COMPARISON OF ADVAMED’S UNITED STATES AND CHINA CODES OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

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Chart prepared by Reed Smith LLP
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<table>
<thead>
<tr>
<th>AdvaMed Code of Ethics on Interactions with Health Care Professionals (U.S.)</th>
<th>AdvaMed Code of Ethics on Interactions with Health Care Professionals in China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved: December 18, 2008  Effective July 1, 2009</td>
<td>Approved: March 31, 2015  Effective January 1, 2016</td>
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</table>

### I. Preamble: Goal and Scope

1. Defines the terms:
   - “Companies”: companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. These products, technologies and services are defined as “Medical Technologies”.
   - “Health Care Professional”: (HCP) those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States.

2. “AdvaMed China Board”: China-based governance group of AdvaMed member companies’ most senior company executives in China

3. “Institutional Health Care Professionals”: institutions involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the People’s Republic of China

   “Individual Health Care Professionals” individuals employed by these institutions who are also involved in the provision of health care services and/or items to patients and who also purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies…. Unless otherwise specified, the
2. **Medical Technologies**: makes a distinction between Medical Technologies which are highly dependent on “hands on” HCP interaction, and drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means.

3. **Interactions with HCPs**: explains the scope and types of interactions with HCPs.
   a) Promote the advancement of Medical Technologies
   b) Enhance the Safe and Effective use of Medical Technologies
   c) Encourage Research and Education
   d) Foster Charitable Donations and Giving

4. **The Purpose of the Code of Ethics**: recognizes that HCP’s first duty is to act in the best interest of patients, and the obligation to facilitate ethical interactions between Companies and HCPs.

5. A footnote notes that the principles are derived from a number of authorities, including the federal Anti-Kickback Statute. Reference to “unlawful inducement” relates to the Anti-Kickback Statute prohibitions.

4. **Medical Technologies**: Equivalent

5. **Interactions with HCPs**: equivalent, but adds a 5th type of interaction:
ed) Support Appropriate and Efficient Use. Providing service, technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.

6. **Interactions with Third Party Sales and Marketing Intermediaries**

   Notes it is often necessary for Companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the Companies’ products or services, e.g., distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives with which the Company has a direct contractual relationship (“Third Party SMIs”).

   Notes it is essential that Companies’ interactions with Third Party SMIs, as well as Third Party SMIs’ behavior on a Company’s behalf (including Third Party SMI interactions with Health Care Professionals and governmental officials) are conducted pursuant to all applicable legal and ethical principles.

7. **Purpose of the Code of Ethics**: Equivalent

8. **Local Laws, Regulations and Government Guidance Shall Prevail**

   All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws, regulations and government guidance within the jurisdictions that they operate. Applicable laws, regulations or
government guidance may provide more specificity than this Code, and Companies should seek counsel to address any additional questions. Code is intended to facilitate ethical behavior but is not legal advice. The Code is not intended to define or create legal rights, standards or obligations. Overriding principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

### II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.

1. **Annual Certification**  Companies that adopt the Code are strongly encouraged to submit an annual certification that the Company has adopted the Code and has implemented an effective compliance program. Certification should be signed by the CEO and Chief Compliance Officer. AdvaMed will publish a list of Companies that have certified.

2. **Contact Information**  AdvaMed member Companies must, and non-members may supply contact information for the Company’s Compliance Department or anonymous hot line to facilitate reporting of possible violations. AdvaMed will publish this information.

3. **Elements of an Effective Compliance Program**  Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program.

   a) Written policies and procedures;
   b) Designated compliance officer and compliance committee;
   c) Conduct effective training and education;

   Equivalent, but more specificity as to who must certify:

1. **Annual Certification**  Companies wishing to certify to the Code must submit to AdvaMed an annual certification signed by the most senior executive responsible for Medical Technology operation in China. For Companies headquartered in China, this would be the Chief Executive Officer or individual with equivalent responsibility within the certifying company. For Companies headquartered outside of China, this would be the most senior representative of the certifying Company’s Medical Technology operation in China. This certification must additionally be signed by the Company’s Chief Compliance Officer for China or individual with equivalent responsibilities within the certifying Company.

