

Title:

Vendor Access / Conduct

Department:

Compliance / Supply Chain

Management

Effective Date:

4/2022 Reviewed:

Previous Version(s):

5/08, 2/12, 8/16, 8/17, 5/19, 8/21

Policy & Procedure

Replaces:

Vendor Access

The reader is cautioned to refer to the Central Document Database for the most current version of this document and not rely on any printed version.

| Approval | Signature: | Ray Vara | | |
|----------|-----------------|------------------|--------|---|
| Name: | Ray Vara | | Title: | President & Chief Executive Officer |
| Approval | Signature: | Dave Stumbaug | h | |
| Name: | Dave Stumbaug | gh | Title: | Vice President, Supply Chain Management |
| Approval | Signature: | Katie Shigemitsi | u | |
| Name: _ | Katie Shigemits | u | Title: | Compliance Officer |

Approved by the HPH Compliance Committee on April 13, 2022

Scope:

The purpose of this document is to provide guidance and instructions for sales representatives and vendors who are doing business or intend to do business with Hawai'i Pacific Health (HPH), which includes Kapi'olani Medical Center for Women & Children (KMCWC), Hawai'i Pacific Health Medical Group (HPHMG), Kaua'i Medical Clinic (KMC), Pali Momi Medical Center (PMMC), Straub Medical Center (SMC), and Wilcox Medical Center (WMC). It is also intended for all employees, Hawai'i Pacific Health Medical Group (HPHMG) Providers, and independent contractors (hereinafter referred to collectively as "Employees") of Hawai'i Pacific Health.

This document applies to:

- Conduct of Employees with pharmaceutical, biotechnology, medical device, and/or any other supplier of a product or service related entities and their employees, representatives and other agents (hereinafter referred to collectively as "Vendors") both on and off-premises owned or leased by HPH.
- Conduct with Vendors whether or not the particular Vendor entity actually does business with HPH.

Statement:

This document is intended to provide parameters for appropriate decision-making regarding the acceptance or provision of business gratuities, gifts, activities and courtesies and other interactions between Employees and Vendors. All Employees shall receive training regarding potential conflicts of interest in interactions with Vendors. Any questions as to whether a particular collaboration, interaction, relationship, gift, or social occasion would be appropriate in a specific circumstance should be directed to the Compliance Department.

Federal and state laws and regulations (anti-kickback, Stark, and civil monetary penalty statutes and regulations) prohibit the acceptance of any item of value (remuneration) made directly or indirectly, in case or in kind, that may induce or appear to induce the purchase, recommendation to purchase or referral of any kind of health care goods, services, or items reimbursed by a federal or state health care program such as Medicare and Medicaid. Consequently, the acceptance of any gifts or business

courtesies from any third parties with whom HPH conducts business or who are seeking to do business with HPH may implicate federal and state prohibitions.

Gifts from Vendors are prohibited regardless of any value because even gifts of nominal value may be viewed as influencing or potentially influencing Employees in the conduct of their duties or responsibilities. Gifts that are impermissible to Employees are also impermissible when given to family members or guests of the Employees.

HPH is an Integrated Delivery Network (IDN), and is a member of a Group Purchasing Organization (GPO). The GPO agreements for supplies, equipment and services will be given preference when choosing a vendor. GPO contracted vendors will be seen and products evaluated in accordance with this policy. Non-GPO contracted vendors will not be seen, nor will their products be evaluated or used in the facilities unless a contract for that commodity has been established or the Vice President/Director of Supply Chain Management or the Materials Manager has approved an exception.

Vendors without a contract with this GPO, who wish to do business with HPH facilities, should contact the Director of Supply Chain Management or Materials Manager for the process of submitting information for evaluation.

Definitions:

Gift: Anything of value an Individual receives from a Vendor for which the Individual

has not paid or for performed services in a manner that is routine in commercial

transactions. (See Item I.A.2 below)

HIPAA: All Vendors agree to comply with all applicable federal and state laws concerning

privacy, security and confidentiality of patient health information, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

and regulations issued there under.

Vendor: Pharmaceutical, biotechnology, medical device, any other supplier of a product

or service related entities and their employees, representatives and other agents. Non-typical Vendors such as, but not limited to, consultants and auditors are also classified in this definition. *Employees, practicing physicians, student interns,*

patients and their visitors are not considered Vendors.

