

Service Area: Corporate Compliance	YALE NEW HAVEN HEALTH POLICIES & PROCEDURES		
Title: Interactions with Vendors			
Date Approved: 3/26/2019, 04/27/2021		Approved by: System Compliance Committee	
Date Effective: 3/26/2019, 04/29/2021		Date Reviewed/Revised: 03/26/2019, 4/15/2021	
Distribution: MCN Policy Manager		System Policy Type (I or II): Type I	
Supersedes: Gifts & Gratuities; Gifts & Business Courtesies from Vendors Guidelines; Gifts & Gratuities; BH - Gifts & Gratuities II.D.5; YNHH - Gifts to Employees NC:G-5; GH-B02-Gratuities – Tipping			

PURPOSE

The purpose of this policy is to provide guidance regarding appropriate interactions of workforce with vendors; minimize influence of vendors on the business decisions of workforce and the practice patterns of YNHHS professionals; and support safety and privacy of patients.

This policy should not be considered exhaustive. Rather, it provides guidance for various common circumstances and it sets the standard for all who represent YNHHS. Any question regarding interactions with vendors should be directed to a supervisor or the Office of Privacy and Corporate Compliance (OPCC).

APPLICABILITY

This policy applies to Yale New Haven Health System (YNHHS), and each of the affiliated entities including, but not limited to HSC and Grimes controlled directly or indirectly by YNHHS, including each affiliated hospital (Bridgeport Hospital, Greenwich Hospital, Yale-New Haven Hospital, Lawrence + Memorial Hospital, Westerly Hospital, and any other hospital that affiliates with YNHHS) and other providers (including but not limited to Northeast Medical Group and Visiting Nurse Association of Southeastern Connecticut) and each of their subsidiary entities.

DEFINITIONS

- A. Delivery Network** – For the purposes of this policy, HSC, Grimes, Bridgeport Hospital, Greenwich Hospital, Yale-New Haven Hospital, Lawrence + Memorial Hospital, Westerly Hospital, Northeast Medical Group Visiting Nurse Association of Southeastern Connecticut, Home Care Plus, and each of their subsidiary entities, as well as Provider Service Agreements (PSA).
- B. Fair Market Value (FMV)** – A value or range of values that results from commonly accepted valuation principles and/or from data that establishes what compensation would be in a similar transaction, but in which parties are not in a position to refer or otherwise generate additional business for each other.

Interactions with Vendors

- C. **Gifts** – Item(s) of value given to someone for their benefit and something of equal value is not provided in exchange. The term includes, but is not limited to pens, notepads, mouse pads, memory sticks, article reprints, coffee mugs, meals and entertainment, travel, food, cash, equity, gift cards, or other ownership interest.
- D. **Occasional** – Not more than quarterly and not on a general or routine basis.
- E. **Vendors** – Entities and persons that have or are seeking to enter into business relationships with YNHHS (e.g., to provide any equipment, product, supply, facility, item or service for which payment may be made, including but not limited to a pharmaceutical product, medical device, or other clinical equipment, product, or supply), as well as the representatives and agents of such entities or persons.
- F. **Workforce** – YNHHS employees (regardless of employment grade/level or FTE status – i.e. exempt, non-exempt, per diem, casual, full-time, voluntary, etc.), including employed medical staff members, nurses, Advanced Practice Providers (APPs), pharmacists, volunteers, residents, students, trainees, and those with a contractual relationship that must abide our YNHHS policies and procedures, including but not limited to PSA agreements.

POLICY

It is the policy of YNHHS that interactions with vendors comply with applicable law, meet ethical standards, avoid or minimize conflicts of interest, protect patient confidentiality, and promote fair and open dealings.

PROCEDURES

A. **Gifts From Vendors to YNHHS**

1. Vendors may seek to cultivate relationships with healthcare providers by offering gifts, gratuities, entertainment, and other items and services of value. These activities have a high potential for fraud and abuse and raise anti-kickback and conflict of interest concerns. If even one purpose of the offer of an item or service is an award or retention of business that is reimbursable by any federal healthcare program, the arrangement potentially violates the federal Anti-kickback Statute.
2. To avoid the risk of bias in decision-making, it is the YNHHS policy that workforce **may not** accept any gifts, regardless of value, from any vendor, except as defined in paragraph B(1)(b). Gifts include cash in any form, cash equivalents such as gift certificates.
3. Workforce may not participate in any vendor survey that provides an honorarium in exchange for completing the survey. If the survey is sent via email, the workforce member needs to unsubscribe and notify OPCC by emailing compliance@ynhh.org.

