

Drug Representatives, Service Technician, etc. VRs may be vendor employees, contract workers, per-diems, or independent representatives.

APPLICABILITY:

This policy and procedure is applicable to all Vendor Representatives (VRs) and all Employees and Professional Staff at the New York-Presbyterian Hospital and Offices Interacting with VRs.

PROCEDURES:

Vendor Credentialing:

Each VR and the vendor he/she represents must be registered in the Hospital's Vendor Credentialing System (VCS). The registration process must be completed on line at vcsdatabase.com. This process must be completed before a VR may be granted access to any NYP facility for the purpose of conducting business. Once registered, each VR is cleared for entrance to NYP facilities for one year, after which the VR will need to re-register. Should a vendor be sold, or change its name, the vendor and all of its registered VR's must update their registration information within 30 days of such change, or they will not be permitted access to Hospital property.

1. Registration

To initiate a business relationship with the Hospital, each VR must register themselves and the organization they represent with the Vendor Credentialing Service at vcsdatabase.com.

- A. All VRs must register and become credentialed with the Vendor Credentialing Service before entrance to NYPH properties will be allowed. For newly acquired vendors, a grace period of 30 days is allowed.
- B. A "Vendor Representative Guide," containing all information relevant to registering with the credentialing service, along with NYPH information necessary to maintain a business relationship with NYPH is available on the Credentialing Service website.
- C. Requirements of vendor credentialing are dependent upon the areas of NYPH that the vendor would be accessing. Requirements per area of access are:

Level 1 – Level 8

- Read All Relevant NYPH Policies and Procedures supplied on line (all levels)
- Complete a Vendor Profile Record (all levels)
- Provide documentation of education/certification on service or equipment being provided (different for each level)
- Complete all NYPH required Educational Training Courses (different for each level)

- Comply with the NYPH Medical Screening requirements (different for each level)

D. It is the responsibility of each Vendor to ensure that the names of their registered representatives are accurate. The Procurement & Strategic Sourcing Department must be informed, via vendorcred@nyp.org, of any VRs that no longer represent their enterprise at NYPH within 30 days of the VRs separation from the Vendor.

It is the responsibility of each Vendor to ensure that their VRs maintain their credentialing on a yearly basis with the vendor credentialing service. If credentialing is not maintained, access to NYPH property will not be granted.

2. Access to NewYork-Presbyterian Hospital Buildings

A. VRs must enter the Hospital through an entrance designated for VRs. These entrances are:

- NYP/The Allen Hospital at 5141 Broadway
- NYP/Morgan Stanley Children’s Hospital at 3959 Broadway
- NYP/Columbia University Medical Center -The Vivian & Seymour Heart Center at 173 Fort Washington Avenue
- NYP/Weill Cornell Medical Center - M-Building at 530 East 70th Street
- NYP/Weill Cornell – Weill Greenberg Center at 1305 York Ave
- NYP/Payne Whitney Westchester - Information Building
- NYP/Ambulatory Care Network Practice sites

Access to Ambulatory Care Network sites and clinics by VRs is not allowed unless the site is approved for access by the Chief Medical Officer for Ambulatory Care

Access to individual areas in NYPH facilities is determined by the sensitivity of each area and the VR’s level of access. Vendor Representatives will be permitted access only to those areas for which their authorization is approved.

Level 1 Access – Non Patient Care / Procedure Areas

Level 2 Access – Restricted Patient Care Areas

Level 3 Access – Non Restricted Patient Care Areas

Level 4 Access – General hospital areas – administrative areas only, deliveries only

Level 5 Access – General hospital areas and grounds – no access to patient care areas when patients are present

Level 6 Access – Contracted personnel who access patient care areas and have patient contact.

Level 7 Access – Pharmacy representatives who access MD offices, but not the hospital.

Level 8 Access – Non Contracted personnel who have access to PHI (consultants, IT, Legal, Finance, Interpreters)

B. VRs are permitted to access Hospital buildings only when they have an appointment with a member of the attending staff, nurse practitioner, a management employee in

an applicable area, or a member of the procurement staff. VRs are prohibited from setting up appointments with students, house staff, nursing staff, pharmacy staff, or laboratory staff. Unannounced visits to any area of the Hospital are not allowed.

