

WEST PENN ALLEGHENY HEALTH SYSTEM

Policy Name: Vendor Conduct Policy

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PURPOSE

Vendors in many respects are extensions of the West Penn Allegheny Health System (WPAHS) and should be expected to conduct their activities in a manner that is consistent with WPAHS' expectations of its own personnel. The purpose of this policy is to establish guidelines for the conduct of Vendors providing supplies and services to WPAHS.

SCOPE

This policy applies to all WPAHS Vendors and supplements the existing WPAHS policies below:

1. Code of Ethics and Acknowledgment <http://www.protechcompliance.com/wpahs>
2. Vendor Interaction Policy
3. Purchasing Policies

In all cases where this policy is more restrictive than the above policies, this policy shall prevail.

STATEMENT OF POLICY

It is the policy of WPAHS that Vendors and their Vendor Representatives conduct business activities in a manner that is compliant with WPAHS policies and procedures. This policy is intended to guide all forms of conduct of Vendor Representatives, yet the following specific limitations and guidelines are not intended to cover all possible forms of conduct. For any situations not specifically listed, WPAHS personnel and Vendor Representatives should consult, in advance, the WPAHS organization's materials manager, compliance officer, WPAHS Corporate Contracting and/or the WPAHS Compliance Office.

DEFINITIONS

WPAHS Personnel and Facilities - for the purpose of this policy, WPAHS personnel are defined as all personnel, whether employed, contracted, or affiliated with WPAHS, including all physicians, healthcare providers, and students of WPAHS. WPAHS facilities are defined as all facilities and respective campuses, whether owned, leased, rented or controlled by WPAHS.

Vendor(s) - for the purpose of this policy, Vendors are defined as manufacturers, suppliers, or providers of products, equipment or services, whether medical and non-medical or pharmaceutical and non-pharmaceutical.

Vendor Representative(s) – for the purpose of this policy, Vendor Representatives are defined as any representative (i.e., sales person, company technician, manager, liaison, account executive, contact, administrator), manager, medical/scientific liaison of a manufacturer or company visiting WPAHS for the purpose of providing, repairing, soliciting, marketing, or distributing vendor products or services.

SPECIFIC GUIDANCE FOR VARIOUS VENDOR CONDUCT

VENDOR INTERACTIONS

Vendor Representatives will conduct themselves in an ethical and moral manner consistent with the WPAHS Code of Ethics and Vendor Interaction Policy.

PATIENT SAFETY

Any Vendor Representative who reasonably believes an incident or more serious event has occurred shall report the incident or serious event verbally to WPAHS personnel who are in a management or supervisory position. Incidents may also be reported directly to the Patient Safety Department of the respective WPAHS facility. The Patient Safety Department collects information and analyzes actual or potential incidents/occurrences involving inpatients, outpatients, employees and visitors. An incident is defined as an event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient, but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.

SAMPLES

Samples, including medical, non-medical, pharmaceutical and non-pharmaceutical items, provided by Vendors will be limited to those items listed on the WPAHS approved formularies. The WPAHS approved formularies include items contained in the WPAHS Corporate Contracting master item file, any of the hospital approved pharmacy formularies and the pharmacy formulary included as part of the WPAHS employee health benefit plan.

However, samples may be provided in the following circumstances:

- 1) During a Corporate Contracting sponsored product evaluation event, samples may be permitted from Vendors for products not listed on the WPAHS approved formularies provided such samples are cleared in advance through Corporate Contracting, are requested using a \$0.00 purchase order and are received by the hospital Materials Management and/or Pharmacy Departments.
- 2) Sample medications may be provided in a manner consistent with the WPAHS distribution of drug samples policies such that:
 - a) sample medications designated as “controlled substances” are not permitted;
 - b) sample medications are not permitted as floor-stock for use on hospitalized inpatients;
 - c) the Vendor Representative will “log in” all sample medications delivered to the ambulatory areas using blank copies of the “Sample Medication Tracking Form;”
 - d) in the event such sample medications are mailed to an ambulatory area, such mailing will be in accordance with all applicable laws, rules, and regulations and will be accompanied by a no charge invoice;

- e) the Vendor Representative shall not have unsupervised access to the sample medications or other medications;
- f) sample medications shall only be distributed to practitioners that are legally authorized to prescribe such sample medications;
- g) sample medications are provided only as “starter” packs; and
- h) sample medications are not charged or billed to the patient by the provider.

Questions regarding the formulary status of a sample item can be resolved by contacting Corporate Contracting (master item file items), hospital pharmacy (hospital pharmacy formulary items), or Human Resources (employee benefit plan formulary items). Acceptance and distribution of such samples must be done in compliance with WPAHS policy.