B. **Meals or Other Food from Vendors to YNHHS**

1. **On-site**
 - a. Vendors may not provide or fund (and workforce may not accept) meals or other types of food or drink.

Interactions with Vendors

- b. It is customary for vendors to offer perishable items such as fruit baskets, cookies, candy, and flowers from Thanksgiving through the end of the calendar year. These types of gifts are permitted so long as they are only accepted during this season, are not valued more than \$50 and are shared amongst the staff in the department.
2. Off-site
 - a. Workforce are strongly discouraged from attending promotional speaking events sponsored by industry at non-YNHHS sites. If they attend, they have to pay for their own food and drinks.
 - b. Invitations for industry sponsored dinners or social events may not be accepted at any YNHHS location. If the invite is mailed to a department, it may not be posted or forwarded, hardcopy or electronic, to any department or member of the workforce.
 - c. Vendors may not provide or fund (and workforce may not accept) meals outside of YNHHS sites other than at a vendor's office premises per the contract terms. (Please review Section G for further information).

C. Vendor-sponsored Entertainment

1. Gifts such as a pair of tickets or invitations to sporting events, theatrical events, or golf outings unaccompanied by the host may not be accepted. However, if offered by a vendor, a member of the workforce may purchase his/her own tickets at face value and provide personal transportation to and from an event or activity.
2. Vendors must never be solicited by the workforce to pay for any entertainment events or activities (for example, any of the above illustrative events or activities, retirement parties, or holiday parties). Please refer to the YNHHS Solicitation and Distribution Policy for more information.
3. Inclusion of a workforce member's spouse or other guests is not appropriate. Offering a "take-out" meal (such as "dine & dash" programs) is not permissible.

D. Site Access by Industry Representatives

Please review **Vendor Visitation Policy**

1. Sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment.
2. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for such purposes as:
 - a. Service training of workforce for research or clinical equipment of devices already purchased.
 - b. Evaluation of new purchases of equipment, medications, devices, or related items.
 - c. Appointments for these purposes may be made

Interactions with Vendors

3. All vendor representatives must be fully registered and signed into the appropriate vendor management system upon each visit to the hospital. Representatives are not allowed to conduct business at YNHHS without full registration in the vendor management system.
4. When fully registered and upon signing into the system upon each visit, the Vendor representative will then be allowed to print a vendor badge with photo ID, that must be worn visibly on a part of the clothing located above the waist. If the kiosk is unable to print the badge, the vendor will need to use the mobile application. Those representatives who are witnessed not wearing a badge will be questioned by workforce, advised of the policy and immediately referred to the facility's Procurement Coordinator or other Supply Chain Management workforce.

E. Participation in Industry-Sponsored Programs

1. Speaking for Industry

- a. The position of the Association of American Medical Colleges (AAMC) is that participation by faculty in industry-sponsored speaker bureaus should be strongly discouraged.
- b. Workforce is not permitted to participate in the following activities:
 - i. Industry-sponsored "speaker bureaus" (i.e., contractual relationships to give talks) in which the topic(s) are determined and/or the content is provided by the company. Please review #4 below for clarity on speaking engagements.
 - ii. Dedicated marketing and training programs designed solely or predominately for sales or marketing purposes.
- c. Workforce may speak at an industry-sponsored program only if all of the following are met:
 - i. The workforce member retains full control and authority over the meeting or lecture's content, including slides and written materials that the workforce member presents and does not allow such communications or presentations to be subject to prior approval by any commercial interest;
 - ii. A company does not have the contractual right to dictate what the workforce member says;
 - iii. The workforce member is not permitted to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the company's contribution of funds or services;
 - iv. The workforce member must explicitly describe all of his or her relevant financial interests (recent, existing, or planned) to the audience prior to the lecture;
 - v. The arrangement complies with YNHHS's policy on conflict of interest and the workforce member must disclose his/her relationship.
 - vi. All speaking engagement requests need to be reviewed with the workforce member's direct supervisor and approved by the workforce member's Vice President or above;
 - vii. Fair Market Value (FMV) analysis must be obtained from the vendor to ensure that compensation is just and reasonable.

