct or indirect input into payer coverage and reimbursement policies.
- Promoting accurate Medicare and other payer claims by providing accurate and objective information and materials to HCPs regarding Aerocrine’s devices, including identifying coverage, codes and billing options that may apply—remember all materials used or employed must be PRC-approved.
- Providing accurate and objective information about the economically efficient use of Aerocrine’s devices, including where and how they can be used within the continuum of care.
- Providing information related to Aerocrine’s devices regarding available reimbursement and associated costs. (For Example, using PRC approved cost calculators)
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate an HCP’s decision to buy or use Aerocrine device(s).
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use of the Company’s devices.
- Facilitating patient access to Aerocrine devices by providing HCPs with assistance in obtaining patient coverage decisions from payers. This assistance may include providing information and/or training on payer policies and procedures for obtaining prior
authorization, and providing sample letters and information on medical necessity and appeals of denied claims.

Any materials used with the activities above must be accurate and balanced and must have the approval of the PRC. The PRC will delineate which employees may have certain reimbursement discussions as discussed above. At no time may Aerocrine interfere with an HCP’s independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement to use an Aerocrine device. For example, Aerocrine may not provide, subsidize or underwrite services that eliminate or reduce an overhead or other expense that an HCP would otherwise incur as an ordinary business expense or business operational expense.

Conventions and Symposia Exhibits (Non-CME)

All device-specific promotional and scientific activities are under the jurisdiction of the FDA. For national conventions, symposia and other large meetings, all floor plans, exhibit booth space (layout of the Aerocrine portion only), activities, pre-conference training, and information/material/items to be disseminated at all exhibits must be reviewed and approved by the PRC. Exhibit fees at large conventions and symposia must be paid directly to the institution(s) or organization(s). The exhibit fees – regardless of the amount - may never be provided to individual physicians or physician-owned groups.

It is Aerocrine policy that commercial booths/exhibits may be utilized at national medical conventions, congresses, or symposia where the following specialties are present: allergy, pulmonology, ENT, pediatrics, and primary care. This is independently ascertainable by previous history, the brochure, or calling the sponsoring organization itself. To reinforce proper device promotion, Aerocrine will have a pre-con meeting at all national medical conventions or symposia for all Aerocrine employees that promote any Aerocrine device at that convention or symposia.

Promotional vs. Medical Booths

**Commercial Booths:** The commercial side of booths is promotional in nature. Thus, all materials located in, or distributed from, the commercial side of the booth must be consistent with the associated device’s User Manual and must be approved for promotion by the PRC. Aerocrine Sales and Marketing personnel may not discuss off-label uses of devices with HCPs who visit the commercial side of the booth. If an HCP asks an off-label question, Sales or Marketing personnel must direct the HCP to the Medical Affairs side of the booth (to the extent that there is one at the congress/symposia) or direct the HCP to the MIR process. Promotional items may be distributed from the commercial side of the booth subject to PRC approval, and/or the organization’s policies.

**Medical Booths:** The medical information side of booths is a non-promotional venue used to provide HCPs with an appropriate range of clinical and scientific information. The medical information side of
the booth must be staffed only by Medical Affairs or Clinical employees; no Sales or Marketing personnel may be located in, or distribute information from, the medical information side of the booth (an HCP may be escorted over for a warm transfer). Promotional activity is not permitted at the medical information side of the booth. Under certain circumstances and with prior approval by PRC, personnel staffing a medical information booth may distribute reprints, or peer-reviewed scientific information.

At a conference or convention where Aerocrine has both a commercial and a medical information side of a booth, there must be a clear demarcation between the two sides. As a result, each side must be easily distinguishable from the other and have an overall different appearance to ensure clear separation of promotional and educational intent. Generally, if the commercial and medical booths are part of one “footprint” the PRC will review the booth in its entirety before it is used.
International Anti-Corruption Chapter

The Company prohibits the promising, authorization, offering or furnishing with a corrupt or other illegal intent of money or anything of value to influence (or attempt to influence) an HCP, Government Official or any other person to act improperly. The payment of a Bribe (or any payment with the intent to influence) or inducement to Government Officials is illegal in every country in which Aerocrine does business. In many instances, Bribes are also prohibited if the recipient is in the private sector. The Company also prohibits all employees from requesting, seeking, or accepting Bribes in relation to conduct of all Company business affairs. All of the above prohibitions apply irrespective of whether the offer, provision, request, or acceptance of the Bribe occurs directly by the employee or through a Third Party. Please note that in most countries outside of the U.S., HCPs are Government Officials, thus outside of the U.S., HCPs are deemed Government Officials for purposes of anti-corruption purposes.

This Chapter provides specific guidance on how to avoid corruption risks and adhere to Company ethical standards in circumstances that may arise in the conduct of our business. The Chapter does not change, alter or amend any other Chapter or Policy in this Manual, but highlights certain activities, when performed or employed internationally, may inadvertently implicate various anti-corruption laws outside of the U.S.

Other Chapters or Policies in the Manual set forth specific guidance concerning the following topics as they relate to international or global circumstances:

- Charitable Contributions
- Political Contributions
- Gifts, Meals, and Entertainments
- Sponsoring Non-U.S.-Based Doctors To Attend Medical Congresses, Continuing Medical Education (CME) Events, or Meetings or Informational Sessions Organized by Aerocrine

This Chapter sets forth specific guidance concerning the following topics as they relate to international or global circumstances:

- Relationships with Distributors, Consultants, Joint Venture Partners, and Other Third Parties
- Visits to Company Facilities and other Travel Benefits
- Post-Marketing and Other Studies
- Facilitating Payments

The policies set forth in this Chapter and Manual help explain how the U.S. Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act 2010 (the "UK Act"), the Criminal Law of the People’s Republic of...
China and the Anti-Unfair Competition Law of the Peoples Republic of China, Brazil's Clean Company Act, and similar anti-corruption laws apply to circumstances that can arise in our day-to-day business. Many other countries around the world have adopted legislation that is similar to the FCPA and the UK Act, underscoring that eliminating any type of bribery or corruption is an international concern.⁴

Compliance with the policies and procedures contained in this Chapter and the Manual is mandatory and is each employee’s responsibility. In addition to penalties that may be imposed by law or regulation, any employee (or Third Party or other contractor of Aerocrine performing services on behalf of Aerocrine) who violates the policies or procedures in this Chapter or Manual may be personally liable pursuant to applicable law. All Company employees are expected to adhere to and familiarize themselves with the policies and procedures in this Chapter and Manual, and to seek advice from Compliance or Legal or the Compliance Officer.

This Chapter applies to all Company employees, and its agents/vendors, and other Third Parties irrespective of location (whether operating outside the U.S. or operating within the U.S. when dealing with matters involving operations or persons located outside the U.S.). With respect to our employees in Sweden and subsidiaries outside the U.S., this policy also applies to their conduct in the U.S.

All employees who conduct Aerocrine business outside of the U.S. are responsible for familiarizing themselves and complying with the policies and procedures in this Chapter. All company Third Parties must also familiarize themselves with this Chapter and are prohibited from engaging in any act or omission which would cause the Company or its employees to run afoul of the terms herein.

How and When to Seek Advice

Corruption issues often are not black and white. Whether a payment is permissible will always depend on the unique set of facts and the surrounding circumstances. That means that changing just one fact might turn a permissible action into an impermissible one.

While this Chapter and Manual is intended to provide some basic guidance, it cannot anticipate the many questions that can arise in this area. If you find yourself in a situation where you are unsure whether an action could breach this Manual, you must SEEK ADVICE from Legal or Compliance. There are many people within Aerocrine that can help assess a situation and determine whether an action could violate the policies in this Manual. Those resources will vary depending on the country in which you work, but they can include:

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³ A short summary of the FCPA can be found as Attachment A to this Chapter. The UK Act is discussed in Attachment B. A short summary of the Criminal Law of People's Republic of China and the Anti-Unfair Competition Law of People's Republic of China can be found as Attachment C.
If you ever find yourself in doubt about a particular situation, you have a duty to act, which means that you must seek advice and/or report the situation. Make no mistake: corruption-related issues can have significant consequences for the Company and for you. Do not feel that it is your responsibility to make those difficult judgment calls alone.

**Relationships with Distributors, Consultants, Joint Venture Partners, and Other Third Parties**

The Company’s Third Parties play an important role in Company operations, including its supply chain. Aerocrine relies on its Third Parties to provide a range of services that vary across markets.

Special issues are raised when a Third Party must interact with an HCP or other Government Official on behalf of Aerocrine, or when a Third Party will prepare work product that will be submitted to a government agency for review or consideration on matters relating to Aerocrine’s product. Of particular concern is the possibility that a Third Party will make an improper payment, or corruptly give something else of value to a Government Official, in order to obtain some benefit for Aerocrine or another party in return. A Third Party may never engage in conduct that is prohibited under Aerocrine policies. If one of Aerocrine’s Third Parties makes a prohibited payment, that creates a risk to Aerocrine – and also to any Aerocrine employees who are involved. In certain cases, this risk arises even if the recipient of the Bribe is in the private sector.

For these reasons, each relationship with a potential Third Party must be carefully scrutinized with corruption risks in mind. While each proposed Third Party relationship must be evaluated on its specific facts, there are several “red flags” that employees must constantly be alert to because they may signify a heightened risk to Aerocrine. “Red flags” include situations where:

- **A Government Official recommends a specific Third Party to Aerocrine to distribute Aerocrine products, help obtain a permit, or provide some other service.** In some cases, a Government Official may seek to enrich himself through kickbacks received from a favored Third Party. Your business unit should not enter into any agreements with Third Parties who were recommended by a Government Official without first consulting with the Compliance/Legal Department.


The proposed Third Party has a personal, business, or family relationship to a Government Official. The Third Party may use this relationship to provide Bribes to the Government Official in order to obtain or retain business for Aerocrine.

A proposed Third Party requests fees which are much greater than the fair market rate for comparable work carried out in the relevant market without any reasonable explanation. A request for unusually high compensation may indicate that part of the fee will be used for improper payments. The fact that the fee would be covered in the price is irrelevant. Seek guidance from the Compliance Officer before agreeing to pay such fees.

The agreed price for a sale is unusually large, or the final contract price is higher than Aerocrine’s offering price, especially in the context of a government tender. Above-market prices or unilateral price increases may reflect additional funds needed to cover improper payments to influence decisions of Government Officials.

A consultant or Third Party proposes to be paid a large success fee if, for example, a permit is obtained or a study is accepted. The consultant or Third Party could intend to use a portion of the success fee to make an improper payment.

A distributor or other proposed Third Party refuses to certify that it will not take any action in furtherance of an improper payment. All legitimate distributors and other Third Parties should be prepared to certify that they conduct business in accordance with the law.

A distributor, consultant or other Third Party has a reputation for paying Bribes or engaging in other inappropriate or ethical activities. All Third Parties must be vetted through the proper channels, namely the Compliance Department. If it is discovered that a potential Third Party has a questionable reputation, great care should be exercised prior to use of such Third Party. The Compliance Officer must approve any such Third Party or potential vendor if there are any such reputational concerns.

A distributor, consultant or other Third Party requests payment in cash. Cash payments may indicate that some of the money will be used for improper payments. Aerocrine or its employees must not pay a Third Party in cash without Compliance authorization to do so.

A distributor or other Third Party suggests that an additional fee is warranted to pay for the “expenses” of doctors or Government Officials. Such payments by the distributor or other Third Party may be unlawful, and by funding them you could place Aerocrine – and yourself – at risk.
An Aerocrine consultant or other Third Party requests that his or her agreement be kept secret from his or her employer. Secret agreements imply that some improper relationship may exist or that Aerocrine would be complicit in eviscerating the employers’ policies.

The proposed Third Party refuses to disclose the identities of subcontractors and sub-agents that may be used to perform work for Aerocrine. This refusal calls into question the reputation of the subcontractor and sub-agent. The business unit must obtain the names of any subcontractors and sub-agents which the Third Party may retain to help perform work for Aerocrine and perform some form of due diligence on such persons.

A distributor, or consultant or other Third party requests that payments be made to another party or to a third-country bank account, or requests other unusual financial arrangements. Such a request may indicate that the money is being used for improper purposes. While the practice may be acceptable if properly justified and is not necessarily illegal, the request should raise a red flag. In addition, alternate payment methods or delivery locations after the negotiation of the contract raises similar red flags (Compliance and Legal must approve any changes to payment methods or delivery locations).

In assessing potential Third Parties, Aerocrine employees must adhere to the following:

- There must be a sufficient business justification for retaining the Third Party.
- The potential Third Party must have the necessary qualifications and resources to perform the tasks which will be covered by the agreement.
- A written statement must be submitted to Compliance to vet the proposed Third Party.

Compliance will utilize the information provided to perform the due diligence. Compliance may outsource the due diligence depending upon the risk inherent in the type of activity proposed and the location of the services to be provided. The due diligence may include, but is not limited to, the proposed Third Party, its principals, owners, shareholders, employees, subsidiaries, and any other individual or entity associated with the Third.

Once Compliance is satisfied with and has approved the due diligence of the Third Party, the Company may proceed with hiring the Third Party. Unless otherwise directed by Compliance, all agreements with Representatives must be in writing and contain anti-corruption contractual provisions.

If at any time you learn or suspect that a distributor or other Third party has made an improper payment to a doctor or other healthcare professional, some other Government Official, or any other person, you must bring that concern to the attention of the Compliance Department immediately.
All payments, including expense reimbursements, provided to Third Parties must be accurately reflected in the books and records of the relevant Company business unit.

Visits To Aerocrine Facilities And Other Travel

Whether and under what circumstances Aerocrine is permitted to pay for Government Officials and other customers and persons to visit Aerocrine offices/facilities or other business-related locations is one of the most recurring issues involving anti-corruption and other laws.

Under some circumstances, it is permissible for Aerocrine to pay for a HCP’s or another party’s travel and accommodation expenses for visiting an Aerocrine site or other business-related location, including Aerocrine’s manufacturing facilities. However, there are three important limitations:

First, the travel must be for a legitimate business purpose, such as meetings to discuss regulatory or compliance issues concerning Aerocrine, such as conduct of site-inspections;

Second, the expenses must be reasonable and Fair Market Value;

Third, the expenses must not violate applicable local laws or government policies or official staff rules or codes of conduct.

As described below, prior approval is required for all travel and travel-related expenses that Aerocrine pays on behalf of Government Officials, including all non-U.S. doctors and other healthcare professionals. All such requests are subject to the following policies and procedures:

PRIOR APPROVAL REQUIRED FOR TRAVEL REIMBURSEMENTS: All travel-related expenditures made on behalf of Government Officials (including all non-U.S. doctors and other healthcare professionals) or other persons must be approved in advance. This review must include a careful assessment of the reasonableness of the expenses and the business need for the trip. Special scrutiny should be given when international travel is involved. Travel will not be approved unless:

- the travel is for a legitimate business purpose;
- the expenses are reasonable;
- no friends or family members of the Government Official or other person are traveling at Aerocrine’s expense;
o no stopovers are planned that are not directly connected to the business purpose of the travel, unless the stopover is at the expense of the Government Official or other recipient and results in no additional cost to Aerocrine; and

o the travel reimbursement conforms to the Aerocrine Travel & Entertainment Policy.

**METHOD OF PAYING FOR TRAVEL AND RELATED EXPENSES:** Travel expenses may only be reimbursed against appropriate receipts or equivalent documentation—preference is made to direct payment by Aerocrine’s travel agent. Under no circumstances may cash be transferred to another party on the understanding that the other party will arrange for his or her own travel.

**PER DIEM PAYMENTS ARE PROHIBITED.**

**BOOKS AND RECORDS:** All travel and related expenses must be accurately reflected in the books and records of the relevant Company business unit.

**Post-Marketing And Other Studies**

From time to time Aerocrine conducts post-marketing studies in markets where healthcare professionals are employees of government institutions or otherwise affiliated with government entities. These studies can generate important data that can lead to product improvements and innovations, and that can help Aerocrine optimize the safe and effective conditions of use of its marketed devices in the target patient population.

As industry codes of conduct reflect, post-marketing studies have been susceptible to abuse in the past by some companies in our industry. Accordingly, a post-marketing study can only be pursued if the purpose is to obtain legitimate data useful to Aerocrine. The following policies must be observed for all post-marketing and similar studies:

- **All post-marketing studies must be approved in advance by the appropriate medical or clinical committee, and must be consistent with the Medical Affairs objectives that are prospectively created.**

- **A study may not be approved if it possesses any of the following characteristics:**

  o **Payment of unreasonably or uncharacteristically large fees.** Any fees paid to healthcare professionals who participate in a study must be to compensate the participant for his or her time or effort devoted to the study. Fees must be reasonable in relation to the time and effort expended by the participant. Any fee substantially outside the range of reasonable fees suggests that participants are being paid for something more than their participation in the study, and raises the
question of whether the payment was made in exchange for prescribing or using Aerocrine’s devices. Fee payments must not violate applicable laws or policies.

- **Participant selection criteria based on objective Medical factors and criteria (the HCP’s use or future use of Aerocrine's devices may not be considered).** Use of other selection criteria, or unclear selection criteria, to choose healthcare professionals to take part in the study could suggest that the motive for the study is something other than the generation of useful data.

- **Absence of study protocols.** If a study has a legitimate useful purpose and is designed to produce useful data for Aerocrine, there should be guidelines and parameters for the participants to follow that will increase the likelihood that the data generated by the study are valuable to Aerocrine. The absence of a study protocol, or the use of a vague protocol, suggests the absence of a genuine need for data generated by the study.

- **Absence of reports.** Aerocrine can only review data from studies if participants are provided with a mechanism to convey the results to Aerocrine. The absence of such a reporting mechanism suggests the absence of a genuine need for the data generated by the study.

- **No plan to evaluate or utilize resulting data.** Data generated from a post-marketing study must potentially be worthy of review and evaluation, and must be collected in a form that permits review and evaluation to occur. Upon review, data generated by post-marketing studies do not always prove useful. However, the data must be of sufficient interest to Aerocrine at least to merit evaluation. The absence of any plan to review data from a post-marketing study suggests an inappropriate motive for the study.

**Facilitating Payments**

Facilitating Payments are strongly discouraged, impermissible under the laws of most countries (UK Bribery Act), and must be avoided whenever possible. Under the UK Bribery Act, a facilitation payment is a type of Bribe and should be seen as such. A common example is where a government official is given money or goods to perform (or speed up the performance of) an existing duty. Facilitation payments were illegal before the Bribery Act came into force and they are illegal under the Bribery Act, regardless of their size or frequency.
A Facilitating Payment is a small, unofficial payment that is designed to secure or expedite a routine performance of a routine or necessary government action by a Government Official. They are sometimes referred to as ‘speed’ or ‘grease’ payments. The payer of the facilitation payment usually already has a legal or other entitlement to the relevant action. Examples include obtaining a license to do business in a foreign country, processing a visa, scheduling an inspection, providing police protection, securing mail pick-up or delivery, getting utilities such as power or phones connected, and moving perishable goods through customs.

Facilitating Payments are not prohibited under U.S. law. However, employees must take great care to distinguish facilitating payments from prohibited Bribes. Importantly, a payment that is intended to affect the result of a governmental decision-making process is not a facilitating payment. Thus, payments that are intended to alter the outcome of a government decision in any way may not be made under any circumstances. For instance, employees are strictly prohibited from making corrupt payments to obtain, retain or direct government business or a tax advantage to the Company or any other party.

Any and all Facilitating Payments MUST be submitted for advance approval by Compliance. As a general matter, Facilitating Payments will not be permitted other than in exceptional circumstances. The list below provides some guidance for the review of Facilitating Payments:

1. Criteria: A Facilitating Payment may not be made unless it meets all of the following criteria:

   - **NECESSARY ON OBJECTIVELY JUSTIFIABLE GROUNDS TO SECURE OR EXPEDITE A ROUTINE GOVERNMENT ACTION:** If the payment is intended to influence the outcome of a government decision, then it is prohibited.