Policy / Procedure:

I. Policy

A. Gifts from Vendors:

- 1. Acceptance of Vendor gifts within the facility (and facility-sponsored activities) as defined in this policy is prohibited.
- 2. Prohibited gifts include, but are not limited to: cash in any form, cash equivalents such as gift certificates, property or the use of something of value. Gifts can also include meals, goods; hospitality; services; travel, and travel expenses; the use of something of value, such as a vacation home; tickets or admission to events or functions, including but not limited to sporting events, cultural events, and social entertainment; payment of obligations; and any other items of value.
- 3. Gifts and promotional items excluded from this policy include:
 - a. product samples intended for patient use;
 - b. patient education material that directly benefit patients; and

- c. loan of a device for a trial period not to exceed ninety (90) days for the purpose of evaluating the device (only if coordinated through Supply Chain).
- 4. Employed staff acting on behalf of HPH may not accept meals or entertainment from any vendor on or off campus.
- 5. In lieu of gifts to individual departments, vendors may choose to provide donations to any designated entity Foundation within HPH. All donations will be coordinated through the relevant entity Foundation Directors for allocation to the appropriate accounts.

B. Exception(s):

- 1. The exception applies to gifts that can be accepted by an HPH affiliated Foundation, which can ensure appropriate stewardship of the gift while simultaneously maintaining an arms-length between the Vendor and the direct provider so the provider may maintain control and make decisions without being influenced by the gift. Contact your entity Foundation Director to determine if the gift may be accepted by the Foundation.
- General professional conferences and seminars that offer meals, promotional items or door prizes may be accepted as long as such items are offered to all conference or seminar attendees. These items are considered to be included in the conference/seminar registration fees.
 - a. What is considered a "general professional conference or seminar"?

Meetings or conferences sponsored by a professional association, institute of higher learning or other entity whose purpose is to promote health care and/or education rather than to manufacture, consult, sell or distribute products or services that might be used by health care providers or patients will generally be considered "general professional conferences or seminars".

b. What is NOT considered a "general professional conference or seminar?"

Generally, a gathering is not considered a "general professional conference or seminar" if it is:

- sponsored or underwritten by a Vendor;
- organized for the purpose of promoting use of a Vendor's product(s) or service(s); and
- held on an invitation-only basis and is not open to general registration.
- invitation-only gathering held at restaurants rather than a conference facility are particularly suspect.
- 3. It is recognized that Employees within HPH may, in the course of their leadership roles in non-profit professional and scientific organizations, be expected to participate in programs, meetings and events that involve Vendor relationships. Employees should use discretion in participating in these events. However, Vendors are not permitted to purchase tickets to fundraising events and gift tickets to Employees.
- 4. Vendor support for research related activities occurring throughout HPH must be processed through the HPH Research Institute.
- 5. Vendor support for HPH sponsored continuing medical education (CME) is processed through the individual HPH entity's CME coordinator to ensure compliance with the Accreditation Council for Continuing Medical Education Standards.

6. Visits to vendor sites for training are acceptable if the cost of such training visits is included and itemized in the quotation and included in the signed final contract. Vendor site visits for the evaluation of Vendor products and/or services are sometimes appropriate parts of the purchasing decision. When such visits are necessary, Executive Management must approve the visit and the visit must be paid with department / administrative funds. Vendor support for such trips is prohibited.

II. Procedure

A. Vendor Access

- 1. All Vendors are required to comply with the HPH COVID-19 Vaccination Program policy when providing services to HPH, an HPH affiliate or its patients within certified hospital space, as defined in Section VI.A of that policy. Please refer to Section IV of the HPH COVID-19 Vaccine Program policy for more information.
- 2. All approved Vendors visiting our hospital facilities are required to register on our vendor credentialing system. Those who choose not to register, may still conduct business with HPH, however, they may not physically visit HPH facilities.

a. Requirements for Access

All vendors are expected to abide by HPH Standards of Conduct, HPH COVID-19 Vaccine Program policy and when applicable, Medical Staff regulations as prescribed at each facility. Vendors are also expected to complete additional requirements which may include but are not limited to annual health screening obligations, HIPAA training, and service / product competencies.

b. Check-In

Vendors registered in Reptrax must <u>check-in</u> on the HPH vendor credentialing system at the designated kiosk area at each facility upon arrival at the hospital facility. A badge will be issued only after check-in and only for the day of the visit. Upon leaving the facility, the Vendor must also <u>check-out</u>. Failure to follow procedures will affect the Vendor compliance score. Compliance scores of less than 90% will result in a sales representative's loss of access to all facilities. Compliance scores are tracked in the vendor credentialing system.

c. Sales Representative Badges

Vendors must wear an HPH identification badge as delineated by this policy even when their own company identification is worn. The badge must be visible at all times.

d. Appointments

Vendors will not be seen without an appointment. Appointments must be made in advance. Drop-ins or "cold calls" will not be tolerated unless there is an urgent or compelling reason. Wandering around the department or waiting for an unscheduled visit with the physician or hospital staff is prohibited.