2. Consulting for Industry

- a. Workforce members may consult with industry to provide scientific advice, provided:
 - i. Payment is reasonable; Fair Market Value (FMV) analysis must be obtained from the

Interactions with Vendors

- vendor and provided to management at time of approval.
- ii. The arrangement is governed by a written agreement specifying the service(s) to be provided.
- iii. The arrangement complies with the YNHHS Conflict of Interest policies and the workforce member must disclose his/her relationship.
- iv. All consulting requests need to be reviewed with the workforce member's direct supervisor and approved by the workforce member's Vice President or above.
- v. The "Industry Engagement Checklist" (Attachment A) must be completed by the workforce member to ensure that all the above compliance requirements are met. Please retain a copy of the Checklist in accordance with the YNHHS Document Retention and Disposition Policy.
- b. Vendors have been known to compensate providers for time spent listening to sales representatives market products. In some cases, these payments are characterized as "consulting" fees and may require providers to complete minimal paperwork. Other companies pay providers for time spent accessing websites to view or listen to marketing information or perform "research." All of these activities are highly suspect under the Anti-kickback Statute, are highly susceptible to fraud and abuse, and are therefore strictly prohibited.

3. **Non-Industry Speaking Engagements**

- a. Workforce members may engage in speaking for not-for-profit organizations, associations such as the Connecticut Hospital Association (CHA), etc., provided:
 - i. All speaking requests need to be reviewed with the workforce member's direct supervisor and approved by the workforce member's Vice President or above.
 - ii. The arrangement complies with the YNHHS Conflict of Interest policies and confidentiality policies. The workforce member must disclose his/her relationship as required under this policy.

4. **Understanding the Differences: Industry Speaking Engagements vs. Industry Speaker Bureau Participation (Speaker Programs)**

Industry Speaking Engagements	Industry Speaker Bureau Participation (Speaker Programs)
Permitted as long as:	Prohibited
Workforce member retains full control and authority over the meeting or lecture's content. Company does not have the contractual right to dictate what the workforce member says.	Contractual relationship to give talks in which the topic(s) are determined and/or content is controlled by the company. Contract terms include at least 1 year commitment, maximum number of talks and participation in mandatory speaker training .
Venue varies , i.e. Conferences, Grand Rounds, etc.	Venue is typically a local, fancy restaurant or a physician's office.
Workforce member is not required by the industry sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the industry sponsor contribution of funds for services.	Vendor Representative/Marketing advertises the speaker program to other healthcare providers in the local area.
No minimum attendance required.	Minimum number of prescriber RSVPs required in order for the program to be held.
Any Honorarium paid is assessed as Fair Market Value.	Honorarium ranges \$1k-\$3k/per talk.
Could be for an accredited or certified continuing education program.	Not certified as an accredited or certified continuing education program.

F. Accepting Unrestricted Grants from Industry

1. Unrestricted funds from industry may be used to support individual lectures by faculty from other institutions, provided the sponsoring YNHHS department has complete control over the choice of speaker, the setting, invitations to attendees, and other arrangements.
2. Scientific or medical professionals representing the sponsoring company may attend the program, but they may not engage in marketing activity and no company or product literature or exhibits may be distributed or displayed. However, the company's support should be publicly disclosed and acknowledged.
3. Industry support of medical educational programs involving more than an individual lecture is addressed in the CME Commercial Interest policy.

G. Vendor Sponsored Training and Education

1. From time to time it may be necessary for a vendor to provide on-campus support or training related to a product or service that it currently furnishes to YNHHS or to a product that YNHHS has purchased. Vendor sponsored training and education should be conducted on or near the campus of YNHHS unless the training is consistent with the contract terms and requires staff to participate in training offsite. With regard to vendor supported training and education, please follow the table below:

If....	Then....
The training is directly related to a product or service sold by the vendor and currently provided to YNHHS pursuant to a written contract.	<p>Workforce may participate in vendor sponsored training, however meals cannot be provided. The request for the training/education session must be approved by the Vice President or above.</p> <p>The training cannot be in the form of an industry-sponsored speaker program, which are non-CME. Speaker programs are prohibited at any YNHHS location.</p> <p>If on-site, vendors must register through vendor management system and wear appropriate identification consistent with YNHHS Vendor Visitation policy</p>
The training is specifically addressed in a written contract between YNHHS and the vendor.	Training is conducted consistent with the terms of the written contract.
The training is to orient and advise physicians and clinical staff on the proper use or calibration of a product that has already been acquired by YNHHS.	<p>The vendor is present as a consultant and must solely advise on the specific device and should not be allowed to market other products and not be involved in clinical decision making.</p> <p>Attending physicians must ensure that vendor involvement in any clinical activities is disclosed to patients verbally and in writing and patient's consent must be documented in Epic.</p>