   - **NECESSARY TO PREVENT DAMAGE TO AN IMPORTANT COMMERCIAL INTEREST OF AERCRAINE OR HARM TO AN EMPLOYEE.** Facilitating Payments may not be made simply because it may be convenient to have some governmental action taken more quickly. Early performance of the action in question must be necessary to prevent serious damage to an important commercial interest or harm to the health or safety of an employee.

   - **MODEST IN AMOUNT:** Facilitating Payments must in all circumstances be modest in amount.

   - **CUSTOMARY:** Facilitating Payments may only be made in countries where, and in situations in which, such payments are customary.
• **NO REASONABLE ALTERNATIVE:** A Facilitating Payment should be viewed as a final resort. If there is any reasonable alternative for securing the required routine governmental service, or if any expected delay can be reasonably accommodated, the Facilitating Payment may not be made.

2. **Prior Approval:** No Facilitating Payment may be made without advance written approval by Compliance.

3. **Accurate Accounting:** All Facilitating Payments must be accurately described and recorded in the appropriate accounting books and records of Aerocrine.
ATTACHMENT A

U.S. Foreign Corrupt Practices Act Overview

The U.S. Foreign Corrupt Practices Act (“FCPA”) was enacted in 1977 and amended in 1988 and 1998. The anti-bribery section of the FCPA prohibits U.S. companies and their foreign subsidiaries, including their officers, directors, employees, agents and shareholders, from corruptly offering, paying, giving, promising, or authorizing the provision of any money or thing of value to a “foreign official” to obtain, retain, or direct business to any party. The FCPA does not require the foreign official to take any action (i.e., the Bribe does not need to succeed). The mere offer and promise of a Bribe is sufficient to cause a violation of the FCPA. The FCPA’s anti-bribery prohibition applies not only to direct bribes, but also to the corrupt provision of money or things of value to a Third Party while Knowing that all or a portion of that money or thing of value will be used to Bribe a Government Official. The Knowing standard, discussed further below, is very broad. For example, any payment to a foreign official by an Aerocrine’ local agent, representative, consultant, or venture partner is prohibited if it is made with a corrupt intent in return for such official exercising his or her influence to help Aerocrine to obtain new business or to retain existing business.

The term “foreign official” is defined broadly. It includes (i) officers and employees of any national, regional, local, or other governmental entity, including elected officials; (ii) any private person acting temporarily in an official capacity for or on behalf of any governmental entity (such as a consultant retained by a government agency); (iii) officers and employees of government-controlled or government-owned companies; (iv) candidates for political office at any level; (v) political parties and their officials; and (vi) officers, employees, or official representatives of public (quasi-governmental) international organizations, such as the World Bank, the World Health Organization, the United Nations, the IMF, etc. Again, it is important to note that physicians are generally “foreign officials” outside of the U.S.

Under the FCPA’s “Knowing” standard, a company has knowledge of prohibited conduct if the company is (a) actually aware that the third party (to whom company resources are given) is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur or (b) has a firm belief that such circumstance exists or that such result is substantially certain to occur. A company is also deemed to have knowledge of a particular circumstance if the company is "aware of a high probability of the existence of such circumstance, unless the person actually believes that such circumstance does not exist." Thus, a U.S. corporation can be held liable if its actions indicate a conscious disregard or deliberate ignorance of circumstances that should reasonably alert the company to the high probability of illegality. A U.S. corporation cannot turn a blind eye to suspicious activities of its Third Parties, hoping not to learn of prohibited activity. It is as a result of this high “knowing” standard that U.S. companies are required to perform due diligence on Third Parties to ensure that they do not have a history or reputation for corruption.
The recordkeeping and accounting provisions of the FCPA are extremely broad. Public companies, such as Aerocrine, are required to maintain books and records that accurately and fairly reflect, in reasonable detail, all company transactions and expenses, including those of certain of its subsidiaries, joint ventures, and affiliates which it owns and controls. Aerocrine and its employees are prohibited from making any false or misleading entries on the books. Thus, for example, Aerocrine would be in violation of this prohibition if one of its subsidiaries paid a commission that it knew would be used to fund a bribe and described the payment on its books as a “commission.” Calling a bribe a commission (or a Compliance/Legal expense, a payment for materials, etc.) constitutes a prohibited falsification of Aerocrine’s books. Because there is no materiality standard in the FCPA, companies are required to account accurately for all transactions, not merely for sums deemed material in the traditional financial sense. This also means that an inaccurate entry in Aerocrine’s books and records could violate the FCPA even if it is not related to a corrupt payment to a foreign official.

The FCPA also obligates public companies such as Aerocrine to devise and maintain effective internal accounting controls. This means that employees must ensure that all payments and expenditures incurred with respect to Aerocrine business are properly authorized.

The FCPA is a criminal statute. Aerocrine could be fined $2,000,000 per willful violation of the FCPA’s anti-bribery provisions and $25 million per willful violation of the FCPA’s accounting provisions. Any officer, director, shareholder, employee or agent of Aerocrine who willfully violates (i) the anti-bribery provisions of the FCPA would subject to a fine of up to $100,000 and imprisonment for up to five years, or (ii) the accounting provisions of the FCPA could be subject to a fine of up to $5 million per violation and a maximum prison sentence of 20 years.

All employees are urged to consult with the Compliance/Legal Department whenever a question arises regarding the FCPA.
ATTACHMENT B

The UK Bribery Act

The UK Anti-Bribery Act (the “UK Act”) prohibits Bribes to UK and other Government Officials as well as employees of private-sector entities in the United Kingdom or elsewhere in the world. The UK Act applies to Aerocrine commercial entities and employees that have a connection with the United Kingdom. Specifically, the UK Act applies to (i) Aerocrine’s UK subsidiaries; (ii) certain of Aerocrine’s U.S. and other non-UK entities that directly or indirectly (through other Aerocrine subsidiaries or third parties) engage in business in the United Kingdom; (iii) Aerocrine employees of any nationality who reside or engage in business in the United Kingdom; and (iv) Aerocrine employees who are UK citizens irrespective of whether they reside or engage in business in or outside the United Kingdom. [NB. These 4 classes of individuals/entities that the Act applies to is too proscriptive - the Act will apply (according to sections 7(3) and 12(5)) to all Aerocrine’s subsidiaries and employees. The Act claims jurisdiction for corporate liability for acts committed by any person, in any jurisdiction providing that the company is incorporated/formed in the UK or the organization carries on a business/part of a business in the UK. This is a matter for common sense and if the UK subsidiaries act independently from the parent company, it cannot be said to be carrying on business in the UK. However, it may be worth revising the above so that it is clear that the Act is very broad in terms of its applicability]

The UK Act prohibits a person from offering, promising, or giving (directly or indirectly through a Third Party) a financial or other advantage to a recipient with (i) the intention that the advantage induce the recipient to perform improperly a relevant function or activity or to reward a person for the improper performance of such function or activity, or (ii) the knowledge or belief that the acceptance of the advantage would itself constitute the improper performance of a relevant function or activity. This offense will occur irrespective of whether the recipient is in the public or private sector in the United Kingdom or elsewhere.

The UK Act also prohibits individuals in the public and private sectors from accepting or requesting Bribes for the improper performance of a relevant function. As a result, the International Anticorruption Chapter prohibits Aerocrine employees from demanding or accepting Bribes in relation to the Company or its business.

Commercial organizations will be strictly liable under the UK Act if they fail to prevent bribery. Specifically, this corporate offense is committed when a person associated with a commercial organization (such as an employee, agent, subsidiary, contractor, or a joint venture partner or entity) Bribes another person with the intention of obtaining or retaining business for the organization or a business advantage in the conduct of business for the organization. An organization can defend against such potential liability if it can prove that, despite the instance of bribery, it had adequate
procedures in place designed to prevent persons associated with the organization from committing bribery. The International Anticorruption Chapter is part of Aerocrine’s efforts to maintain adequate procedures to prevent bribery. It is imperative that Aerocrine’s employees adhere to the guidelines set forth in this Manual.

Under the UK Act, individuals guilty of bribery may be subject to a maximum penalty of imprisonment for up to 10 years and/or subject to a fine of an unlimited amount. Commercial organizations guilty of bribery or failure to prevent bribery may also be subject to a fine of an unlimited amount as well as debarment from government contracts. [There may also be proceeds of crime applications in which all financial benefit that cannot be proved by the defendant/defendant company was legitimately acquired is confiscated. Any company director convicted may also be disqualified.]

All employees are urged to consult with the Compliance/Legal Department whenever a question arises regarding the UK Act.
ATTACHMENT C

Brazil's Anti-Bribery Law ("Clean Company Act") Law No. 12,846

The Brazil Clean Company Act ("BCCA") was enacted August 1, 2013, and took effect on January 29, 2014. The BCCA applies to both Brazilian companies and multinational companies operating in Brazil, and imposes severe civil and administrative sanctions for (i) bribing domestic or foreign government or public officials, and (ii) engaging in fraud in connection with public procurement activities. The BCCA applies to Aerocrine as it has representatives, as well as an office in Brazil. Unlike the U.S. Foreign Corrupt Practices Act ("FCPA") the BCCA imposes strict liability (i.e., no intent is required). The BCCA will find one or more offences committed in a company's interest or for a company's benefit as sufficient to demonstrate a violation.

A government or public official is a person(s) who holds a position in any public agency or entity. The BCCA expressly prohibits companies and individuals from offering or giving, directly or indirectly, an improper benefit or undue advantage to a public agent, or to a third party related to such agent (i.e., foreign and Brazilian public officials). The BCCA also prohibits the use of an intermediary to conceal the interest or identity of the beneficiaries; the funding or sponsoring of illegal acts; the frustrating or defrauding of the public bidding process; and the hindering of investigations; or audits by public officials or entities. Unlike the FCPA, the BCCA does not contain a "Facilitating Payments" exception. "Facilitating Payments" means a payment is made to a government official to expedite the performance of routine governmental action—a non-discretionary functions that those government officials are required to perform.

Violating the BCCA can result in Aerocrine receiving a range of sanctions including fines and judicial penalties. The fines range from 0.1% to 20% of Aerocrine’s gross revenue during the year of the government investigation. If gross revenue cannot be calculated, the government may impose fines ranging from R$6,000 (approximately $3,000 USD) up to R$60,000,000 (approximately $30,000,000 USD). Notwithstanding this range, the BCCA provides that fines may not be "less than the benefit gained" and the application of penalties "does not exclude the obligation to fully indemnify the damage caused," which means that liability can potentially extend beyond the R$60,000,000 set forth above. In addition to fines, violating the BCCA can result in widespread publication of the violations in various forms of media as well as multiple judicial penalties. Judicial penalties include loss of assets, injunctions, debarment, or suspension of Aerocrine’s activities and dissolution of the company. Violating the BCCA may also impose joint liability on some or all of Aerocrine’s companies, Affiliates, and or subsidiaries.

Fines can be mitigated if companies demonstrate that they maintain effective anti-corruption compliance programs, if the voluntarily disclose violations to the authorities; and if they cooperate in relevant investigations. In that regard, voluntary disclosures and reports of misconduct before it comes to the attention of the government; cooperation; and ceasing the unlawful activity before
being asked to do so could qualify a company for "Leniency Agreements." Leniency Agreements can include a reduction of up two-thirds of the fine that would have been otherwise imposed, as well as reductions in other sanctions. As such, Aerocrine encourages all employees, agents, and Affiliates to report any potential or actual violations of the BCCA to the Compliance Officer.

Aerocrine is aware of the existing legal framework (e.g., Brazilian Penal Code, Law on Administrative Improbity (No. 8,429/1992), Bid Law (No. 8,666/1993), and Code of Ethics for Public Officials of the Brazilian Federal Administration (Decree No. 1,171/1994) and encourages all employees, agents, and Affiliates to comply with them.
The primary laws controlling anti-bribery and anti-trust in China are The People's Republic of China Criminal Law ("PRC Criminal Law") and the Anti-Unfair Competition Law of People's Republic of China ("AUCL"). China recognizes two forms of bribery, i) Commercial (active and passive), and ii) Official Bribery. While both the PRC Criminal Law and AUCL regulate Commercial Bribery (active and passive bribery that takes place in the private sector); Official Bribery (giving articles of property to "state functionary" to seek improper benefit) is only regulated by the PRC Criminal Law. For purposes of Aerocrine's compliance efforts, "property" is broadly defined and includes: cash, tangible property, marketing fees, promotion fees, sponsorship fees, research fees, service fees, consultation fees, commissions and reimbursements, and offering travel inside or outside China.

Commercial Bribery under AUCL:

The AUCL broadly defines Commercial Bribery. Article 8 of the AUCL prohibits any Aerocrine employees, agents, or Affiliates from offering money or goods or using any other means in order to purchase or sell products in a manner that restrict free competition.

Commercial Bribery under the PRC Criminal Law:

The giving of money for the purpose of securing any improper benefits may trigger criminal liability and constitute a bribe under the PRC Criminal Law. For an active commercial bribery to constitute an offense under the PRC Criminal Law, the value of the transaction or bribe must be:

- At least RMB 10,000 (approximately US $1,600), where committed by an individual.

- At least RMB 200,000 (approximately US $32,000), where committed by a company or other organisation.

Official Bribery Under the PRC Criminal Law:

Under the PRC Criminal Law, an Aerocrine employee has committed an act of Official Bribery when he or she "gives articles of property to 'state functionaries' in order to seek improper benefit." Accordingly, Official Bribery can take place in any of the following forms: acceptance of a bribe by a public official; acceptance of a bribe by a public entity (including state owned enterprises and other public entities); active bribery of a public official by an individual; active bribery of a public entity
(including state-owned enterprises and other public entities, by an individual or an entity); or active bribery of a public official by an entity.

The term “state functionaries” is defined broadly in Article 93 of the PRC Criminal Law and refers to all personnel of "state organs." Article 93 further explains that a state functionary includes:

- persons who perform public service in state organs (e.g., the legislative, administrative, or judicial bodies or the military), in state-owned enterprises, units, or state institutions;

- persons assigned by state-owned entities to companies, enterprises or institutions not owned by the state to perform public services;

- other persons who perform public services according to law, including physicians.

As such, the definition of "state functionaries" shall include employees of state-owned enterprises, as well as non-state-owned enterprises.

Please note that as of 2011, and as a result of China's commitments under the United Nations Conventions against Corruption ("UNCAC"), the PRC Criminal Law also includes the prohibition of bribes to "foreign officials" and "officials of international public organisations." UNCAC defines a "foreign public official" as any person holding a legislative, executive, administrative or judicial office of a foreign country, whether appointed or elected; and any person exercising a public function for a foreign country, including for a public agency or public enterprise. The UNCAC also defines "an official of an international public organisation" as an international civil servant or any person who is authorized by such an organisation to act on behalf of that organisation.

Penalties under the PRC Criminal Law can vary depending on the party giving and or receiving bribes. Penalties include, but are not limited to: short term detention, confiscation of property, or life imprisonment. In addition, unlike the U.S. Foreign Corrupt Practices Act there is no facilitation payments exception.

Commercial Bribery under the AUCL is administratively punished. Penalties under The AUCL can range from RMB 10,000 to RMB 200,000. Penalties under the AUCL will depend on the conduct. Penalties under the AUCL can also include the confiscation of income generated or obtained through illegal means.

All employees are urged to consult with the Compliance Officer whenever a question arises regarding the above legislation.
Aerocrine

Personal Service Arrangements Policy

Aerocrine may obtain services from individuals, including HCPs and other professionals, to assist Aerocrine in achieving its legitimate objectives. These services may take the form of consulting, speaking, royalty arrangements for intellectual property, or advisory board arrangements. This Policy contains the Company’s minimum requirements with respect to all such agreements. Each particular agreement may have other requirements as set forth in this Manual.

This Policy applies to all Aerocrine employees that create or negotiate any type of personal service, or consulting agreement, with an HCP or person that can influence the use and/or purchase of an Aerocrine device (e.g., medical directors of a managed care entity). Sales Personnel may not create or negotiate personal services arrangements with HCP’s. For additional information see the Personnel Services arrangements policy.

Types of Service Arrangements

The below list describes various types of personal service agreements. Some of these types of agreements are discussed in-depth in other parts of this Manual. This section is descriptive only and may not be relied upon as the definitive policy on the particular agreement type.

The following are types of personal service agreements:

- **Advisory Board or Steering Committee** – A type of Consultant Meeting (as defined below) whereby the Company solicits meaningful consultation from attendees.
- **Consultant** – An HCP hired by Aerocrine to provide useful and necessary services to the Company. Consultants may work individually (e.g., a Speaker) or as a member of a consultant group (e.g., Advisory Board).
- **Consultant Agreement** – The legal document or contract between Aerocrine and the Consultant that sets forth and memorializes requirements of the consultant arrangement.4
- **Consultant Meeting** – A meeting held by the Company wherein a small number of consultants to Aerocrine provide services to the Company. The primary purpose of the event is usually for the Consultants to provide meaningful information/consultation and feedback to Aerocrine. An Advisory Board is an example of a Consultant Meeting.
- **Market Research** – A form of an arrangement in which third-parties external to the Company provide feedback to Aerocrine about areas of interest to Aerocrine’s business. Generally, Aerocrine will hire an outside vendor to perform completely blinded research—meaning Aerocrine does not know or otherwise suggest who the advisors are. It is

4 Please note that in some countries, certain prohibitions apply when flying HCP consultants. Specifically, Italy does not permit business class tickets for Italian HCPs.
important to note that if Aerocrine directly chooses or suggests the HCP advisors, or in any way influences the decision of HCPs being utilized for the Market Research (irrespective of whether it is a third-party that performs the activities on Aerocrine’s behalf), the HCP would be treated as a Consultant and those payments would be reportable pursuant to the Sunshine provisions of PPACA. For more information, please see the Transparency chapter.

- **Investigator Meeting** — A meeting of current and potential investigators for a Company-sponsored trial, including Company-sponsored registry trials, whereby there is a bona fide need to gather staff from the sites and/or the principal investigators to discuss a new protocol, solicit information on patient recruitment issues, safety information, or other reason as approved by the Compliance Officer or Legal Department.

- **Royalty Arrangement** — An arrangement whereby an HCP, institution, or group of HCPs are expected and reasonably believed by Aerocrine to make a novel, significant or innovative contribution to the intellectual property associated with an Aerocrine device/technology, process or method. In some rare cases, Aerocrine may have an agreement to purchase independently developed intellectual property. The basis for any such compensation should be well-documented and justified in connection with the contribution made. It should reflect the Fair Market Value of the contribution.

- **Speaker** — A Consultant hired typically to speak about Aerocrine’s devices or related disease states.

- **Speaker Training Meeting** — A form of a Consultant Meeting where the purpose is to provide extensive training to potential Aerocrine promotional speakers on the Aerocrine devices and compliance with FDA regulatory requirements.

- **Device Training Meeting** — An agreement between Aerocrine and individual HCPs whereby there is a bona fide need to perform hands on training with HCPs and other allied health personnel/technicians on the use and operability of the Aerocrine device. The venue may be at a third-party neutral site, or may be at an internal Aerocrine location. This type of arrangement may include travel, meals and lodging costs, but may never include an honorarium for the attendees’ training time. Consultants who attend Device training meetings to teach may be paid under the terms of their consulting agreement.

### Guidelines Applicable to All Personal Service Arrangements

Aerocrine policy requires that all proposed service arrangements with HCPs must be reviewed and approved by your manager to ensure they are acceptable prior to making any commitment to the HCP. Once approved, all personal service arrangements with HCPs must meet all of the following guidelines:

- **Appropriate Purpose.** Fee-for-service arrangements must provide necessary and useful services to Aerocrine. Aerocrine does not condition fee-for-service arrangements upon any explicit or implicit agreement or understanding to use, purchase, order, recommend,
arrange, provide formulary status for, or dispense any Aerocrine products. Fee-for-service arrangements may never be used to reward past purchases or recommendations or encourage the potential for future purchases or recommendations to use Aerocrine products.

