



Compliance Manual

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Siemens Healthcare Sector USA Compliance Manual

(For Use in the United States Only)

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Siemens Healthcare Sector USA Compliance Manual

In consideration of the fact that the policies and procedures contained in this compliance manual may change from time to time, the official copy of this compliance manual is located on the intranet at:

<https://intranet.healthcare.siemens.com/cms/sso-hq/en/departments/compliance/Pages/compliance.aspx>

Although updates to this compliance manual may be directly communicated to you, it is imperative that your behavior and actions are consistent with the policies and procedures set forth in the official copy of this compliance manual.

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1. SCOPE AND PURPOSE

All Siemens business units and employees are expected to be familiar with and perform their operations and business functions in accordance with the Siemens Business Conduct Guidelines available at

https://workspace.siemens.com/content/10002365/DocLib_new/00%20Policies%20and%20Guidelines/BCG2009_Brochure_online_en.pdf. Also, please note that any and all

interactions with our customers must have compliance approval and the request should be entered into the CAP tool located at

<https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>. In

addition, those companies and business units that are part of Siemens Healthcare Sector USA (“H USA”) must also become familiar with and operate in accordance with the H USA Code of Conduct available on the H USA Compliance Intranet site at

<https://intranet.healthcare.siemens.com/cms/ssohq/en/departments/compliance/Pages/compliance.aspx>.

Because the healthcare industry is so highly regulated, H USA believes it is important and necessary to provide our employees with more detailed guidance than is provided in the H USA Code of Conduct on how to interact with our customers, vendors, and government agencies in a manner that is compliant with applicable law. This Compliance Manual governs many aspects of H USA relations with customers, including customer education and training; sponsoring customers’ attendance at professional conferences and CME programs; contracting for site visits; grants to doctors and hospitals; consulting agreements; speaking sponsorships; entertainment; and gifts and charitable contributions. In order to understand how the Compliance Manual applies to certain common interactions with customers, we have also developed a set of “Frequently Asked Questions,” which are available on the Compliance Intranet site

<https://intranet.healthcare.siemens.com/cms/ssohq/en/departments/compliance/Pages/compliance.aspx>.

Our relations with our customers are legally governed by, and the guidance addressed in our Compliance Manual principally emanates from, the Federal Anti-Kickback Statute (42 U.S.C. §1320a-7(b)). (There are also related state laws, many of which apply regardless of whether federal healthcare programs are involved, and guidelines such as the AdvaMed Code on Interactions with Healthcare Professionals and NEMA Code of Ethics). The Federal Anti-Kickback Statute establishes severe civil and criminal penalties for anyone who knowingly and willfully offers or pays (or solicits or receives) any “remuneration” in cash or in kind, directly or indirectly, to induce someone (e.g. a physician or a hospital) to purchase, lease, order, arrange for or recommend purchasing, leasing, or ordering any item for which payment may be made under any federal or state healthcare program. Under current judicial and administrative decisions, a violation may be found even if only one purpose of the “remuneration” is to induce the purchase of products; it does not matter if there are other legitimate purposes for the payment. In addition, there does not have to be an agreement to purchase in exchange for the remuneration, and there is no requirement that the remuneration result in an increase in state or federal healthcare expenditures.

In addition, federal and state governments have enacted laws to prevent, detect, and punish fraud and abuse of healthcare plans and programs. At the federal level, these

laws include (but are not limited to) the Federal Civil False Claims Act (31 U.S.C. §3729-33).

Many states have enacted similar laws. A person that violates the False Claims Act is liable for damages up to three times the amount the government is defrauded plus mandatory penalties of \$5,500 to \$11,000 for each false claim submitted.

This Compliance manual applies to your interactions with HCPs to the extent that they provide services or medical technologies in the United States. This would include interactions with HCPs who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). This Compliance Manual does not specifically govern your interactions in a foreign country with an HCP native to and working in a foreign country; in such circumstances, you should follow the requirements on such interactions set forth in the relevant country. Of course, additional foreign legal and ethical considerations may pertain to interactions with HCPs located both inside and outside the US. If you have questions relating to your interaction (in or outside the United States) with international HCPs, please contact Compliance. Furthermore, to the extent you are interacting with foreign HCPs in the United States regarding promotional services, please consult Compliance.

2. PROMOTION IN ACCORDANCE WITH FEDERAL REGULATIONS

It is the policy of H USA to comply fully with all federal requirements in every aspect of its business involving H USA products that are reimbursed by the government. All employees are expected to comply fully with all federal and state healthcare program requirements as well as with the H USA Compliance Manual.

Officers, managers, and other persons in a supervisory capacity must make the contents of the Compliance Manual known to the appropriate employees in their organizations and ensure the execution of all applicable provisions.

It is not expected that every employee will be fully versed in the laws affecting his/her responsibilities. However, it is expected that every employee with significant responsibilities will have a working knowledge of the permissible activities involved in his/her work and will seek guidance from a superior, Compliance, or the Legal Department concerning any matter on which there is any question.

3. CHARITABLE CONTRIBUTIONS

H USA may make donations for a charitable purpose, such as supporting indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations that are separate from the customer (i.e., an independent charitable foundation, which may be affiliated with a customer). However, provision of charitable donations can still implicate the Anti-Kickback Statute and the False Claims Act. This Section 3 is designed to enable H USA and its employees to provide legitimate charitable donations in a manner that does not create an appearance of impropriety.

Scope

It is generally appropriate for H USA to support charitable organizations and local or community-oriented non-profits and their missions by making donations for charitable purposes. The amount of any charitable donation made by H USA to any particular charitable organization may not be based on, or related to, the past, present, or future volume or value of business generated for Siemens by that charitable organization or related organization. H USA will not make charitable donations directly to hospitals, physicians, or other customers; political parties or causes; or religious groups for religious purposes. Charitable donations may only be made to IRS tax-exempt charitable organizations, including charitable foundations affiliated with hospitals, as long as the foundation is truly a separate entity from the hospital.

Process

All charitable contribution requests must be submitted through the Compliance Approval Process Tool (CAP) at <https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>. This link can also be found on the H USA Intranet Homepage as well as the Compliance Intranet site.

Once submitted, each request will be reviewed by Compliance to ensure that it is in accordance with the requirements of this Compliance Manual. All requests must be submitted at least 10 business days before an event. Requests not submitted within this time frame may be escalated to the Chief Compliance Officer for H USA.

Requirements

Charitable contributions are permitted only if they meet the following requirements:

- I. The contribution is intended solely for charitable purposes, such as providing funds or equipment for patient care, patient education, or public education. If H USA receives anything of value in return, the dollar value must be deducted from the portion of the request that would be considered charitable; therefore, the

requesting organization should make this distinction on any documentation it provides as support for the request.

- II. The recipient is a qualified tax-exempt charitable organization. (A copy of the organization tax-exempt status letter must be included in any request for a donation or must be readily available).
- III. The recipient is a truly separate charitable organization from the customer with a board of directors and management independent of the customer.

A charitable contribution is **NOT** permitted if it is any of the following:

- Intended as a price term or offered in place of a price concession.
- Contingent on the purchase of any H USA products.
- Intended to encourage the recipient to use, purchase, or recommend H USA products.
- Intended to reward or compensate the recipient for purchasing, using, or recommending H USA products.
- Made at the request of a healthcare professional in his/her individual capacity (e.g., a request by a physician to fund his/her favorite charity).
- Funding an endowed chair at an educational institution since it is the same as providing an unrestricted cash gift to a healthcare professional.

All requests for charitable contributions must be supported by a letter from the entity requesting the contribution and the purpose of the contribution (for example, to donate to the American Cancer Society) and confirming that the requesting party is a charitable entity. This letter should have as much supporting information as possible in order for H USA to conduct its due diligence upon request.

H USA employees may not make charitable donations on behalf of H USA. Additionally, sales, marketing, or service personnel should not approve requests for charitable donations or attempt to influence H USA decision-making with respect to a request for a charitable donation. If you receive a request for a charitable donation or other request to sponsor fundraising events, please submit the request to the CAP Tool before any commitments are made. The CAP Tool can be found on the Compliance Intranet site, or by clicking the following link:

<https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>.

If an employee wants to support a charity in his/her individual capacity and that charity is a customer or affiliated with a customer, then the donation must meet the following criteria:

- The donation is made directly to the charity.
- The donation is made anonymously.
- The customer is never informed directly or indirectly about the donation.

Any other questions regarding charitable contributions should be submitted to Compliance.

Charity Events

If H USA makes a donation to a charity event sponsored by a charitable organization (e.g., golf tournament, charity gala) the proceeds of the event must be used for charitable purposes rather than for purposes of funding capital, operating, or overhead expenses of an affiliated customer (e.g., building of a new oncology wing at a hospital).

Attendance by designated H USA employees at charitable events may be permitted in order for H USA to demonstrate support for the charity through personal attendance at a charitable event. However, inviting customers or healthcare professionals to these charity events is not appropriate under any circumstance. By way of further example, if the event is a golf outing or gala dinner, H USA may not golf with a customer representative in a foursome.

In the event H USA has fewer attendees than the number of allotted event tickets or golf slots, the remaining tickets or slots should be returned to the charity. The charity, in its sole discretion, may decide to place other paying attendees at the H USA table or with the H USA golf group. H USA may not, directly or indirectly, influence who the charity may place with H USA.

Inviting customers or healthcare professionals to these charity events is not appropriate under any circumstance. By way of further example, if the event is a golf outing or gala dinner, H USA may not golf with a customer representative in a foursome.

If H USA denies a request to fund a charity event, it is not appropriate for the H USA employee to, nevertheless, provide sponsorship to the event using his or her own personal funds or attend the event on behalf of or in representation of H USA.

Contributions for Health Fairs / Medical Screenings

Charitable contributions may be requested to support community health fairs or medical screening days intended to promote disease awareness and provide testing for early diagnosis. Examples include any medical test or screening event offered free to the community such as prostate cancer screening.

H USA may contribute funds or product to an independent third-party that qualifies as a tax-exempt charitable organization to support health fairs or screenings if the following requirements are met:

- The request for funds must be received from an independent third-party that qualifies as a tax-exempt charitable organization. H USA cannot provide funds or product to a private healthcare professional or practice group or any charity that is controlled or operated by a private healthcare professional or practice group.
- More than one medical group or more than one healthcare professional, each from different medical groups, must take part in the health fair or medical screening.
- The health fair or medical screening must be free and open to all community members.

- If you receive a request for a charitable contribution that does not comply with H USA's policies or this Compliance Manual, you should inform the person making the request that H USA's policies do not permit the contribution.

Audits

All charitable contributions are subject to audit to ensure compliance with H USA policies and this Compliance Manual. The government (e.g., IRS) may also request to audit/review charitable contributions.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

4. DRAWINGS AND SWEEPSTAKES

Drawings and sweepstakes, which offer the opportunity for a customer, patient, healthcare professional or anyone else to receive something of value, such as a prize, from H USA in a drawing, sweepstakes, or similar situation are to be avoided. Requests by a conference organizer for H USA to supply funds for drawings, sweepstakes, or similar situations must be approved by Compliance and Legal. Furthermore, items to be used for a drawing or sweepstakes must comply with the requirements of Compliance Manual Section 12, "Business Gifts."

All requests to support a third-party drawing, sweepstakes, or similar situation must be approved in advance by Compliance by submitting a request to the Compliance Approval Process ("CAP") Tool. The CAP Tool can be found on the Compliance Intranet site or by clicking the following link:

<https://usi03-medssoit.ww005.siemens.net/CAP/default.asp?Organization=other>.

5. FREE GOODS

“Free goods” is the term for a product or service that is provided at no charge. Depending on the business unit, “goods” may be consumable material, software and related licenses, imaging devices, or product-related services. H USA may never provide free goods to customers, such as laboratories or healthcare professionals, if even only one purpose of such action is to encourage them to use or purchase H USA products.

General Policy

Free goods or services may generally be provided only for warranty/repair/replacement, dispute settlement, limited-time pre-purchase evaluation, research purposes, validation, correlation or waste, etc., after evaluation. Any such transaction must be approved and documented by qualified employees as described below. (Free goods provided to qualified charities should follow Compliance Manual Section 3, “Charitable Contributions”). Free goods may NOT be provided for any other purpose. Free goods provided in connection with a product sale (i.e., “buy one, get one free”), must comply with Compliance Manual Section 7, “Providing Discounts and Rebates,” in this booklet.

Generally, no patient results may be reported and/or billed for when utilizing free goods provided for research.

Product Specific Policies

A number of H USA products are sold in configurations that require additional guidance as to the handling of Free Goods. Each group may supplement this policy as necessary. Any documented supplemental policy must be approved by the Legal Department. Such supplemental policies will be made accessible via a link from this online Policy. It is the responsibility of the sales director or marketing director, as appropriate, to ensure that any new hire receives the supplemental free goods policy within 30 days of the new hire date.