2. **Contact Information:**  Equivalent

3. **Elements of an Effective Compliance Program:**  Equivalent

4. **[NO EQUIVALENT SUBSECTION]**  Companies strongly encouraged to ensure that interactions with individual Health Care Professionals (or to individual units within an Institutional Health Care Professional) are appropriately disclosed to the institution or
d) Develop effective lines of communication (including an anonymous reporting function);

e) Conducting internal monitoring and auditing;

f) Enforcing standards through well-publicized disciplinary guidelines; and

g) Responding promptly to detected problems and undertaking corrective action.

4. **Note**: Companies adopting the Code shall communicate the principles of the Code to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

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<tr>
<th>III. Company-Conducted Product Training and Education</th>
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<tr>
<td>1. The Code defines:</td>
<td>1. Definitions: equivalent, but references to FDA and grand rounds are omitted</td>
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<tr>
<td><strong>Training</strong>: training on the safe and effective use of Medical Technologies</td>
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<td><strong>Education</strong>: communicating information directly concerning or associated with the use of Companies’ Medical Technologies, e.g., information about disease states and benefits to certain patient populations.</td>
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<tr>
<td><strong>FDA Required Training</strong> The Code points out the FDA often mandates training and education to facilitate the safe and effective use of Medical Technologies.</td>
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<tr>
<td><strong>Training and Education</strong>: include but are not limited to “hands on” training sessions, cadaver workshops, lectures and presentations, and grand rounds.</td>
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<td>2. Companies should adhere to the following <strong>principles</strong> concerning training and education:</td>
<td>2. <strong>Principles</strong>: Equivalent, but “conductive setting” includes statement that it may be appropriate to deliver training in cooperation with an institutional HCP</td>
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<td>a) <strong>Conducive Setting</strong> Programs should be effective transmission of information. Settings may include clinical, educational or conference sites including hotels and other meeting facilities. They may also include the HCP’s site.</td>
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<td>b) <strong>Hands on Training</strong> Training should be conducted at training facilities, medical institutions or laboratories.</td>
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Training staff should be qualified. Sales employees may conduct the training if they have the technical expertise.

c) **Modest meals and refreshments** may be provided if they are modest in value and subordinate in time to the training or education.
d) **Travel and Lodging** Out-of-town travel and modest lodging may be provided the HCPs if there are objective reasons to support the need.
e) **No Guests** Meals, refreshments, travel and lodging may be provided only to HCPs with a *bona fide* reason to attend the training.

### IV. Supporting Third-Party Educational Conferences

*Bona fide* independent, education, scientific and policymaking conferences include educational conferences include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers.

Companies may support these through:

**Conference Grants** Grants must be provided to the conference sponsor to reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other HCPs in training. Grants may be provided when:

- a) The gathering is primarily dedicated to promoting objective scientific and educational activities, and
- b) The training institution or conference sponsor selects the attending HCPs in training.

- Grants should be paid ONLY to organizations with a genuine educational function
- The may be used to reimburse legitimate expenses for *bona fide* educational activities.
- The conference sponsor controls the selection of program content, faculty, methods and materials.

**IV. Supporting Third-Party Educational Conferences**

Equivalent

**Conference Grants** Equivalent

[NO EQUIVALENT SUBSECTION]

A. **Support for Conference Attendance by HCPs.** Under the following conditions, Companies may sponsor individual HCPs to attend third-party educational conferences:

- A. Companies cannot reimburse HCPs’ travel expenses directly to the HCP;
- B. Companies may recommend the list of HCPs to attend educational meetings, from an educational and scientific perspective, and should develop internal procedures to ensure that company-sponsored attendees are properly qualified;
- C. Companies should establish internal controls to evaluate and
### Conference Meals and Refreshments

Companies may provide:
- Funding to conference sponsors to support the provision of meals and refreshments to conference attendees
- Meals and refreshments themselves if they are provided:
  1. To all HCP attendees (note exception below)
  2. Consistent with applicable standards established by the conference sponsor and any accrediting body.