- **Legitimate Need.** Aerocrine must have a legitimate need for the services obtained. This need must be clearly identified in advance of requesting the services, in writing with respect to certain events, including but not limited to, Advisory Boards. The Chief Compliance Officer must approve the legitimate need of the service. Please see further discussion on Advisory Boards in Advisory Board chapter.

- **No Token Arrangements.** Token arrangements (i.e., arrangements where there is no need or use for the information or advice provided by the Consultant) are prohibited. Examples of token arrangements include paying an HCP to complete a survey designed by Sales, paying royalties for non-innovative work, or paying for an HCP to provide advice on a topic for which Aerocrine already possesses sufficient information. In all examples, Aerocrine has no legitimate need for the Consultant’s services.

- **Reasonable Number.** Aerocrine may not retain more individuals to perform a service than is reasonably necessary to achieve the identified purpose of the arrangement. The size of the total pool of Consultants may take into consideration the reality that not all Consultants’ schedules will align with the timing of Aerocrine’s need for services.

- **Written Agreement.** Aerocrine requires all fee-for-service arrangements to be governed by a written contract. These contracts should comply with the Personal Services Safe Harbor to the Anti-Kickback Statute. Among other requirements, the agreement must specify the nature of the services, the financial terms, and the basis for the Fair Market Value payment. It is important to note that a written contract must be executed prior to any work being performed on behalf of Aerocrine.

- **Qualifications and Expertise.** Aerocrine shall choose Consultants based on qualifications and expertise directly related to the identified need. Only Medical Affairs – or its designee with the expertise necessary to evaluate the qualifications of potential Consultants – may select Consultants. Decisions regarding the selection or retention of Consultants must be made based on defined criteria, such as medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area.

- **Fair Market Value (FMV).** Payment for personal service arrangements may not exceed the fair market value of the services provided. In this Manual, the Aerocrine FMV Matrix for promotional speaker programs and for Advisory Boards is provided in the Promotional Speaker Programs Policy and the Advisory Boards Policy, respectively (at Attachment A--FMV Matrix for Promotional Speakers, and at Attachment A--FMV Matrix Ad Board). For general consulting or other consulting, attached hereto as Attachment A is the FMV Hourly Rates at Attachment A--FMV Hourly Rates. Payment may not vary based upon the volume or value of the Consultant’s prescriptions of Aerocrine products, or upon the value of any
past or future purchases or recommendations to use Aerocrine products. Determination of FMV should be documented for each arrangement.

- **Reimbursement of Reasonable Expenses.** Generally, Aerocrine may reimburse a Consultant’s reasonable expenses (i.e., travel, lodging, and meals) in connection with the Consultant's services if such reimbursement is specified in the agreement (the conditions and the extent to which Aerocrine may reimburse is set forth in various chapters in this Manual). Aerocrine will not, however, pay for any expenses associated with the Consultant’s spouse and/or guest. In addition, all travel expenses must be consistent with Aerocrine’s Travel & Entertainment Policy.

- **Appropriate Venue.** The venue and circumstances of any meeting relating to a personal service arrangement must be conducive to the consulting services. Activities related to the services must be the primary focus of any such meeting. Meetings may not be held at a venue that has independent value (e.g., a resort venue that is often frequented as a vacation destination) unless such meeting is occurring concurrently with or immediately adjacent to (pre- or post-) a medical meeting/congress/symposia whereby the selection of the venue is uncontrolled by the Company and there are efficiencies in holding the meeting at that venue (e.g., quality or quantity of the KOLs present, etc.). If the associated medical meeting/congress/symposia is a CME program, unless permitted by local law, Aerocrine may not pay for the travel of any Consultant who attends the CME program. Aerocrine may pay for a Consultant’s hotel night(s) if it is required for the consulting services meeting and is outside the dates of the CME program. Please see the Sponsoring Non-U.S.-Based Doctors to Attend Medical Congress, CME Events, or Meetings or Informational Sessions section for additional information.

- **No Entertainment or Recreation.** Aerocrine may not provide any recreational or entertainment events to Consultants (e.g., golf, ski tickets, sports tickets, etc.). A modest business meal or reception is not considered an entertainment activity.

- **Written Work Product.** With the exception of speaking engagements and device training meetings, personal service activities should generally result in a written work product (e.g., a report, summary of advice, written analysis of reviewed data, etc.) developed by the Consultant for Aerocrine. If the Consultant’s advice was verbal, the advice should be captured in meeting minutes or in a transcript of the meeting. In the case of a royalty arrangement, the contributions made to the Aerocrine device, technology or process must be novel, significant or innovative.
Attachment A – FMV Hourly Rates

GENERAL CONSULTING OR OTHER CONSULTING

FMV Matrix in development, please consult with Marketing until the FMV Matrix is final.
Aerocrine

Promotional Speaker Programs Policy

A speaker program is a promotional activity controlled by Aerocrine in which an HCP presents scientific or clinical information to an audience of two or more HCPs. Like all promotional activities, speaker programs are highly regulated.

Aerocrine is responsible for the conduct and the content of its promotional speaker programs. This includes all information presented by the speaker, any payments related to the program, as well as the venue and all other details of the event, including attendee selection. This Policy is relevant to all Aerocrine employees who conduct or attend promotional speaker programs.

Who is a speaker?

An appropriate promotional speaker, at a minimum, is an HCP that: is licensed (and in good standing) in a state to practice his or her respective professional service, including but not limited to medicine, nursing, etc., and actually utilizes the Aerocrine device and has experience in the relevant therapeutic area. Aerocrine may never offer an HCP the opportunity to speak on Aerocrine’s behalf solely for the HCP to gain experience in speaking, or to provide the HCP with experience in the particular Aerocrine device. The HCP’s knowledge and understanding of the Aerocrine device must precede the invitation to speak on Aerocrine’s behalf, and there must be a legitimate need to disseminate the Aerocrine device information.

Prior to speaking on Aerocrine’s behalf, all promotional speakers must: execute a Promotional Speaker Services Agreement, receive training on the Aerocrine device for which he/she has experience from an Aerocrine employee (preferably someone in Clinical or Medical Affairs), and receive FDA/Compliance training from the Compliance Officer or his/her designee (either live or automated). To remain an active promotional speaker in the Aerocrine Speaker’s Bureau, all speakers must speak on Aerocrine’s behalf at least twice in the twelve months following the training.

What is the Content of A Speaker Program?

All content provided during a promotional speaking program must be:

- Accurate and truthful
- Consistent with the device’s labeling
- Supported by substantiated and scientifically-sound data and
- Appropriately balanced with information on both benefits and risks.

Aerocrine controls the content for every promotional speaker program. Therefore, a promotional speaker may only use a PRC-approved slide deck and accompanying handouts (to the extent there
are any), subject to the “case study” exception below. If the promotional speaker wants to include any slides in addition to the approved content, any additional slides/content must be reviewed and approved by the PRC before the speaking event.

Investigational uses or off-label information about a Company device (or any other FDA regulated item) may never be proactively disseminated. A promotional speaker may respond to unsolicited off-label questions by: noting that the answer is not consistent with the User Manual, noting that the answer provided is based upon his or her medical/professional experience, and responding only to the individual that asks the question, in a non-public, one-on-one discussion (this complies with the FDA guidance on public v. non-public responses to unsolicited questions). When responding directly to the requester who had an unsolicited request for off-label information, a promotional speaker may utilize his/her own slides (or it may be based upon his/her professional opinion/experience), but the amount of information provided or slides used must be narrowly tailored to answer the unsolicited question posed (it may not be a springboard to discuss any off-label uses of the Aerocrine device).

A promotional speaker may use “case studies” in his/her presentation only if the following conditions are satisfied:

- The slides are PRC-approved prior to first use
- The slides are used along with the Aerocrine-approved device slides. The presentation cannot consist solely of the case study without any fair balance (assuming that the talk is branded)
- The case study slides cannot mention any Aerocrine device claim unless the claim is consistent with the current approved User Manual
- The case study slides are followed by Aerocrine-approved device slides that support the conclusions drawn in the case study slides and contain appropriate risk information and
- To protect patient privacy, there is no identifiable patient information in the case study slides.

In addition, a speaker may not provide personal practice-related promotional materials or engage in any practice building activities/discussions in connection with an Aerocrine promotional speaker program. More precisely, a promotional speaker may not speak on behalf of Aerocrine if the intent is to drive referrals to that speaker’s practice.
What is an Appropriate Venue?

In determining where a speaker program will be held, the Aerocrine employee(s) conducting the speaker program must ensure that the venue:

• Is conducive to the exchange of scientific information. The purpose of the program is to convey information about Aerocrine, Aerocrine device(s), or a disease state. The environment of the venue should not detract from that purpose.
• Is considered modest by local standards.
• Does NOT involve recreation or any other entertainment component. The venue may not have independent value outside of just being the venue for a scientific/educational exchange (e.g., dinner cruises, dinners in a loge during a sporting event, etc.).

It is Aerocrine's policy that any Aerocrine-conducted device training event or speaker program that will take place outside an HCP’s place of business must be reviewed and approved in advance by your manager and must be consistent with the Company's reasonable and appropriate venue standard.

Who is an Appropriate Attendee?

Aerocrine is solely responsible for the selection of attendees at an Aerocrine promotional speaker program. The audience should consist of HCPs with a legitimate interest in the information being shared. Attendees' reasonable travel and lodging may only be provided if necessary, and guests of HCPs are prohibited. It is Aerocrine policy that there must be at least two HCP attendees who are not part of the promotional speaker’s medical practice or institution, subject only to the “touring KOL” discussion below. This is a good faith policy, meaning that the Aerocrine employee believes in good faith that at least two HCPs from outside the promotional speaker's practice or institution will attend the program.

Aerocrine is prohibited from creating a promotional speaker program with the intent of paying a speaker to speak solely to members of his or her own medical practice or institution. In order to determine whether HCPs work within the same practice or institution for the purposes of applying this rule, the Aerocrine employee(s) conducting the speaker program must make a good faith effort to determine whether the HCPs receive compensation as employees from the same business entity. If they do, then they are members of the same practice or institution.

Important Note: Some states have established certain dollar thresholds that may prevent HCPs from attending where food and/or beverages are provided. For example, some state employees may be prohibited from accepting gifts/meals from device companies by state law (i.e., VT, which has an absolute ban, and possibly CA if the self-imposed dollar threshold is exceeded). Similarly, some states require the disclosure of meals/gifts over a certain dollar threshold (i.e., CA, VT, MA, and NV). Please
see the Transparency Laws chapter set forth in this Manual for a description of each state’s law and an overview of the federal Sunshine Act.

Aerocrine Sales persons must be aware of whether their state, or states in their territory, have any law(s) that may limit or impact promotional activities. If there are any questions, please contact the Compliance Officer.

KOL Promotional Speaking Tours

A Sales person may bring a national, regional or local speaker (those are the designations utilized to establish the appropriate “fair market value”) to a single office or practice for a speaker program if the following conditions are met:

- The KOL is visiting an individual office/practice at the request of Aerocrine and the site is chosen and the presentation is organized by Aerocrine; this event may be tied to other company-sponsored promotional talks on the same date (or within a reasonably short period of time);
- The attendees at the office are unaffiliated (to members of his or her own medical practice or institution) with the KOL
- At least two HCPs from the local office are invited and in good faith are expected to attend (however, circumstances may dictate otherwise)
- The HCPs invited to the program were not chosen in order to drive referrals for the speaker
- The speaker is brought to the office/practice to engage in a promotional presentation using Aerocrine-approved slides or an approved clinical reprint about an Aerocrine device or disease state, and not to provide the office/practice with time to “consult” with an expert on topics or cases of interest. Example: “Bring your most challenging clinical asthma cases to discuss with Dr. X” is not an appropriate method to promote a promotional presentation; and
- The promotional talk complies with all other Aerocrine policies and procedures.

It is important to note that the speaker may answer unsolicited questions from the practice’s physicians, subject to the same restrictions that apply to all Aerocrine promotional programs. However, the speaker may not engage in a consultation and may not review charts or files of individual patients in that practice. Moreover, the Aerocrine sales person may not promote the encounter with the paid speaker as a “bring your most difficult patient questions” or otherwise bait such questions.
What is the Appropriate Payment?

It is Aerocrine's policy to pay HCPs that speak on Aerocrine's behalf the Fair Market Value (“FMV”) for their services. Attached to this policy as Attachment A, is the FMV Matrix for Promotional Speakers. The Promotional Speaker Agreement sets forth how a speaker is paid under the FMV Matrix. It is Aerocrine policy that in a calendar year, a promotional speaker may not earn more than $100,000 of promotional honoraria (this excludes travel fees, non-promotional consulting fees, or other non-promotional related fees from Aerocrine, including but not limited to clinical and/ or research spend). All expenses for speakers must be consistent with the Aerocrine Travel & Entertainment Policy.

Speakers are paid under the FMV Matrix depending upon their designated status. The status is determined by the objective criteria set forth below as determined and judged by Medical Affairs in consultation with Marketing:

**Local:** KOLs must meet at least two of the criteria below:

- Member of a relevant specialty (pulmonary, allergy, ENT) or an experienced primary care physician, pediatrician or other HCP (NP, PA, RT) department at a hospital or teaching institution, or an experienced respiratory therapist
- Board Certified in pulmonology, allergy or primary care, or their respective profession for non-MD professionals
- Experience with the Aerocrine device about which the KOL is speaking and
- Experience with Fractional exhaled Nitric Oxide (FeNO) Testing.

**Regional:** KOLs must meet the criteria for a Local KOL and at least 2 of the criteria below; non-MD KOLs must meet at least 2 of the criteria below:

- Spoken/Presented at a medical congress
- Named clinical investigator in a clinical trial
- Published research relevant to respiratory disease

**National:** KOLs must meet the criteria for a Regional KOL and at least 1 of the criteria below; non-MD KOLs must meet at least 1 of the criteria below:

- Chairperson of medical department at a hospital or teaching institution (or their respective field, including nursing)
- Named principal investigator (“PI”) in a clinical trial (not just Aerocrine Company-sponsored trials)
- Published in a peer-reviewed journal
- Primary author of a poster at a medical congress
- Officer of a national medical trade association
- Had “oral” presentations at national or international medical congresses.
- Standing or previously served as a member of a medical advisory committee for a state or federal government agency and/or a cooperative group, including but not limited to the FDA, NIH, or CMS (note this criteria may subject the physician to the agency’s conflict of interest policy if the HCP still resides on the committee, and additionally, a member of any committee may not be selected due to pending, foreseeable, or likely/future Aerocrine business before the committee).

**International:** KOL must satisfy both of the following:

- Must be designated as a National KOL and
- Must be viewed by peers as a National/International authority in their respective medical area/practice (indicia include, but are not limited to, numerous (more than three) publications in a peer-reviewed journal and numerous clinical studies wherein the KOL was the PI).

International KOLs are capped at five per promotional speaker’s bureau, and deemed so important to the brand that they command a FMV that is no more than 20% greater than the National KOL FMV rate (be it the hourly rate or the rate for services in the various matrices).
Attachment A – FMV Matrix for Promotional Speakers

The FMV Matrix is under consideration, please consult with Marketing as to the appropriate payment for the promotional speaker.
Advisory Boards and Hands-On Training Policy

There are times when Aerocrine may need to gather HCPs or allied professionals to solicit advice or train on the proper use of an Aerocrine device. In either case, the meeting is non-promotional (meaning it does not directly drive business for Aerocrine).

**Advisory Boards:** In order to ensure that Aerocrine has accurate and current information regarding disease states, the marketplace, treatment practices, therapeutic interventions, safety, customers, patients and their needs, Aerocrine conducts Advisory Boards and other consultant meetings with consultants, including healthcare professionals, scientists and technical consultants (Advisory Boards). The purpose of the Advisory Board is to obtain meaningful consultation with information that is not otherwise efficiently available to the Company by soliciting the advice from the attendees.

**Hands-On Training or Device Training Meetings:** Companies have a responsibility to provide and make training and education on their devices and technologies available to HCPs. HCPs need to understand the safe and effective use of Aerocrine devices. At times, Aerocrine will gather HCPs to provide hands-on training to HCPs and allied health professionals.

This policy applies to all Aerocrine employees who are involved in the planning, implementation, and execution of Advisory Boards or Hands-On Training, as well as any and all Company employees or agents that attend the Advisory Board or Hands-On Training. For purposes of this policy, the policy applies to both types of meetings unless specifically bifurcated or carved-out where differences apply.

**Advisory Board and Hands-On Training Requirements**

The following must be satisfied when conducting and holding either an Advisory Board or Hands-On Training Meeting: (Note that in general only Medical Affairs and Marketing can host advisory boards)

**Need:** Advisory Boards and Hands-On Training may only be conducted: in the case of Advisory Boards, to obtain in-depth insight, input, reactions, feedback, and information from advisors in order to answer specific questions that could not be otherwise practically determined without the meeting, or in the case of Hands-On Training, to provide training to HCPs and allied health professionals on the safe and effective use of the Aerocrine device. Advisory Boards and Hands-On Training may only be conducted to address *bona fide* and otherwise unmet business or medical needs or training. The *bona fide* business need for either type of meeting must be clearly identified and approved in advance of requesting the meeting.

**Non-Promotional and Objective:** Advisory Boards and Hands-On Training should never be used as a means to promote current or investigational devices or off-label indications. In both cases, there may
not be more Consultants than required to achieve the objectives of the program. An Advisory Board may not contain a target number of more than 15 attendees to solicit meaningful consultation from each and every advisor (this threshold only applies to the break-out sessions in which the meaningful consultation is solicited; therefore, a larger meeting may have smaller break-out sessions of no more than 15 advisors per break-out group). For Hands-On Training, the number of attendees must be narrowly tailored to achieve training. Specifically, Aerocrine may not invite a large number of clinicians from a given geographic area with the intent to deliver promotional messages to a big audience, which may constitute a significant portion of the local market. Rather, Aerocrine may invite a limited number of clinicians interested in receiving and participating in meaningful device training. In either case, Aerocrine may not pay for an attendee’s spouse, including the spouse’s meal(s), travel, or any other expense related directly to the spouse.

It is not appropriate for Sales to attend Advisory Boards unless they have a specific role in the program as designated by the sponsoring function/organizer (this prohibition does NOT include Vice President, or global director level employees). For Hands-On Training, Sales may attend if they are useful in executing the training on-site. In the event that Sales or other Field employees must attend, the Compliance Officer must approve any such personnel prior to the meeting. It may however be appropriate for Sales management (Directors and above) to attend the input sessions for devices or new indications in the pre-launch phase (6-9 months prior to an anticipated launch).

Content: The agenda should demonstrate that the time spent providing information by Aerocrine is subordinate to the time spent gathering information from the attendees. A minimum ratio is 60/40 (meaning at least 60% of the time is spent gathering information whereas the other 40% of the time is spent providing information that is necessary to solicit meaningful consultation). Only presentation materials that are relevant and appropriate to meet the objectives of the Advisory Board meeting may be used. Generally, all materials used must be reviewed by the Compliance Officer, Legal, and Medical Affairs prior to the event. That said, should there be changes to the materials on-site, the sponsor must send the updated materials for review post-event.

Hands-On Training: The agenda should be narrowly tailored for device training. All content provided must correlate directly to proper use of the device. Some discussion of medical conditions as they relate to the use of the device may be appropriate. Variations in device usage – within the FDA cleared indications – as practiced by the consultant-educators may be covered during the meeting if approved in advance by Aerocrine.