- e. At the areas where Reptrax kiosk is not available (includes satellite locations)
 - Vendor/Contractor representatives must report to the front desk, vendors must check-in to the credential system online or via the mobile application where Vendor's compliance with HPH COVID-19 Vaccine Program policy or other requirements will be validated.

- ii. Once Vendor/Contractor's compliance with HPH COVID-19 Vaccine Program policy or other requirements is validated, Vendor/Contractor representative will be issued a badge. Vendor/Contractor badge will be worn at all times while conducting business in the medical center.
- iii. At the end of the visit, the vendor/contractor representative will return to the front desk, sign out, and return the vendor identification badge.
- iv. Vendors/Contractors will not be allowed to visit any department on a walk in basis.
- v. Prior authorization (appointment) will be required for any visitation to any department in the clinic.

3. Vendor Solicitation

- a. Vendors are prohibited from soliciting on premises. Materials advertising products or services may not be distributed on hospital grounds without express consent of Administration, Human Resources or Compliance.
- b. Any vendor product or material left on campus without the express consent of Administration, Human Resources or Compliance shall be removed and discarded without notice to vendor.

4. Exceptions

Vendors/Contractors that have been contracted to perform any type of maintenance, repair work or alterations to the facility must check-in with Facilities Management. If work is to be scheduled for after hours, Security must be notified.

5. Operating Room (OR) Vendors

Additional procedures have been developed specifically for those who supply or participate in procedural cases in the Operating Rooms. Please see the OR Business Manager or Director for additional procedures and requirements.

6. Product Introductions, Changes and Upgrades

- a. Vendors will introduce any new, changed, or upgraded products through the Director of Supply Chain Management or Materials Manager or designee(s) prior to introducing any product to the facility for approval.
- b. Products may be introduced directly to the OR Director/Business Manager (or designee) and the Cath Lab Supervisor (where applicable) for their department specific supplies. On occasion, the physician may request a new product from the Vendor, in which case, it is the Vendor's responsibility to notify the appropriate hospital staff of the request.

7. Product Decisions

The Products Review and Standardization Committee (PRSC) or Value Analysis Team (VAT), comprised of facility key department physicians/directors/managers and nursing leadership, will make the final decision on whether a product is accepted or rejected. Exceptions may be made by the Material Managers for non-routine purchases as needed.

8. Contract Compliance

The HPH selected GPO has established contracts with vendors and manufacturers. It is HPH's policy to comply with these contracts to the best of its ability.

9. Purchase Orders

- a. The purchasing personnel are the only authorized representatives of the hospital allowed to commit funds and to place purchase orders.
- b. Any product brought into a HPH facility without a purchase order or prior approval by the Vice President, Supply Chain Management, Materials Manager or the OR Business Manager will be considered a <u>donation</u> and provided by the Vendor at <u>no</u> charge to the facility.
- c. Billsheets for vendor supplied items should be submitted within forty-eight (48) hours or two (2) business days of the completion of the surgical case. If billsheets are not submitted in a timely manner, the facility will rely on what was documented in the EMR to facilitate billing and charges. Implants / Supplies unaccounted for will be considered a donation to the facility.

10. Product and Equipment Trials

Trials for new products and equipment must be approved by the Director of Supply Chain Management or Materials Manager. Vendors who receive approval to "trial" specific products or equipment within the hospital will comply with the following requirements:

- a. Work with the materials manager of the facility to acquire a no charge purchase order (PO) for the trial period;
- b. Provide sufficient product to conduct a trial for up to four (4) weeks for designated units or departments. This will be done at no cost to the hospital;
- c. Provide in-service training/education for all nursing units, departments and staff involved in evaluating trial products or equipment. This will be coordinated by the vendor in advance through the hospital Education department and Materials Management, after approval has been received to trial the product or equipment;
- d. Provide evaluation forms in advance of the trial to help determine efficacy of the trial;
- e. Provide assistance, guidance, monitor and document the progress of the trial; and
- f. If evaluation product is electrical, vendor must provide documentation verifying electrical safety and proper operation. Equipment and documentation must be checked-in through Sterile Processing Department/Central Supply or OR prior to onset of evaluation.