Evaluation

H USA may provide evaluation samples of consumable products and loaned equipment to customers, at no charge, in connection with customer product pre-purchase evaluation, provided that the sample quantities and/or goods provided are not more than is reasonably necessary for evaluation of the product by the customer and the duration of the evaluation period does not exceed ninety (90) days. The location of products given to customers for evaluation must be documented. Evaluation goods must be provided to customers together with documentation of what was provided, including if the goods are consumable samples, a statement that the hospital, physician, or other customer shall not seek reimbursement nor charge any public or private insurer or patient for any materials provided at no charge by H USA. Goods must be retrieved at the conclusion of the trial period unless the customer decides to buy or lease the goods and enters into an appropriate agreement with H USA.

Additional information on the loaning of equipment is found in the Compliance Manual Section 6, "Loaner Equipment."

Evaluation products do not need to be reflected as a discount or rebate if no patient is charged.

Service

Consumables such as reagents or electrodes may be replaced when used during the servicing of an instrument. Only that amount attributed to the servicing may be replaced.

Validation or Correlation

H USA may agree to provide customers with free goods for purposes of conducting various types of validation studies. However, the value of these materials must be disclosed to the customer and must be considered a discount, rebate, or reduction in price to the underlying H USA product.

Waste

H USA may sell product to a customer that does not process a sufficient volume of tests to use the entire product before it expires. The unused product is considered "waste." In these instances, sufficient free goods may be provided to the customer to account for the waste. It is the responsibility of the sales representative and his/her manager to document the provision of free goods to replace waste and to ensure that only the amount of product sufficient to account for waste is provided.

Additional Guidance

Products **MAY** be marketed as free goods. **HOWEVER**, they must be reflected as a discount on the invoice. For example, it is permissible to state "buy 4 get one free;" however, the invoice should reflect this as a 20% discount. For further information, consult the Compliance Manual Section 7 "Providing Discounts and Rebates."

H USA may provide free goods to individuals or entities involved in performing research services for H USA pursuant to a written research services agreement. For additional information, see Compliance Manual Section 23, "Clinical Research and Clinical Study Support."

Goods provided as an "apology" are "free goods" subject to this policy and are NOT permitted. When there is bona fide warranty/service/performance issues – replacement product or a credit may be offered provided that the transaction is documented with the warranty safe harbor language, which must be evaluated and obtained from the Legal Department.

Questions

All questions regarding Free Goods should be referred to Compliance, the Legal Department or Ask Us.

6. LOANER EQUIPMENT – SALES

This Section 6 provides guidance only with regard to loaner equipment provided in the sales context.

“Loaner equipment” is the term for equipment that may or may not have commercial value and is provided at no charge. Except as described elsewhere in this Compliance Manual, H USA may never provide loaner equipment to customers, such as laboratories or healthcare professionals, if even one purpose of such action is to encourage them to use or purchase H USA equipment or products.

General Policy

Any loaner equipment provided must be provided pursuant to a written agreement approved by the Product Loan Group (e.g., an equipment evaluation agreement).

Loaner equipment provided in connection with a product sale (i.e., “buy X units obtain use of equipment at no charge”), must comply with MOR 2.3/03e.

Questions

All questions regarding loaner equipment should be referred to the Legal or Compliance Department.

If you are providing loaner equipment to a customer as part of a clinical collaboration, please also see Compliance Manual Section 23, “Clinical Research and Clinical Study Support,” MOR 2.3/05, and Compliance Manual Section 33, “Computer Hardware and Training.”

7. PROVIDING DISCOUNTS AND REBATES

H USA may generally provide discounts, rebates and other price concessions to customers provided the conditions of this Section 7 are met. In order to ensure that H USA complies with the provision of the Discount Safe Harbor to the Anti-Kickback Statute, the terms of all price reductions must be disclosed in written contracts that notify recipients of their obligations to report the arrangement to government payors, such as Medicare and Medicaid.

General Limits

All discounts, rebates, or other price concessions given on sales must be openly and fully reported on the invoice for such sales. Any products given to the customer must be reported on an invoice noting the fair market value of the product and the fact that a discount was given on the product. No items or services should be provided “below the line.” Additionally, “Side Letters” or price concessions offered outside of written contracts, are strictly prohibited. Notwithstanding the foregoing, the Legal Department may be consulted to draft letters that reflect unanticipated credits. It is the responsibility of the requestor to ensure that these letters be included in the contract history files.

Discounts

Discounts are price concessions that are provided and disclosed on the invoice or the contract at the same time of execution at the time the product is sold. H USA must fully and accurately report discounts on the invoice submitted to the customer at the time the product is furnished and inform the customer on the invoice of its potential obligation to report the discount to payors and insurers, as appropriate.

Rebates

Rebates are price concessions based on purchase volume or the fulfillment of other established criteria where the final amount of the price concession may not be known at the time of product invoice or contract signing. If the value of a rebate is not known at the time of invoice or contract signing, the invoice or contract should reflect that additional discounts may be provided. H USA should provide credit memos that accurately explain the reason for the credit and reflect the true value of the rebate. In the written contract and on invoices or credit memos, H USA must notify customers that they may be required to report discounts and other price concessions to government payors, such as Medicare and Medicaid.

Questions

All questions regarding discounts or other price concessions should be referred to Compliance or the Legal Department.

8. INTERACTIONS WITH FEDERAL GOVERNMENT EMPLOYEES

The federal laws and regulations governing gifts, business meals, speaker grants, educational grants, and travel compensation provided to federal government employees, including part-time government employees, are much stricter and more specific than the laws and regulations for private customers. This Section 8 is designed to help you avoid any conduct that presents the appearance of impropriety.

Scope

Federal government employees include anyone (military or civilian) who is employed by a facility associated with the Department of Defense (e.g., military or “DoD”), the Department of Veterans Affairs (“VA”), Federal Public Health Service (“PHS”) entities, the Indian Health Services, National Institutes of Health (“NIH”), or other federal government entities. According to federal law, a government employee includes part-time employees of the government and part-time workers at a government facility.

This Section 8 does not cover fee-for-service arrangements with government employees. Please refer to Compliance Manual Section 16, “Payments for Speakers, Consultants, Advisory Boards, and other Fee-for-Service Arrangements.”

For example, the following **are** considered government employees:

- A resident while he or she is doing a rotation at the VA.
- A physician who works part-time at the VA and part-time at a civilian institution (the amount of time spent at the VA hospital is irrelevant).

The following, however, is **NOT** considered a government employee:

- An individual who works at a civilian facility that has a contract with the government to treat government beneficiaries (e.g., a civilian physician at a TRICARE facility).

General Prohibition

You may not offer or provide any gift, business meal, entertainment, travel reimbursement, or anything else of value – regardless of amount – to a federal government employee. You may not provide gifts, meals, entertainment, travel reimbursement, or anything else of value to spouses or guests of government employees. For example, it is clearly not permissible to buy a government employee lunch when you visit the government employee at his place of business in order to discuss the services we are providing, etc.

It is permissible, however, to supply a modest meal to a federal government employee if the meal is provided in conjunction with a contractually agreed upon purpose (e.g., food provided at a contractually arranged training). This is a very limited exception to the

above stated general prohibition, and you should error on the side of following the general prohibition.

Limited Exception for “Widely Attended Gatherings”

Government officials may attend certain “group” events of a medical or educational nature, referred to as “widely attended gatherings,” sponsored by H USA. Widely attended gatherings include events sponsored by industry associations that are open to both government and civilian officials (e.g., AACC conference). In order for a H USA-sponsored event to be considered a “widely attended gathering,” the event must be open to **ALL** attendees of the conference or convention, (e.g., an H USA-sponsored keynote address at the annual AACC convention). You may not invite government employees to attend an H USA-sponsored limited target audience event (e.g., dinner at a “H USA table” at a HIMSS, RSNA, or AACC Conference).

Limited Exception for Speaker & Educational Grants

Grants to support government speakers may only be provided to bona fide third-party organizations (such as Jackson Foundation, True Foundation, Geneva Foundation, or similar organization) established for the purpose of accepting and disseminating grant funds on behalf of federal entities, including the Department of Defense and Veterans Affairs. H USA may provide funds to these organizations for educational purposes, including sponsoring a government official to speak at or attend a medical conference, only if the third-party organization, not H USA, determines how the funds are used. Grants must be consistent with the third-party organization’s character or authority.

All grant requests for funding Government speakers and Government attendance at medical education and training events must follow the process described in Compliance Manual Section 21, “Grants for CME, CEU, and Third-Party Educational Conferences,” and require CAP submission.

Record Retention

Accounting must maintain the payment request package for a minimum period of six years.

Audits

Spending for gifts and business meals is subject to audit to ensure compliance with this Section. Educational grants are subject to audit by the Operational Review department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review educational grant payments at any time.

9. STATE LAWS AND STATE EMPLOYEES

State Employees

There are various state laws that govern conduct with state government employees, such as healthcare professionals who work at state or county hospitals. You should exercise extreme caution when providing anything of value to a state government employee in the way of meals, payments for services, reimbursement for travel expenses, or similar legitimate business expenses to healthcare professionals who may be employees of a state, county, or local government. If you are unsure whether an individual is a state employee, consult the individual, the facility where the individual practices, or the Compliance Intranet site.

General Prohibition

You may not offer or provide any gifts or entertainment to a state government employee – regardless of the amount or whether the gift may benefit patients or provide genuine educational value. You may not provide gifts, meals, entertainment, travel reimbursement, or anything else of value to spouses or guests of state government employees.

State Laws Regulating Sales and Marketing

A number of states have recently adopted laws restricting the sales and marketing activities of pharmaceutical and medical device manufacturers. For additional information regarding state laws that govern sales and marketing to our customers, please see the Compliance Intranet site. Additionally, please note that this Compliance Manual will be amended to reflect the ongoing changes in state law.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, “Requirements when Interacting with Massachusetts Healthcare Professionals.”

Record Retention

Accounting must maintain the payment request package for a period of six years or longer as required by law or the Corporate Record Retention Policy.

Audits

Spending for gifts and business meals or other business expenses associated with state government employees is subject to audit to ensure compliance with this Section. Educational grants are subject to audit by the Operational Review department to ensure

compliance with these policies. The government (e.g., IRS) may also request to audit/review educational grant payments to state government employees at any time.

10. PROHIBITION ON ENTERTAINMENT & RECREATION

General Policy

H USA interactions with healthcare professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, H USA will not provide, arrange for, or pay for any entertainment or recreational event or activity for any healthcare professional who is not an employee of H USA. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the healthcare professional provides services to H USA under a consulting agreement; or (3) whether the entertainment or recreation is secondary to an educational purpose.

11. BUSINESS MEALS

H USA may pay for an occasional, modest meal when you are meeting with a customer and discussing business. H USA policy prohibits employees from offering anything of value to a healthcare professional or provider to encourage that person to purchase, order, or recommend H USA products, as this could violate the Anti-Kickback Statute and relevant state statutes.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, “Requirements when Interacting with Massachusetts Healthcare Professionals.”

Scope

The Section covers interactions with all healthcare professionals who may purchase, lease, recommend, use, or prescribe or arrange for the purchase or lease of H USA products. Note that the definition of healthcare professional is very broad and includes individuals other than physicians and nurses, such as laboratory directors, distributors, technicians, and medical office assistants.

General Rule

It is generally appropriate for H USA to provide occasional and modest meals to non-government healthcare professionals in connection with a discussion of H USA products, disease states relevant to H USA products, medical education, or other legitimate discussions related to H USA products. Taking a healthcare professional to dinner or other meal solely for “relationship building” is not acceptable. Please see Compliance Manual Section 8 (“Interactions with Federal Government Employees”) and Compliance Manual Section 9 (“State Laws and State Employees”) for further information regarding interactions with government employees.

These business meals should involve only individuals who are necessary for the conduct of H USA business. This means that meals should not be provided to spouses, guests, or office staff that do not actually attend the meeting, or any other person who does not have a bona fide professional interest in attending the meeting.

It is not appropriate to:

- simply drop food off with a customer;
- provide a meal for an entire office staff where everyone does not attend the meeting;
- reimburse a healthcare professional for personal meals.

Business meals may not be provided to encourage any individual or account to purchase, use, prescribe, or recommend H USA products.

Setting for Business Meals

The business meal must occur in a place and manner conducive to business discussion. Meals may occur at the customer's place of business. However, offering meals without a H USA representative present or providing "take-out" meals is not allowed.

Spending Guidelines

Meals provided to a healthcare practitioner in connection with a meeting involving the exchange of scientific, educational, or business information must be "modest." Meals costing \$100 per person, including tax and gratuity, generally meet the "modest" standard. However, the definition of "modest" will often depend on circumstances surrounding the event, such as time of day, venue, and geographic location. For example, for conferences and speaker events, a modest meal might be what a healthcare professional would routinely spend on dining at his or her own expense. Additionally, as the determination of "modest" is different for breakfasts and most lunches than for most dinners, it is generally unacceptable for breakfasts and most lunches to cost \$100 per person. For more informal occasions, such as hospital or office visits, business meals should generally be limited to snacks or sandwiches.