Attendee Selection and Cap: The criteria for selecting advisors must be based upon the advisor’s credentials/expertise and directly related to the bona fide business need. Attendees for either type of meeting should never be selected in return for, as an inducement to, or in any way in consideration of, their current or potential prescribing, purchasing, use, formulary status, or dispensing of
Aerocrine devices. Attendees must sign an Advisory Board Letter of Agreement or a Device Training Agreement with Aerocrine prior to attending either type of meeting. Advisory Boards must have no more Consultants than required to achieve the objectives of the program. Larger Advisory Board meetings may have no more than 15 advisors participating in break-out sessions to ensure all Consultants have an opportunity to participate in meaningful discussion. There is no cap on Hands-On Training meetings as the number of attendees must satisfy the business justification for the meeting.

**Aerocrine Attendees:** There is no cap on Aerocrine attendees. For illustrative purposes, the ratio of Consultants to Company attendees should not exceed 2 to 1, although circumstances may dictate the need to exceed that ratio with the number of Company attendees. The meeting organizer (the organizing Company function) shall establish the number of Aerocrine attendees for each meeting, and the Compliance Officer in consultation may determine who may attend should there ever be a question about Company attendees.

**FMV:** The amount of compensation paid to an advisor must be reasonable, set in advance, and based on the FMV of the consulting services. Aerocrine has established its own FMV Matrix for Advisory Boards. The Half Day Advisory Board and Full Day Advisory Board FMV Matrices are attached to this policy as Attachment A, at Attachment A—FMV Matrix Ad Board. For Hands-On Training, Aerocrine may only provide compensation for modest meals, and for travel and lodging if necessary. It is never appropriate to pay honoraria or for time at a Hands-On Training meeting.

**Record Retention:** The sponsoring function (Marketing, Market Access, Medical Affairs, or Clinical Development) must maintain all records for their meeting, which would include the underlying content/slide deck, the pre-approval form, all contracts related thereto, and with respect to an Advisory Board only, the post-Advisory Board summary and all attendant action items emanating from the Advisory Board. Copies of these records must be forwarded in a single e-mail to the Chief Compliance Officer at the end of each individual meeting.

**Meals:** Meals may be provided so long as they are incidental to the program and are modest as judged by local standards. Set forth in Attachment C are the FMV rates for meals provided attendant to an Advisory Board or Hands-On Training meeting, at Attachment C—FMV for Advisory Board or Hands-On Training Meals.

**Venue:** Advisory Boards must be conducted in a venue that is conducive for education or, in the case of Advisory Boards, meaningful consultation. Unless the venue selection is out of the control of Aerocrine (e.g., meetings concurrent with or immediately adjacent to preexisting medical meetings/congresses), the venue may not have independent value (e.g., a resort venue that is often frequented as a vacation destination). Moreover, generally the following hotels are examples of
appropriate venues (this list is not exhaustive): Marriott, Starwood properties, Hyatt, and Hilton (not including the highest brand of each, e.g., St. Regis for Starwood).

Forms

As both Advisory Boards and Hands-On Training are non-promotional, they must be conducted in a way that results either in the capture of bona fide, legitimate, and useful information, or the appropriate dissemination of the use of the Aerocrine device. The following documents must be submitted either prior to or immediately after the meeting as indicated below.

Pre-Approval Proposal Form

Prior to conducting any individual or series of meetings, a Pre-Approval Proposal Form must be created and approved by Compliance. (The cover page of the Aerocrine Approval Form is attached to this policy as Attachment B, at Attachment B—Pre-Approval Proposal Form; please note that the attachment is just the first page of a 5 document that must be filled out.) Each Proposal Form must provide detailed information on the objectives and questions to be answered, as well as how the information will be captured and used. This form must be approved by the appropriate functional area sponsor and the Compliance Officer. The approved Form must be kept in the sponsoring function's documents pursuant to the Document Retention Policy. The Pre-Approval Proposal Form must include, at a minimum, the following information:

- **Specific Objectives.** The objective of an Advisory Board or Hands-On Training meeting that details the bona fide need for information from advisers in order to answer specific questions.
- **Agenda.** The agenda for Advisory Boards must be conducted in a way that results in the capture of bona fide, legitimate, and useful information in accordance with the meeting's objectives. The agenda for Hands-On Training must demonstrate the appropriate use of the Aerocrine device.
- **Consultant Selection Criteria.** The selection of Consultants for either type of meeting must be based on their experience or expertise in the agenda topics and their ability to provide the contracted services. Attendees should never be selected in return for, as an inducement to, or in any way in consideration of their current or potential prescribing, purchasing, use, formulary status, or dispensing of Aerocrine devices.
- **Number of Consultants.** Advisory Boards must have no more Consultants than required to achieve the objectives of the program. Generally, discussion groups should consist of no more than 15 Consultants to ensure all Consultants have an opportunity to participate in the discussion. For Hands-On Training, the number must be directly correlated with the business need for the education and demonstration of the safe and effective use of the Company device.
• **Consultant Agreement.** Prior to providing any services, attendees must execute a written agreement, which specifies that at no time will Aerocrine pay/compensate for time; it will only pay for modest meals, and modest travel and lodging if necessary.

**Post-Meeting Forms**

The Conclusions and Recommendations Document must be prepared within 60 days of completion of an Advisory Board meeting. It is important to note that any similar document from a Company agent will suffice, as the intent is to create action items and learnings from each and every Advisory Board. Copies of all post-meeting documentation must be forwarded to the Compliance Officer, and the original documentation must be retained as part of the official files in the sponsoring function's department. The document must describe how Aerocrine will use the information gathered and what actions will be taken as a result of the Advisory Board's recommendations, or what direction the Company may take in reaction to some of the learnings.

**Records Retention**

Following each Advisory Board or Hands-On Training meeting, all documents and forms must be filed in the sponsoring function’s files. All documents relating to the meeting must be retained according to the Aerocrine Document Retention Policy.
Attachment A—FMV Matrix Ad Board

Aerocrine Advisory Board FMV Matrix (any and all terms that denote the type of HCP are consistent with the designation of an HCP as discussed in the Promotional Speaker Programs Policy):

The FMV Matrix for Advisory Boards is still under consideration; please consult with Marketing as to the appropriate payment for half-day and full-day Advisory Boards.
Attachment B—Pre-Approval Proposal Form

Please consult with Marketing for the Pre-Approval Form for Advisory Boards
Attachment C—FMV for Advisory Board or Hands-On Training Meals in U.S.

Meal
Fair Market Value

Please consult with Marketing to determine the appropriate FMV for meals at Advisory Board. The FMV Meals Matrix is still under consideration.
Dissemination of Medical and Scientific Information to HCPs

Medical and scientific activities, including discussions with patients or HCPs, when permitted by local law, may only be undertaken by scientifically or medically trained personnel and should be scientific and educational in nature. For example, in the European Union, direct to consumer advertising is prohibited. Please consult with your local laws to ensure compliance.

When permitted by local law, Aerocrine may provide non-promotional materials to Healthcare Professionals. Non-promotional materials must not promote products. They must be medical or scientific in nature, and must be presented in an objective and balanced manner.

All medical and scientific materials must be approved before use through the PRC. When required by local law, any materials distributed by Aerocrine must be accompanied by the approved device User Manual.

Subject to the approval of PRC or any other review committee, Aerocrine will permit the distribution of various categories of balanced, accurate, truthful, non-misleading scientific information to HCPs. Distribution will be in accordance with the following guidelines set forth below.

This Policy applies to any and all employees that are authorized by the Company to provide reprints, peer-reviewed journal articles, or any other truthful and scientifically accurate medical articles to HCPs.

Categories for Reprints

The following classes may be utilized by PRC:
1. ESA – On Label
2. EOL—Off Label
3. ESR—Restrictions apply, on label in some countries and off label in others

Descriptions for Classes of Reprints

The following short descriptions are general guidance to be used by PRC and other review committees when making a determination about the appropriate Class designation for a specific reprint/journal article. These descriptions are in no way binding upon the determination of the PRC or respective review committee, but should be used as general guidance.

ESA : ESA reprints include the following:
- Peer-reviewed reprints that are scientifically sound and consistent with a given device’s labeling or that provide “substantial evidence” about the use of the device (the PRC is the
sole arbiter to determine whether and to what extent a reprint satisfies the “substantial evidence” test; see the immediately following bullet)

- Proactive dissemination of a reprint that may contain some inconsistencies as related to the User Manual (such reprints need to satisfy the current Good Reprint Practices (cGMP) at FDA Guidance on Good Reprint Practices
- Non-branded disease state peer-reviewed reprints that would not violate the FDA Draft Guidance for Industry on “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Device and Device Firms.

Consistent with Aerocrine policy and direction from the PRC, Sales and Marketing may distribute any item designated as ESA. The PRC may provide restrictions or guidance as they deem necessary and appropriate, including but not limited to whether or not a cover page would be necessary, the extent to which portions of a reprint may not be discussed, and other required circumstances for distribution.

Once designated by the PRC as ESA, these articles may be proactively furnished to HCPs by any Aerocrine employee (including Sales and Marketing), or be mailed/ emailed (assuming the Company has the rights to e-mail the reprint) directly to the physician. It is important to note that any and all ESA materials must be accompanied with the brief summary as created by PRC. The PRC must determine the best means for disseminating ESA materials, and the PRC will determine what, if any, discussion may be provided by the regional manager. Regional managers may respond to unsolicited on-label questions using information from a PRC-approved Q&A (to the extent that such a piece exists or is necessary) or the device User Manual. All inquiries that fall outside the scope of the Q&A or the User Manual must be forwarded to Medical Affairs for reply/follow-up.

EOL: EOL materials are only appropriate for use by a medical affairs, CSLs and/or the Medical Information staff in response to an unsolicited question. EOL materials may include scientific literature concerning pulmonology, asthma, posters, or peer-reviewed journals in medical or scientific journals. These articles may include discussion of information that is not consistent with an Aerocrine device’s approved labeling; however, all materials disseminated by medical affairs, CSLs and/or Medical Information staff accompanying such articles must be balanced, accurate, truthful and non-misleading.

EOL materials must carry a cover sheet (attached to this policy as Attachment A) that identifies the journal citation, article title, authors, as well as information on device approved uses and required disclosures. The approved User Manual must also be attached to the article.

ESR: ESR materials can be used in those counties where on-label in a manner similar to ESA above. In countries, where these materials are not consistent with the User Manual, they can be used as EOL materials.
Attachment A – Cover Sheet for Reprints

Please consult with the PRC for the appropriate cover letter and form.
Press Release Policy

Aerocrine is a publicly listed company on NASDAQ Stockholm ("Stockholm Stock Exchange") and as such, is required to comply with rules on the disclosure of information and Stockholm Stock Exchange’s Regulations for Issuers. These regulations require information to be accurate, relevant and clear and to not be misleading. The basic principle for Aerocrine’s disclosure of information is that information that is of significance to the evaluation of the price of Aerocrine’s shares (share-price-sensitive information) must be disclosed as soon as possible by means of a press release.

The CEO is ultimately responsible for the company’s disclosure of information and all information provided by the company must first be approved by the CEO or a person appointed by him/her. The Chairman of the Board approves all press releases before publication/distribution but may delegate this to the CEO.

All Aerocrine employees are obliged to comply with the Aerocrine Communication Policy which has the objective to (i) to ensure that equity market participants receive quick, simultaneous, accurate, relevant, clear information about the company, and (ii) to ensure that share price-sensitive information is handled confidentially before it is made public and that no unauthorized party gains access to such information.

In addition to the Aerocrine Communications Policy, this Press Release Policy applies to any and all device-related or Aerocrine press releases in the U.S. and around the world. Corporate Communications (in connection with PRC) will implement the underlying policies and processes.

Subject to the conditions below, Aerocrine employees may not use or disseminate Aerocrine press releases for promotional purposes.

Non-Promotional Press Releases

In general, press releases are not intended to be promotional. The following press release types should be considered non-promotional and may not be disseminated to HCPs by any Aerocrine employee or third-party affiliate without PRC approval:

- **Stockholm Stock Exchange Filings:** Applicable to Stockholm Stock Exchange required disclosures of information.
- **Corporate Transactions and Arrangements:** Factual announcements about new business alliances, recalls or safety issues (Note: other appropriate materials that address recalls or safety issues will be provided for distribution but the press release itself may not be disseminated without authorization to do so), clinical trials, other financial performance announcements, and other corporate announcements.
• **New Studies:** This applies to the first release of new study results regarding an Aerocrine device or a device in which Aerocrine has a significant interest. Press releases announcing results from a new study must describe the size of study, the statistical significance of the findings, the most common AEs seen in the study, significant exclusion and inclusion criteria (it is at the discretion of Regulatory and Legal whether to include those if at all), and whether the device is or is not approved for the use described in the study. The press release may not omit material information about the study (which might include whether the study contradicts other findings). The press release must have appropriate fair balance language or disclosures about the study itself or if the device is currently approved (for a different use).

It is important to note that if promotional language or tone is used, then the press release must include the appropriate fair balance. Press releases may not be disseminated by Sales and Marketing without approval by the PRC, as set forth in the Promotion policy. The FDA or applicable regulatory agency may impute a press release to be promotional even if the press release discusses material information. It is for that reason that Legal and/or the Compliance Officer) must review any and all press releases.

**Promotional Press Releases**

Generally, a device-related press release will be promotional, whether it discusses an investigational device or an approved device, and subject to regulation by Center for Devices and Radiological Health (CDRH).

The following are indicative of a promotional tone or language (this list is not exhaustive and is provided for illustrative purposes only):

- Effectiveness claims
- Safety claims
- Superiority claims
- Comparative claims
- “First and only” claims
- “Uniqueness” claims
- “Best in class” claims
- “Favorable” tolerability claims
- Other “device of choice” claims

If the press release is promotional in tone, or contains promotional language, then the press release must satisfy each of the following conditions:
• PRC must approve the press release
• There must be appropriate fair balance, including contraindications, warnings, precautions, Adverse Events, approved indications, other material information, etc. An unapproved use should be conspicuously noted or described as “investigational”
• If studies are discussed, material information about the study should be disclosed (size, significance, and other disclaimers suggested in the New Study section above)
• It should not contradict the FDA-approved User Manual or draw conclusions about an unapproved use (such as by claiming that a study “demonstrates” that the device is effective for an unapproved use or unapproved indication) and
• It may not draw conclusions about device safety without appropriate qualification.

Any press release describing the FDA clearance of any Aerocrine device must be PRC-approved.

**Device Contracting Policy**

Contracts are enforceable agreements between parties to engage in some activity, and can be written or oral. If you are in a position which involves negotiating contracts on behalf of Aerocrine for its devices you must remember that your actions may bind Aerocrine even in the absence of a written agreement. That is why Aerocrine employees must never make an oral promise or sign an agreement before receiving all necessary approvals. In doing so, it could result in Aerocrine having to perform under a contract it does not wish to enter.

From time-to-time, Aerocrine may enter into discount arrangements with hospitals or other providers. Generally, when negotiating with these entities, the customer will pay in relation to list price for each device purchased.

This Device Contracting Policy applies to all Aerocrine employees that initiate, discuss and/or negotiate any trade terms, including but not limited to Sales, Marketing, Managed Markets/Market Access, Finance, and Legal.

**Device Evaluation Policy**

Where allowed, Aerocrine may provide one of its medical devices to HCPs at no charge for non-commercial evaluation or demonstration purposes with the following limitations:

• Single Use Devices. The number of single use medical devices provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the medical device under the circumstances.
Demonstration: "Not-For-Human Use" – medical device devices. It is permissible to provide non-sterile single-use or mock-up multiple use devices for use for HCPs and patient awareness, education and training. Demonstration devices are typically not intended for patient care and are typically clearly marked "Sample" or "Not For Human Use.”

Questions on permissible practices should be directed to Legal or Compliance. At no time, however, may you add free sensors or other items that have a value without Legal or Compliance approval. All demonstration and evaluation periods must be limited to a 90-day period and limited to one per practice. In the case of a large practice where one device is impracticable, your Manager and Compliance’s approval is necessary. Should any evaluation period exceed 90 days, the value of the device is reportable pursuant to U.S. Federal Sunshine.

Antitrust Compliance

Pursuant to antitrust statutes and laws, the federal and state governments prohibit unfair trade or restrictions on trade. There are various federal and state agencies that prohibit unfair trade, including the Federal Trade Commission. The statutes that the agency enforces are commonly referred to as the “antitrust statutes”.

Under the antitrust statutes, competitors are prohibited from entering into any agreement that may unreasonably restrict competition. To ensure full compliance with antitrust statutes, there should never be discussions of the following topics with or among competitors of Aerocrine at any time:

- Aerocrine's pricing policies
- Aerocrine's discounts or rebate practices
- Aerocrine's current or future prices, or other terms and conditions of sale
- Aerocrine's current or projected profits or profit margins
- Aerocrine's current or projected costs
- Aerocrine's business, marketing, and promotional plans
- Aerocrine's bidding policy or its intent to bid or not to bid for particular business
- Aerocrine's plan to do business or not do business with particular customers and/or
- Aerocrine's intention to engage or not engage in particular research activities.

Off-Invoice Discounting

Aerocrine offers, sells or otherwise provides its devices to hospitals and other provider purchasers. Those purchasers may report their costs to the Federal Government or other foreign governments. The true cost of the device must be passed on to or provided to the purchasers in a manner that is true and accurate. All discounts provided to Aerocrine’s purchasers must be conspicuously reported on the invoice to the purchaser. The purchase of a device may never be conditioned upon a grant,
research grant, or any other payment or remuneration between Aerocrine and the purchaser. It is for this reason that Aerocrine employees may never discuss grants, additional service contracts, or other items of value in connection with a sale of a device. This is known as “off-invoice discounting”, as the invoice does not truly reflect the purchase price of the device. Off-invoice discounting may implicate the Anti-Kickback Statute as discussed in the Introduction of this manual.

Discounts and Administrative Fees

From time-to-time, Aerocrine may offer discounts, rebates, and credits on its devices to customers. Although discounts are inducements to purchase Company devices, they are exempted from anti-kickback laws (see discussion of Safe Harbors in the Introduction) because they are regarded as beneficial in bringing down costs to providers and government programs. However, under “safe harbor” regulations issued by the federal government, in order for the exemption to apply, the Company and the customer receiving the price reduction must meet certain documentation and reporting requirements.

Discounts

Discounts are price reductions made at the time of the sale by the Company to the direct purchaser. The price reduction may be calculated as a percentage off the list price for the device.

For a direct sale (i.e., a sale that is not through a wholesaler), the price net of discounts must be reported on the Company invoice or other appropriate documentation. Undocumented discounts are not permissible and WILL NOT be honored. In addition, the invoice or other appropriate documentation must contain a statement notifying the customer of its obligation to report the discount on claims or cost reports submitted to federal and state government healthcare programs to the extent required, and to provide the invoices and/or other appropriate documentation to the government on request.

GPO Administrative Fees

Aerocrine may pay administrative fees to Group Purchasing Organizations ( "GPOs") under certain conditions. A GPO is an entity that acts as a purchasing agent for a number of hospitals or other providers that are members of the GPO. The administrative fee paid to a GPO is intended to compensate the GPO for negotiating pricing for its members. Typically, a GPO will charge an administrative fee that is a percentage of the volume of sales of the Company’s device(s) to the GPO’s members.

Administrative fees paid to GPOs are allowable under the following conditions per the federal government:
• The GPO must be acting as a purchasing agent under a written agreement with its members, and must not own, nor be affiliated with its member facilities.
• The agreement between the GPO and its members must disclose that the GPO receives administrative fees from manufacturers of 3 percent or less, or if the GPO receives more than 3 percent, the agreement must disclose the amount the GPO receives from each vendor.
• The GPO must disclose annually to its members the actual amount of administrative fees it has received from each vendor.
• The Company’s agreements with GPOs should require the GPO to represent and warrant that it will meet these requirements.