- E. VRs must enter through a designated hospital entrance for VRs. They then must swipe their badge in and out with the security personnel at each site, or at the Vendor Kiosk provided, to receive a "day Pass" for the period of their visit.
- C. All VRs must wear a Photo ID issued by the Vendor Credentialing Service at all times when they are on Hospital property.
- D. An entry in the "Vendor Representative Visitation Log" will automatically be completed within the Vendor Credentialing System. The names and locations of all individuals that the VR is scheduled to visit and the purpose of their visit must be pre-established to allow the VR access to the building. Visitation by a VR to any area not included in the Visitation Log will be considered a violation of this policy.
- E. On occasion, VRs may bring with them members from the vendor they work for who do not regularly visit our Hospital. These individuals MUST be accompanied by a registered VR at all times and must wear a Photo ID issued by their commercial enterprise. Individuals who visit the Hospital more than two times a year with a registered VR are encouraged to file their own registration through the Vendor Credentialing Service.

3. Visitation Hours

Vendor Representatives should conduct business from 9 AM - 5 PM on weekdays unless a duly authorized individual from the Hospital specifically requests visitation or if there is a specific need to conduct business during alternative hours of the day or on weekends (i.e. in-service training, delivery of a product required to address an urgent patient need or emergency, etc).

4. Areas of Visitation

VRs are not allowed on patient care areas in the inpatient or ambulatory environments (including nursing units and clinics) or in work areas (Pharmacy distribution areas, Microbiology work areas, Laboratories, etc.).

- A. VRs are not allowed to visit areas beyond their level of access.
- B. Meetings with VRs shall be held only in public or administrative areas unless otherwise determined by NYPH management staff.
- C. VRs may be present but shall not wait in common hospital areas (such as building lobby areas, eating areas, parking areas, public telephone areas,

etc.) for the purpose of initiating unsolicited contact with health care professionals and detailing the individuals on their products.

5. Patient Confidentiality and Privacy

VRs should not have access to any patient specific information not required to perform business transactions.

- A. VRs should not be present in any patient care area or at meetings or functions where patient specific information is discussed, unless directed by NYPH staff.
- B. Training by VRs for new equipment or devices that may involve exposure to patients is highly discouraged. When training by a VR is necessary, that involves exposure to a patient or information about a patient, approval from the Attending Physician AND patient consent, documented in the patient's chart, is required. The Operating Room has specific policies related to training provided by VRs which must be followed in those areas.
- C. VRs shall only have access to any electronic or paper information that is patient specific, or could be associated with a particular patient, unless required to perform business transactions. This includes patient charts, laboratory information, patient bills, etc.

6. Marketing Activities

VRs are authorized to promote their products and disseminate information within the following parameters:

- A. VRs should confine their promotional activities within the Hospital to attending medical staff, nurse practitioners, pharmacy management staff, management staff in areas where the commercial enterprise's supplies and equipment could be used, and the Procurement & Strategic Sourcing Department.
- B. VRs will respect and abide by the decisions of the Medical Board and its subcommittees, such as the Formulary and Therapeutics Committee. VRs are not permitted to promote medications, supplies or equipment contrary to the New York-Presbyterian Hospital Policies or Guidelines as approved by hospital committees.
- C. Before visiting members of the medical staff to promote medications, Pharmaceutical VRs should meet with a member of the Drug Information Center staff to inform/provide them with any of the information they will be using to promote their product(s). Any information/materials deemed inappropriate or biased by the Drug Information Service may not be used as information provided to individuals in the Hospital. VRs must also meet with a member of the Drug Information Center to determine whether there are NYPH restrictions or guidelines regarding the use of the

agent(s) they wish to promote. Examples of policies/guidelines VRs are expected to follow include:

- Promotion of restricted products to only those attending physicians who are authorized to prescribe them
- Promotion of products within guidelines where NYP recommends specific dosing, the agents are restricted at NYP for specific indications, clinical parameters must be met prior to use of the agent at NYP, etc.