There is no specified limit on the maximum amount H USA may spend on any customer in a twelve-month period. However, you are responsible for using good judgment to ensure the aggregate value and quantity of gifts and/or business meals to any recipient is reasonable, modest, and occasional. It is important to remember that the government may view gifts and/or meals that are provided too frequently or are too expensive as an improper inducement to purchase H USA products.

If hosting a customer for the entire day, the meal amounts cannot be aggregated. For example, you cannot spend \$25 for breakfast, \$75 for lunch, and then make up the difference by spending \$200 for dinner. Regardless of what was spent on the previous meals, the dinner allowance remains \$100.

Retail Value – Amount to be Recorded

The retail value of a meal, not the amount you or H USA paid for it, determines whether the meal is modest and within the \$100 guideline. When providing business meals, you or H USA may take advantage of discounts, such that the retail value of a meal may be higher than what you or H USA actually paid for it. Retail value should be used to determine if the cumulative value of gifts or meals is appropriate. Business meals that were not planned but occur due to a business meeting/training extending into meal times do not require advance approval by Compliance so long as they adhere to the guidance outlined in this Manual.

Other limits:

- **No Spouses or Guests** - A business meals should involve only individuals who have a bona fide professional interest in the H USA product discussion. Therefore, spouses or other guests must never be included.
- **Office Staff Attendees.** A business meal may only be provided to those members of a healthcare professional's office staff who have a bona fide professional interest in the information being shared at the meeting.
- **No Cash or Cash Equivalents** – You may never give a healthcare professional cash or cash equivalents (e.g., gift certificates, your credit card) to purchase a meal.

The following are examples of meals that are **NOT** appropriate:

- Taking the same physician to dinner at a four-star restaurant (e.g., Morton's) every month (not occasional/too expensive to be modest)
- Meeting a laboratory manager at a "take-out" restaurant and discussing H USA products while waiting for the food (venue/location not conducive to an educational discussion)
- Giving your credit card to a healthcare professional and telling him/her to "buy lunch" or make some other purchase (credit card provided in this manner is a "cash equivalent;" no H USA employee present; no conduct of H USA business can be confirmed)
- Taking an imaging technologist and spouse to dinner in a "foursome" with your spouse (including a spouse or guest at a business meal is inappropriate)
- Providing pizza for all physicians and staff at the radiology clinic even though the only attendees at the H USA meeting were the two technologists receiving training; (food provided to an audience larger than that being presented to is inappropriate)

Providing Meals to Federal Government Employees

There are special rules for business meals provided to Federal government employees (e.g., military and Department of Veterans Affairs). Before providing a business meal to a government employee, including part-time employees, you must consult Compliance Manual Section 8, "Interactions with Federal Government Employees."

State Laws and State Employees

There are various state laws that govern conduct with state employees, such as healthcare professionals that work at state or county hospitals. You should exercise extreme caution when providing any business gifts or meals to healthcare professionals who may be employees of a state, county, or local government. If you are unsure whether an individual is a state employee, consult the individual, the facility where the individual works, or the Compliance Intranet site.

In addition, a number of states have recently adopted laws restricting the sales and marketing activities of pharmaceutical and medical device manufacturers. For additional information regarding state laws that govern sales and marketing to our customers, please see Compliance Manual Section 9, "State Laws and State Employees," and the Compliance Intranet site.

Procedures

Before providing a business meal, ask yourself:

- Will H USA business be discussed?
- Is the venue appropriate?
- Will the meal have a bona fide commercially reasonable purpose?
- Is the amount of the meal modest?
- Is an H USA representative present?
- Will the frequency and the total value for all gifts and business meals to this healthcare professional and/or organization be considered modest and reasonable?
- Am I reasonably certain that there are no additional considerations, such as whether the healthcare professional is a government employee or practices in a state with special reporting requirements?

The answers to all of these should be "yes" for the business meal to be appropriate.

Documentation of Business Meals

Business meals may be recorded through your Travel and Expense Form ("T&E") and in conformity of the T&E policy then in effect. Below is a brief description of the T&E policy.

T&E entries must include:

- Full name of the customer receiving the business meal (e.g., Dr. Jane Smith)
 - It is not acceptable to list only a generic position or department (e.g., "technician" or "three laboratory directors"). Each attendee should be identified by name; it is not acceptable to list "Memorial Hospital."
 - For events with many attendees (e.g., departmental lunch) where all names may not fit on the electronic form, the H USA employee should use a sign-up sheet to ensure that all attendees are listed. This list should include the date of the event, total cost, and names of attendees. You should attach the list to your T&E and forward the full T&E and supporting documentation through the proper approval channel. Keep a copy for your own files. To the extent that a state requires additional information to be reported, you must include all such information in your T&E entry.

- Facility with which the customer is affiliated (e.g., Cleveland Clinic or Johns Hopkins)
- Location of the expense (e.g., Ruby Tuesday's)
- Amount spent (e.g., \$23.95)
- For tracking purposes, unless you indicate otherwise, the total amount of the expense will be divided among the number of attendees to determine the amount spent on each person. For example, if you take two laboratory technicians to lunch and the total bill is \$42, \$14 should be attributed to each technician (with the remainder reflecting the cost of your meal) ($\$42/3 = \14). To the extent a state requires this calculation to be done differently, you must adhere to the requirements of that state.
- Specific purpose of the expense
- It is not acceptable to list only a generic description of the purpose of the expense (e.g., "product discussion")

Record Retention

T&E documents are retained by the Accounts Payable Department for a period of six years or longer as required by law or the Corporate Record Retention Policy.

Audits

Spending for business meals is subject to audit to ensure compliance with this Section, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review expense reports.

12. BUSINESS GIFTS

H USA policy and this Compliance Manual prohibit employees from offering anything of value, including a business gift, to an HCP to encourage the HCP to prescribe, purchase, or order H USA product(s), or to recommend the prescription, purchase, or ordering of H USA product(s). Offering or providing gifts or items of value to encourage HCPs to prescribe, order, or recommend H USA products could violate the Federal Anti-Kickback Statute and other relevant state statutes.

Scope

This Section covers interactions with all HCPs who may purchase, lease, recommend, use, or prescribe H USA products. Note that the definition of HCP is very broad and includes individuals other than doctors and nurses, such as laboratory directors, technicians, and medical office assistants.

Acceptable Business Gifts – General Rule

All gifts must benefit patients or serve a genuine educational function. The fair market value of any gift provided to an HCP may not exceed \$100 (other than medical textbooks, see Section 24, “Providing Medical Textbooks and Other Text Material”).

Gifts may **never** include payments in cash or cash equivalents, such as (a) gift cards; (b) gift certificates; (c) loans; (d) savings bonds; (e) lottery tickets; or (f) airline upgrade coupons.

Prohibited Business Gifts

Branded promotional items that are not educational can no longer be given to HCPs, regardless of whether the item has minimal value, and is related to the HCP’s work or benefits patients. Examples of non-educational, branded promotional items include pens, notepads, mugs, and other items that have the company’s name, logo, or product name or logo.

Pre-Approval Requirement

All gift requests must have Compliance approval and should be submitted to the CAP Tool. The CAP Tool can be found on the Compliance Intranet site, or by clicking the following link:

<https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>.

Spending Limits for Gifts

The limit for gifts is \$100 per gift (other than medical textbooks, see Section 24, “Providing Medical Textbooks and Other Text Material”). There is no specified limit on the maximum amount H USA may spend on any HCP in a twelve-month period. However, you are responsible for using good judgment to ensure the aggregate value and quantity of gifts and/or business meals to any recipient is reasonable, modest, and occasional. It is important to remember that the government may view gifts and/or meals that are provided too frequently or are too expensive as an improper inducement to purchase H USA products.

Retail Value – Amount to be Recorded

The retail value of a gift and not the amount you or H USA paid for it determines whether it is modest and within the \$100 limit. H USA often takes advantage of bulk or other discounts, such that the retail value of some gifts may be higher than what you or H USA actually paid for them. When listing the value of any gift, textbook, or meal, you should always list its retail value and the amount you or H USA paid for the item, if the amounts differ. Retail value should also be used to determine if the cumulative value of gifts or meals is appropriate.

Examples

The following are examples of **appropriate** business gifts:

- Resident handbooks
- Anatomical models
- Educational DVD on medical conditions and treatment

The following are examples of business gifts that are **NOT** appropriate:

- Tickets to a football game (personal items that do not benefit patients and do not serve a genuine educational function)
- Any gift, regardless of cost, that rewards an HCP for purchasing H USA products
- CDs with the latest popular music, golf balls, sports bags, cuff links or clothes – even if they contain a Siemens logo or product logo (no benefit to patients; no educational function)
- Any “dual-purpose” gift, such as television, VCR, computer equipment, DVD player, iPod, or MP3, even if the cost is less than \$100 and the HCP indicates it will be used for medical purposes; (gift does not primarily benefit patients)
- Branded or non-branded pens, notepads, mugs

Gifts to Federal Government Employees

It is not appropriate to provide any type of gift to Federal government employees (e.g., military and Department of Veterans Affairs). For more information on gifts, meals, and other business interactions with Federal government employees see Section 8, "Interactions with Federal Government Employees."

State Laws and State Employees

There are various state laws that govern conduct with state employees, such as HCPs that work at state or county hospitals. You should exercise extreme caution when providing any business gifts or meals to HCPs who may be employees of a state, county, or local government. If you are unsure whether an individual is a state employee, consult the individual, the facility where the individual practices, or the Compliance Intranet site.

In addition, a number of states have recently adopted laws restricting the sales and marketing activities of pharmaceutical and medical device manufacturers. For additional information regarding state laws that govern sales and marketing to our customers, please see Compliance Manual Section 9, "State Laws and State Employees," and the Compliance Intranet site.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

Procedures

Before providing a gift, ask yourself:

- Will it benefit patients?
- Does it serve an educational function?
- Is the amount modest?
- Will the frequency and the aggregate value for all gifts and business meals to this HCP and/or organization be considered modest and reasonable?
- Am I reasonably certain that the recipient does not require additional considerations, such as whether he/she is a government employee or HCP who practices in a state with special restrictions or reporting requirements?

The appropriate company spending policy must be followed when procuring a medically related gift.

Documentation of Gifts through the T&E

Gifts may be recorded through your Travel and Expense Form (“T&E”). Below is a brief description of the T&E policy.

T&E entries must include:

- Full name of the HCP receiving the gift (e.g., Dr. Jane Smith)
 - It is not acceptable to list only a generic position or department (e.g., “laboratory director” or “doctor”).
- Facility with which the HCP is affiliated (e.g., Cleveland Clinic or Johns Hopkins)
- Description of the gift (e.g., PET textbook)
- How the gift benefits patients or provides a genuine educational function for the HCP (e.g., the model will be used as a communication tool for the doctor and patient)

It is not acceptable to list only a generic description of the purpose of the expense (e.g., “medically relevant”).

Document Retention

T&E documents are retained by the Accounts Payable Department for a period of six years or longer as required by law or the Corporate Record Retention Policy.

Audits

Spending for gifts is subject to audit to ensure compliance with this Section, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review related spending.

13. DISTRIBUTOR RELATIONSHIPS

Note that the definition of healthcare professional is very broad and includes individuals other than physicians and nurses. Distributors, laboratory directors, technicians, and medical office assistants are included as healthcare professionals.

General Policy

Incentives, in cash or in kind, may NOT be provided directly to distributor personnel. Promotional programs may be run with a distributor directly; however, it is up to the distributors to determine how to apply any compensation they are provided.

For example, H USA may offer an incentive to a distributor to increase sales by 5% over the year. H USA would pay the incentive to the distributor and not to its staff.

It is permissible to give plaques and certificate awards to distributor staff for exceptional work. Any recognition should NOT be in the form of cash, or readily convertible to cash.

Questions

All questions regarding Distributor Relationships should be referred to Compliance or the Legal Department.

14. ADVISORY BOARDS

Advisory boards provide H USA with significant and valuable feedback on its products and product plans. Payments for advisory boards must be in accordance with the following requirements and typically require Compliance or Legal review:

- If, at the request of H USA, a customer visits an H USA facility or some other location specifically to review and comment on a product, to discuss a research product, or explore collaborative research, a fair market value payment for time spent may be paid, so long as the services to be provided are genuine and not token.
- If the customer attends an advisory board the customer may be paid a fair market value fee for time spent participating in the advisory board and reimbursement for reasonable, out-of-pocket expenses so long as the services provided are genuine and not token.
- H USA may not provide a thank-you gift.
- For advisory boards, the following applies:
 - The purpose of the meeting must not be to promote a product.
 - The number of physicians in the advisory board must be reasonable.
 - The H USA employee hosting the advisory board must take minutes of the meeting that are sufficient to document the time and effort contributed by the participants.
 - The total dollar amount involved for a particular advisory board must be reasonable.
- Any payment to a customer in connection with an advisory board must be made pursuant to a written agreement as described in Section 16, “Payments for Speakers, Consultants, Advisory Boards, and Other Fee-for-Service Arrangements.”
- To the extent required by contract or terms of employment, participants must obtain permission from their companies prior to participating in an advisory board.
- Any meals or refreshments must be provided in accordance with Section 11, “Business Meals.”