Service Agreements for Ancillary Services
From time-to-time, Aerocrine may utilize Managed Care Payers and/or Customers ("MCCs") to provide services that are separate and apart from the underlying contract for Aerocrine’s device. Aerocrine may need to utilize the MCC for particular services to provide services to those HCPs or members. Accordingly, per the federal government, the following must be satisfied prior to utilizing MCCs to provide services:

• The underlying contract with the MCC for the purchase of Aerocrine's device has already been executed by both parties;
• The service agreement is separate and apart from any purchase agreement (and during the negotiation of the purchase agreement there is no discussion, directly or indirectly, of the possible services provided by the MCC);
• There is a bona fide need to procure the services by Aerocrine (meaning Aerocrine would procure the service irrespective of the supplier, in this case an MCC; or the MCC has a class of membership with whom other vendors do not have access and Aerocrine has a bona fide need to utilize the MCC);
• The rate is FMV e for the services being provided; and
  • All other elements set forth in the Personal Service Arrangements Policy are satisfied.

Interactions With Payers, MCCs and Compliance With All Laws
Payers often seek or inquire about the uses of Aerocrine’s products, including and all possible uses to determine their exposure and costs. Because of the nature of any discussion describing pricing, and other discounts, the AdvaMed Code permits truthful and accurate conversations about Aerocrine's devices, and its coverage, reimbursement and health economic information with Aerocrine's customers. Aerocrine may only provide “off-label” information to an MCC upon an unsolicited request by the MCC. To the extent that the information is off-label, Medical Affairs must
provide that information to the MCC. While it is perfectly acceptable for the National Accounts employee and Medical Affairs to provide a joint discussion in response to the unsolicited question by the MCC, the National Accounts employee may only discuss on-label information, whereas the Medical Affairs representative may provide all information about the Aerocrine device.

Payers are acutely interested in these types of discussions prior to the approval of a new device. Accordingly, if the device is not approved, or if the use of the device is off-label, only Medical Affairs may provide "off-label" information in response to an unsolicited request from the MCC.

**Global Government-Employed HCP, Physician, and Government and Public Official Interactions Policy**

As discussed in various sections of this Manual's Introduction, all interactions with HCPs are intended to benefit patients and enhance treatment and medical educations. The primary purpose of all interactions should include educating Healthcare Professionals on the risks and benefits of Aerocrine devices, treatment options, scientific research and other topics intended to advance medicine. No transfer of value, whether direct or indirect, in kind or as payment, may be provided or offered to a Healthcare Professional in exchange for, as an inducement to, or as a reward for purchasing an Aerocrine device, or recommending, supplying, or administering Aerocrine devices. Offering or accepting Bribes is expressly prohibited and will not be tolerated by Aerocrine. Local laws regarding interactions with Healthcare Professionals vary by country. When in doubt, employees, contractors and agents are responsible for communicating with Legal to discuss the appropriateness of a proposed interaction before the interaction occurs.

In the US, among Aerocrine's customers are federal government agencies and institutions, including the Department of Veterans Affairs ("DVA") and its hospitals and medical facilities, and government-employed HCPs (state or federal, including but not limited to the National Institutes of Health HCPs). At times, Aerocrine employees may interact with doctors, and other HCPs who work for these government agencies and institutions and are public employees. Unlike the interactions with non-DVA/non-Department of Defense ("DoD") physicians, the interactions with HCPs employed by the government are subject to scrutiny beyond the healthcare fraud and abuse considerations discussed in this Manual's Introduction. Specifically, the Veterans Health Administration Directives and the Office of Government Ethics Rules govern these interactions.

Internationally, please beware that in many circumstances, doctors and other HCPs who are employed and/or act on behalf of a government authority or the respective national health service may be considered a "Government Official" for purposes of the anti-corruption laws. For this reason, if you are operating outside of the U.S., you must assume that the following are Government Officials: all doctors, pharmacists, nurses, physician assistants, paramedics, medical professors,
administrators and employees of state-owned, operated, or affiliated hospitals, universities, or other organizations.

This chapter limits the range of allowable Aerocrine/industry interactions with HCPs employed by the government, who may be defined as "Public" or "Government Officials" by anti-corruption laws. As a result, calls and other sales activities that are permissible when conducted with HCPs who do not work for the government may be prohibited. This policy is applicable to any Aerocrine employee who calls on an HCP, a federal government HCP, or a Public/Government Official to promote an Aerocrine device or provides an on-site in-person educational activity (including the CSLs).

Lobbying

Lobbying activities are subject to significant regulatory oversight on both the federal and state level. Federal law defines lobbying activities to include:

- Any effort to influence the formation, modification, adoption, or administration of any federal legislation, regulation, order, rule or position of the federal government;
- Any attempt to influence the nomination or confirmation of any individual to federal office; and
- Any endeavor to influence the negotiation, award or administration of a federal contract or grant.

Lobbying does not, however, include: making an administrative request, such as a request for a meeting or for clarification of a statute or regulation, so long as the requestor makes no attempt to influence a federal matter; or monitoring legislative activities, by itself. Most states and some localities also have laws that establish what constitutes lobbying, and that place limitations on lobbying activities.

Aerocrine is committed to conducting all lobbying activities in compliance with federal, state and local laws. Because of the complexity of rules related to lobbying, and to ensure a consistent corporate message, only the personnel authorized by the Chief Executive Officer and his/her designees may engage in lobbying activities or may retain a third party lobbyist on Aerocrine’s behalf. This Manual advises Aerocrine employees of their responsibilities and restrictions related to lobbying activities conducted on Aerocrine’s behalf. This Manual does not restrict the ability of Aerocrine employees to engage in personal lobbying (i.e., other than on Aerocrine’s behalf) on their own time, so long as no Aerocrine funds, resources, or facilities are used to support those lobbying activities and the activities comply with Aerocrine’s policies.
In some states, certain individuals may be subject to special state lobbying registration requirements (see the section on Miami-Dade County, Florida, in the Transparency Laws chapter). Any Aerocrine employee who is uncertain whether his or her activities constitute lobbying should contact the Legal/Compliance Department to discuss.

Gifts to Government Officials and Public Employees

Gifts, meals, and entertainment may not be provided to government officials or public employees, unless specifically approved in advance by the Compliance Officer or his/her designee. Under no circumstance may a benefit be provided with any corrupt intent or as a quid pro for any official action by the recipient. All such expenses must be accurately reflected in the books and records of the relevant Company business unit.

Campaign Contributions

It is important to understand the difference between lobbying and grassroots efforts and campaign contributions. Lobbying and grassroots efforts are intended to influence government policy. Campaign contributions are intended to influence campaigns and elections.

Aerocrine employees are occasionally approached by local, regional or national political candidates or political parties seeking corporate contributions for political campaigns. The request may come directly from a politician himself or herself, or it may be communicated through a common acquaintance or other intermediary.

Political contributions and fundraising activities by Aerocrine raise special concerns for several reasons. First, the laws governing corporate political contributions vary widely among the countries in which Aerocrine does business. Second, some countries have a history of diverting corporate political contributions to private use, or exchanging political contributions for special favors. Third, even where corporate political contributions are appropriate and accepted, favoring some politicians or political parties over others may not advance the long-term interests of Aerocrine. Fourth, an organization that is perceived by many to be a company operating in the U.S., Aerocrine may be seen as influencing the results of elections outside the U.S., and it can draw strong responses from citizens of other countries.

U.S. federal and state laws generally prohibit a corporation from making contributions to candidates and political parties. In addition, federal and state anti-bribery laws impose criminal penalties for offering gifts or campaign contributions to government officials in exchange for a change in policy, entering into a federal or state contract, or agreeing to engage in any other official act. Accordingly, any proposed donation or expenditure of corporate funds that possibly relates to a political event, election, voter registration or mobilization initiative, or that is requested by a political party,
candidate or elected representative, or that would be disbursed to a political entity or organization (including organizations affiliated or associated with a candidate or representative), must be submitted for prior review and approval by both Compliance and Legal.

To implement this directive and explain its application in countries outside the U.S., Aerocrine has adopted the following policies concerning corporate political contributions:

- **Corporate contributions to political candidates and political parties in countries other than the U.S. are prohibited.** This prohibition covers contributions of any kind, including cash, loans, gifts, membership fees, and all other non-cash contributions (including so-called “in-kind” contributions such as holding or sponsoring political fundraisers, donations of office space, office supplies, or other non-cash items or services of value).

- Aerocrine employees may not cause Aerocrine to make payments to lobbying firms, charities, contractors, or other third parties as a way of circumventing Aerocrine restrictions on political contributions.

- This policy is not intended to prevent employees themselves from engaging in appropriate lobbying activities for the benefit of Aerocrine, or to restrict the right of Aerocrine employees to make personal political contributions or otherwise participate in U.S. political activities on their own time, provided that such activities (i) are permitted under applicable law, and (ii) are not related to the Company or its business. However, all non-U.S. political activities, especially by employees who are not nationals of the country in which such activities occur, must be approved by the Compliance and Legal.

- Aerocrine employees are prohibited from discussing past, present or future campaign contributions with a government official or public employee.

### On-Site, In-Person Promotional/Educational Activities

On March 5, 2012, the DVA promulgated its Final Rule for Industry “Representatives”, which is defined broadly to include any and all Aerocrine employees that enter a VA facility—including CSLs. The Final Rule is intended to "reduce or eliminate any potential for disruption in the patient care environment, manage activities and promotions at VA facilities, and provide medical device company representatives with a consistent standard of permissible business practice at VA facilities."

The Final Rule may be found at:


It is mandated that each Aerocrine employee who visits a VA facility read and adhere to the Final Rule. Among other conditions, the Final Rule provides the following:
• The Rule ONLY applies to on-site, in-person promotional or educational activities
• Company employees must have an appointment prior to entering a VA facility
• Any materials that are handed out on-site must be approved by both Aerocrine's PRC and the VA facility, and devoid of a company/trade logo, with the exception of "FDA labeling" and
• New devices (not on the VA National Formulary) can be discussed upon certain conditions; but if deemed "non-promotable" by the DVA, the device may not be discussed on-site and in-person.

If approved, any on-site, in-person activities must conform to Aerocrine's compliance principles:

• use only PRC- and VA facility-approved materials
• stay on-label
• discuss only approved devices and indications and
• never engage in any activities that would violate the Anti-Kickback Statute and associated Aerocrine policies and procedures.

Promotional Materials

In a Department of Veteran Affairs (DVA)/Department of Defense (DoD) setting, the promotional materials must be PRC-approved and approved by the DVA/DoD facility prior to use on-site, when provided in-person. When calling on federal institutions, do not leave promotional materials in patient areas without first obtaining approval from the institution. As always respect patient privacy by not conducting presentations in-patient care areas. In addition, be aware of rules pertaining to how and when Aerocrine employees may leave promotional materials for HCPs at federal institutions. For example, some institutions have particular requirements related to leaving promotional materials for non-formulary devices.

Meals in Connection with Educational Presentations

*Due to the U.S. government employee gift ban of unsolicited gifts, Aerocrine will not allow government employed HCPs to attend a meal.*

Consulting Services

When HCPs are also government or public officials, as defined by ant-corruption laws, local laws may prohibit these arrangements or impose strict requirements on the HCP or Aerocrine. Generally, Aerocrine prohibits any contracts with or compensating a government employee HCP to speak on
Aerocrine’s behalf or attend an Advisory Board. The only exception to this general rule is if all of the following are satisfied:

The government employee:

- Is permitted by his/her government agency or institution to accept outside fees and provides written confirmation that he/she has received confirmation from the relevant authority (typically his/her institution or hospital, but in France it is a government agency) that the benefits do not violate local law or regulations and approval or authorization to participate. If that is not possible, the HCP may provide written confirmation that the arrangement is in line with his/her professional duties and obligations.
- Is speaking in his/her individual capacity and not as part of the employee’s official duties
- Is speaking because s/he is a subject matter expert on a topic and not because of his/her official position
- Is not speaking on a matter pending before the government agency or institution
- Is speaking on his/her personal time rather than government working time and
- Is not conveying information which draws on ideas or official data that is non-public information

In additional, all benefits provided to the HCP must be transparent, documented, and memorialized. Services may not be initiated until the HCP and Aerocrine have signed a consulting agreement, as set forth in the Personal Service Arrangements Policy. Compensation must be based on Fair Market Value and must be appropriate for the relevant geographic area. Compensation may be provided only after services are performed. Aerocrine must ensure all appropriate withholding taxes and VAT for services rendered are paid. Reimbursement of travel-related expenses may also be appropriate. The agreement shall specify that the HCP must meet all legal requirements in order to entitle him/her to accept payments in consideration for his/her work.
Transparency Laws

In recent years, numerous states have enacted laws that directly impact Aerocrine's various sales, marketing and pricing activities. In addition, the federal government has, through the passage of Section § 6002 of the Patient Protection and Affordable Care Act, enacted what has been referred to as the “Sunshine Act” (hereinafter, the “Federal Sunshine Act”) that will similarly require disclosure of certain spend and activities between Aerocrine and physicians and teaching hospitals across the country.\(^5\) The Federal Sunshine Act preempts certain state disclosure requirements that will require duplicative disclosures of certain payments or transfers of value to physicians and teaching hospitals. Aerocrine is committed to complying with all state and federal laws that may affect the marketing of its devices and its relationships with HCPs and HCOs. This chapter is an overview of applicable current state laws requiring disclosure of certain activities and other related obligations, such as lobbyist registration and compliance program certification.

This section addresses several U.S. state laws that require certain disclosures and other obligations. This policy applies to all Aerocrine employees who, directly or indirectly, are involved in promoting, marketing and/or providing any remuneration, directly or indirectly, towards HCPs or HCOs. This includes, but is not limited to: Sales, Marketing, Clinical Development, and Medical Affairs, including CSLs. It is important to note that some states’ laws apply to the HCP license holder, regardless of the location of the activity. For example, the activity may take place outside of the jurisdiction in question, but the expenditure must still be tracked or, more importantly, the state’s prohibition is still applicable.

With certain state-specific differences, an HCP is a provider of medical or health services licensed in the U.S., or any other person in the U.S., that furnishes, bills, or is paid for healthcare in the normal course of business. This definition of an HCP includes, but is not limited to, physicians, nurse practitioners, advanced practice nurses, physician assistants, registered nurses, pharmacists, researchers, investigators, hospital personnel, representatives of managed care organizations, such as health maintenance organizations and pharmacy benefits managers, and formulary committee members. For purposes of the Federal Sunshine Act, an HCP is a “physician,” which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors.

An HCO is an organization that provides medical or health services or an organization that represents or serves HCPs or consumers in the U.S. The definition of an HCO includes, but is not limited to, teaching hospitals, hospitals, academic institutions, nursing homes, clinics, pharmacies, rehabilitation

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\(^5\) The Federal Sunshine Act requires the disclosure of certain spend (this includes, but is not limited to, clinical trial spend) with “physicians” and “teaching hospitals.” On February 8, 2013, the Centers for Medicare and Medicaid Services published the final regulations implementing the Federal Sunshine Act, which was included as section 6002 of the Affordable Care Act of 2010. All reporting commenced on August 1, 2013. The first Aggregate Data report for 2013 spend (August-December of 2013) was to be filed by March 31, 2014, and the detailed report was due June 30, 2014. Please see the Introduction for more information on Aggregate Spend and the Federal Sunshine Act provisions.
facilities, professional, educational and patient organizations, continuing medical education providers, non-profit hospital foundations, health benefit plan administrators, and managed care organizations. For purposes of the Federal Sunshine Act, an HCO is a “teaching hospital.” CMS will publish annually a list of the teaching hospitals to facilitate the identification of reportable entities.

California

California Health and Safety Code §§ 119400 - 119402 requires device companies (device manufacturers, packagers, labelers, and distributors of dangerous devices, and any person who “engages in device detailing, promotional activities, or other marketing of a dangerous device in [California] on behalf of a device company”) to establish a Comprehensive Compliance Program (“CCP”) relating to their interactions with HCPs.\(^6\) The CCP must be in accordance with both the AdvaMed Code and the Office of the Inspector General Compliance Program Guidance for Device Manufacturers (“OIG Guidance”). This law further requires companies to make conforming changes to their CCP within six months of any updates or revisions to the AdvaMed Code or the OIG Guidance.

This law requires each device company to:

- Establish in its CCP “a specific annual dollar limit on gifts, promotional materials, or items or activities that the device company may give or otherwise provide to an individual [HCP]”
- Make an annual written declaration that it is in compliance with its CCP and this law
- Make its CCP and its annual declaration of compliance available to the public on its website and
- Provide a toll-free number to obtain a copy of the CCP and the annual written declaration.

The following are exempt from the annual limit:

- Payments made for legitimate professional services provided by an HCP, such as consulting services, if such payments do not exceed fair market value (“FMV”) and conform to OIG Guidance and AdvaMed
- Financial support for continuing medical education forums, so long as the support conforms to OIG Guidance and AdvaMed
- Device samples intended for free distribution to patients (Aerocrine does not provide any device samples for distribution of any kind.)

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\(^6\) California law defines “medical or health professionals” as “any of the following:

1. a person licensed by state law to prescribe devices for human patients.
2. a medical student.
3. a member of a device formulary committee.”
• Financial support for health educational scholarships, so long as the support conforms to OIG Guidance and AdvaMed.

Aerocrine has established that the annual aggregate limit on covered promotional expenditures is $3000 per covered HCP for each annual compliance period. Aerocrine will collect and track applicable expenditures against this limit for all California HCPs.

Massachusetts

The Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Law (Mass Gen. Laws ch. 111N) and implementing regulations (105 Mass. Code Regs. 970.000) require certain annual disclosures, adherence to prohibitions, and the promulgation of a comprehensive compliance program.

On July 8, 2012, the Governor signed into law House Bill 4200. House Bill 4200, among other things, amends the Device and Medical Device Manufacturer Conduct Law by allowing the marketing code of conduct adopted by the Massachusetts Department of Public Health to permit pharmaceutical and medical device manufacturers to provide modest meals and refreshments in connection with non-CME educational presentations. On December 7, 2012, final regulations became effective, implementing changes to the Device and Medical Device Manufacturer Conduct Law.

The disclosure component of this law requires device or medical device manufacturing companies to annually disclose to the Department of Public Health “the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.” Covered recipients include the following:

• Physician
• Hospital
• Nursing home
• Pharmacist
• Health Benefit Plan Administrator
• Healthcare Practitioner and
• Any other person authorized to prescribe, dispense, or purchase prescription devices or medical devices in the State of Massachusetts.

The disclosure and prohibitions apply to all HCPs licensed to practice in Massachusetts, regardless of where the HCP practices or where the reportable or prohibited activity takes place. The above disclosure report is due annually on July 1.
Meal Prohibition/Limitation

Massachusetts prohibits medical device companies from providing or paying for meals for HCPs that:

- are part of an entertainment or recreational activity
- are offered without an informational presentation made by a device company representative or without a representative being present or
- are provided to an HCP’s spouse or other guest.

As a result of amendments to the law and regulations, Massachusetts now permits medical device manufacturers to provide “modest meals and refreshments in connection with non-CME educational presentations for the purpose of educating and informing HCPs about the benefits, risks and appropriate uses of prescription devices or medical devices, disease states or other scientific information.” Such modest meals and refreshments provided in connection with an informational or educational presentation may be inside or outside an HCP’s office or hospital setting (now also includes a restaurant venue too).

The regulations define a modest meal as “food and/or drink provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to an HCP that, as judged by local standards, are similar to what an HCP might purchase when dining at his or her own expense.”

Device and medical device manufacturers who provide modest meals and refreshments outside of an HCP’s office or hospital setting must file quarterly reports detailing all non-CME educational presentations in which they provide such meals or refreshments. The reports must include the following information:

- The location of the non-CME presentation
- Description of any medical devices or other devices discussed
- Total amount expended on such presentation and
- An estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation.