Vendor Site Visits

Vendor site visits are visits by WPAHS personnel to Vendor sites including, but not limited to, Vendor corporate headquarters, Vendor manufacturing sites, Vendor show sites, or Vendor customer sites where compensation is limited to reimbursement of reasonable travel expense and the purpose of the site visit is to evaluate new technologies, strategic relationships, or qualify Vendors and products for an authorized bid event.

Vendor site visits, including travel and lodging, may be accepted when the business value to the organization outweighs any recreational or entertainment value of the training event provided the appropriate approvals are obtained in advance. Consult the WPAHS Vendor Promotional Training Policy for further detail.

When arranging site visits, Vendor Representatives should inform the Department Chair, Vice President or Executive Vice President, Hospital Operations of the intent to arrange a site visit, including the date of the visit, the location, the WPAHS personnel attending and the purpose of the site visit. WPAHS personnel should ensure they acquire permission from their respective Department Chair, Vice President or Executive Vice President, Hospital Operations. Consultation with the Vice President, Corporate Contracting, and the Vice President, Corporate Compliance, is advised to ensure the absence or disclosure of any potential conflicts. All vendor site visits should be scheduled and approved in advance and at times that would not compromise WPAHS personnel responsibilities to WPAHS.

OTHER VENDOR INTERACTIONS

WPAHS personnel should avoid potential conflicts of interest in all other vendor interactions and consult with their Department Chair, Executive Vice President, Hospital Operations, Compliance Officer and/or the Vice President of Corporate Contracting if further guidance is needed in any of the following situations:

Consulting Relationships

Agreements that identify specific tasks and deliverables restricted to non-marketing purposes and efforts with funding and/or payment commensurate with the tasks assigned and deliverables required.

Proposals for all consulting relationships should be provided to the respective Department Chair, Vice President or Executive Vice President, Hospital Operations and clearly articulate the content and expectations of the consulting relationship. Consultation with the Vice President, Corporate

Contracting, and Vice President, Corporate Compliance, is advised to ensure the absence or disclosure of any potential conflicts. Consulting relationships between Vendors and WPAHS personnel should be approved in advance by the respective Department Chair, Vice President or Executive Vice President, Hospital Operations.

Grant Support

Grants for general support of research and education procured and processed through WPAHS authorized divisions of research and education may exclude requirements for tasks and deliverables provided the grants are not designated for use by specific individuals.

Grant support proposals should be provided to the respective Department Chair, Vice President or Executive Vice President, Hospital Operations and clearly articulate the content and expectations of the grant support. Consultation with the Vice President, Corporate Contracting, and Vice President, Corporate Compliance, is advised to ensure the absence or disclosure of any potential conflicts. Grant support provided by Vendors should be approved in advance by the respective Department Chair, Vice President or Executive Vice President, Hospital Operations.

Education Support

Support for education and training, including continuing medical education events that comply with the WPAHS policies and/or ACCME Standards for Commercial Support of Educational Programs, whether or not credit is awarded for attendance at the event and are negotiated through, and executed by, WPAHS departments. For more specific guidance consult the WPAHS Policy on Disclosures of Proprietary or Financial Conflicts in Continuing Medical Education, Graduate Medical Education and Continuing Education for Nurses and Allied Health Professionals Programs.

The Vendor Representative shall notify the corresponding WPAHS Pharmacy Department and/or Corporate Contracting at least two weeks in advance of the intent to support an educational program, in-service or clinical conferences so any potential conflicts with respective product formularies may be reviewed, determined and/or resolved. Educational programs and in-services sponsored by Vendor Representatives will be permitted provided they meet the following requirements:

- 1) a Department Chair or Department Director (or designee) from the sponsoring department will be present;
- 2) the speaker is not a Vendor Representative;
- 3) objectives are clearly identified and provided for all educational programs;
- 4) programs focusing exclusively on an individual product, service or drug are on existing product formularies. Programs or presentations that include discussions of product classes or functional or therapeutic equivalents are permitted and may include non-formulary products, services, or drugs. A list of references shall be provided to attendees for all programs and presentations delivered by non-WPAHS staff;
- 5) promotional materials provided by Vendor Representatives are limited to those approved for use by the Food and Drug Administration (FDA);
- 6) Vendor Representatives may address specific questions from WPAHS employees about products marketed by their company in accordance with FDA guidelines.

Vendor Representatives cannot select the speakers or the topics to be presented at educational programs or in-services. These decisions are the responsibility of WPAHS staff.