D. Pharmaceutical Representatives; the following are **acceptable forms** of information for dissemination by VRs within the Hospital provided that the drug is a Formulary item and the materials are approved for distribution by the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Food and Drug Administration and the Hospital's Drug Information Center.

- Reprints of primary literature from peer-reviewed journals
- Promotional materials that are deemed unbiased and are approved for distribution by the Hospital's Drug Information Center

E. Pharmaceutical Representatives; the following are **unacceptable** forms of information for dissemination by VRs at the Hospital:

- Abstracts related to potential benefits of a drug marketed by the vendor
- Any information deemed as inappropriate or biased by the Hospital's Drug Information Center
- Information related to the unapproved use of medications as determined by the Food and Drug Administration (this information may only be obtained if a hospital employee or a member of the medical staff requests this information through the Medical or Scientific Affairs Division of the vendor)
- Any comparative cost analysis related to the product being promoted

F. Food may not be provided by a VR within the Hospital except as part of an educational program that meets the criteria discussed in Section 7 of this policy.

G. Gifts, such as pens, notepads, or any other promotional item bearing the Vendor's logo or information, may not be distributed within the Hospital.

H. VRs may not post any notices in the Hospital that promote their products or a program that they are sponsoring. Program notices must be posted by the Hospital representative responsible for that program in concordance with hospital policies for posting notices. Promotional materials may only be given to an individual during an appointment and may not be left in hospital areas, including public areas.

I. Pharmaceutical Representatives; Violations of applicable laws governing the promotion and marketing of drug products will be reported by representatives of the institution to the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Food and Drug Administration.

7. Educational Programs

The Hospital is pleased to accept unrestricted educational grants, which are made without stipulation regarding the content of teaching sessions.

- A. Program funds will be administered by the university CME office or a specific university or hospital department
- B. Checks for operating expenses such as meals and speakers' honoraria are to be made payable to the University or the Hospital. **All** expenses and honoraria will then be paid directly by the host body.
- C. Speakers must disclose at educational programs, any financial support or conflict of interest they may have related to the materials they are presenting.
- D. If a VR is providing financial support for a CME approved program (such as Grand Rounds), the Hospital will allow the VR to attend the program provided they do not display advertising or promote their products to the staff attending these programs.
- E. VRs are not allowed to attend non-CME approved teaching sessions that are attended by students, residents, pharmacy, nursing, or laboratory staff.
- F. The Hospital does not allow VRs to meet with students, residents, pharmacy, nursing, or laboratory staff on hospital property. Staff are encouraged to carefully assess the unbiased educational value of programs held outside of the Hospital when they are considering attending programs sponsored by commercial enterprises. The AMA Ethical Opinions on CME suggest that when selecting formal CME activities, the physician should, at a minimum, choose only those activities that:
 - Are offered by sponsors accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), a state medical society, or other certifying organizations
 - ii. Contain information on subjects relevant to the physician's needs
 - iii. Are responsibly conducted by qualified faculty
 - iv. Conform to AMA guidelines on gifts to physicians (Opinion 8.061)
- G. The Hospital will not provide the names or addresses of students or staff to VRs.
- H. The Hospital does not allow house staff or fellows to accept direct gifts, favors, or trips from VRs. A VR may donate requested educational resources to the Hospital or University or sponsor a trip to a legitimate educational meeting provided that the funds are unrestricted and are channeled through the Hospital or university.
- I. Faculty and Hospital employees who are offered speaking engagements, consultantships, etc., should follow policies as outlined in the university or hospital Conflict of Interest policy.

8. VR Access to NYPH Information

VRs are not allowed access to verbal or written information that refers to patient specific information, quality of care issues, or information that would jeopardize the process for product selection or competitive pricing.