CME, Third-Party Scientific or Educational Conferences, and Professional Meetings

Massachusetts’s law prohibits device and medical device companies from providing the following:
• Financial support for the cost of travel, lodging, or other personal expenses of non-faculty HCPs attending any CME event, third-party scientific or educational conference, or professional meeting
• Funding to compensate for time spent participating in any CME event, third-party scientific or education conference, or professional meeting
• Direct payments to an HCP at any CME event, third-party scientific or educational conference, or professional meeting or
• Sponsorship or payment for CME or independent medical education (“IME”) that does not meet the standards established by the Accreditation Council for Continuing Medical Education (“ACCME”) for Commercial Support, or other equivalent standards for the relevant continuing education accrediting body, or that provides payment directly to an HCP.

However, Massachusetts’s law permits the following:

• Compensation or reimbursement paid to an HCP serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, if the payment is reasonable, based on FMV, and complies with the standards for commercial support established by the relevant accreditation entity
• Sponsorship or payment associated with any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting provided that the payment is made directly to the conference or meeting organizers and
• The use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific educational or professional meetings or conferences.

Other Payments to HCPs

Massachusetts’s law prohibits device and medical device companies from providing the following:

• Entertainment or recreational items of any value to any HCP who is not a salaried employee of the device or medical device manufacturing company (i.e., theater or sporting event tickets, concerts, sporting equipment, or leisure or vacation trips)
• Payments of any kind, such as cash or cash equivalents, equity in kind, or tangible items, including complimentary items (i.e., pens, coffee mugs, gift cards, etc.), except as compensation for bona fide services
• Grants, scholarships, subsidies, support, consulting contractors, or educational or practice related items in exchange for prescribing, disbursing, or using prescription devices, biological or medical devices or for a commitment to continue prescribing, disbursing, or using prescription devices, biologics or medical devices and
• Rebates or kickbacks prohibited under applicable federal or state fraud and abuse laws, or regulations including the federal anti-kickback statutes and equivalent Massachusetts laws.

Massachusetts’s law permits the following:

• Reasonable compensation for bona fide services and reimbursement of other reasonable out-of-pocket costs incurred by an HCP as a result of the performance of such services, if the compensation and reimbursement is specified in and paid under a written agreement
• Payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of HCPs on the use of a medical device
• Provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical information
• Purchase of advertising in peer-reviewed academic, scientific, or clinical journals
• Provision of prescription devices to an HCP solely for use by the practitioner’s patients
• Provision of reasonable quantities of medical device demonstration and evaluation units to an HCP to assess the appropriate use and functionality of the device and to determine if and when to use or recommend the device
• Provision of price concessions (i.e., rebates or discounts) in the normal course of business;
• Provision of reimbursement information regarding devices
• Provision of payments or free outpatient prescription devices to HCPs to benefit established patient assistance programs, provided that the program meets the criterion for a permissible program in accordance with the relevant published guidance or is otherwise permitted under applicable federal laws and regulations including the anti-kickback statute and
• The provision of charitable donations provided that the donation is not a kickback, and does not violate any provision of the regulations.

Miami-Dade County, Florida

The Miami-Dade County Lobbyist Disclosure Law (Code of Miami-Dade County, Florida § 2-11-1(s)) requires any individual who seeks to encourage the actions, decisions, or recommendations of the County Commission, County Manager, County Personnel, or any county board or committee to annually register as a lobbyist with the Miami-Dade Board of County Commissioners.

Any vendor that approaches a Miami-Dade doctor (generally Jackson Memorial Hospital or Mercy Hospital) for a physician preference is required to register as a lobbyist if the: (1) physician serves on a procurement review or selection committee; or (2) vendor is seeking to influence the action, recommendations, or decision of County personnel. A device representative is required to register as a lobbyist if he or she approaches University of Miami doctors regarding the purchase of devices or
services that “foreseeably” will be reviewed by the Public Health Trust Board of Trustees or a PHT board or committee.

**Lobbyist Registration**

This law requires any individual engaged in lobbying to register with the Clerk of the Board of Commissioners. Lobbyists are required to complete an ethics course within sixty (60) days after registering as a lobbyist. Additionally, this law requires each principal or company that employs an individual to engage in lobbying on its behalf to file a Lobbyist Activity Authorization form with the Clerk.

**Lobbyist Reporting Requirements**

Each lobbyist must submit a Lobbyist Expenditure Report to the Clerk for each principal and company that the lobbyist is authorized to represent. The report must include, in the aggregate, all reportable expenditures exceeding $25.00 that the lobbyist incurred during the preceding calendar year that fall within the following categories:

- Food and beverage
- Entertainment
- Research
- Communications
- Media/Advertising
- Publications
- Travel
- Lodging and
- Special events.

The following expenditures are exempt from the reporting requirements:

- Expenditures that do not exceed $25.00
- Political contributions and expenditures reported under election laws, and campaign-related personal services provided without compensation and
- The lobbyist’s or principal’s salary, office expenses, and personal expenses for lodging, meals, and travel.

A Lobbyist Expenditure Report must be submitted by July 1 of each year for expenditures incurred during the preceding calendar year (January 1 - December 31).
Nevada

The Nevada Pharmaceutical Marketing Code of Conduct Law (Nevada Revised Statutes Ch. 639) requires that device companies:

- Adopt a written marketing code of conduct for all employees
- Conduct an annual audit to monitor compliance with the code of conduct and certify the audit was completed
- Adopt a training program on the marketing code of conduct to provide regular training to appropriate employees
- Adopt policies and procedures for investigating instances of non-compliance, including, without limitation, the method for maintaining effective lines of communication for employees to report non-compliance, the process for investigating reports of non-compliance, and the procedure for taking corrective action in response to non-compliance. This also includes reporting instances of non-compliance to law enforcement authorities in appropriate circumstances
- Appoint a Compliance Officer to oversee a comprehensive compliance program and
- Provide the following to the State Board of Pharmacy by June 1 on an annual basis:
  - A copy of the company's marketing code of conduct (if different from the AdvaMed Code)
  - A description of its training program
  - A description of its investigation policies
  - The name, title, address, telephone number and e-mail address of its compliance officer and
  - Certification that the company has conducted its annual audit and is in compliance with its marketing code of conduct.

To facilitate compliance, all employees must adhere to the following:

- Comply with all training programs conducted;
- Cooperate with audit teams when audits are conducted; and
- Become familiar with the marketing code of conduct.

Vermont

Vermont’s Prescribed Devices Gift Ban and Disclosure Law (VT. Stat. Ann. Tit 18 §§ 4631a and 4632) requires device companies to disclose allowable expenditures and permitted gifts made to any healthcare provider, academic institution, non-profit hospital foundation, or professional, educational, or patient organization representing or serving HCPs or consumers, located in or providing services in Vermont, or to any members of Vermont’s Green Mountain Care Board
Device companies must register their Compliance Officer with the Vermont Attorney General by January 1 and must report all permitted gifts and allowable expenditures provided during the prior calendar year by April 1.

Vermont law requires the disclosure of the “value, nature, purpose, and recipient information” of permitted gifts and allowable expenditures (with certain exceptions, which are not subject to reporting, and examples of which are listed below). The name, address and institutional affiliation must also be identified, as well as the Vermont license number of any prescriber or pharmacist or, in the case of an institution, foundation, or organization, the federal tax identification number or the identification number assigned by the Vermont Attorney General. The prescribed devices being marketed must also be disclosed.

Pursuant to Vermont’s gift ban, device companies are prohibited from providing “any payment, food, entertainment, travel, subscription, advance, service or anything else of value” to any HCP, academic institution, non-profit hospital foundation, or professional, educational, or patient organization representing or serving HCPs or consumers, located in or providing services in Vermont, or GMCB members free of cost, unless it is explicitly permitted or allowed or the recipient reimburses the Company at fair market value. The Vermont gift ban is a strict liability statute; therefore, Aerocrine employees may not provide a gift (e.g., meal) to any licensed and active Vermont HCP or GMCB member, regardless of whether the activity takes place in Vermont.

The following are examples of gifts that are banned:

- Monetary donations given to physicians or other Vermont recipients other than free clinics;
- In-office lunch provided by a regional manager in conjunction with discussion of device information, unless the office reimburses the device regional manager for the meal; and
- Breakfast provided to non-prescribing staff members in a physician’s office.

The following are examples of permitted gifts and allowable expenditures that are not subject to the disclosure requirements:

- Royalties and licensing fees paid to an HCP in return for contractual rights to use a patented or otherwise legally recognized discovery for which the HCP holds an ownership right;
- Prescribed devices distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program; and
- Rebates and discounts for prescribed devices provided in the normal course of business.

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7 Additionally, Vermont requires the reporting of all samples of prescribed devices and discount mechanisms (e.g., vouchers, co-pay cards, etc.) provided to healthcare providers during the preceding calendar year.
The following are examples of permitted gifts that are subject to the disclosure requirements:

- Articles or journals and other educational items provided to an HCP as long as they are peer-reviewed academic, scientific, or clinical articles or journals, or serve a genuine educational function and are for the benefit of patients;
- Scholarships or other support for medical students, residents, and fellows to attend a significant educational, scientific or policy making conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association;
- Allowable gifts to academic institutions and professional, educational or patient organizations representing or serving HCPs or consumers located in or providing services in Vermont, with certain exceptions with respect to reporting; and
- Food to an HCP as part of fair market value compensation package for service – e.g., service on advisory board, consulting, or speaking.

The following are examples of allowable expenditures that are subject to the disclosure requirements:

- Payment to a sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, if and only if:
  - The payment is not made directly to the HCP
  - Funding is used solely for bona fide educational purposes except that the sponsor may, in the sponsor’s discretion, apply some or all of the funding to provide meals and other food for all conference participants and
  - All program content is objective, free from industry influence, and does not promote specific devices.
- Honoraria and expenses of an HCP who serves on the faculty at a bona fide significant educational, medical, scientific or policy making conference/seminar, if and only if there is a contract with specific deliverables restricted to medical issues and not marketing, and the content of the presentation, including slides and written materials, is determined by the HCP.
- Gross compensation for a research project that constitutes a systematic investigation is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or HCPs working in the particular field of inquiry.
  
  Payments related to bona fide clinical trials, including gross compensation for the Vermont location or locations involved, direct salary support per principal investigator per year, and expenses paid on behalf of investigators or other HCPs paid to review the clinical trial.
For a more in-depth discussion of Vermont’s disclosure laws, please see the Guide to Vermont’s Prescribed Devices Gift Ban and Disclosure Law for 2014 Disclosures.

International

Similar to the U.S., which has both state and the federal Sunshine reporting obligations, there are various countries in the European Union and outside of the U.S. that have reporting obligations for certain spend or the provision of a “thing of value” to an HCP (such jurisdictions include, but are not limited to: France, the Netherlands, Australia, the United Kingdom, and Japan). In addition, some industry groups have enacted or may enact self-regulatory codes that have reporting requirements about interactions with HCPs. Aerocrine is committed to complying with all applicable government and industry code reporting requirements concerning interactions with HCPs. Please consult with Compliance to determine if and whether there may also be a reporting obligation with HCPs in a particular country.
Aerocrine

Grants, Charitable Giving and Charitable Donations Policy

Charitable contributions are an important reflection of the Company's commitment to the communities in which Aerocrine operates around the world. Aerocrine supports a range of charitable causes and projects, from hospitals, to schools, to nonprofit community health organizations. The charitable contributions that Aerocrine makes in local communities help to foster improved healthcare around the world.

When permitted by local law, Aerocrine provides non-promotional funding to third-party professional, educational and charitable groups in the form of unrestricted educational grants, charitable contributions, or the provision of free devices for certain charitable causes. This policy is relevant to all Aerocrine employees who are asked questions regarding requests for unrestricted educational grants for programs providing CME credits in accordance with the guidelines from the ACCME or similar CME accreditation bodies, charitable contributions, and/or the provision of free devices. In the EU, Aerocrine may provide sponsorship money and content for symposia. In that case, the materials and content must be approved by PRC.

Non-ROI

It is important to understand the differences between grants and charitable contributions, and sponsorships. Grants and charitable contributions are “non-return on investment” (non-ROI) endeavors. That means that it is never appropriate to expect any direct return on Aerocrine itself from the funding of a grant or charitable contribution (other than community goodwill). Therefore, Sales and Marketing Personnel must be completely removed from the determination of whether to fund certain grants or charitable contributions.

As discussed below, by removing Sales and Marketing Personnel from the decision-making, and requiring review and approval by the Grants Review Committee (“GRC”), which is comprised of a multi-disciplinary team that includes Medical Affairs, Compliance, and Legal, Aerocrine seeks to minimize the risk that an educational grant or charitable contribution could be approved, or be perceived to be approved, for an improper purpose. It is never appropriate to link an educational grant or charitable contribution with the performance, increased use, or formulary status of an Aerocrine device. Aerocrine support may not be made with the intent, directly or indirectly, implicitly or explicitly, to influence or encourage the recipient to prescribe, purchase, recommend, sell or arrange for the prescribing, purchasing, or sale of any Aerocrine device or as a reward for any such past behavior. The only reason to support an educational grant or charitable contribution is to support programs and organizations that advance the treatment of patients with conditions associated with the therapeutic areas with which Aerocrine is associated.
It is important to note that there may be an ancillary benefit to the Company from time-to-time when funding either a grant or charitable contribution (e.g., a table at a gala, or the ability to provide a table-top exhibit and display at an event). Any such ancillary benefit gained may not be considered by the respective committees when making a determination to fund the event.

**Definitions and Scope**

**Grants:** An educational grant is appropriate for those activities that directly educate an HCP or other healthcare providers, or educate a broad patient base or patient education outreach. Funding must be given to a third-party entity to support a specific educational, scientific or health-related activity. The third-party entity must provide CME credits in accordance with the guidelines from the ACCME or similar CME accreditation bodies.

**Charitable Contributions:** Charitable contributions are appropriate for activities that are primarily directed towards patients and the community at-large (in whatever disease state the Company determines appropriate). To be eligible to apply for a charitable donation, the organization must be a tax-exempt organization, generally but not always a 501(c)(3) entity. The donation must be for patient education, patient advocacy, or improved patient access to care.

**Fellowships and Scholarships:** Aerocrine may, from time-to-time, provide financial support for fellows and scholars in asthma or pulmonology or other appropriate therapeutic areas that interest the Company. Fellowships and scholarships are considered unrestricted educational grants as they directly educate HCPs and other healthcare providers. Aerocrine may provide grants to support a fellows program or scholarship to a medical congress as long as the grant is provided to the entity (the hospital itself) and Aerocrine cannot control the decision or determination of who will receive the support (for this reason, the Medical Affairs or Clinical group must make all Fellowship or Scholarship determinations).

**Sponsorships:** Sponsorships are those activities where there is either a promotional or significant branded public relations opportunity for Aerocrine's investor relations, Marketing or Sales personnel. **Sponsorships may never be funded with a grant or charitable contribution as a sponsorship is an ROI endeavor.** Therefore, sponsorships should be funded through the Marketing and/or Sales budgets. Generally, fundraising events where there is the ability to have an Aerocrine table (promoting the device or the Company) are considered a request for sponsorship. When permitted by local law, Aerocrine may pay for or reimburse an HCP for attending and participating in an Aerocrine-sponsored meeting. This sponsorship must be documented in a written agreement. In particular, the agreement must state the purpose of the sponsorship and the total amount to be paid, which should be based on a reasonable estimation of the cost for transportation, lodging, and meals.
Requests for Grants and Charitable Contributions

It is important to note that any and all grant requests and charitable donation requests must be sent to Aerocrine via Medical Affairs.

At no time may an Aerocrine employee verbally promise to fund any grant or charitable contribution prior to review by the GRC or the Charitable Giving Committee. If you receive a request for a grant or charitable event, please provide the requester with contact information for Medical Affairs and have the requester submit to the appropriate committee for review. It is important to note that the Field may never promise or guarantee funding, nor aid in the submission for a requester—the onus is on the requester to submit a request to the appropriate committee. Medical Affairs will provide the requester a list of the information needed for the committee’s review.

Educational Grants

Legitimate professional and educational initiatives that can be supported with educational grants include activities like continuing education for HCPs. Educational grants are permissible only if they are “unrestricted”, which means that the content must be developed independently of Aerocrine's influence. Aerocrine employees may not actively influence the content of the sponsored activity or the manner in which it is conducted (i.e., focus, venue, food, agenda, speakers, etc.). Aerocrine may never fund an unrestricted educational program unless the sponsor is an entity, foundation, or hospital. Grants may never be provided to individuals or individual HCP practices.

All educational grants must conform to the following four principles:

- Broad Educational Output
  - Medical or scientific education to enhance the practice of medicine is the focus
  - Business topics may not be the focus of the program (such topics include coding, HIPAA compliance, office management, and office quality improvement)
  - Educational output is created and disseminated to a community of physicians and/or other appropriate HCPs
  - Serves a broad audience of providers (e.g., all qualified HCPs are able to attend).

- Independence
  - Payment of the grant cannot be based on whether Aerocrine’s devices are treated favorably
  - Input into speakers or accuracy of the content may not be provided (except for non-CME programs) and
Upon approval from the GRC, a written agreement must be executed prior to the event.

- Balanced and Objective
  - Educational programs must be objective and “balanced” so as to address the relevant therapeutic options and
  - Programs should not primarily focus on the profile of a single device (the discussion of one device should not be the entire purpose of the education).

- Reasonable Costs
  - Financial support may include reasonable fees for speakers (to be used as a proxy only – Attachment A - FMV Matrix for Promotional Speakers is a promotional endeavor but nonetheless it is a generally good guidepost for honoraria and speaking);
  - Financial support should not include:
    - Faculty compensation that is disproportionate to the amount/value of the work
    - Compensation for non-faculty physician/HCP attendee unless the HCP is outside of the U.S. and local law or association rules permit such payments; or
    - Direct subsidies for attendee costs for travel, lodging, or personal expenses (this does not include scholarships whereby the recipient is chosen by a third-party and Aerocrine has no input on the selection of the recipient).

All educational grant requests must be sent to Medical Affairs via the means set forth above. The GRC will determine in its sole capacity the merits of each request. All requests must, at a minimum, provide the following information:

- Description of the activity, including educational purpose and, if applicable, identity of program host, date and location, target audience/projected attendance, brief description of the program topic, speakers (if selected) and where they are from, whether continuing education (“CE”) credits will be awarded, provider of CE/CME credits, and the tax ID number of the organizer
- An executed CME or non-CME Agreement
- A statement of independence from Aerocrine influence, with the grant recipient taking responsibility for selecting content, speakers, faculty and logistical elements of the educational program and
- Amount of funding requested from Aerocrine, including a detailed budget. For all grants, a full-itemized budget regardless of the amount of the grant request will be required.

It is important to note that if the following conditions are satisfied, the Field may distribute CME invitations:

- The GRC has made a final determination to fund the event
The CME provider, based upon a written (and unsolicited) request, solicits the GRC to use the Field to aid in the distribution of the event’s invitation

- The invitation does not contain or use an Aerocrine device’s name, brand colors, trademark or in any other way, directly or indirectly, make a claim about an Aerocrine device and

- The invitation is distributed to all HCPs in the defined geographical area (the invitation may not be distributed to a select few within the selected geography).

**Sponsoring Non-U.S.-Based Doctors to Attend Medical Congress, CME Events, or Meetings or Informational Sessions**

One of the ways that the Company contributes to the development of medical education is by sponsoring non-U.S. doctors to attend congresses, and other medical meetings. In addition to disseminating important medical knowledge, these events may also result in building goodwill for Aerocrine—an ancillary benefit.