Industry Sponsored Meetings, Speakers Bureaus or Industry Support for Off-Campus Meetings

Vendor-sponsored meetings, speakers' bureaus or other off-campus meetings where Vendor support is provided to promote evidence-based practice and/or advance research or instances where WPAHS Personnel are participating as speakers.

Such support proposals should be provided to the respective Department Chair, Vice President or Executive Vice President, Hospital Operations, and clearly articulate the content and expectations of the support. Consultation with the Vice President, Corporate Contracting, and Vice President, Corporate Compliance, is advised to ensure the absence or disclosure of any potential conflicts. Support provided by Vendors should be approved in advance by the respective Department Chair, Vice President or Executive Vice President, Hospital Operations.

Support for Scholarships or Fellowships or Other Support of Students, Residents or Trainees

Acceptance of industry support from Vendors for scholarships or discretionary funds to support trainee or resident travel or non-research funding support shall comply with the WPAHS policies and/or ACCME Standards.

Support proposals should be provided to the respective Department Chair, Vice President or Executive Vice President, Hospital Operations, and clearly articulate the content and expectations of the support. Consultation with the Vice President, Corporate Contracting, and Vice President, Corporate Compliance, is advised to ensure the absence or disclosure of any potential conflicts. Support provided by Vendors should be approved in advance by the respective Department Chair, Vice President, Medical Education or Executive Vice President, Hospital Operations.

NOTICE

All Vendors will provide WPAHS a comprehensive list of all Vendor interactions upon request. Such request will be limited to all Vendor interactions in the following areas provided to WPAHS during the preceding 12 months:

- 1) Vendor site visits;
- 2) consulting relationships;
- 3) grant support;
- 4) education support;
- 5) industry-sponsored meetings, speakers bureaus or industry support for off-campus meetings; and
- 6) support for scholarships or fellowships or other support of students, residents or trainees.

Such information requests shall be limited to the amount of support provided, the form of such support (cash, product, or in-kind), the date such support was provided, to whom it was intended and to whom it was provided.

VENDOR REGISTRATION

All Vendor Representatives will register annually in the VendorStat application, pay applicable annual fees and provide all information in the form of actual documents or attestations required of the registration process as determined and modified from time to time by WPAHS.

VENDOR SITE ACCESS

Interactions with Vendor Representatives are appropriate as it relates to the exchange of valid information and other data as well as training intended to advance health care. The decision to allow access to a WPAHS facility shall be determined at the sole discretion of WPAHS, and such determinations shall be based on several factors including, but not limited to, the status of a contracted relationship, the compliance with vendor interactions and protocol and the Vendor's registration in the VendorStat application.

Vendor Representatives will be permitted access to WPAHS facilities for the purpose of marketing if the Vendor Representative is registered in the VendorStat application, has been cleared for visitation by the WPAHS facility, their visit has been confirmed by a department and the Vendor is in compliance with vendor interactions and protocol. In the event the Vendor Representative is not registered in the VendorStat application, the WPAHS facility may provide temporary access privileges to the Vendor Representative after confirming their appointment with the department and the Vendor's compliance with vendor interactions and protocol. Such temporary access will be granted at the sole discretion of WPAHS. Otherwise, Vendor Representatives will be denied access to the WPAHS facility at the sole discretion of WPAHS.

VENDOR CONTRACTING

In order to ensure that decision making for Vendor products and services is based solely on the best available information, it is the policy of WPAHS that committees overseeing item formularies and vendor contracting may exclude WPAHS personnel who have benefited from interactions with Vendors.

Individuals having a direct role in making decisions on equipment, products, services or drug procurement must disclose any vendor interaction and any financial interest they or their immediate family have in companies that might substantially benefit from the decision to their Department Chair, Department Vice President, the WPAHS Compliance Office and Committee Chair, if applicable, prior to participating in any such decision-making process. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision.

It is the policy of WPAHS that any new product or service be reviewed and approved by the respective Supply Chain Team, ad hoc committees, and/or System Pharmacy & Therapeutics Committee prior to introduction in the health system.

All products and equipment provided to WPAHS must be authorized prior to placement by a valid purchase order number. Orders are not considered binding nor will respective invoices be paid without a corresponding purchase order and receiving report provided to the respective receiving location. If such receiving location is not the Materials Management Department, a corresponding copy should be provided to both locations. Any orders placed directly to a Vendor by a department (unauthorized request issued by department) are not valid. Any loaned or trial items must be authorized prior to placement with a "no charge" purchase order.

Vendor Representatives will not be able to promote all products they desire. All Vendor Representatives are responsible to know what can and cannot be promoted. Clarification must be sought through the WPAHS Corporate Contracting Division and the primary department that the Vendor visits.