- A. Information discussed or distributed at Medical Board Subcommittees (e.g., Formulary and Therapeutics Committee) or their Subcommittees (e.g., Subcommittee on Critical Care Therapeutics) may NOT be provided to or obtained by VRs. Information needed by VRs to insure promotion of their products is within guidelines or policies approved by the Formulary and Therapeutics Committee will be provided by the Drug Information Center or other appropriate information source for supplies and equipment.
- B. Institution specific data related to prescribing practices, product consumption, or prices may not be provided to VR's except by individuals authorized by the Hospital to negotiate contracts.

9. Process for Product Review and Selection

Only attending medical staff can request the addition of a medication to the NewYork-Presbyterian Hospital Formulary (See Hospital Policies and Procedures Manual: Formulary System Policy). Formulary Request Forms may not be completed by a VR under any circumstance.

- A. New products are recommended for hospital or operating Room use by the Operating Room Committee, Clinical Support Committee, or the Product Evaluation Committee only after successful clinical evaluation and review for suitability, effectiveness, safety, cost, and convenience of product.
- B. During pre-implementation of a new product, VRs are permitted access to staff in patient care areas for the purpose of providing education specific to product implementation. These sessions are prescheduled with the management of each area affected by the implementation.

10. Drug Samples

Drug samples are not permitted on the premises at NYP in Article 28 facilities and offices (See Hospital Policies and Procedures Manual: Drug Samples). It is the responsibility of the commercial enterprise to ensure that drug samples are not distributed within the institution. If drug samples are found during any routine inspection of patient care areas, the commercial enterprise whose name appears on the label of the drug sample will be held accountable and appropriate action will be taken.

11. Policy on Trial Equipment/Products

Clinical evaluations of new FDA approved products must be coordinated through the Procurement & Strategic Sourcing Department.

- A. The medical center employee recommending the clinical evaluation must submit a written descriptive statement to the Operating Room Committee Chairperson or the ICU Technology Committee, or the Clinical Support Committee.
- C. Product supplies submitted for evaluation must be left with the Procurement & Strategic Sourcing Department or in a location designated by the Procurement & Strategic Sourcing Directors. NYP will not be responsible for supplies, equipment, or material delivered to persons other than those designated.
- D. Materials, including equipment for evaluation or loan cannot be shipped or left at the hospital without an evaluation purchase order. The hospital will not be liable for theft, damage, freight or any other charges if this requirement is not met.
- E. Equipment that has been approved for clinical evaluation must be inspected by Biomedical Engineering before use.
- F. If the appropriate hospital committee has declined to test or approve the item, the VR should not attempt to reintroduce the item until it has been substantially improved or altered in such a manner as to overcome the initial objections of the committee.

12. Compliance and Enforcement

It is the responsibility of every member of the professional staff and employees of NYP to ensure that this policy and procedure is enforced.

- A. Medical Center staff who witness violations of these policies and procedures should report infractions to the Vice President of Procurement & Strategic Sourcing Department or Pharmacy Director for Drug Use Policy and Acquisition or their designees. The suspected infraction will be reviewed by the Apothecary-in-Chief and/or Vice President of Procurement & Strategic Sourcing and, if necessary, the Chairs of the appropriate committee, such as the Formulary and Therapeutics Committee.
- B. If VRs are found to violate the policies outlined in this document and those referenced in this document, disciplinary actions up to and including suspension or termination of privileges at NYP for the individual VR and the marketing division of the commercial enterprise may be taken.

RESPONSIBILITY:

Vice President Procurement & Strategic Sourcing

NewYork-Presbyterian Hospital
Sites: All Centers
Hospital Policy and Procedure Manual
Number: P230
Page 10 of 10

POLICY DATES:

Reviewed: May 2002 (Previously Policy #P190.1)

Revised: January 2003 (**Formerly named "Purchasing: Monitoring Sales Representatives"**)

May 2008; May 2010; February 2011; August 2012

Reviewed: February 2011; October 2014; **October 2016**

Approvals:

Executive Committee:

NYP/CUMC: 11/12/02, 12/17/02

NYP/WCMC: 12/19/02

Medical Board: 1/9/03, 3/15/15