**Note:** meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus to the purpose of the conference and separate from the educational portion of the conference.

### Faculty Expenses

Grants may be made for reasonable honoraria, travel, lodging and modest meals for *bona fide* faculty members.

### Advertising

Companies may purchase advertisements and lease booth space for Company displays.

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### V. Sales, Promotional, and Other Business Meetings

Companies may conduct business meetings with HCPs:
- **Business Discussion** Discuss Medical Technology features, sales terms or contracts
- **Meals** Occasional modest meals and refreshments may be provided
- **Travel** HCP meetings often occur close to the HCP’s place of business. When necessary, (e.g., plant tours or demonstration of non-portable equipment) reasonable travel costs and lodging may be provided

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**Conference Meals and Refreshments, Faculty Expenses, Advertising**

All equivalent

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**V. Sales, Promotional, and Other Business Meetings**

Equivalent, but notes that meetings sometimes occur in other cities within China or in overseas locations.
d) **No Guests** Meals, refreshments, travel or lodging may not be provided for guests of HCPs or anyone without a *bona fide* interest in the information being shared at the meeting.

### VI. Consulting Arrangements with Health Care Professionals

Companies may pay HCP consultants fair market value for services that fulfill a legitimate business need and do not constitute an unlawful inducement. The following standards apply:

- **Agreements** should be written and describe all the services to be provided. Clinical research services should have a written research protocol.
- **Legitimate need** for the services should be identified and documented in advance of any arrangements.
- **Selection** should be based on the consultant’s qualifications and expertise to meet the defined need.
- **Compensation** should be fair market value and not based on past, present or anticipated business.
- **Expenses** Companies may pay for actual, reasonable and documented expenses, including travel, modest meals and lodging, incurred by the consultant to carry out the arrangement.
- **Venue** and circumstances of any meetings should be appropriate for the subject of the consultation, and conducive to the effective exchange of information.
- **Meals and refreshments** should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Recreation or entertainment should not be provided.
- **Sales Involvement** Sales personnel may provide input about the suitability of proposed consultant, but should not control or unduly influence the selection decision.

#### Provisions on Payment of Royalties

Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method.

### VI. Consulting Arrangements with Health Care Professionals

Equivalent, but adds a new subsection stating: Compensation paid to a consultant should not be paid in cash.

#### Provisions on Payment of Royalties

Equivalent
Calculation of royalties should preserve the objectivity of medical decision-making and avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company’s product or technology or a requirement to market the product or technology upon commercialization.

Companies may elect to enter into separate agreements with HCPS for marketing services and are strongly encouraged to consider the appropriateness and practicality of excluding the HCP consultant’s purchases from the calculation of royalty payments.

### VII. Prohibition on Entertainment and Recreation

Companies should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Examples include: theatre, sporting events, golf, skiing, hunting, sporting equipment, and leisure of vacation trips. Such events or items should not be provided regardless of:

1. Their value,
2. whether the HCP is a speaker or consultant, or
3. whether the entertainment or recreation is secondary to an educational purpose.

### VIII. Modest Meals Associated with Health Care Professional Business Interactions

Modest meals may be provided as an occasional business courtesy involving the presentation of scientific, educational, or business information, consistent with the following limitations:

**Purpose** The meal should be incidental to the *bona fide* presentation of scientific, educational or business information, and should be provided in a manner conducive to the presentation. It should not be part of an entertainment or recreation event.

**Setting and Location** The setting should be conducive to *bona fide* scientific, educational or business discussion. Meals may occur at the HCP’s place of business, however, if that place is not available or conducive to such discussions, meals may be provided off-site. Examples include: (1) where the medical technology cannot easily be transported to the HCP’s location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on site.
**Participants (No Guests)** Meals may be provided only to HCPs who actually attend the meeting, and may not be provided for an entire staff where everyone does not attend the meeting, i.e., no “dine and dash” programs. Meals may not be provided for guests of HCPs or any one not having a *bona fide* professional interest in the information being shared.