B. Business Requirements / Conditions

- 1. Vendors desiring to do business with the hospital are expected to provide upon request the following for all products to be considered for use in the hospital:
 - a. Product literature;
 - b. Published information on clinical/technical evaluations and product trial results;
 - c. Price lists;
 - d. Cost comparisons and analysis to establish financial feasibility of product use;
 - e. Product samples at no cost to the hospital;

- f. In-service training/education for all nursing units, departments, and staff involved; and
- g. List of hospital references (hospitals currently using the product, equipment or service).
- All Vendors are expected to comply with the Facilities' rules, regulations, policies and procedures. Non-compliance will not be tolerated. HPH reserves the right to enforce this policy by restricting and/or revoking Vendors' access to HPH Facilities and from doing business with HPH.

III. Enforcement

- A. HPH Managers and staff shall be responsible for enforcement of this policy. All violations must be reported to the Compliance Department and/or Supply Chain Management for appropriate resolution.
- B. Exceptions to this policy can only be granted by the HPH Compliance Officer.

| Standard / Reference & Year: | Anti-kickback statutes; Civil Monetary Penalties; Stark laws PhRMA Code of Ethics (revised September 2019): https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhR | | |
|--|--|--|--|
| Action: | ☐ New ☐ Reviewed ☐ Revised ☐ Consolidated: | | |
| Author(s) (Department(s)/Title(s)): | Compliance Officer; Supply Chain Management | | |
| Required Reviewer(s) (Department(s)/Title(s)): | HPH Compliance Committee | | |

Hawai'i Pacific Health Vendor Policy

Frequently Asked Questions (FAQs)

I. Policy Objective and Purpose

A. Why do we need a policy regulating relationships with Vendors?

In keeping with our Standards of Conduct, every employee of Hawai'i Pacific Health (HPH) is expected to adhere to the highest standards of ethical behavior whenever he or she acts on behalf of HPH, whether in dealing with other employees, with patients and their families, with vendors, with government regulators or with the general public.

This policy is designed to provide guidance to employees of HPH in their dealings with Vendors in ways that are consistent with our mission of providing quality patient care to our patients. We have defined appropriate interactions with Vendors and identified those outside interests (*i.e.* gifts, etc.) that may be perceived as potential conflicts of interest that could affect or be perceived as affecting the integrity of clinical decision-making.

B. Does the policy apply to me?

Yes. The policy applies to all HPH employees, HPHMG Providers and Independent Contractors regardless of their job classification.

C. What is the difference between a vendor and a contractor?

Vendor reps work with the clinicians and sell products for their use. Vendors build long term working relationships and are consistently working with HPH staff.

Contractors come in to provide a service, such as a plumber, or an electrician who usually are only onsite until the job is complete.

D. Are contractors allowed on HPH premises?

Yes. Contractors are allowed on HPH premises provided they sign the Covid-19 Vendor Vaccination Attestation form.

II. Meals and Other Hospitality

A. Can a Vendor bring lunch for my staff and me?

No. The policy specifically prohibits gifts, food or entertainment provided by a Vendor except when it is part of a general professional conference or seminar. A workplace presentation by a Vendor would not be considered a "general professional conference or seminar" under the policy.

B. What is considered a "general professional conference or seminar"?

Meetings or conferences sponsored by a professional association, institute of higher learning or other entity whose purpose is to promote health care and/or education rather than to manufacture, consult, sell or distribute products or services that might be used by health care providers or patients will generally be considered "general professional conferences or seminars".

C. What is **NOT** considered a "general professional conference or seminar?"

Generally, a gathering is not considered a "general professional conference or seminar" if it is:

- sponsored or underwritten by a Vendor;
- organized for the purpose of promoting use of a Vendor's product(s) or service(s); and
- held on an invitation-only basis and is not open to general registration.

Invitation-only gathering held at restaurants rather than a conference facility are particularly suspect.

D. May I accept an invitation from a Vendor/company inviting a group to an offsite meal held at a restaurant or similar facility?

You may attend but are responsible for the cost of your meal.

E. What are some of the potential issues with industry sponsored speaker programs where health care professionals are paid to speak and attendees receive remuneration in the form of free meals or other gifts?

The Office of Inspector General (OIG) issued a Special Fraud Alert – Speaker Programs (Nov. 16, 2020)¹ highlighting their skepticism of industry-sponsored speaker programs.

- Warns that all* parties involved in speaker programs may be subject to increased scrutiny.
- Suspect factors include:
 - Alcohol is available to attendees;
 - Venue is not conducive to education (e.g., restaurants);
 - Repeat programs without new information presented;

¹ https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf

Sales and marketing roles involved in selecting speakers and attendees based on past or expected prescriptions.