For information regarding your interaction with foreign HCPs, please see Compliance Manual Section 1, “Scope and Purpose,” and the Compliance Website.

15. H USA-SPONSORED PRODUCT TRAINING & EDUCATION EVENTS

H USA recognizes the importance of providing training on the company's products and education on topics directly relating to the company's products to healthcare professionals and purchasers.

"Training" means training on the safe and effective use of the company's products.

"Education" means communicating information directly concerning or associated with the use of the company's products such as information about disease states and the benefits of the product to certain patient populations.

It is generally appropriate for H USA to financially sponsor or furnish such product training and education to healthcare professionals. H USA-sponsored education events are typically promotional events at which the presenter is speaking on H USA's behalf. H USA employees may only control and influence the speaker or program content in cases when the only topics of discussion are approved uses of H USA products.

A representative from H USA must attend each program.

For information regarding your interaction with foreign/international HCPs, please see Compliance Manual Section 1, "Scope and Purpose," and the Compliance Website.

Payments to Speakers and Attendees

Speakers may receive a fair market value payment for their services, but all payments must be made pursuant to a written contract, and require Compliance and/or Legal review. In addition, speaker contracts and payments must comply with Section 16, "Payments for Speakers, Consultants, Advisory Boards, and other Fee-for-Service Arrangements."

Attendees may not receive anything of value (cash, cash equivalent, gifts, etc.) in connection with the event other than meals and refreshments. Any such meals and refreshments should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.

H USA will only pay for reasonable travel and modest lodging costs incurred by an attending customer if travel is necessary in order for H USA to efficiently deliver training on the company's products. If the customer travels more than four hours door-to-door in order to attend the training, it must be approved through the CAP Tool available at <https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>. This link can also be found on the H USA Intranet Homepage as well as the Compliance Intranet website.

It is not appropriate for H USA to pay for the meals, refreshment, travel, or other expenses for guests of customers or for any other person who does not have a *bona fide* professional interest in the information being shared at a training program or education meeting.

Program Topics and Location

Topics must address approved uses of H USA products and be of a scientific or medical nature. For example, training and education programs can include “hands on” training, cadaver workshops, educational lectures, and grand rounds. Topics such as “Retirement Planning” or “Billing & Coding” do not meet this criteria.

The location of the program must be conducive to the exchange of information and to the presentation format planned for the program. Training and education programs should be conducted in clinical, educational, conference, or other settings, including hotels or other commercially available meeting facilities conducive to training. Programs providing “hands on” training should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. Locations that are, by their nature, entertainment (such as a dinner riverboat cruise) are not appropriate.

The training staff should have the proper qualifications and expertise to conduct a training program. Training staff may include qualified H USA employees who have the technical expertise necessary to perform the training.

H USA employees participating in training are prohibited from soliciting or providing information on unapproved uses of H USA equipment/devices. If asked to assist in specific prescribing decisions, do not do so.

Any healthcare professional who requests information on an unapproved use should be directed to Regulatory Affairs.

CME Accreditation

Under the ACCME Standards for Commercial Support (www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf), CME credits may not be issued for H USA product training programs since these events are financially sponsored by H USA and the content of the program is primarily controlled by H USA. To the extent that product training is being undertaken for education credit (e.g., CEUs) through an accreditation organization other than ACCME, you must adhere to the guidelines set forth by that organization.

In addition, it is unlikely that ACCME credits will be issued for education programs sponsored by H USA since, as described above, these events are typically promotional events at which the presenter is speaking on behalf of H USA. As a result, the content of the program is considered to be controlled or influenced by H USA and the ACCME will not issue CME credits for programs financially sponsored and controlled by a manufacturer. To the extent that an accreditation organization’s policies permit the issuance of continuing education credits, if an education program is sponsored by H USA, you must adhere to the guidelines of the applicable accreditation organization.

Massachusetts-specific Policy

NOTE: For all employees working with customers **licensed** in Massachusetts, please see Compliance Manual Section 34, “Requirements when Interacting with Massachusetts Healthcare Professionals.”

16. PAYMENTS FOR SPEAKERS, CONSULTANTS, ADVISORY BOARDS, AND OTHER FEE-FOR-SERVICE ARRANGEMENTS

In order to avoid any violation of the Anti-Kickback Statute, Siemens Healthcare Sector USA (Siemens) has established a Fair Market Value (FMV) Policy that provides strict guidelines that focus on our financial relationship with HCPs and provides us with a methodology to assess the maximum compensation level that must not be exceeded for their services. Such services include, but are not limited to, speaking engagements, training, contracting for site visits, consulting agreements, advisory boards, R&D arrangements, etc. As a result of continual updates in the industry's Fair Market Value rates, the policy and corresponding rates are published and made available on the Compliance website. Please check the Compliance Website for the FMV Policy and Guidelines at <https://intranet.healthcare.siemens.com/cms/ssohq/en/departments/compliance/Pages/compliance.aspx>.

Massachusetts-specific Policy

NOTE: For all employees working with customers **licensed** in Massachusetts, please see Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

17. SITE VISITS, PLANT TOURS, AND ROAD SHOWS

Site visits and attendance at road shows provide a significant vehicle for customers to learn of and evaluate H USA equipment and H USA's research and development activities that cannot practically be provided in another forum. Additionally, customers may visit H USA facilities, designated customer sites, and off-site locations to learn about the capabilities of H USA products and observe them in operation, including their safe and effective use.

If the visiting customer is a foreign national coming to the United States, the Healthcare Sector US Compliance Officer must first be informed of the purpose and details. Both the Healthcare Sector US Compliance Officer and the Compliance Officer for the customer's country of origin must approve the visit in writing, and this Compliance Manual governs your interactions with such visiting foreign nationals.

Purpose of Site Visits

Current and prospective customers may visit a site for purposes of becoming familiar with H USA products and observing product demonstration(s) in environments similar to that of their work environment. Such visits generally include sales presentations, product demonstrations, scientific discussions, and/or tours of the manufacturing and operational facilities.

For visits that involve a government employee, please see Section 8, "Interactions with Federal Government Employees" and Section 9, "State Laws and State Employees."

H USA should not arrange for a site visit and demonstration where there is no legitimate business need for the visit.

Reimbursement of Expenses

H USA may pay reasonable and necessary travel expenses of customers visiting sites for legitimate business purposes in situations where the business purpose cannot be achieved without such a visit (e.g., demonstration of a large imaging unit).

H USA can also reimburse reasonable and necessary travel expenses for a customer visiting an H USA site for purposes of providing information, education, or a demonstration of a product. H USA may also reimburse a customer's reasonable and necessary travel expenses for educational, training, and demonstration programs that occur at off-site locations, such as a hotel or conference center (e.g., regional sites). However, H USA may not reimburse the customer or pay the customer a fee for taking time off from the customer's business to attend the site visit.

H USA should generally purchase airline tickets and make arrangements to pay hotels, so that business guests do not incur these costs and H USA can ensure that arrangements are consistent with applicable H USA policies on reimbursement for business travel.

H USA is not permitted to reimburse travel or other expenses of spouses or guests in connection with site visits.

Third-Party Conferences

H USA may never use a site visit or demonstration as a pretext for reimbursing a customer for a trip that was not intended for education on H USA products. Specifically, H USA may not reimburse a customer for participating in a third-party conference or trip of a personal nature (e.g., HIMSS, RSNA, AACC, etc.).

18. INQUIRIES ABOUT OFF-LABEL USES OF H USA PRODUCTS

If a doctor, laboratory director, or other healthcare professional asks an unsolicited question about uses other than the approved/cleared “intended use” for H USA products, you must direct him or her to the Director of Regulatory Affairs. You should neither answer these questions, nor solicit this type of inquiry.

Procedures

If a discussion of an off-label use is initiated by anyone outside H USA, employees may confirm with the Director of Regulatory Affairs whether H USA is aware of that use, but they must then advise the inquirer that H USA policy prohibits them from discussing off-label uses. The employee should refer the inquiry to the Director of Regulatory Affairs by providing to the requestor the telephone or telefax number of the Director of Regulatory Affairs.

Additional Guidance

Soliciting Discussion: It is against H USA policy for a sales representative to hand an article discussing approved or unapproved uses to a doctor or laboratory director, hoping that the doctor will then ask about unapproved use. Similarly, H USA representatives may not encourage off-label talk at events such as doctor dinners or “plant” questions in the audience that are likely to lead to an off-label discussion.

Budget or quotas: Budget or quotas are not to be construed as an instruction to promote unapproved uses.

19. INVENTORY EXCHANGES

General Policy

This Section 19 governs inventory exchanges of H USA products. In connection with the purchase of H USA products, H USA may exchange an existing inventory of H USA products for new or upgraded products from H USA. For example, when a customer upgrades to the latest technologies, the old product may be exchanged for the new product.

The value of the product provided to the customer should be equal in fair market value of the product received from the customer. If the value of the product provided to the customer **exceeds** the value of the product received from the customer, the difference should either be invoiced to the customer as its fair market value or the customer should be notified in writing of the fair market value of the difference, and that this difference may constitute a discount or reduction in price that must be disclosed and appropriately reflected by the customer in claims to health insurers, including the government.

Example

A laboratory upgrades from the Immulite 1000 to the Immulite 2500. H USA exchanges, at no charge, all of the existing assay inventory that is only compatible with the Immulite 1000 with new assay inventory compatible with the Immulite 2500. The old assays were purchased for a price of \$2,000. The value of the replacement assays is \$4,000. The result is that the laboratory, in essence, received a \$2,000 discount on the new assay inventory. H USA must provide the laboratory with an invoice that notes the difference in price and notifies the laboratory that the price differential may constitute a discount that must be disclosed and appropriately reflected by the customer in claims or cost reports to health insurers, including government programs.

Competitive Displacement/Inventory Exchanges: Generally

In connection with an agreement with an institutional customer to purchase or stock H USA products and supplies, H USA may exchange H USA products for the customer's existing inventory of competing products under the standards described below. Inventory exchanges with institutional customers must be documented in a written agreement, limited to a reasonable amount of product, and must be for a limited-time period to allow the customer to make the transition to H USA products. Inventory exchanges may only be undertaken with institutional customers, and drug products and consumer products are not subject to inventory exchanges under this Compliance Manual.

For purposes of this Compliance Manual, arrangements with institutional customers involving exchanges or similar allowances for capital equipment are referred to as "trade-in" programs. Trade-in allowances must be consistent with the fair market value of

the equipment received. All trade-in programs must be reviewed by the Legal Department.

Further, "trade-in" offers to patients that allow a patient to obtain an H USA product in exchange for a similar existing H USA or competitor product of comparable value are covered by the above stated General Policy.

Finally, it is generally impermissible to fund other customer costs associated with the conversion to H USA products. In limited circumstances, it may be permissible to fund certain reasonable, documented direct costs that are actually incurred by customers to convert to H USA products. All such arrangements must be approved in advance by the Legal Department.

Inventory Exchanges

General: Because inventory exchanges represent an exchange of value that is designed to facilitate standardization of products by customers' employees in clinical practice, the customer must relinquish its existing inventory to H USA. In other words, the customer cannot receive "free" H USA products and retain the ability to use its existing inventory.

Type of products subject to inventory exchanges: Inventory exchanges may be undertaken with respect to operating supplies used by institutional customers. They may not be undertaken with respect to capital equipment, prescription drugs, or consumer products. (Trade-in programs for capital equipment and similar programs for consumer products, however, may be permissible under the standards described below).

Timing and quantity of exchange: The exchange should be made prior to or concurrent with the delivery of the new H USA products. The inventory exchange should be completed within a set period, defined in advance, in writing. The period for exchange should be limited to a 30-day supply, and representing a reasonable time period for the customer to use up existing stock. Any inventory exchange for more than a 30-day supply requires advance approval from the Legal Department. The exchange should be limited to products that the customer has in inventory at the time of the agreement. H USA may not offer to exchange inventory purchased by the customer after the date of the agreement.

Equivalent fair market value: Inventory exchanges represent an exchange of items of comparable fair market value. Thus, in order for an exchange to be permissible, the value of H USA products provided must be consistent with the fair market value of the customer's existing inventory. Fair market value must be determined on a case-by-case basis. As a general matter, the determination of fair market value must be based on an assessment of the market prices of the competitive product and the H USA product. Alternative valuation methods must be approved by the Legal Department. If you have questions, consult with the Legal Department for further guidance on questions related to this topic.

Excess value of H USA products: In the event that the value of the H USA products exceeds the value of the exchanged products, the amount of the excess must either be paid by the customer or be treated as a discount and deducted from the price of other H

USA products purchased under the arrangement. (To the extent that multiple H USA products are being purchased, the discount value must be allocated to all products consistent with H USA policy.) H USA must advise the customer in writing that their facility may be required to report the value of the excess as a discount on cost reports or claims submitted to federal healthcare programs to the extent required by law.