<table>
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<tr>
<th>NO EQUIVALENT</th>
<th>IX. <strong>Travel Associated with Health Care Professional Business Interactions</strong></th>
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<td>A Company's interactions as outlined in Sections III, IV, V and VI may require Individual HCPs to travel within China or internationally. Companies may provide reasonable travel expenses for Individual HCP travel consistent with this section. Additional principles apply when Companies provide travel expenses for Individual Health Care Professional travel to Third Party Educational Conferences. These additional principles are described in Section IV of this Code of Ethics.</td>
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<td></td>
<td><strong>A. Purpose.</strong> There must be a <em>bona fide</em> scientific, educational, or business purpose to provide travel to an Individual HCP and the length of the trip must be commensurate with this purpose. Companies must not provide recreational activities, side trips, city tours, or any other activities that do not support the <em>bona fide</em> professional interest of the travel.</td>
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<td></td>
<td><strong>B. Location.</strong> Companies should adopt objective criteria to select locations and venues. Local alternatives should be considered before sponsoring travel for Individual HCPs. Further, Companies are encouraged to consider China-based alternatives before sponsoring international travel for Individual HCPs.</td>
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<td><strong>C. Reasonable Expenses.</strong> Companies may provide for</td>
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reasonable flights, hotels, meal and incidental expenses for Individual HCP travel.

D. Participants. A Company may not provide travel or other expenses for guests of Individual Health Care Professionals, or for any other person who does not have a bona fide professional interest in the activity requiring travel.

E. Reimbursement. Companies are encouraged to pay for flights/hotels directly where practical. Reimbursement of travel-related expenses over RMB 500 should not be made in cash.

### IX. Educational items; Prohibition on Gifts

- Items that benefit patients or serve a genuine educational function occasionally may be provided to HCPs.
- Items should have a FMV of less than $100, except text books and anatomical models.
- Items must not be capable of non-educational or non-patient-related uses, e.g., DVD player.
- Non-educational branded promotional items may not be given to HCPs, even if of minimal value and related to the HCPs work or benefit patients.
- Items such as wine, flowers, cookies, gift baskets, holiday gifts etc., or cash or cash equivalents are not permitted.

### X. Educational items and Branded Promotional Items

As permitted by applicable laws and regulations, occasional items to benefit patients or serve genuine educational function can be provided.

- “Modest fair market value” – not specified.
- No items capable of use for non-educational, non-patient-related purpose, e.g., smartphone, tablet computer, laptop
- Permissible to provide branded promotional items of minimal value if related to HCP’s practice, e.g., stationery items, USB drives, mouse pads, and other items bearing a company’s logo. Such items should have a value of RMB 200 or less.
- Not permitted: alcohol, tobacco, cash, gift cards, or other cash equivalents

### X. Provision of Coverage, Reimbursement and Health Economics Information

Companies may provide accurate and objective reimbursement information on their products to HCPs, professional or patient organizations, patients and payors as follows:

- Identifying the clinical value of their technologies and services
- Collaborating on joint advocacy on coverage, reimbursement and health economics issues
- Providing information identifying coverage, codes and billing

**NO EQUIVALENT**
options regarding technologies on which they may be used

- Providing information about the economically efficient use of their technologies
- Providing information related to available reimbursement revenues and associated costs
- Providing information relating to changes in coverage or reimbursement amounts
- Providing support in the appropriate and efficient use of their technologies
- Assisting to obtain coverage decisions and in the preparation and submission of coverage requests, prior authorizations and appeals.

Companies may not interfere with HCPs independent clinical decision making or provide information as an unlawful inducement or suggest mechanisms for billing for unnecessary services or fraudulent practices to achieve inappropriate payment.