Vendor Representatives may discuss pricing or terms and conditions with departments, but must be directed to WPAHS Corporate Contracting prior to finalizing any contract. Terms outlined to departments are subject to modification and do not represent agreement by WPAHS. Vendor Representatives are not to approach or obtain signature from departments on any contracts. Vendor Representatives are not to discuss content of any request for bid/proposal directly with any department while it is open for vendors to respond to the hospital and/or clinic. The discussion is to be facilitated by and with the appropriate WPAHS Corporate Contracting personnel.

PROMOTIONAL ACTIVITIES

Vendors are not permitted to post any type of printed or handwritten material, advertisements, signs or other such promotional materials anywhere in WPAHS facilities. Vendors may provide medical educational materials for patients provided it does not include posters displayed. In addition, WPAHS shall not produce any advertising that references a vendor product or contains a vendor logo.

Vendor Representatives shall be enabled to detail and promote their products to WPAHS personnel provided the following requirements are met:

- 1) information provided or presented shall be current, accurate, unbiased, and non-misleading;
- 2) provision of information shall be consistent with WPAHS guidelines, restriction, and policies for product, service, or medication use (pharmaceutical information is available from the WPAHS site Drug Information Service);
- 3) information must pertain to hospital formulary products, services or drugs with the following exceptions:
 - a) non-formulary items may be discussed if they pertain to introduction of the item for formulary consideration, the discussion is requested by WPAHS personnel and is disclosed and approved by WPAHS Corporate Contracting prior to discussion and in consultation with respective WPAHS pharmacy directors when required;
 - b) discussion of individual non-formulary items shall not occur in the form of an in-service or educational program unless the discussion is requested by WPAHS personnel and is disclosed and approved by WPAHS Corporate Contracting prior to discussion and in consultation with respective WPAHS pharmacy directors when required;
- 4) all promotional or informational material provided must be explicitly requested by WPAHS personnel;
- 5) Department Chair, or designee, must be present in order to detail residents, fellows or students;
- 6) Vendor Representatives are prohibited from providing patient-specific recommendations concerning individual products, services, or medications.

VENDOR COMMUNICATION

Distribution by WPAHS personnel of WPAHS policies and internal memoranda developed on behalf of WPAHS to Vendors and Vendor Representatives is prohibited without express authorization. Dissemination of any such policies and memoranda by Vendor Representatives is prohibited.

PROCESS OF APPROVAL

VENDOR INTERACTIONS

All Vendor Representative conduct shall be in compliance with this policy and some conduct as indicated requires prior written approval of the Department Chair and Executive Vice President, Hospital Operations. Prior to approving such Vendor Representative conduct, the Department Chair and Executive Vice President, Hospital Operations, shall consult with the Vice President of Corporate

Contracting, the Vice President, Compliance, the respective pharmacy director and other constituents to review such Vendor Representative conduct for conflicts with any current WPAHS contractual term and commitment, and determine if any waivers of or additional limitations on such interactions shall be placed.

REPORTING AND ENFORCEMENT

WPAHS personnel shall report all violations of Vendor Representative conduct. Alleged violations of this policy shall be investigated by the WPAHS Compliance Office. Violations of this policy shall be reported to the respective pharmacy director, Department Chair, Executive Vice President, Hospital Operations and WPAHS Compliance Officer who shall determine what actions, if any, to take. Violations of this policy may result in any of, or any combination of, the following actions depending upon the seriousness of the violation, whether the violation is a first or repeat offense, whether the Vendor Representative knowingly violated the policy or attempted to hide the violation:

1. written reprimand, documented in the VendorStat application;
2. banning the Vendor Representative from any further Vendor interaction for a period of time;
3. requiring the Vendor Representative to complete additional training on vendor interaction, vendor conduct and conflict of interest;
4. terminating the Vendor contracts with WPAHS.

Violation of any of the above procedures by Vendor Representatives shall result in disciplinary action which may include, but shall not be limited to, the following:

1. First violation: verbal and written warning to Vendor Representative; written notification to district manager or Vendor Representative's supervisor.
2. Second violation: suspension of Vendor Representative and/or Vendor from WPAHS Facilities for six months.
3. Third violation: suspension of Vendor Representative and/or the Vendor from WPAHS Facilities for one year or more and review of multi-source products obtained from the Vendor for conversion.

Vendor Representatives found in violation of vendor registration and/or vendor site access protocol as defined in this policy will be escorted from the premises and the Vendor notified as appropriate. Furthermore, Vendor Representatives not registered in the VendorStat application may be denied access to WPAHS facilities at the sole discretion of WPAHS.