Excess value of competitor's product: In the event that the value of a competitor's product exceeds the value of the H USA product, the competitor's product value should be captured appropriately, and a credit against future H USA product purchases, or additional H USA product, but not cash, may be provided.

Documentation: H USA must enter into a written agreement for all inventory exchanges and should prepare documentation of the exchange of value to the customer. The documentation should notify the customer that their facility may be required to report any excess value as a discount on cost reports on claims submitted to federal healthcare programs to the extent required by law.

Trade-Ins

General: Although it is not permissible to undertake an “inventory exchange” with respect to capital equipment, it is permissible to enter into trade-in arrangements under which the customer may receive a credit toward the purchase price of an H USA capital product.

Value of credit: Similar to the principles applicable to inventory exchanges, the value of any credit associated with a trade-in of capital equipment must be consistent with the fair market value of that equipment. Trade-in programs offering equal value to all customers are preferred. Determining the fair market value of capital equipment raises a number of additional considerations. Specifically, the determination of fair market value must take into account the useful life and age of equipment received, and the potential value of the equipment on the secondary market, if one exists (e.g., if refurbishers acquire used products). H USA must consult the Legal Department before entering into any trade-in program for competitors' capital equipment. Certificates of destruction for trade-ins are generally not appropriate, absent a process to confirm that the product has, in fact, been destroyed.

Other Conversion Costs

H USA generally may not fund customers' other costs associated with the purchase of H USA products. For example, if a customer will return leased equipment to a competitor in order to purchase or lease H USA products, H USA may not reimburse the customer for early termination fees on that lease.

To the extent that customers must incur costs associated with conversion of H USA products — e.g., recalibration of systems, installation of equipment, or training for staff — it is preferable that H USA provide that service directly itself, as a value-added service or component of delivery, rather than providing funding for a third party to do so.

However, where an institutional customer must incur direct costs itself as part of the conversion, H USA may provide some limited assistance. The assistance must be based on an itemized description of the particular costs that must be incurred. The expenses must be reviewed and approved in advance by the Legal Department. In each case, the facility must then document that it actually incurred those costs and the amount of those costs prior to receiving payment. For example, H USA may reimburse a customer for the direct costs associated with calibration or recalibration of equipment, upon receipt of documentation from the customer of the amount of actual incurred costs. Indirect costs, such as time lost to staff in training or the costs of hiring temporary staff while regular employees are trained in the use of H USA equipment, are not appropriate for reimbursement. All agreements to pay for conversion costs must specify on a line-item basis the particular conversion costs to be reimbursed, and must be approved by the Legal Department.

20. SALES AND PROMOTIONAL MEETINGS AND CONVENTION SERVICES

The purpose of this Section 20 is to provide guidance for H USA employees on the appropriate standards of conduct relating to H USA's sales and promotional activities and convention services in accordance with applicable national, state, and local laws and regulations, as well as applicable industry guidelines.

Additional information regarding compliance with specific state laws can be found at Compliance Manual Section 9, "State Laws and State Employees," and on the Compliance Intranet site, <https://intranet.healthcare.siemens.com/cms/sso-hq/en/departments/compliance/Pages/compliance.aspx>. See also Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

This Section establishes a framework of standards of conduct for H USA employees relating to legal compliance of all H USA-sponsored sales meetings, promotional activities, and convention services (whether directly or indirectly through distributors, agents, and sales associates, in whole or in part).

Venue

It is appropriate for you to meet with healthcare professionals to discuss product features, contract negotiations, and sales terms. Sales and promotional meetings should occur at a location near the healthcare professional's place of business, at an H USA facility, or at a location selected because of its convenience to a large number of targeted healthcare professionals (e.g., the site of a well-attended convention or educational program), where H USA can minimize the need to pay the cost of travel, lodging, and meals.

For example, it would be permissible to bring a healthcare professional from New York to Nashville if that was the closest location where a product could be effectively demonstrated. However, it would be inappropriate to demonstrate a product for a New York healthcare professional in Puerto Rico if the product was available locally. Generally, it is not appropriate to conduct these meetings at resort locations.

Meals and Travel

H USA may provide occasional meals and refreshments in connection with sales and promotional meetings. These meals and refreshments must be provided in a location that is conducive to the exchange of business information. H USA may not pay, reimburse, or arrange for any entertainment or other recreational activity in connection with such meetings, including without limitation, golf or other sporting events or the theater. Meals and refreshments may not be provided for spouses, guests, or others who do not have a legitimate need to attend the meeting.

When necessary, H USA may pay for travel costs of a healthcare professional who needs to travel to the meeting. H USA should only pay for necessary and reasonable

travel and payment should be limited to special circumstances where the meeting cannot be conducted at a location that does not require the healthcare professional to travel. Examples of potentially necessary and appropriate travel might include plant tours or demonstrations of non-portable equipment. It would not be appropriate, however, to conduct a sales or promotional meeting at a resort location and pay for a healthcare professional's travel to that location.

For additional information, please see Compliance Manual Section 11, "Business Meals."

Selection of Attendees

Only healthcare professionals who have a legitimate business need to attend H USA sales meetings and promotional activities should be invited. You may not invite healthcare professionals to sales and promotional meetings based on their purchasing habits or to "reward" large purchasers of H USA products. In addition, you may not invite guests or spouses of healthcare professionals to attend. Should uninvited guests or spouses of healthcare professionals attend, any meals they consume must be at their own expense.

Federal Government Employees

It is generally not appropriate to pay for meals, refreshments, or travel for Federal government employees (e.g., military and Department of Veterans Affairs). For more information on business interactions with Federal government employees see Section 8, "Interactions with Federal Government Employees."

State Laws and State Employees

There are various state laws that govern conduct with state employees, such as healthcare professionals that work at state or county hospitals. You should exercise extreme caution when providing any meals or travel for healthcare professionals who may be employees of a state, county, or local government. If you are unsure whether an individual is a state employee, consult the individual, the facility where the individual practices, or the Compliance Intranet site.

In addition, a number of states have recently adopted laws restricting the sales and marketing activities of pharmaceutical and medical device manufacturers. For additional information regarding state laws that govern sales and marketing to our customers, please see the Compliance Intranet site.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

21. GRANTS FOR CME, CEU, AND THIRD-PARTY EDUCATIONAL CONFERENCES

H USA provides educational grants solely to support independent, educational conferences and meetings that promote scientific knowledge, medical advancement, and/or the delivery of efficient healthcare (“educational conferences”). Offering an educational grant to encourage healthcare professionals to prescribe, purchase, use, or recommend H USA products could constitute a violation of the Federal Anti-Kickback Statute.

General Rule

Educational grants may be paid only to support independent educational conferences sponsored by the following Conference Sponsors: (1) national, regional, or specialty medical associations; (2) charitable foundations or medical schools affiliated with teaching institutions, or (3) continuing medical education (“CME”) or continuing educational unit (“CEU”) providers that have been accredited by an organization such as the Accreditation Council for Continuing Medical Education (“ACCME”) or other relevant accreditation organization.

Grants should be made consistent with relevant guidelines established by professional associations, including ACCME and AdvaMed. In addition, H USA and the Conference Sponsor must abide by the provisions set forth in the Food and Drug Administration’s Policy statement on Industry-Supported Scientific and Educational Activities.

An educational conference supported by an H USA educational grant must be for scientific or educational purposes and not for the purpose of promoting any H USA product. Any discussion of H USA’s products at the educational conference must be objective, balanced, and scientifically rigorous. Any H USA product exhibit booth at these events must meet all sponsor and/or accreditation organization rules and the exhibitor fee must be based on a reasonable rental space value. H USA will not pay an exhibitor fee that reflects a premium assessed for access to healthcare professionals.

Grants may not be conditioned, in whole or in part, on the purchase of H USA products or directed toward specific healthcare professionals who are in a position to use or order H USA products. H USA may not contribute to programs sponsored by a customer unless the program is accredited for education credits (e.g., CME, CEU, or other applicable credit) or is sponsored by a charitable foundation or medical school affiliate.

The terms, conditions, and purposes of the H USA grant must be included in a written agreement between H USA and the Conference Sponsor as further described below.

Recipient of the Grant

H USA may provide a grant:

(1) Directly to a Conference Sponsor to reduce educational conference costs. Grant funds cannot be used to offset expenses not directly related to the educational

conference, such as rent for the Conference Sponsor's office or other overhead costs the Conference sponsor incurs.

(2) Directly to a Conference Sponsor to help cover reasonable travel and modest lodging expenses of healthcare professionals in training (e.g., residents, fellows, and medical students) attending the educational conference, if the Conference Sponsor selects the attendees.

Control of the Conference

The Conference Sponsor, not H USA, must have independent control of and be responsible for the content, faculty, educational methods, materials, and selection of attendees for the educational conference. The Conference Sponsor must make all decisions regarding the use of financial support from H USA.

Modest Meals & Hospitality

A portion of an H USA educational grant may be used by the Conference Sponsor to defray the cost of modest meals and refreshments for attendees at the educational conference.

H USA may also directly provide meals and refreshments for educational conference attendees if such meals and refreshments are: (1) provided to all attendees; (2) provided in a manner that is consistent with the applicable standards established by the Conference Sponsor and, if applicable, the entity accrediting the educational activity; (3) modest in value; and (4) subordinate in time and focus to the purpose of the educational conference; and (5) clearly separate from the educational portion of the conference.

H USA employees may conduct sales or promotional meetings with one or more attendees at an educational conference and provide meals or refreshments as long as the meetings are conducted and the meals and refreshments are provided in accordance with the Conference Sponsor's guideline, Section 11, "Business Meals," and Section 20, "Sales and Promotional Meetings and Convention Services."

Faculty Expenses

All or a portion of H USA educational grants may be applied by the Conference Sponsor to pay for reasonable honoraria, travel, lodging, and modest meal expenses for educational conference faculty members selected by the Conference Sponsor.

H USA may not direct a Conference Sponsor to use the grant funds for specific faculty members. H USA may not pay individual faculty members directly unless the faculty member has: (1) entered into a written speaker or consultant agreement with H USA that complies with Section 16, "Payments for Speakers, Consultants, Advisory Board Members, and Other Fee-for-Service Arrangements" and (2) disclosed to the Conference Sponsor that his/her expenses and/or honoraria are being paid by H USA.

To the extent that H USA has contracted with an HCP to provide a training or presentation at an H USA sponsored event, you may pay for HCP's reasonable travel expenses so long as such payment is pursuant to a written agreement.

Programs with CME Credit

If a faculty member has a financial relationship with H USA, H USA should ensure that the financial relationship is disclosed to the Conference Sponsor since the program presented by such faculty member may be ineligible for CME credits under the ACCME Standards for Commercial Support.

H USA Involvement In Educational Grants

H USA employees may NOT be involved in the following activities associated with educational grants:

- Selecting the content, faculty, educational methods, materials, or venue for the educational conference.

H USA may respond to unsolicited written requests from a Conference Sponsor for suggestions of names for possible speakers only. H USA must provide (where reasonable) the names of more than one speaker, a description of each suggested presenter's qualifications, and a disclosure of any significant financial or other relationship between H USA and the suggested presenter.

- Promoting H USA or H USA products during any educational conference funded, even partially, by an educational grant.

H USA employees may participate in educational conferences supported by H USA grant funds as attendees but, if they are attendees, they may not engage in formal or informal promotional activities inside or outside the meeting room(s). It is acceptable for H USA employees not attending the educational conference to conduct appropriate promotional activities outside program meeting rooms, such as at an adjacent exhibit. If no educational grant funds are provided, H USA employees may attend and exhibit at the educational conference.

Contractual Provisions

Educational grants may only be awarded to Conference Sponsors that have entered into a written agreement with H USA. The agreement must require that the Conference Sponsor disclose the following information to all attendees:

- H USA's funding of the educational conference and any significant relationships between the Conference Sponsor and H USA
- Financial or other relationships between individual presenters or moderators and H USA
- Fact that a presenter was suggested by H USA

- Any limitations on information that is presented at the programs, such as data represents ongoing research, interim analysis, preliminary data, or unsupported opinion
- When an H USA product or a competitor's product is to be the subject of substantial discussion, the data must be objectively selected and presented. Both favorable and unfavorable information about the product must be fairly represented and any discussion of the prevailing body of scientific information on the product must be reasonable and
- If applicable, the fact that uses of H USA product(s) that were discussed are not approved by the FDA.

Unacceptable Educational Grants

A grant is not permitted if it is any one of the following:

- Intended as a price term, or offered in lieu of a price concession.
- Intended to encourage off-label use.
- Contingent on the purchase of H USA products.
- Intended to encourage the recipient to use, purchase, or recommend H USA products.
- Intended to reward or compensate the recipient for having purchased, used, or recommended H USA products.
- Made at the request of a healthcare professional (e.g., request to fund a "pet project"). It is acceptable for a healthcare professional to request a grant in his/her official capacity, such as the head of a hospital department.
- Made in return for anything of value provided to H USA by the recipient, with the exception of disclosure in program materials that the program is funded by H USA.