However, it is important to ensure that the sponsorship is not a disguised way of securing an improper advantage or improper performance or undue influence for Aerocrine. For that reason, as explained below, non-U.S. doctors may only be sponsored to attend congresses, CME events, or Aerocrine-sponsored meetings or informational sessions after careful review of the purpose of such sponsorship, the mechanics of payment, and other relevant facts. The following policies must be observed with respect to sponsored attendance at medical congresses, CME events, or similar Aerocrine meetings or informational sessions:

- Each proposed sponsorship of an ex-U.S. HCP must be submitted to and approved by the Grants Committee in advance and in writing, and written documentation of the decision must be retained in accordance with the Records Retention Policy. The proposal must include an explanation of why the healthcare professional(s) in question should be sponsored. This review process must include an assessment of the reasonableness of the expenses, particularly in the case of Aerocrine-organized events.

- Every sponsorship must comply with local law and any applicable industry and professional guidelines in the relevant market. If you have any questions about the laws or guidelines that apply in your market you must consult with the Compliance/Legal Department.

- Sponsorship is prohibited unless the primary purpose of the healthcare professional’s attendance at the event is to expand medical knowledge within the relevant medical community.
• Sponsorship is prohibited if it is offered as an incentive to, or in exchange or as a reward for, using, purchasing or recommending Aerocrine’s products or obtaining any other improper advantage for Aerocrine.

• If the sponsorship includes travel, all travel-related expenditures must comply with the policies contained in the Visits to Aerocrine Facilities and Other Travel section of the International Anti-Corruption chapter.

**Sales Attendance at CME Events**

Generally, Sales and Marketing individuals may **not** attend CME events funded by Aerocrine. Often times, there are large CME symposia or events at national or international medical congresses (or conferences). If Aerocrine (via the GRC) has funded a CME event at a national or international congress, Sales and Marketing employees may attend if all of the following conditions are satisfied:

- The attendance at the CME event is for the further educational development of and/or to gain competitive intelligence for the Sales or Marketing employee
- The Sales and Marketing employee is inconspicuous at the CME event meaning: the Sales and Marketing employee should remain in the back of the room, the Sales and Marketing employee should never engage in any Aerocrine device discussion, and the Sales and Marketing employee should not make any appointments or discuss future activities with any physician during the CME
- The CME event is multi-sponsored (Aerocrine and at least one other entity has funded the CME event)
- All other Aerocrine policies set forth in this chapter, and the conditions set forth in the ACCME guidelines, are satisfied.

Alternatively, Sales and Marketing employees **may** attend CME events that are not funded by Aerocrine (this would include both national or international congresses and local CME events) provided that:

- The CME sponsor permits non-HCP attendance
- The Sales and Marketing employee remains “inconspicuous” as defined above and
- All other Aerocrine and ACCME policies are satisfied.

If there is ever a doubt about whether a CME event would satisfy the above conditions, please consult with the Compliance Officer.
Charitable Contributions

Eligible charitable contributions may be device only or financial contributions. Charitable Contributions may also include those made for general support of independent, not-for-profit organizations, and for activities that educate patients or the community at-large.

The purpose of the request must be related to support healthcare activities in a community and benefit those members of the community. All charitable contributions must conform to the following:

- Request must be sent to Medical Affairs
- Requestor must be a tax-exempt entity, provide the IRS Letter of Determination, and also provide the tax-identification number
- Requestor must be an entity that conforms to all relevant Aerocrine policies, and must also be in compliance with all relevant industry guidance
- Requestor must provide all of the relevant information requested by the Company for Charitable Contributions
- The purpose of the request conforms to any of the following: patient education, patient advocacy, or improved patient access to care.

Requests from Government Officials

As a general rule, contributions may be made to charitable organizations, including organizations that are customers or affiliated with customers, provided that the contribution serves a genuine public benefit and interest such as promoting the advancement of medical knowledge and patient care. As leaders of their communities, Government Officials (including healthcare professionals) are often involved in requesting charitable contributions from Aerocrine. Sometimes contributions are requested for undertakings of national concern, but more often they are directed at regional or local projects. Sometimes a Government Official will request a contribution on behalf of his or her hospital or other institution. Other times, the requested contribution would benefit the broader community.

While charitable contributions are encouraged, contribution requests must be examined carefully anytime they originate from a customer, and even more carefully when the request originates from a Government Official (directly or indirectly including, but not limited to, an immediate family member). Any and all charitable contributions and fundraising efforts must be submitted to the Charitable Giving Committee who must satisfy themselves that (i) the contribution/effort is not a disguised way of conferring a personal benefit on a Government Official, and (ii) the contribution/effort is not connected to a decision on purchasing, supplying, procurement, prescribing, administration, recommendation or other decision involving Aerocrine products.
including, but not limited to, the issuance of any government approval, license, permit or other authorization.

The purpose of the request must be related to support healthcare activities in a community and benefit those members of the community. All charitable contributions must be subject to some form of due diligence and conform to the following:

- **Elements**
  
  - The recipient must be a genuine and properly constituted charity and not a false front for a Government Official.
  
  - Requests must be sent to the Charitable Contributions Committee. Please discuss with Medical Affairs on how to request support.
  
  - Requestors must be a tax-exempt entity or a public institution/facility (depending upon the law in the particular jurisdiction).
  
  - Requestors must be an entity that conforms to all relevant Aerocrine policies, and must also be in compliance with all relevant industry guidance.
  
  - Requestors must provide the amount requested.
  
  - Contributions may never be made as part of an exchange of favors with any Government Official, even if the recipient organization is a bona fide charity. If a Government Official has promised any benefit, or issued any threat, in connection with a contribution request, the contribution request must be denied.
  
  - The charitable donation recipient must issue a written receipt and the donation amount must be accurately recorded in the Company’s books and records.

- **Determination:**
  
  - The decision to make a charitable contribution must be made by the Charitable Contributions Committee against objectively defined criteria.
  
  - Under no circumstances may Aerocrine make a charitable contribution in cash (or cash equivalent, such as a check or wire transfer) or in-kind or other remuneration directly to a Government Official or individual healthcare professional, or to any personal bank account.
CSL Interaction Policy

Aerocrine CSLs are dedicated to providing customers with the most current scientific and clinical information. Critical areas of contribution are identifying strategic opportunities through Company-sponsored studies, IITs, research initiatives, publications, and establishing a close rapport with key members of the medical community. These positions also form an outreach network assuring continued interaction with local, regional, and national KOLs (see the Promotional Speaker Programs Policy discussion regarding KOL designations). This policy is applicable to all Sales, Marketing, and other employees that interact with CSLs in the field.

CSL Job Function

CSLs, including any contract CSLs in the U.S. or EU, are charged with establishing, developing, and maintaining long-term sustainable scientific working relationships with members of the medical community. Through these collaborative relationships, CSLs advance the awareness of therapeutic areas/medical information and issues relating to Aerocrine’s ongoing device development efforts in the asthma market, and the Company's marketed devices. In this role, the CSL may provide research support and information to HCPs, or initiate discussions with HCPs regarding potential research or development activities (as demonstrated and documented by the Medical Affairs Department) based upon the research need for investigators or a gap in the Company’s research). In addition, these individuals serve as a medical information resource to managed care efforts and may facilitate various Company educational programs. At all times, the CSL may provide truthful, accurate and non-misleading information in response to HCP or payer questions, although the CSL may not proactively discuss data that is inconsistent with an Aerocrine device’s approved labeling).

The scope and function of a CSL differs significantly from that of a Sales person. Due to the fact that CSLs are afforded more flexibility to talk “peer-to-peer” with HCPs, it is important that a clear separation between the CSL and Sales exists to protect the CSL function. If the CSL is imputed to be a promotional agent similar to a Sales representative, the flexibility is eviscerated and would subject the Company to the various fraud and abuse laws set forth in the Introduction.

One key difference with the CSL role is that the CSL may appropriately respond to unsolicited off-label questions. Accordingly, at all times, the CSL’s compensation is devoid of any calculation based upon sales or the sale of any Aerocrine device other than the global corporate goals that are published each year. Moreover, any and all unsolicited requests must be tracked by Medical Affairs.

All materials utilized or employed by the CSL must be approved by the Medical Affairs review committee. CSLs may provide modest meals to HCPs when providing medical or scientific information. At all times, the limits and state law restrictions apply equally to CSLs as with Sales persons.
Field Interactions – Meet and Greets

CSLs work with the Field to identify the local needs for on-label, disease state, and related scientific/medical information (information consistent with the labels of Aerocrine devices). CSLs coordinate their activities with the Field in territories within their region in response to the HCP's needs. The CSL is not subservient to Sales, but is a member of the regional team, thereby permitting a certain level of coordination and collaboration by and between Sales and Medical Affairs.

The Field and/or CSLs may facilitate an introduction to KOLs or HCPs, typically known as a "meet and greet", whereby the intent is purely an introduction. "Meet and greets" are generally appropriate during the pre-approval period of an Aerocrine device, or during the time when something is "new", meaning a new indication, new CSL, new customer, new sales representative, or new territory.

It is important to note that the Field shall not participate in any scientific exchange during a “meet and greet” should there be an unsolicited request from the HCP for medical information. Should there be any scientific exchange during the “meet and greet,” the Sales person may not participate in any way, either directly or indirectly. The Sales person should leave the room if possible, but may remain in the room if not feasible provided the Sales person does not participate in the discussion either directly or indirectly.

If the CSL, in his or her sole discretion, believes that the scientific exchange during a “meet and greet” would be too robust and/or too significant, the CSL may defer any scientific exchange to a more appropriate time without any Sales presence. It is important to note that should there be food provided at a “meet and greet” there may never be any scientific exchange between the CSL and the HCP.

Outside of the “meet and greet” context, it is appropriate to notify the Sales person that a MIR has been completed. It is not appropriate, however, to provide the content of the MIR or the subject matter of that request. The notification is purely a business courtesy to the Sales person that a request has been completed. By implication, it is not appropriate to provide notification that a request has been made. The business courtesy is only provided upon completion of the MIR.
The following table depicts the respective roles of Sales and CSLs during “meet and greet” interactions:

<table>
<thead>
<tr>
<th>Venue</th>
<th>CSL and Sales Together?</th>
<th>Food Being Provided?</th>
<th>Scientific Exchange?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Office</td>
<td>Yes – true &quot;meet and greet&quot; intent</td>
<td>Yes</td>
<td>No Scientific Exchange</td>
</tr>
<tr>
<td>Local Office</td>
<td>Yes – true &quot;meet and greet&quot; intent</td>
<td>No</td>
<td>Scientific Exchange solely at discretion of CSL, and it must be unsolicited</td>
</tr>
<tr>
<td>Medical Congress</td>
<td>Yes – at a restaurant venue during the Congress</td>
<td>Yes</td>
<td>Upon an unsolicited request, CSL may respond (but question cannot be baited and the purpose of the meal must be to discuss Aerocrine device)</td>
</tr>
<tr>
<td>Medical Congress/Restaurant/Local Office</td>
<td>Just Medical, no Sales present (CSL or Medical Affairs has been requested to answer questions)</td>
<td>Yes</td>
<td>Yes, the purpose of the meal was to respond to unsolicited questions; no Sales present and the CSL or Medical Affairs is conducting the meeting</td>
</tr>
</tbody>
</table>

**CSL Use in Promotional Programs**

There are times when a third-party speaker cannot attend or cancels a promotional speaker program. In the event that an unforeseen circumstance occurs, the CSL may be asked to present the promotional clinical data in the stead of the third-party speaker. If this occurs (it must be the exception and not the norm), the following must be satisfied:

- The CSL is a promotional agent of behalf of Aerocrine; and
- The CSL is not permitted to answer any unsolicited off-label question contemporaneous with the event (during or immediately after the event).

A CSL may attend promotional programs at his or her discretion. Consistent with the above, the CSL may not answer any unsolicited off-label question during, or immediately following the promotional program. Any such follow-up must be done at a separate time and place, and may only be provided to the individual HCP requester.

The above conditions and restrictions in no way limits the CSL from providing internal training to Aerocrine employees.
Clarification on the Role of CSLs

CSLs are not members of Sales. Although CSLs and the Field work collaboratively at times, CSLs do not promote Aerocrine’s device(s). To be clear, the following list provides specific examples of activities, though not exhaustive, where CSLs may not be engaged:

- CSLs do not conduct sales calls (proactively promote an Aerocrine device) with the Field.
- CSLs do not drive sales or otherwise promote devices.
- CSLs are not a means to solely create access to accounts.
- CSLs cannot “generate noise,” “buzz”, or otherwise promote devices pre-approval.
- In general, CSLs cannot proactively discuss off-label information about Aerocrine devices with anyone outside of Aerocrine, including new indications for which Aerocrine may be seeking approval (CSLs may respond to unsolicited requests for this information).
- CSLs cannot render general practice-related medical, business or billing consulting services.
- CSLs cannot make patient-specific therapy or treatment recommendations.
Clinical Investigator and Medical Research Policy

For many HCPs, conducting device company-funded medical research may be a source of income. As a result, selecting an HCP to be a clinical investigator or to receive a research grant for an Investigator-Initiated Trial (or Study) ("IIT") from Aerocrine could raise significant issues under the healthcare laws if done for inappropriate or improper intent and motivations. Any agreement with an HCP or institution must comply with local laws and institution policies, in accordance with the Personal Services Arrangements chapter. In particular, contracts with clinical investigators must not create any conflicts of interest that could jeopardize the health or welfare of human subjects participating in a clinical trial or that could impact, directly or indirectly, the design, analysis or results of the trial. Compensation shall not be tied to the outcome of clinical studies and shall not include Aerocrine stock or stock options for work on individual studies. No payment shall be made to Healthcare Professionals outside a clinical study for referring subjects to investigators for entry into any clinical study.

This policy applies to any and all Aerocrine employees that have discussions with HCPs or clinical investigators about possible Aerocrine support for clinical research or clinical development of an Aerocrine device.

Legitimate Clinical Research

As with other financial transactions that occur between Aerocrine and HCPs, attempting to influence an HCP’s device usage by providing money for research is illegal (see the FCPA or Anti-Kickback Statute discussion within the Introduction for more information). The effect or impact on an HCP’s device usage or influence on other HCPs’ device usage may never be taken into consideration when making a determination whether to engage or fund a clinical investigator, or to provide funding for a clinical research project. All requests for medical research support must be referred to a CSL or Medical Affairs directly who will refer it to the appropriate Medical or Clinical Affairs employees. Only Aerocrine Clinical Affairs and/or Medical Affairs employees may commit to and provide funding and/or devices for medical research.

Aerocrine will only fund or support legitimate medical research. Such research must seek to answer a genuine scientific or clinical question that is consistent with Aerocrine’s clinical trial and research needs. The researcher or institution must be qualified to conduct the intended research, and be selected on the basis of his/her applicable experience and training. Compensation will be based on the FMV of the research services provided and will be set forth in a written agreement with Aerocrine (either a Clinical Trial Agreement or an IIT Agreement).
It is never appropriate for any Aerocrine employee other than Clinical or Medical Affairs to aid a clinical investigator, for either an Aerocrine-sponsored study or an IIT, in the recruitment/enrollment of patients in a study.

Aerocrine may never support an HCP’s medical research in order to:

- Establish or improve Aerocrine's relationship with the HCP
- Create experience for the HCP with the Aerocrine device
- Gain or improve access to the HCP
- Reward past device usage or induce future usage or recommendations
- Influence formulary decision making or
- Garner influence at an institution.

**Company-Sponsored Trials (or Studies)**

Company-sponsored trials are those studies that are designed, conducted, supervised and funded by Aerocrine and where Aerocrine holds regulatory responsibility. Aerocrine compensates investigators who participate in these trials based on the FMV of their expertise and effort in conducting the research.

From time to time, Sales personnel may be asked to make an introduction to various HCPs. Such request is permissible to the extent that the interaction is to provide access to the Aerocrine Clinical or Medical employees, and the Sales person does not in any manner promote the Aerocrine device’s current indication or discuss an Aerocrine device or indication for which there is not an FDA approval.

In Aerocrine-sponsored trials, Aerocrine's decision whether to hire an HCP as an investigator must be made without regard to the HCP's prescribing history or relationship with Aerocrine employees, other than the appropriate Clinical or Medical Affairs personnel. All decisions about clinical investigators for Company-sponsored trials must be made by the appropriate Clinical or Medical Affairs personnel.

Furthermore, Aerocrine employees may not recommend an HCP to be an investigator if one of the purposes for choosing the HCP is either to influence his/her current or future device usage habits, or develop the physician’s experience with the Aerocrine device. Investigators must be selected solely on their research experience and clinical training, not on their current or future device usage habits.

It is important to note that any registry trial or study is a Company-sponsored trial. Therefore, the restrictions and obligations set forth in this chapter shall equally apply to any and all Company-sponsored registries.
Investigator-Initiated Trials ("IIT")

Aerocrine provides grants to investigators who wish to conduct their own clinical trials using Aerocrine devices, often referred to as IITs. These grants may be in the form of funding and/or the provision of a study device. Aerocrine may not design, conduct, or supervise IIT; they must be conducted completely without Aerocrine’s influence or guidance. Aerocrine may provide feedback on IIT proposals to investigators, but may not be involved with drafting proposals or protocols.

All proposals for an IIT grant must be referred to the IIT Committee for consideration, or it may be referred to Medical Affairs/CSL who in turn will ensure that the proposal receives the appropriate review and evaluation by the IIT Committee. Because research grant payments could potentially influence device usage patterns, the decision to fund an IIT must be made without any input from Sales and/or Marketing. This is to mitigate the risk that an HCP’s past support of Aerocrine or future device usage might be considered in making a research funding decision.

It is important to note that a strategic Marketing employee may maintain a seat on the IIT Review Committee as a non-voting member. By definition, the strategic marketing person may be the VP, Marketing, or may be a Marketing employee that has no in-line Marketing responsibility at all.

Requests for Demonstration Project

A request for a demonstration device within a study to support legitimate clinical or pre-clinical medical research should be referred to Medical Affairs. At all times, the demonstration period must be fixed and short in duration.
Clinical Data Publication and Presentation Policy

Aerocrine is committed to timely public disclosure of the design and results of all interventional clinical trials in patients, regardless of their outcome. Aerocrine, from time to time, may collaborate and work with HCPs to assist the Company in publishing or presenting the results of a Company-sponsored trial in accordance with the requirements below. It is important to note that, with respect to the publication of data, all authors should meet the authorship criteria set forth by the International Committee of Medical Journal Editors (“ICMJE”) in addition to the policies set forth in this Policy. This Policy applies to all Aerocrine employees that interact with, or negotiate with HCPs for the purpose of having that HCP publish or present clinical data, or plan, review or edit a publication sponsored by Aerocrine.

It is important to note that the Federal Sunshine provisions obligate Aerocrine to disclose the value of any assistance to clinical investigators as described in this chapter.

Publication of Company-Sponsored Study Results

The following applies to presentations that do not offer CME credit.

The Company may collaborate with one or more HCPs to author a manuscript/abstract for publication of the results of a Company-sponsored trial. Selection factors include but are not limited to the PIs involved with the trial itself, or an HCP that was significantly involved with or contributed to the conception or design of the trial or the data analysis and interpretation of the trial. If selected, the HCP must execute an Aerocrine agreement, either as part of the Clinical Trial Agreement or as a stand-alone Consulting Agreement.

The authors must have full editorial control over the manuscript, abstract, or presentation.

In addition to Company personnel who meet authorship criteria and participate as authors, the Company may provide staff to help the authors with the analysis and interpretation of study data and/or the drafting of the manuscript. If the manuscript is submitted for publication, the Company will require the corresponding author to disclose that the Company was sponsor of the study and provided support for the preparation of the article, and the identities of Company personnel that provided assistance with analysis, interpretation, and drafting so that they can be acknowledged as contributors in the article.