H. Vendor Site Visits, User Meetings, Focus Groups, & Presentations (off-campus)

1. From time to time, vendors may organize meetings for their customers to become further acquainted with the vendor's products and service and to meet other users of the vendor's products and services to identify or compare best practices. These activities traditionally take place off-campus and include travel, lodging, and meal expenses. With regard to such activities, please follow the table below:

If....	Then...
If a member of workforce is:	Travel expenses and food and drinks may be

Interactions with Vendors

<ul style="list-style-type: none">• Presenting at a conference;• Participating in a meeting for the purpose of sponsored research protocol review• Participating in a user group meeting (i.e. focus group) hosted by a vendor with whom we have a signed written agreement;• Participating in a vendor site visit to evaluate new products, technologies, strategic relationships, or qualify a vendors and/or product for an authorized bid event.	<p>accepted.</p> <p>The appropriate Senior Leadership (Vice President or above) will determine whether the amount of time engaged in substantive matters predominates over an incidental recreational or entertainment activities.</p> <p>The workforce member shall make available any material supporting the itinerary of the trip.</p> <p>Travel expenses and reimbursement may not be extended to the workforce member's spouse or family member.</p>
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2. Senior Leadership will be conscientious of the appearance of being influenced in any decision.

I. Attending Organizations & Associations Meetings/Conferences

1. Members of the workforce are permitted to accept meals that are being provided by an organization or association. Examples include Connecticut Hospital Association. American Medical Association, etc.

J. Items for the Benefit of the Patient

1. Vendor donations to Delivery Networks for patient items, (i.e. glucometers, infant formula) must be made to the Delivery Network Development/Foundation Office as a gift in-kind donation. Department Management is not permitted to solicit such items from vendors for patients.

K. Endorsements

1. There will be no endorsement by YNHHS for any vendor in exchange for a donation or grant, nor will YNHHS provide any other special benefit in return for the donation.

L. Responsibility

1. It is the responsibility of the department directors and managers to enforce this policy within their respective departments. Any violation of this policy may be subject to disciplinary action up to and including termination.
2. Violations need to be reported immediately to the OPCC and the NEMG Chief Medical Officer, if it pertains to an NEMG provider.
3. For issues related to interactions with vendors that are not addressed in this policy, contact the OPCC at (203) 688-8416 or compliance@ynhh.org
4. Situations involving a gift, favor, or interaction which appear to improperly influence workforce should be reported to the appropriate Administrative Supervisor, Human Resources Department, OPCC, or through the Corporate Compliance Hotline [1-888-688-

7744 or www.ynhhscomplianceprogramhotline.com]

REFERENCES

AAMC Report on Industry Funding of Medical Education

CFR 1001.952

Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers – April 2003

OIG Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries – December 2016

OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries – August 2002

OIG Special Fraud Alert: Speaker Programs – November 2020

PhRMA Code on Interactions with Healthcare Professionals – July 2002

Section 1128A(i)(6) of the Act; 42 CFR 1003.101

Section 1128A(a)(5) of the Social Security Act

RELATED POLICIES

YNHHS CME Commercial Interest Policy

YNHHS Document Retention and Disposition Policy

YNHHS Solicitation and Distribution Policy

YNHHS Travel and Business Expense Policy

YNHHS Vendor Visitation Policy

ATTACHMENTS

A. Industry Engagement Checklist

Interactions with Vendors

Attachment A: Industry Engagement Checklist

A copy of the contract must be provided with this document. You cannot commit to participation without prior approval.

Employee Name, Job Title	
Department	
Manager	
Today's Date	
Engagement Terms along with time commitment	
Program/Company	
Description of Services requested (i.e. Advisory Board, Speaker, etc.)	
Anticipated Benefit to YNHHS, if applicable	
Compensation Details	<input type="checkbox"/> FMV has been obtained from vendor and is attached here for reference.

If applicable, I certify that:

- ☐ this activity will not take place during my regularly-scheduled YNHHS work hours, unless permitted by management.
- ☐ the contract for this activity clearly states that participation in this engagement has not been determined in a manner that takes into account the volume or value of any business otherwise generated between you and the company and shall not obligate you to purchase, use, recommend, or arrange for the use of any product (s) of the company or its affiliates.

All Industry Engagements must be approved by your Vice President or above in advance of participation. If approved, the Conflict of Interest survey must be completed/updated within 30 days to include the newest engagement. Link to survey: <https://ynhh.coi-smart.com/login.php>

Please retain a copy of this checklist in accordance with the YNHHS Document Retention and Disposition Policy.

Vice President Approval Signature: _____ Date: _____