Educational Grants to the Department of Defense Entities

All educational grants to the military must be provided through the Henry M. Jackson Foundation for the Advancement of Military Medicine or similar third-party organizations set up to receive grants on behalf of the Department of Defense. Once grant funds are provided to the grant recipient, including the Jackson Foundation or similar organizations, no one at H USA may control or influence the purposes for which the grant is utilized.

No Promotional Activity

H USA may not engage in any promotional activities, such as presentations by sales representatives, or promotional exhibits, in the same room or in an obligate path to the educational activity, unless the exhibit is within an area that is designated for general exhibits and includes exhibits from different companies marketing alternative or

competing therapies. Materials disseminated in conjunction with the program may not include advertisements for H USA's products.

Relationship to Other Policies

Grants for clinical trials or medical research are not "educational grants" for purposes of these policies, and must be provided in accordance with Section 23, "Clinical Research and Clinical Study Support."

Educational or other speaker events controlled by H USA are not considered "educational grants" for purposes of these policies and must be provided in accordance with Section 15, "H USA-Sponsored Product Training and Education Events."

Electronic Process

All educational grant requests must be entered through the CAP Tool available at <https://usi03-medssoit.wv005.siemens.net/CAP/default.asp?Organization=other>. Requests must be submitted 10 business days in advance to guarantee a response.

The grant request must include a letter on the Conference Sponsor's letterhead that is signed, addressed to H USA, and:

- Describes the purpose/intended use of the educational grant or references other documents attached, such as a brochure, flyer, agenda, or memo that describes the purpose/intended use of the grant. It is not acceptable to list a generic description (e.g., "educational grant") as the purpose of the expense.
- Confirms that the educational grant will be used for educational purposes.
- Confirms that the educational grant will not be used to target the general overhead of any specific Conference Sponsors or for expenses of attendees.
- Acknowledges that H USA may audit or review the use of the educational grant.
- Confirms that H USA's funding and relationship with the Conference Sponsor, presenters, or moderator will be disclosed to attendees.

Record Retention

The Legal Department maintains copies of all contracts and supporting documentation surrounding educational grants for a period of six years or longer if required by law or the Corporate Record Retention Policy.

Audit

All educational grants are subject to audit to ensure compliance with these policies. The government (e.g. IRS) may also request to audit/review educational grant documents.

Massachusetts-specific Policy

NOTE: For all employees working with customers **licensed** in Massachusetts, please see Compliance Manual Section 34, "Requirements when Interacting with Massachusetts Healthcare Professionals."

22. PROFESSIONALS WEEK

Each year national, state, and local professional organizations sponsor “Professionals Week” to increase public understanding and appreciation of the work that various non-physician professionals contribute to the patient care and the healthcare industry. For example, ARST sponsors “National Radiologic Technology Week” in November and ASCLS sponsors “National Medical Laboratory Professionals Week” in April each year. Labs, diagnostic imaging centers, hospitals, and other healthcare companies typically celebrate Professionals Week by offering educational events, holding open houses, providing meals to their staff, giving away prizes or gifts, holding fundraisers, etc.

Our customers may ask H USA to sponsor a Professionals Week by, for example, providing pizzas for a staff luncheon or providing branded promotional items that can be given away as prizes or gifts. While H USA supports the educational purpose and goals of Professionals Week, any financial or other support H USA provides to customers in connection with Professionals Week must be made in accordance with other applicable sections of this Compliance Manual including Section 4, “Drawings and Sweepstakes,” Section 11, “Business Meals,” Section 12, “Business Gifts,” and Section 24, “Providing Medical Textbooks and Other Text Material.”

Meals

H USA may only provide a modest meal during Professionals Week if it is provided in connection with a business presentation of H USA products, disease states relevant to H USA products, medical education, or other legitimate discussions related to H USA products (e.g., a “Lunch and Learn” program).

The business meal must occur in a place and manner conducive to business discussion. The meal should only be provided to staff that actually attend the presentation. For additional guidance on business meals and the documentation requirements, see Section 11, “Business Meals.”

Gifts

Any gifts distributed to customers and their staff during Professionals Week must comply with the requirements set forth in this Manual. For additional guidance and the documentation and approval requirements for gifts, please see Compliance Manual Section 12, “Business Gift,” and Compliance Manual Section 24, “Providing Medical Textbooks and Other Text Material.”

Drawings and Sweepstakes

Drawings and sweepstakes, which offer the opportunity for a customer or a member of its staff to receive something of value from H USA must be carefully reviewed by the Legal Department to ensure that they comply with federal and state law. For further guidance, please see Compliance Manual Section 4, “Drawings and Sweepstakes.”

23. CLINICAL RESEARCH AND CLINICAL STUDY SUPPORT

All clinical research and clinical studies supported by H USA should promote legitimate research goals. A research grant may come in the form of equipment, services and supplies, and/or monetary/non-capital support. H USA may enter into an arrangement to sponsor or authorize clinical research or clinical studies for the purpose of developing clinical information concerning H USA products, both pre- and post-market, provided that the clinical information sought is reasonably necessary to achieve a commercially reasonable business purpose. Support for any research or clinical study cannot be provided with the requirement or expectation that H USA's support will induce or encourage the purchase or order of H USA products. For further guidance regarding the regulatory and operational aspects of initiating and managing clinical collaborations, please see MOR 2.3/05., as well as Compliance Manual Section 33, "Computer Hardware and Software."

Additionally, there may be requirements unique to clinical collaborations that involve international HCPs or that take place outside of the United States. If you are involved in such a clinical collaboration and have questions, please address your questions to Compliance.

When H USA contracts with a healthcare institution for research, the research relationship should be clearly spelled out in a written contract and approved by the Legal Department that, at a minimum, includes:

- A statement of the research or clinical objectives
- A comprehensive written formal contract between the institution and H USA including a research protocol specifying the equipment, services and supplies, and/or monetary support to be provided by H USA to the institution
- Identities of the principal investigator(s)
- Handling of intellectual property rights
- Milestone timing
- Relevance to H USA
- A written budget detailing the financial and other support to be provided by H USA
- A requirement for progress reports and, where applicable, a final written report

The proposed research must be evaluated by and any resulting research agreements must be negotiated and managed by H USA employees who have no role in selling products or services to the research institution.

Recipients of H USA's financial support for research and clinical studies should be made aware that H USA reserves the right to audit the use of its money and will expect documentation, such as progress reports, to show that its financial support has been used properly.

H USA may not sponsor or authorize clinical research that is not intended to, or does not, develop clinical information concerning H USA products. H USA may not compensate a clinical investigator based on the volume or value of business generated or to reward him/her for past purchases. H USA cannot seek to further the pre-approved or unapproved use of H USA devices under the guise of a less-than-adequate study.

“Investigators’ Meetings,” where H USA gathers people doing clinical research studies to discuss the status of their research, are not promotional in nature and must not be utilized for such purposes. Sales representatives must not attend such meetings.

24. PROVIDING MEDICAL TEXTBOOKS AND OTHER TEXT MATERIAL

As described in this Section 24, you may generally provide gifts if they are of modest value and either serve an educational purpose or primarily benefit patients. A “modest” gift should be valued at no more than \$100. However, medical textbooks often cost more than \$100. This Section provides specific procedures permitting limited textbook gifts in circumstances where the textbook can benefit several physicians and the patients they treat.

Medical Textbooks

Medical textbooks may be offered only through Marketing and, textbooks valued at more than \$100 may be provided only to a hospital, practice group, or other entity where the number of physicians in the group ensures that the value of the textbook does not exceed \$100 per physician. A textbook valued at more than \$100 should never be given to only one individual. Note that offering any gift other than a textbook with a value exceeding the \$100 guideline limit, without review and approval by Compliance, is not allowed even if it is provided to a group for use by multiple individuals.

You must follow this procedure carefully for your own protection and for the protection of H USA. Gifts of textbooks are only allowed if you comply with this procedure. Do not procure textbooks on your own through your expense account. You must always consider the retail value of a textbook along with other business gifts and meals in determining if the items provided to any one physician and/or practice could create the appearance of an improper inducement. Also, this Section 24 should not be interpreted as permission to “build a personal library” for any physician or physician practice group.

Other Printed Booklets and Text Materials

Other printed medical booklets and text materials such as review guides, pocket books, and handbooks, etc. may be obtained from Marketing.

Questions and Title Suggestions

All questions regarding availability and title suggestions for textbooks and other printed booklets should be communicated to the Marketing Department.

Prior Review and Approval of All Printed Materials

All booklets and printed materials must be reviewed and approved consistent with H USA policies before they can be distributed. Distribution of any printed material, textbook, or any other publication without proper technical review and approval is a direct violation of H USA’s Code of Conduct.

Federal Government Employees

You may not provide medical textbooks to Federal government employees (e.g., military and Department of Veterans Affairs). See Section 8, “Interactions with Federal Government Employees.”

State Laws and State Employees

There are various state laws that govern conduct with state government employees, such as healthcare professionals who work at state or county hospitals. You should exercise extreme caution before providing medical textbooks to healthcare professionals who may be employees of a state, county, or local government. If you are unsure whether an individual is a state employee, consult the individual, the facility where the individual practices, or the Compliance Intranet site.

In addition, a number of states have recently adopted laws restricting the sales and marketing activities of pharmaceutical and medical device manufacturers. For additional information regarding state laws that govern sales and marketing to our customers, please see Compliance Manual Section 9, “State Laws and State Employees,” and the Compliance Intranet site.

Massachusetts-specific Policy

NOTE: For all employees working with customers located in Massachusetts, please see Compliance Manual Section 34, “Requirements when Interacting with Massachusetts Healthcare Professionals.”

25. COMPLIANCE TRAINING

Within 90 days of being hired, an employee must complete two (2) hours of healthcare fraud and abuse compliance training. The training covers:

- The H USA Sector US Compliance Program
- Proper methods of marketing and selling products that are reimbursed by Government programs
- The employee's personal obligation to ensure that Government-reimbursed products are marketed and sold in accordance with all applicable requirements of the Government programs
- The legal rules and sanctions for violations that relate to products reimbursed by those programs

If a new employee does not complete this training within 90 days of hire, the new employee will be suspended for one week without pay. If, after that one week, the training is still not completed that employee will be terminated.

All employees will receive at least one additional hour of "refresher" training annually.

In addition, all other employees of the H USA Sector US Sales and Service Organization will receive a copy of the Code of Conduct within 90 days of joining H USA.

Certification

All employees will be required to complete a certification, which may be in electronic form, confirming that they have completed the applicable training.

26. REVIEW OF COMPLIANCE TEXT MATERIALS

H USA is committed to appropriate and timely communications to all employees regarding significant changes in the Compliance Manual and the H USA Code of Conduct materials.

H USA will annually, or more often if necessary, review the Code of Conduct, Compliance Manual, and the compliance training texts to determine if revisions are appropriate. Any necessary revisions will be published based on this review.

Note: The official copy of this Compliance Manual, which will be updated regularly, is available on the Compliance Intranet site at <https://intranet.healthcare.siemens.com/cms/ssohq/en/departments/compliance/Pages/compliance.aspx>.

Code of Conduct revisions are distributed to all employees within thirty days of finalizing such changes. Participants must certify that they have received, read, understood, and will abide by the revised Code of Conduct within thirty days after distribution of revisions.

The relevant portions of any revised Sections in this Compliance Manual will be distributed to all employees whose job functions are related to the revised Sections within thirty days of the effective date of the revision.

The compliance training programs are updated as necessary and/or as a result of the text reviews.

27. THE “TELL US” CONFIDENTIAL DISCLOSURE PROGRAM

The “Tell Us” HelpDesk allows employees to disclose, confidentially and without retaliation, to the H USA Compliance Officer any identified issues, questions, or suspected violations of the laws and Company policies, practices, or procedures.

Mechanism

The primary mechanism for the “Tell Us” HelpDesk is a toll-free telephone line (1-800-303-5999) administered by a third-party vendor.

The vendor provides this service twenty-four hours per day, seven days per week. Each report is assigned a Report Control Number and a Pin code, which will be provided to the caller. Callers may be provided a date on which to make a follow-up call for the purpose of receiving a response from H USA Sector Compliance or for the caller to provide additional information. The reports will be transmitted to H USA Compliance.

28. THE “ASK US” COMPLIANCE QUESTION PROGRAM

“Ask Us” is a resource developed by Siemens AG to provide employees around the world with an opportunity to ask compliance questions that arise in a day-to-day business context. The “Ask Us” resource is available to all US-based Siemens employees. Compliance-related questions are submitted online.

The Compliance team at Siemens will consult with subject matter experts at Siemens AG and affiliates and provide you with guidance on how to accomplish your business objectives legally and in compliance with our Business Conduct Guidelines, [https://workspace.siemens.com/content/10002365/DocLib_new/00 Policies and Guidelines/BCG2009 Brochure online en.pdf](https://workspace.siemens.com/content/10002365/DocLib_new/00_Policies_and_Guidelines/BCG2009_Brochure_online_en.pdf), and other Siemens policies.