It is important to note that pursuant to some journal guidelines, named first authors or the like may not receive commercial money for a specified period of time prior to the publication. Any first-named
authors should, to the extent that the HCP receives commercial money (promotional speaker bureau or even Advisory Board money), verify with the particular journal that authorship is appropriate.

Presentation of Company-Sponsored Study Data

The Company may retain one or more HCP authors to present the data and results of a Company-sponsored study on behalf of the Company at medical congresses, national or international medical congresses, or professional meetings. Such HCPs will be selected by Clinical in conjunction with Medical Affairs from among the PIs involved with the trial itself, or an HCP that was significantly involved with or contributed to the conception or design of the trial, or the data analysis and interpretation of the trial. If selected, the HCP must execute an Aerocrine consulting agreement.

If the presentation involves a slide deck or a poster, the Company may develop or assist in the development of the slide deck or poster, and, in any event, will have the right to review and approve the slide deck or poster before the presentation. The HCP will be required to disclose prominently and conspicuously to the audience that he or she has been retained by Aerocrine to present the Company-sponsored study results (generally the financial disclosure provided at the beginning of the presentation will suffice). The presentation must include a statement that the Company sponsored the study and disclose any financial relationships between the presenting physician and Company.

Travel for Presentation of Company-Sponsored Study Data

In addition to honorarium for the performance of the underlying services, the Company may reimburse reasonable, documented travel and registration expenses incurred by an HCP to give a presentation described above. The Company will not reimburse travel expenses of a spouse or family member of an HCP. Generally, all travel must comport with the Travel and Entertainment Policy. All payments must be set forth in an Aerocrine consulting agreement and approved by Legal and the Compliance Officer.

Presentation and Publication of Company-Sponsored Study Data by Other Company-Sponsored Study Investigators

An investigator in a Company-sponsored study who has not been retained by Aerocrine as described above for a presentation, or who did not receive any assistance from Aerocrine in the authorship of the article, may give a presentation and/or submit an article for publication on the results of the study in accordance with the terms of the applicable Clinical Trial Agreement between the investigator and/or institution and the Company. Generally, the Company discourages investigators in multi-site studies from publishing or presenting their single-site results until after the primary article or presentation on the entire study has been published or made, because single-site data
often have significant statistical limitations and may not provide meaningful information to HCPs or patients.

The Company will not reimburse travel expenses or provide any other subsidies, compensation, or assistance to an investigator for presentations or publication of results of a Company-sponsored study where the investigator has not been selected by Clinical/Medical Affairs or retained by Aerocrine, as described above.

**Presentation and Publication Assistance for Investigators in IIT**

The Company may provide presentation or publication assistance to HCPs who are participating in an IIT in accordance with the requirements below. For purposes of this Policy, an IIT is a clinical investigation that is funded through a grant of funds or device(s) from the Company in accordance with the [Clinical Investigator and Research Policy](#).

**Publication Assistance for IIT Investigators**

The Company may provide an IIT investigator with publication assistance to prepare an article or abstract based on an IIT, provided that the IIT Agreement sets forth the conditions by which such assistance will be applied (no after-the-fact requests or *ex post facto* requests can be entertained), and the investigator makes the request in writing (email is sufficient).

If the above requirements are met, the Company will provide publication assistance regardless of whether the results of the IIT are favorable to any Aerocrine device(s). For an article or an abstract on an IIT, publication assistance will consist of assistance with statistical analysis or editorial assistance. It is never appropriate for Aerocrine employees to draft, prepare or create the first draft of an IIT article or abstract. An IIT investigator must have **final control** over the content of the article or abstract. It is important to note that any such assistance provided by Aerocrine may implicate the Federal Sunshine provisions (and trigger a disclosure of the value of such services provided).

In accordance with the IIT Agreement between Aerocrine and the IIT investigator, the investigator will be required to acknowledge any statistical analysis assistance or editorial assistance (in addition to study funding provided by Company) in any articles or abstracts related to the IIT that are submitted to journals for publication. The investigator will also be required to use his or her best efforts to cause any journals to include such an acknowledgement in the published article.
Travel Expenses for Presentations or Publications by IIT Investigators

The Company will not subsidize the travel expenses or pay any other compensation to an IIT investigator for the purpose of presenting the data and results of an IIT in a poster or other presentation.

Presentation or Publication Assistance for Other Investigators

The Company may not provide any assistance for publication or presentation of the results of a study that is not a Company-sponsored study or an IIT, i.e., a study that is neither sponsored nor funded by Aerocrine.

The Company may provide support for independent external medical writing assistance upon written request from an investigator or author, with the approval of the Compliance Officer, Legal, and Clinical Affairs or Medical Affairs. The scope of Aerocrine involvement (review, analysis, editing, etc.) must be defined and approved in advance by the Compliance Officer, Legal and Clinical Affairs or Medical Affairs.
Patient-Identifiable Data Policy

Aerocrine respects the confidential nature of patient data. Aerocrine employees, its agents and vendors are inextricably intertwined with the hospital providers when repairing or providing warranty services to an Aerocrine device. Aerocrine is committed to using any and all such data responsibly and in accordance with applicable state, federal and international law, applicable authorizations, the EU Privacy Safe Harbor, and the AdvaMed Code.

This policy is applicable to all Aerocrine employees that come into contact with, utilize, analyze and review either patient-Identifiable Data.

HIPAA and Business Associates – Overview and Summary

One of the most important federal healthcare laws in the area of privacy is called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Recently, HIPAA was significantly expanded by the Health Information Technology for Economic and Clinical Health Act (HITECH). HIPAA and HITECH impose strict limitations on the use and disclosure of protected health information by “covered entities” and their “business associates.”

Aerocrine recognizes that many of the organizations with which it routinely interacts may be subject to these laws.

Aerocrine recognizes the importance of patient and human subject confidentiality and is committed to protecting the confidentiality of patient health information. For the EU, Aerocrine will comply with the EU Privacy Directive and ensure that information does not flow to the U.S. unless all safeguard and consent requirements have been fulfilled.

Summary of the Law

HIPAA governs the activities of certain types of organizations (referred to as “Covered Entities”), including most individual and institutional healthcare providers, when those activities involve the use or disclosure of Protected Health Information (“PHI”), and the activities of third parties (referred to as “Business Associates”) who assist Covered Entities with the Covered Entities’ quality, administration, management and operations functions (referred to as “Health Care Operations”).

HIPAA regulates how Covered Entities and Business Associates can use and disclose certain PHI. PHI includes individually identifiable information, such as a patient or human subject’s name, social security number, patient account number, birth date, dates of service, admission/discharge date, telephone number, email address, street address, and photographs with identifiable images. PHI also includes individually identifiable information about a patient or subject’s family, household members, or employers. The information can be in any form – written, oral or electronic – and may
relate to the past, present or future physical or mental health of the individual or to payment for the patient’s treatment. HIPAA requires Covered Entities and Business Associates to make reasonable efforts to limit the use and disclosure of PHI to the minimum necessary to accomplish the intended objective.

Many states also have laws regarding the confidentiality of health information. HIPAA preempts these laws only when HIPAA is stricter than a state law. In situations when the state law is more restrictive than HIPAA, state law will control. In addition, many states place additional requirements on the use and disclosure of certain types of more sensitive health information, such as information relating to mental health, genetic testing, communicable diseases, or drug or alcohol abuse. Unlike HIPAA, these state laws may apply directly to Aerocrine.

**Business Associate Agreement**

Sometimes HCPs may incorrectly request that a Business Associate Agreement ("BAA") be signed. A BAA is an agreement that is entered into between a “Covered Entity” (e.g., an HCP or a health insurer) and a “Business Associate.” Generally, “Business Associates” are defined as entities or persons who perform work on behalf of a covered entity. Because of the nature of work that a sales or commercial employee performs, it is not appropriate for Aerocrine to enter into a BAA in that context. Please consult with Legal to determine if a BAA is necessary.

Some HCPs will request a BAA when what they really are seeking is a confidentiality agreement to protect their patients’ PHI in the event it is inadvertently disclosed to an Aerocrine representative. To address such requests, submit a request to Legal or Compliance for a confidentiality agreement to offer to the HCP as assurance of intent to keep PHI confidential. The confidentiality agreement that covers patient health information can be signed and provided to an HCP or institution that would like a specific agreement to cover situations where an Aerocrine representative inadvertently comes into contact with PHI.
Training and Monitoring Policy

All Aerocrine employees will receive training on the Manual at least once a year, either in a live training setting or via an online training portal. That training may not be an exhaustive review of the Manual but may be narrowly tailored based upon the function. In addition, Compliance will train all personnel that are employed by Aerocrine, and interact with HCPs, on the appropriate HCP interactions. That training must be included in any new hire training and should be live.

Internal monitoring and auditing techniques are vital parts of Aerocrine’s compliance principles. Effective monitoring can provide Aerocrine with the ability to detect and prevent deviations that can potentially affect Company compliance goals. Additionally, “for cause” audits and reviews are undertaken as appropriate. Aerocrine personnel, at all levels of the organization, are responsible for reporting potential compliance issues of which they become aware to the Compliance Officer and/or his/her supervisor. Consistent with Aerocrine’s Open Door Policy, personnel are encouraged to discuss with their manager, Corporate Compliance, Legal, or Human Resources Departments any compliance issues, concerns, problems and/or suggestions without fear of retaliation and with the assurance that the matter will be kept as confidential as possible.

Compliance, Internal Audit and other functions will create SOPs related to the monitoring and auditing of the following:

- Field Rides
- Promotional Talks
- Advisory Boards

Compliance may also at their sole discretion audit CME activities and its underlying paperwork, Charitable Contributions, or meals and/or gifts provided to HCPs.

If during routine monitoring or auditing, irregularities are uncovered, the Compliance Officer may initiate an investigation pursuant to the Corporate Compliance SOPs.
Training Attestation

The following Training Attestation will be signed by each person upon completion of the required compliance training. The Training Attestation should be sent to Compliance when signed.

This certification/attestation shall not be executed until you have received training from Legal/Compliance:

I, ___________________________________, hereby acknowledge and agree to the following:

• I have received and carefully reviewed a copy of the Aerocrine Compliance and Ethics Manual (the “Manual”)
• I attended the Manual training session in person
• I understand all of the policies set forth in the Manual and will comply with those policies
• I understand that (i) there is a Zero-Tolerance for intentional mistakes, and (ii) there will be disciplinary action for any failure to adhere to, or deviation from the policies set forth in the Manual, Code of Ethics and Conduct, and other Aerocrine policies, up to and including termination.

___________________________________
Signature of Aerocrine Employee/Contractor

___________________________________
Printed Name

___________________________________
Date
Investigation of Suspected Noncompliance

Violations of the law and of Aerocrine policy, including the Code and the Manual, jeopardize the Company’s status as a reliable, honest and trustworthy participant in the healthcare industry. Therefore, employees have an affirmative obligation to report potential compliance issues of which they become aware (see Duty to Act in the Introduction). Upon receipt of reasonable indications of suspected non-compliance, the Compliance Officer, or his/her designee, in consultation with the relevant subject matter experts, will immediately review and/or investigate the allegations.

Each investigation will identify, where possible, the root cause of the problem and a corrective action plan. Aerocrine is committed to taking prompt and consistent action in response to violations of the compliance principles. The investigation will be conducted in accordance with the procedures Investigations SOP.

The Company’s directors, officers and employees are expected to cooperate fully with any audit or investigation by Aerocrine into any compliance-related matter or a suspected violation. Failure to cooperate with any such audit or investigation may result in disciplinary action, up to and including immediate termination.
Discipline

Any employee who fails to follow the policies or guidelines set forth in this Manual, or who otherwise violates the Aerocrine compliance principles, is subject to disciplinary action up to and including:

- Verbal or written warnings
- Suspension
- Financial penalties
- Termination and/or
- Reporting to relevant governmental authorities.

Failure to understand any element of the compliance principles, including this Manual, will not excuse any activity that is inconsistent with it. If corrective or disciplinary measures are taken, the action or discipline must be reasonable, consistent with institutional precedent or other prior Company determinations, and designed to deter similar misconduct in the future.
Commonly Used Acronyms, Terms and Definitions

**ACCME**: Accrediting Council for Continuing Medical Education.

**AdvaMed Code**: A voluntary code regulating all interactions between Aerocrine and HCPs.

**AEs**: Adverse Events.

**Affiliate**: Refers to any entities with a formal corporate relationship with Aerocrine, both in and outside of the U.S., including its parent Aerocrine AB, and any sister corporations or subsidiaries.

**Bribe**: Any illegal payment, or offer or promise of such payment, as described in this International Anticorruption Chapter or applicable law. A Bribe also includes both active and passive inducements and rewards and includes both financial and other advantages. For example A person if guilty of an office if he offers, promises or gives a financial or other advantage to another person and intends the advantage to induced a person to perform improperly a relevant function or activity or to reward a person for the improper performance of such a function or activity.

**Brief Summary**: the technical name for the detailed information that appears in advertisements for Aerocrine's devices. The Brief Summary generally includes who should not use the device; when the device should not be used; possible serious side effects of the device and, if known, what can be done to lower the chance of having them; frequently occurring, but not necessarily serious, side effects.

**CDRH**: The Center for Devices and Radiologic Health

**Chief Compliance Officer**: Refers to the Compliance Officer at the time or his/her designee.

**CME**: Continuing Medical Education.

**CMS**: The Centers for Medicare and Medicaid Services.

**The Code of Business Conduct**: The Code by which all employees must adhere.

**Core Visual Aid**: Also referred to as Core Detail Aid. All PRC-approved promotional pieces that may be used when promoting an Aerocrine device to an HCP or those that can influence the purchase of an Aerocrine device.

**CSL**: Clinical Science Liaison.

**DOD**: The Department of Defense.

**DOJ**: The Department of Justice.

**DVA**: The Department of Veterans Affairs.

**EACCME**: European Accrediting Council for Continuing Medical Education.

**EMA**: The European Medicines Agency

**Facilitating Payment**: A payment made solely to procure or secure the performance of the following
routine legitimate government actions only in accordance with the applicable legislation and rules governing fees charged for such actions:

- obtaining licenses, permits and other official documents to qualify to do business in a foreign country;
- processing governmental papers, such as visas and work orders;
- providing police protection, mail services and inspection of goods or of contract performance;
- providing telephone service, utilities, loading or unloading cargo and protecting perishable goods from deteriorating; and
- actions of a similar nature.

Facilitating Payments are narrowly construed and under no circumstances do they cover corrupt payments or the provision of anything of value to obtain, retain, or direct business.

**FCA:** The False Claims Act.

**FDA:** The Food and Drug Administration, the agency charged with the regulation of medical devices and other technologies (in addition to pharmaceuticals).

**The Field:** The Field is an aggregate reference to all employees that promote Aerocrine's device(s) and are geographically located outside the Company's headquarters. Unless otherwise indicated, the term should be defined as broadly as possible for those that promote Aerocrine device(s), including Sales, National Accounts, and other Sales persons. It is important to note that the term does not include those field-based employees that do not promote Aerocrine's devices, including the Medical Science Liaisons or those employees in Medical Affairs.

**FMV:** Fair Market Value means the value of services in arm's length transactions, consistent with the compensation that would typically be paid for such services as a result of *bona fide* bargaining between well-informed parties to the transaction. Please refer to marketing for questions on FMV.

**Government:** An agency, instrumentality, subdivision or other body of any national, state or local government, including (i) universities, hospitals, or other health facilities which are owned or operated by a government, (i) health or other regulatory agencies, or (iii) government-controlled businesses, corporations, companies, charities, organizations or societies.

**Government or Foreign Official:** Any officer or employee of a government or any of its agencies or a government corporation, or any person acting in an official capacity for any such entity and includes relatives of any such person. A Government Official includes:

- officers and employees of any national, regional, local, or other governmental entity, including elected officials;
- any private person acting temporarily in an official capacity for or on behalf of any governmental entity (such as a consultant retained by a government agency);
- officers and employees of companies in which a government owns an interest;
- candidates for political office at any level;
• political parties and their officials; and
• officers, employees, or official representatives of public (quasi-governmental) international organizations, such as the World Bank, the World Health Organization (WHO), the United Nations, the International Monetary Fund (IMF), etc.

**GPO**: Group Purchasing Organization.

**GRC**: Grants Review Committee.

**HCO**: Healthcare Organization. An organization that provides medical or health services or an organization that represents or serves HCPs or consumers in the U.S. The definition of an HCO includes, but is not limited to, teaching hospitals, hospitals, academic institutions, nursing homes, clinics, pharmacies, rehabilitation facilities, professional, educational and patient organizations, continuing medical education providers, non-profit hospital foundations, health benefit plan administrators, and managed care organizations. For purposes of the Federal Sunshine Act, an HCO is a “teaching hospital.”

**HCP**: Healthcare Professional. With certain state-specific differences, an HCP is a provider of medical or health services licensed in the U.S., or any other person in the U.S. that furnishes, bills, or is paid for healthcare in the normal course of business. This definition of an HCP includes, but is not limited to, physicians, nurse practitioners, advanced practice nurses, physician assistants, registered nurses, pharmacists, researchers, investigators, hospital personnel, representatives of managed care organizations, such as health maintenance organizations and pharmacy benefits managers, and formulary committee members. For purposes of the Federal Sunshine Act, an HCP is a “physician,” which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.

**HIPAA**: The Health Insurance Portability and Accountability Act of 1996.

**IFU**: Instructions for use

**III**: Individually Identifiable Information. Information that can be used to distinguish or trace an individual’s identity and is subject to HIPAA breach notification laws.

**IIT**: Investigator-Initiated Trial or Study.

**Knowing**: For purposes of the International Anti-Corruption Chapter, a person or company is prohibited under U.S. law from providing money or a thing of value to a Third Party while “knowing” that such party would use that money or thing to Bribe Foreign Officials. The “knowing” standard is discussed in more detail in Attachment A to the International Anti-Corruption Chapter.

**KOL**: Key Opinion Leader. Thought leaders and experts in their medical field.

**The Manual or This Manual**: Reference to this Compliance and Ethics Manual in its entirety.

**MCCs**: Managed Care Payers and/or Customers and/or Companies, including but not limited to payers, GPOs or specialty pharmacy/distributors.
MIR: Medical Information Request.

Money or "Anything of Value": The use of the phrase "anything of value" means remuneration in any form, cash or in-kind. It includes, but is not limited to the following: stock; entertainment; gifts; meals; discounts on products and services not readily available to the public; offer of employment; assumption or forgiveness of debt; payment of travel expenses; and personal favors

Marketing: Aerocrine's Marketing Department in its totality.


Patient Data: Any individually identifiable health information about a Patient that is viewed, stored or otherwise copied or stored by Aerocrine pursuant to servicing an Aerocrine device.

Payment: Money, transfer of stock, bonds or any other property, the payment of expenses, the providing of services of any type, the assumption or forgiveness of any indebtedness, or any other transfer of goods, services, tangibles or intangibles that accrues to the benefit of the ultimate recipient or promotes his or her interests.

PHI: Protected Health Information. Information in a medical record that can be used to identify an individual and that was created, used, or disclosed in the course of providing a healthcare service such as diagnosis or treatment.


PRC: The Promotional Review Committee. All promotional materials and/or materials for the Field—including training materials—must be reviewed by this multi-disciplinary review committee.

Sales: Any reference to “Sales” or “Sales persons” refers to all members of Aerocrine’s sales force, from sales representatives to the VP of Sales and Commercial Operations. Sales would not include any person in the Executive Team.


Third-Party Affiliates: Refers to non-employees, distributors, and/or agents who might be contracted by the Company and/or its affiliates.

Third-Party Affiliates: This term includes, but is not limited to, (i) a sales intermediary between the Company and the final customer or end-user of the Company's product(s); (ii) resellers and distributors; (iii) vendors/suppliers/agents to the Company; (iv) certain retailers of the Company; (v) consultants; and (vi) joint venture or other business partners.