*Not only was the drug manufacturer on the hook but the government was also looking at the speakers (those receiving honoraria) and all those attending the presentations.

F. Can we provide food through our facility food service department and have expenses reimbursed by a Vendor or Vendor company?

No. Again, the policy prohibits gifts, food or entertainment to be provided by a Vendor. There is no distinction between providing reimbursement for food and providing the actual food.

G. What if no credit is given to the sponsoring company?

No, the practice is still prohibited. However, the company may consider an unrestricted monetary gift to the Foundation.

H. If a Vendor is allowed to donate funds to the Foundation which can then be used to purchase foods for the department, isn't that the same as the Vendor directly supplying food for the activity?

No. There is a significant difference. The Foundation can ensure appropriate stewardship of the gift while simultaneously maintaining an arms-length between the Vendor and the direct provider, so the provider may maintain control and make decisions without being influenced or appearing to be influenced by the gift.

III. Gifts and Promotional Items

A. What about product samples provided by Vendors?

Product samples intended for patient use are acceptable. Vendors must follow facility-specific Sample Drug policies and procedures.

B. What about educational pamphlets or anatomical models?

Patient education materials that directly benefit patients are acceptable. If there are any questions as to the appropriateness of the gift, contact your facility's Compliance Officer/Liaison.

C. My research activities include the use of Vendor donated supplies. Are these included in this policy?

No, research supply donations are not covered by this policy.

D. Are gifts from Vendors to providers tracked?

Yes. Open Payments is a federally mandated program that collects and publishes information about payments that reporting entities (Vendors) make to covered recipients. The Open Payments database is publicly accessible.

Examples of reported payments may include (not all-inclusive):

- Acquisitions
- Compensation for non-consulting services (e.g., faculty/speaker at an event other than a continuing education program)
- Charitable contribution
- Consulting fee
- Current or prospective ownership or investment interest
- Debt forgiveness
- Education
- Entertainment
- Food and beverage
- Gift
- Grant
- Honoraria
- Long-term medical supply or device loan
- Medical education faculty/speaker compensation
- Research
- Royalty or license
- Space rental or facility fees
- Travel and lodging

Vendors submit information annually to the Centers for Medicare & Medicaid Services (CMS). CMS is required to publish this information on or by June 30 each year and submit an annual report to Congress.

Practitioners can search the Open Payment Data Base to identify any payments posted to them by a reporting entity (Vendor).

https://openpaymentsdata.cms.gov/

IV. Access

A. Are Vendors allowed on campus?

Yes. However, there are explicit requirements in the Vendor Policy to which Vendors must adhere before accessing any of our HPH sites.

Please refer to pages 4-5 of this policy for specific requirements.

B. Must the Vendor have an appointment to be seen?

Yes. Drop-ins or "cold calls" are not acceptable unless there is an urgent or compelling reason. Wandering around the department or waiting for an unscheduled visit with the physician or staff is prohibited.

C. What do I need to tell Vendors that call or drop-in at the facility?

If the Vendor telephones you regarding a desired meeting or visit, please inquire whether they are registered in our vendor credentialing system.

- If they are not registered, the Vendor should contact the Materials
 Management department for further direction. Vendors who are not
 registered with HPH may not visit HPH sites.
- If the Vendors are registered, and you desire to meet with them, they may schedule an appointment. Vendors are required to sign in and obtain a vendor badge when coming on campus.
- D. Is there a situation where it is permissible to allow a Vendor to be present during a patient care treatment or clinical procedure?

Yes. In some clinical situations, Vendors may be present to provide information on the use of a specific device/product and/or supply. Some examples might include surgical and/or interventional procedures. Patient confidentiality must be protected and observed at all times.

V. Miscellaneous Questions

What should I do if I learn that an employee or a Vendor is not complying with this policy?

Please report the incident to the Supply Chain Management Department (808) 522-6911 or the Compliance Representative for your facility. You may use either of the Compliance Hotline options if you wish to submit a report anonymously.

Compliance Representatives:

- HPH & Straub Katie Shigemitsu (522-3368)
- KMCWC & Pali Momi Teresa Pytel (522-4001)
- Wilcox & KMC Tracy Damitio (522-3819)

Compliance Hotline Options:

Telephone (toll-free)

- HPH Compliance Hotline 1 (888) 274-3832
- Straub Compliance Hotline 1 (877) 852-2739
- KMCWC & Pali Momi Compliance Hotline 1 (888) 274-3832
- Wilcox & KMC Compliance Hotline 1 (877) 309-5762

Online

https://app.mycompliancereport.com/MCR