29. DISCIPLINARY STANDARDS

Compliance is mandatory for all H USA employees. Compliance means adherence to legal regulations, a violation of which can lead to sanctions under criminal or administrative law, as well as adherence to internal rules relating to such regulations.

In accordance with the Performance Improvement Process for Compliance Violations addendum to existing Human Resources policies, as well as other applicable H USA policies, any employee guilty of a compliance violation will be subject to disciplinary consequences because of the violation of his/her contractual duties, regardless of the sanctions stipulated by law.

This addendum is accessible at the following link:

https://livelink-dms.med.siemens.com/basis-//livelink.exe/fetch/2000/6766733/6737006/6736458/6736474/10338457/11070960/Addendum_to_Performance_Improvement_Process.pdf?nodeid=27955842&vernum=-2

Depending on the severity of the compliance violation and the local legal situation, the following disciplinary measures are to be used:

- informal warning
- formal warning
- forfeiture of voluntary remuneration elements/stock awards
- forfeiture of variable pay
- transfer to another position
- dismissal

The following regulations define a process of cooperation between the Compliance Organization and the HR Organization to deal with compliance violations on the corporate level and the local level. A monitoring process will be established to ensure that all compliance violations are followed by disciplinary measures.

General Process

Compliance violations that are handled at the local level will be handled as follows:

The Compliance Officer will inform the Head of the Human Resources Department immediately with a written report summarizing provable facts of any alleged breaches of compliance rules and the severity of the compliance violation.

The Head of the applicable Human Resources Department, together with the employee's manager, will be responsible for ensuring that the necessary and appropriate disciplinary measures are taken to deal with the breaches of compliance. The Head of the Human Resources Department and the employee's manager will also decide whether the employee will be suspended. If there is reason to believe that the employee's manager may also be subject to disciplinary measures, that manager's supervisor will decide together with the Head of the Human Resources Department.

The relevant Business Unit Compliance Officer, as applicable, must be notified by the Head of the Human Resources Department of the discipline imposed. The latter will follow up and document the measure that has been taken.

The Head of the Human Resources Department will inform the relevant Business Unit Compliance Officer, as applicable, about the outcome of any employment law conflict arising from the measures adopted.

Catalogue of Disciplinary Measures in Cases of Compliance Violations

Depending on the severity of the compliance violation and the local legal situation, the following disciplinary measures are to be taken. Deviations are only permissible for legal reasons. Insofar as the implementation of the measures set out below will require the prior change of company regulations and/or conditions of employment, such changes have to be carried out with future effect. Participation rights of employee representatives must be observed. When determining the appropriate disciplinary measure, the relevant Business Unit Compliance Officer's judgment regarding the severity of the compliance violation must be taken into account.

The same disciplinary measures and criteria for their adoption outlined below will apply to a manager who participates in a compliance violation of a supervised employee, or who fails promptly to report or stop a violation of which he/she has been notified. Likewise, a manager's failure to exercise proper supervision will be subject to discipline as outlined below, with the appropriate sanction to depend on the severity of the failure to supervise and applicable legal requirements.

1. Informal warning

An informal warning is only appropriate in cases of slight compliance violations. An informal warning consists of (1) an objection to the employee's behavior and (2) the demand to change his/her behavior in a certain way. It does not, however, include the announcement of further measures (particularly the termination of employment) in case the employee does not change his/her behavior.

2. Formal warning

A formal warning is appropriate for compliance violations beyond slight offenses but not of a severity that justifies more severe sanctions up to the termination of employment. A formal warning consists of (1) an objection to the employee's behavior, (2) the demand to change his/her behavior in a certain way, and (3) the announcement of further measures (particularly the termination of employment) if the employee does not change his/her behavior.

3. Forfeiture of voluntary remuneration elements/Siemens stock awards

If the employee is guilty of a compliance violation warranting more than a formal warning, the forfeiture of voluntary remuneration elements may be appropriate, in addition to a formal warning.

If such disciplinary measure is imposed, the employee will forfeit all or part of the Siemens stock awards that he/she has been granted and that are still in the retention period.

Moreover, he/she will not be granted new stock awards in the relevant grant period following a compliance violation. The same applies analogously to other voluntary remuneration elements.

4. Forfeiture of variable pay

If the employee is guilty of a compliance violation warranting more than a formal warning, he/she may also be required to forfeit all or part of his/her variable pay for a defined period of time, (e.g. the Short-Term Incentive Program, or "STIP") in addition to receiving a formal warning, as far as legally possible under the relevant conditions of employment.

5. Transfer to another position

The employee will be transferred to another position if the compliance violation makes a job change necessary according to the employer's discretion. This measure may be taken in addition to or in combination with the measures set out above.

6. Dismissal

a) Compliance training

Every employee who commits a compliance violation must complete a compliance training course. The Chief Compliance Officer will implement adequate training courses. The employee's manager is responsible for ensuring that the compliance training course is completed.

b) Contractual notice of dismissal

A contractual notice of dismissal is appropriate in cases of compliance violations that do not legally justify a summary dismissal but require a termination of employment and are too severe to be sanctioned solely with – exclusively or cumulatively – a formal warning, the forfeiture of voluntary remuneration elements, the forfeiture of variable pay, and a transfer to another position.

c) Summary dismissal

An employee will be dismissed with immediate effect if he/she has violated his/her contractual duties in a manner that warrants summary dismissal and the employer reasonably concludes that employment should not be continued through the next contractual termination date.

Record Keeping

The Chairman of the Corporate Disciplinary Committee will maintain records of matters that come before it. These records will only be used for internal documentation and documentation vis-à-vis the relevant authorities. They will be handled/deleted in compliance with applicable laws. In addition, a record of all compliance violations warranting a formal warning (or another disciplinary measure in addition thereto) and the disciplinary measure(s) imposed thereafter must be maintained in the employee's personnel file for the period permitted under applicable law. Such records must briefly describe: (1) the compliance violation, (2) the disciplinary measure imposed, and (3) the reason(s) why the discipline was sufficient. It is the responsibility of the employee's manager and the head of the relevant Personnel Department to ensure that an adequate record is created and maintained.

Consequences within The Performance Management Process (PMP)

An employee's compliance violation warranting a formal warning (or another disciplinary measure in addition thereto) will, depending on its severity, have an impact on the employee's capabilities evaluation, income, and development actions in the PMP. Such an employee will be excluded from the following PMP Round-Table Discussion and subject to a bilateral discussion between the employee's manager and the relevant Human Resources Manager.

1. Impact on the evaluation of "Passion"

Compliance violations warranting a formal warning (or another disciplinary measure in addition thereto) have an impact on the employee's capabilities evaluation in the PMP. They are taken into consideration in the overall evaluation of "Passion" which consists of three capabilities, two of them being "Professional Ethics" and "Siemens Values." "Professional Ethics" means "the ability to apply the highest ethical and professional standards and to project personal values, especially honesty and integrity into everything you do." Accordingly, a compliance violation warranting a formal warning reflects a lack of "Professional Ethics." "To live and breathe Siemens Values" requires the employee to act according to the high ethical Siemens standards-of-business conduct. Compliance violations are incompatible therewith. Therefore, compliance violations warranting a formal warning will lead to an overall rating of "Passion" with "unsatisfactory" or "needs improvement."

2. Impact on income actions and statements of potential

An employee who receives a formal warning (or another disciplinary measure in addition thereto) due to a compliance violation will be excluded from a salary increase in the following PMP Round Table. Such an employee will also receive a potential statement of "no further potential." The deletion of the disciplinary measure from the PMP documentation, the employee's consideration in future PMP Round-Table Discussions, the possibility for the employee to be subject to salary increases and to a different potential statement in future PMP Round Tables depend on the severity of the compliance violation, the successful and timely completion of the compliance training course (as outlined in item C above) and demonstrated good conduct shown by the employee thereafter. If local law requires that a disciplinary measure be – depending on the individual case – deleted from the personnel file after some time, it must also be deleted from the PMP documentation simultaneously.

3. Documentation of compliance violations in the PMP feedback dialogue form

The fact that an employee has received a formal warning due to a compliance violation must be documented in the PMP feedback dialogue form. It will be amended accordingly.

Controlling and Reporting

The relevant Business Unit Compliance Officer will report, on a regular basis, all compliance violations that have occurred and all disciplinary measures that have been taken to the Corporate Compliance Office. This information will only be used for internal documentation and documentation vis-à-vis the relevant authorities. It shall be handled/deleted in compliance with applicable laws.

The results of the reports will be used, in an aggregated and anonymous form, for systematic internal reporting on compliance cases that have occurred and disciplinary measures that have been taken. Selected data will also be used for external reporting. The Chief Compliance Officer will detail the future reporting process.

30. PRICE REPORTING TO GOVERNMENT ENTITIES

H USA will report, completely and accurately, cost, price, and sales information about H USA products according to the terms reasonably requested by any federal and/or state government agency relating to a governmental healthcare program.

Definitions

Governmental Healthcare Program – Any plan or program that provides health benefits, whether directly through insurance, or otherwise, which is funded, in whole or in part, by the government of any country or state, including Medicare, Medicaid, Tricare, and the Veterans programs.

General Limits

It is not appropriate for H USA to report or generate, directly or indirectly, inaccurate, incomplete, or intentionally misleading information about costs, prices, and sales for H USA products for use by a Governmental Healthcare Program. Under no circumstances may H USA report or generate false, fraudulent, or intentionally misleading cost, price, or sales information about H USA products for submission to a Governmental Healthcare Program.

Reporting Price Information

All H USA reports of price information provided directly or indirectly to governmental healthcare programs should accurately take into account all pricing information, including, to the extent they exist: (1) price reductions, (2) discounts, (3) free goods contingent upon a purchase agreement, (4) rebates, (5) up-front payments, (6) coupons, (7) goods in kind, (8) free or reduced price services, (9) grants, and (10) other price concessions or similar benefits offered to some or all purchasers.

Reports of price information shall not include (unless specifically requested) the value of: (1) charitable grants or donations, (2) research grants, or (3) educational or fellowship grants provided in accordance with the Compliance Manual.

Submission Process

Any H USA employee who receives a survey or request for pricing information from any government entity should forward that request via facsimile to the Government Compliance Group for completion.

Any H USA employee who reports prices to any agency of the federal government or states must submit that pricing data, along with any information pertaining to that request

(i.e., government instructions for calculating prices) to the Government Compliance Group for approval prior to submitting that information to the government.

Record Retention

Marketing will maintain copies of all price submissions to any agency of the federal government or a state or foreign government. Documents will be maintained for six years following the date of their submission to the government, or longer as required by law.

Questions

Any questions concerning a response to a request for pricing information from a government entity should be directed to Compliance or the Legal Department.

31. REIMBURSEMENT GUIDELINES

Siemens Healthcare Diagnostics Government Affairs & Reimbursement Department, as well as Marketing for Siemens Medical Solutions, USA Inc., is responsible for identifying appropriate procedural, product coding, and reimbursement information for their respective groups. This information is obtained from authoritative sources, such as the American Medical Association, the Centers for Medicare & Medicaid Services (“CMS”), regional and local public contractors (carriers, fiscal intermediaries, and durable medical equipment regional carriers), or private insurance contractors.

It is H USA’s policy that reimbursement information is only derived from these authoritative sources and provided to customers to assist them in understanding and complying with CMS and other insurer’s requirements. H USA employees must adhere to the following guidelines when discussing a reimbursement issue with the customer.

H USA sales associates, distributors, and agents may provide insurance coding, coverage, or payment information for H USA products, if the following requirements are met:

- The coding, coverage, or payment information comes directly from an entity authorized to make such determinations, such as CMS or third-party payers.
- H USA offers the same information, in the same format, to all purchasers or potential purchasers of H USA products.
- H USA does not in any way add to, delete, or modify third-party information and must include a disclaimer on third-party information indicating that the information comes from a third-party and is not advice from H USA.

Consistent with requirements set forth above, H USA may provide the customer with billing codes (CPT and HCPCS) to use when submitting claims to third-party payers for H USA products. You may not offer unsolicited comments regarding the amount of reimbursement a customer may receive for an H USA product or procedure.

It is H USA’s policy to promote products based solely on their efficacy, safety, and cost. You may not offer unsolicited comments regarding the amount a customer might receive in reimbursement from Medicare or Medicaid for an H USA product or a competitor’s product.

You may **NOT** provide personal opinions or interpretations of coding, coverage, or reimbursement information, nor should you offer unsolicited comments about such topics. If you are asked about reimbursement issues not related to specific coding, coverage, and payment by a customer or other individual, you should inform that person that it is against H USA policy to provide reimbursement advice and that the individual should consult an appropriate third-party, such as a Medicare carrier or private insurer.

To ensure that the above requirements are met, all information related to insurance coding must be obtained through or be approved by the Siemens Healthcare Diagnostics Government Affairs & Reimbursement Department or the Marketing Department for Siemens Healthcare. If you have any questions regarding promotion of products that are reimbursed by Medicare or Medicaid, contact your supervisor or the Legal Department.