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<thead>
<tr>
<th>XI. Research and Educational Grants and Charitable Donations</th>
<th>XI. Research, Academic and Public Education Grants; Charitable Donations</th>
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<tbody>
<tr>
<td>Companies may provide such grants and donations but not as an unlawful inducement. Companies should:</td>
<td>Equivalent, but adds new section:</td>
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<tr>
<td>a) Adopt objective criteria that exclude purchasing value of the recipient</td>
<td>Companies must ensure donation or grant is (a) handled by the financial department of the Institutional HCP and is used according to the donor or grant agreement for bona fide non-profit activities; (b) accepted by the legal entity of the Institutional HCP, not internal departments or individual HCP; and (c) not conditioned on buying products or services or otherwise linked to other conditions that might affect fair competition.</td>
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<tr>
<td>b) Implement procedures to ensure such grants are not used as an unlawful inducement</td>
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<tr>
<td>c) Document such grants and donations.</td>
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<tr>
<td>Companies’ sales personnel may provide input to, but not unduly influence grant and donation decisions or recipient selection.</td>
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<tr>
<td>Research Grants should have well-defined objectives and milestones and may not be linked to purchases of Medical Technologies</td>
<td>Research Grants Equivalent</td>
</tr>
<tr>
<td>Educational Grants Companies may make such grants to conference sponsors or training institutions but not to individual HCPs</td>
<td>Academic and Public Education Grants. Academic and public information grants may be provided for legitimate purposes, including, but not limited to, the examples below, but are not permitted for Individual HCPs or to Individual HCPs in training.</td>
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<tr>
<td>• Advancement of Medical Education Companies may make grants to support genuine education of medical students, residents and fellows (See also Section IV)</td>
<td>Academic Grants. A Company may make grants to support the genuine medical education of medical students, residents, and</td>
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• **Public Education**- Companies may make grants to support patient or public education on health care topics

**Public Education Grants.** A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

**Charitable Donations** Companies may make donations to organizations with *bona fide* charitable missions such as supporting indigent care, or patient and public education.

**Charitable Donations** Equivalent but omits reference to charitable missions

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<th>XII. Evaluation and Demonstration Products</th>
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<td>This section of the Code discusses the provision of evaluation and demonstration products and is not intended to address any other arrangement.</td>
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**Evaluation Products:**

- Provided at no charge to assess functionality and to determine future purchase and use of that product
- Expected to be used in patient care
  - a) **Single Use/Consumable/Disposable**- may be provided in quantity reasonably necessary for adequate evaluation
  - b) **Multiple Use/Capital**- furnished only for the time reasonably necessary for adequate evaluation. The terms of such an evaluation should be set in writing. Companies should retain title to the product, and the product should be removed promptly upon completion of the evaluation.

**Evaluation Products:** Equivalent introductory sections, but adds:

Companies should ensure that the provision of evaluation and demonstration products is neither conditioned on buying products or services, nor linked to other conditions that might affect fair competition.

**Single Use/Consumable/Disposable**- Equivalent but adds that terms of an evaluation of single-use devices should be disclosed in writing to the HCP; applicable laws, regulations or institutional rules may also require disclosure to a different body

**Multiple Use/Capital**- Equivalent but adds that terms of evaluation of such multiple use products should be set in advance and in writing with the Institutional HCP, not internal departments or individual HCPs.
<table>
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<th>Demonstration Products:</th>
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<tr>
<td>- Typically unsterilized single-use products typically used for HPC and patient awareness, education and training.</td>
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<tr>
<td>- Not expected to be used in patient care.</td>
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<td>- Identified as not intended for patient use and typically designated as “Sample,” or “Not for Human Use,” on the packaging and/or other documentation that accompanies the product.</td>
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Companies should provide HCPs with documentation disclosing the no-charge status of evaluation and demonstration products.

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<tr>
<td>Equivalent but adds in the documentation section that disclosure to a different body may be required by applicable laws, regulations or institutional rules</td>
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<tr>
<th>XIII. Third Party SMI Relationships</th>
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<tr>
<td>Companies are encouraged to adopt a Third Party SMI Management Compliance Program in addition to overall compliance program, applicable to all relevant personnel, including a Company’s senior leadership. Taking into account a variety of risk-based factors, as well as local applicable laws; such programs may include the following elements:</td>
</tr>
<tr>
<td>A. Written Policy/Procedure.</td>
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<td>B. Risk Assessment.</td>
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<td>C. Due Diligence Program.</td>
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<tr>
<td>D. Written Contract.</td>
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<tr>
<td>E. Training and Education.</td>
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<tr>
<td>F. Monitor/Audit.</td>
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<tr>
<td>G. Appropriate Corrective Action.</td>
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