32. PURCHASING DATA FROM CUSTOMERS

This Section 32 describes the circumstances under which H USA may purchase data from customers. H USA may purchase data that is necessary for reasonable business purposes, such as to support the marketing of H USA products or to demonstrate safety and efficacy. This Section prohibits purchasing data from a customer or potential customer if a purpose of the data purchase is to encourage the purchase, use, or recommendation of H USA products, as this could constitute a violation of the Anti-Kickback Statute. Any data purchase must be at fair market value for data actually used by H USA.

Acceptable Data Purchases

Data purchases include any compiled information offered by a customer that may have commercial value, such as product utilization information. Permissible data purchases and other arrangements are those designed to (1) foster increased understanding of scientific or clinical issues in order to improve patient care and/or (2) provide information not otherwise available to H USA in areas relevant to H USA's business activities. H USA must have a legitimate need for the data and, in fact, use the data for legitimate business purposes.

Any data that is purchased should be de-identified and/or maintain confidentiality in line with state and federal privacy laws.

Data must be purchased at fair market value, compared to data that is similar in quality and quantity. The Legal Department makes the final determination as to the reasonableness of fair market value.

Unacceptable Data Purchases

The following are **NOT** permissible data purchases:

- Intended as a price term or given in place of a discount or price concession
- Purchasing data already available to H USA or data which H USA does not intend to use
- Contingent on the purchase of H USA product(s)
- Purchased at an inflated cost
- Purchased separately if the data is already provided pursuant to another arrangement, such as an administrative fee arrangement
- Designed to substitute for or subsidize activities that are a part of the customer's normal business expenses.
- Intended to provide information in areas that are not relevant to H USA's business
- Intended to induce the customer to purchase or recommend H USA products

All purchases of data from an H USA customer must be supported with a written request and a written contract as described below.

Procedures

The purchase of data from an H USA customer may be initiated by the H USA customer or by an H USA employee. In either case, the requestor must first seek approval to

purchase the data, execute the contract and receive the data, and then process the payment. The data must be received before the H USA payment is processed.

1. Obtain Approval for the Data Purchase

a) Prepare a Written Request to Purchase Data

The H USA employee must request in writing to purchase data from an H USA customer. If a contract has been proposed by the seller, it must be attached to the written request form. The form (attached below) includes:

- Business need/purpose and nature of the data being purchased
- Name, address, and tax ID number of the seller of the data
- Proposed fee to seller (must be fair market value or less)
- Expected delivery date of the data
- Duration of the agreement
- Any other special contract terms
- Attach any supporting documentation and proposed contract as available

b) Seek Approval Signatures on Written Request Form

The supervisor reviews the written request form and any supporting documents and determines if the request complies with H USA policies. If appropriate, the supervisor approves the request and forwards it to the applicable Vice President.

The applicable Vice President reviews the request and all supporting documents for compliance with H USA policies. If appropriate, the Vice President approves the request and forwards it to the Legal Department.

The Legal Department reviews the proposed purchase independently and determines whether to approve the request based on conformance with the law and H USA policies.

c) Prepare a Written Contract

A written contract is required when purchasing data from an H USA customer. If a contract is received from the H USA customer, it is attached to the written request for review by the Legal Department. If the H USA customer provides no contract, the Legal Department will prepare one.

The written contract must include a provision to allow H USA to review the data to ensure that H USA is paying fair market value for the data received. The contract must also indicate that H USA will issue payment upon receipt of the data. All written contracts must be reviewed and approved by the Legal Department prior to committing to the purchase.

2. Contract Execution and Receipt of Data

a) Execute the Contract

The employee requesting the purchase forwards two originals of the written contract to the seller of the data for signature. Once the contract has been fully executed, the seller keeps one original and returns the second to the H USA requestor. The H USA requestor maintains a copy of the executed contract and forwards the original to the Legal Department.

b) Confirm Receipt of Data

The requestor obtains the data from the seller and confirms that satisfies the requirements of the contract. The requestor references the contract on the data documents by including on the data document a statement such as “Data received according to contract dated (date) between H USA and (Organization’s Name).” The requestor signs and dates the note.

The requestor must ensure the data is retained according to the record retention requirements of this procedure. The data must be retrievable at any time upon request for audit requirements.

3. Generate Payment Request

c) Compile Payment Request Package

The H USA requestor (initiator) compiles a complete payment request package that includes:

- Approved written request form “Request for Data Purchase”
- Copy of the executed contract

d) Seek Approval for Payment

The requestor must route the completed payment request package for signature approvals. Accounts Payable will only process the request for payment if all documentation is included and if appropriate approvals are on the forms.

Record Retention

The Accounts Payable Department will maintain the payment request package for a period of six years or longer as required by law or the Corporate Record Retention Policy. The Department requesting the data will maintain the data received for a period of six years or longer as required by law or the Corporate Record Retention Policy.

Audit

All data purchases are subject to audit to ensure compliance with this Section, including proper documentation, spending limits, and company spending policy. H USA may also choose to exercise the contract provision with the Customer that allows review of the services purchased. The government (e.g., IRS) may also request to audit/review data purchases.

FORM: Data Purchase Request

Description of H USA’s business need/purpose and the nature of the data being purchased:

Proposed payment for data (must be fair market value): _____

Expected date data will be received: _____

Name and Address of Organization selling the data:

Tax I.D. Number of Organization: _____

Check if appropriate for this request:

- Attached is a proposed contract from the selling organization
- H USA Legal Department to prepare contract
- Other supporting documents are attached as described: _____

The **REQUESTOR MUST** reference the contract on the data documents by including on the data document a statement such as “Data Received According to the contract dated (date) between H USA and (Organization’s Name).” The requestor must also sign and date the note.

Approvals:

H USA Requestor _____	Date _____
Supervisor _____	Date _____
Vice President _____	Date _____
Law & Patents _____	Date _____

33. COMPUTER HARDWARE AND SOFTWARE

H USA generally may not provide “free” office equipment (e.g., fax machines) to a customer, including standalone computer hardware and software. Computer hardware and software may, however, be provided to the extent that they are physically or operationally integrated into an H USA product.

A particular hardware or software is considered operationally integrated when it is necessary for the operation of the product or system and is ordinarily offered as part of the product or system without a separate charge. Prior to any offer of hardware or software to be provided “free” to a customer (or reimbursement to a customer for such hardware or subject), the offer or program making the offer must be reviewed with the Legal Department.

Clinical Research

When you are interacting with a customer who is involved with a clinical collaboration, you are permitted to provide the customer with computer hardware and software necessary for the clinical collaboration only if such computer hardware and software is returned to H USA upon the completion of the clinical collaboration. To the extent that a clinical collaboration involves multiple studies, and particular computer hardware and software are being used only for a specific study, such computer hardware and software must be returned to H USA upon the completion of that study. For further reference, please see Compliance Manual Section 23, “Clinical Research and Clinical Study Support,” and MOR 2.3/05.

Electronic Interface

H USA may reimburse a customer for all, or a portion of, the cost of an electronic interface between an H USA system and the customer’s electronic information system (e.g., laboratory information system, hospital’s RIS/PACS) if the interface is integral in order for the customer’s system to be able to integrate, communicate, and/or exchange information with the H USA system.

For example, H USA may reimburse a customer for all, or a portion of, the cost of connection to an automation system in the customer’s laboratory because the automation system is an integral part of the H USA system in that it is required to allow efficiencies in routing samples for testing.

In all cases, reimbursement for the interface must be disclosed to the customer and may be considered a discount, rebate, or reduction in price to the underlying H USA product. H USA must advise the customer of its obligation to properly disclose and appropriately reflect any discounts or price reductions triggered by H USA’s provision of free hardware or software.

34. REQUIREMENTS WHEN INTERACTING WITH MASSACHUSETTS HEALTHCARE PROFESSIONALS

Massachusetts has created a Marketing Code of Conduct that applies to all medical device companies that interact with Massachusetts Healthcare Professionals. This section of the Compliance Manual describes those requirements that should be followed **in addition to** the requirements listed throughout the rest of the manual when interacting with Massachusetts Healthcare Professionals. It is important to note that these restrictions apply to **all** interactions with Healthcare Professionals **licensed** in Massachusetts, regardless of whether those interactions occur in Massachusetts or outside of Massachusetts.

“Massachusetts Healthcare Professionals” **are**:

- Persons licensed to provide healthcare in Massachusetts, which are (1) physicians, (2) physician assistants, (3) advanced practice nurses, (4) certified nurse-midwives, (5) nurse professionals, (6) psychiatric nurse mental health clinical specialists, (7) dentists, (8) optometrists, and (9) podiatrists.
- Group practices
- Office staff

“Massachusetts Healthcare Professionals” **are not**:

- Hospitals
- Healthcare professionals who are full-time H USA employees or members of the company’s Board of Directors

CHARITABLE CONTRIBUTIONS (See also Compliance Manual Section 3)

You may only make the following charitable contributions to Massachusetts entities:

- Financial support to entities that have been classified by the Internal Revenue Service as “501(c)(3)” entities.
- Product donations for the provision of charity care to patients, regardless of the tax status of the entity.

BUSINESS MEALS (See also Compliance Manual Section 11)

You may pay for occasional, modest meals when meeting with Massachusetts Healthcare Professionals. The following rules apply:

- All meals must be provided with an H USA representative present or in connection with an informational presentation by an H USA representative.

- All meals must be provided in the office setting, the hospital setting (including a restaurant located in a hospital), or an H USA specialized training facility.

These restrictions apply with respect to **all** meals, including those provided in connection with H USA-Sponsored Product Training & Education Events, meals provided in connection with Sales and Promotional Meetings, and meals provided in connection with Site Visits, Plant Tours, and Road Shows.

H USA-SPONSORED PRODUCT TRAINING & EDUCATION EVENTS (See also Compliance Manual Section 15)

Payment will only be made for travel, lodging, and other expenses associated with H USA-Sponsored Product Training programs for Massachusetts Healthcare Professionals if such payments are paid pursuant to and described under a written purchase agreement for the product.

PAYMENTS FOR SPEAKERS, CONSULTANTS, ADVISORY BOARDS, AND OTHER FEE-FOR-SERVICE ARRANGEMENTS (See also Compliance Manual Section 16)

You may reimburse consultants for their out-of-pocket expenses associated with providing consulting services, which could include the cost of meals. Accordingly, if a Massachusetts Healthcare Professional is serving as a consultant, you may take him/her to dinner; however, the Massachusetts Healthcare Professional should pay on a separate check and submit the expense for reimbursement.

GRANTS FOR CME, CEU, AND THIRD-PARTY EDUCATIONAL CONFERENCES (See also Compliance Manual Section 21)

Modest Meals & Hospitality

You may not make direct payments for meals at a CME event or third-party educational conference or professional meeting. (A CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by H USA toward meals for all participants.)

Faculty Expenses

You may not provide funding to compensate for the time spent by a Massachusetts Healthcare Professional participating in any CME event, third-party scientific or educational conference, or professional meeting.

You may, however, compensate or reimburse a Massachusetts Healthcare Professional 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. Such payments must be: (1) reasonable, (2) based on fair market value, and (3) comply with the standards for commercial support established by ACCME or a relevant accreditation entity.

Venue

You may only support CME events or other third-party educational conferences or professional meetings held in Massachusetts or at which Massachusetts Healthcare Professionals are in attendance, to the extent that they are held in a venue that is appropriate and conducive to informational communication and training about medical information.

TRACKING AND DISCLOSURE REQUIREMENT

Massachusetts also requires you to track and annually disclose to the state the value, nature, purpose, and recipient of any fee, payment, subsidy, item of value, or other economic benefit valued at \$50 or more provided to “Covered Recipients.”

“Covered Recipients” **are**:

- Massachusetts Healthcare Professionals
- Hospitals
- Nursing homes
- Pharmacists
- Health benefits plan administrators

“Covered Recipients” **are not**:

- Employees of H USA
- Consumers who purchase H USA products
- Health insurers
- Distributors
- Pharmacies

As noted above, **all** payments or items of value of \$50 or more must be tracked and disclosed. There are some exceptions. These are:

- Payments to Covered Recipients associated with clinical trials and genuine research where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new medical device or “new use” or similar marketing or labeling claim requiring FDA approval.
- The provision of demonstration and evaluation units to Covered Recipients.
- The provision of in-kind items to Covered Recipients used for the provision of charity care.
- Confidential price concessions, such as rebates and discounts.
- Payments to CME or other third-party scientific, educational, or professional meeting organizers, **unless** the meeting organizer is a Covered Recipient.

- Payments to Massachusetts Healthcare Professionals in connection with a market research study in which the individual is unaware of H USA's involvement (e.g., blinded study).
- Charitable donations made to an organization that is not a Covered Recipient and that does not directly or indirectly benefit a Covered Recipient.

To assist you in determining whether the cost of a meal is modest, the Massachusetts Office of General Counsel highlights the following example:

- A meal is provided in a hospital setting (in compliance with Massachusetts regulations). Seven people (6 HCPS and 1 Rep). In order to determine the correct reporting amount, you divide the total bill by the number of HCPs only (i.e., you do not include H USA employees).

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