| **Responsible Department:** Supply Chain Management | **YALE NEW HAVEN HEALTH POLICY & PROCEDURES** |
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| **Title:** Vendor Expectations and Oversight | |
| **Date Effective:** 10/10/2023 | |
| **Approved by:** System Leadership Group | |
| **System Policy Type (I or II):** Type I | |

**PURPOSE**

The purpose of this policy is to provide guidelines for vendor representatives to conduct business in a manner that does not interfere with the normal operations of Yale New Haven Health Services Corporation and its affiliates ("YNHHS"), namely enhances patient care, quality and safety, ensures confidentiality of information, and supports cost effective procurement while complying with YNHHS contractual and ethical policies and standards while fostering an environment of fair competition and appropriate access control.

**APPLICABILITY**

This policy applies across Yale New Haven Health System (YNHHS), including Yale New Haven Health Services Corporation, and each of its affiliated entities, its affiliated hospitals (Bridgeport Hospital, Greenwich Hospital, Yale New Haven Hospital, Lawrence + Memorial Hospital, Westerly Hospital, and any other hospital that affiliates with YNHHS), its affiliated providers (including but not limited to Northeast Medical Group, The Grimes Center, Visiting Nurse Association of Southeastern Connecticut, and Home Care Plus), and each of their subsidiary entities.

**POLICY**

**A.** It is the policy of YNHHS that the conduct of business by vendor representatives is initiated and managed through the local site-based facility Supply Chain Management personnel and YNHHS Corporate Supply Chain Management Department, with special emphasis on all HIPAA requirements to safeguard the privacy and confidentiality of patient health information.

**DEFINITIONS**

**A. Vendor** – Manufacturers, suppliers, distributors, or providers of products, equipment, or services, whether medical or non-medical.

**B. Vendor Representative(s)** – Any representative such as salesperson, manager, liaison, account executive, contact, administrator, company technician, clinical support, nurse clinician, home healthcare personnel, manager, medical/scientific liaison of a manufacturer or company who visits a YNHHS facility in any capacity, including but not limited to, soliciting, marketing, or distributing information regarding the use of vendor products or services.

**C. Vendormate** – Credentialing software utilized by onsite vendor representatives to register to do business with YNHHS.

**PROCEDURES**

**A.** General Vendor Credentialing

1. Vendor representatives, pharmaceutical company representative (PCR), or Medical Liaisons (hereafter referred to as "Vendor Representatives") are required to adhere to YNHHS policies including but not limited to: HIPAA Policies, the YNHHS Code of Conduct and the Procedures outlined in this policy.
2. All Vendor representatives wishing to conduct business at a YNHHS facilities must do so with authorization by the designated Supply Chain Management Department credentialing service (Vendormate) and a Health System department's management (such as Pharmacy Department, Food Services, Facilities/Construction, DN Periop, or IR/Cath Lab).
3. Vendors who have been authorized as YNHHS business partners by Corporate Supply Chain and one (1) of these departments may conduct business, by appointment, with the respective departments, and in accordance with the policy set forth below. Representatives who attempt to conduct business directly with hospital departments or staff without prior authorization of Supply Chain Management or Pharmacy Management and an appointment will be immediately redirected to the Supply Chain Management Department or Pharmacy Management by the affected department and be considered in violation of this policy.
4. All Vendor representatives must be fully registered and signed in to the Vendormate vendor management system upon each visit to the hospital. Once fully registered, the Vendor Representative will be able to print a vender photo ID badge upon signing into Vendormate at each visit. This ID badge is valid for the calendar day only and must be worn visibly on a part of the clothing located above the waist.
    a. Representatives are **not** allowed to conduct business at YNHHS without full registration in the Vendormate System
    b. Those representatives who are witnessed not wearing a badge will be questioned by hospital personnel, advised of the policy, and immediately referred to the facility's senior Supply Chain Coordinator or other Supply Chain Management personnel.
    c. For those vendor representatives that are conducting business at an off-site location (e.g., NEMG practice), the vendor representatives have the option of either going to the closest hospital to obtain a badge or using the digital badge on the Vendormate mobile application.
5. Vendor Representatives must read and acknowledge understanding and compliance with all policies, guidelines, and documentation requirements in Vendormate Credentialing to be issued the Vendormate ID badge.
    a. If non-compliant with any requirements, vendor representative must contact Vendormate Credentialing to resolve the issue. Vendormate Credentialing provides email communication of updated or changed policies that must be reviewed, as well as 90, 60, and 30-day notifications of any other requirements including health screenings/vaccinations needed to remain compliant.
    b. If vendor is still not compliant, the Vendormate ID badge will not print.

   c. Vendor may **not** enter any site or department in this circumstance and must satisfactorily correct the deficiency. Entering any site or department without a current Vendormate ID badge is a violation of policy and will result in vendor suspension from further business at any YNHHS site, or other action, as appropriate.
6. Upon Vendormate registration, the Vendor Representative must read and acknowledge acceptance of the YNHHS PCR guidelines initially and annually thereafter.
   a. Questions regarding these guidelines shall be directed to the contact system within Vendormate, who will then direct the inquiry to the appropriate party within YNHHS.
   b. Site Managers are responsible for enforcing Vendormate badge in all areas.
7. Vendor visits are by advanced appointment only and with full authorization in Vendormate. No "cold calls" allowed.
8. Vendormate Credentialing will automatically inactivate vendors who have not visited the facility within the last 12 months. It is the vendor's responsibility to ensure they remain compliant and are active in Vendormate Credentialing which includes being up to date with vaccinations per YNHHS Policies.
9. Vendors should not enter the hospital if they have a cold, the flu, or symptoms of an infection (e.g., fever, rash, cough, sore throat, nausea, vomiting or diarrhea).
10. Loitering is not permitted in any area of the hospital.
11. Vendors are only allowed to park in Visitor Parking and are responsible for costs. Vendors are not permitted to park or unload their vehicles at patient entrances, patient parking spaces, or areas reserved for patients.
12. Vendors should maintain a patient and patient family focus when onsite and adhere to the YNHHS Code of Conduct.
13. Vendor representatives will not be allowed to conduct business on YNNHS property after 5:00 pm unless prior arrangements have been made for activities such as OR/procedural area technical support, product fairs/demonstrations, in-service programs, or service/repair work.
14. All new technology and new product requests must be initiated by clinicians and are subject to evaluation and endorsement by the appropriate YNHHS committee, which will be determined based upon clinical need and supporting evidence, contract terms and conditions, financial and reimbursement implications, and operational and inventory impact. Please refer to the YNHHS Contracts and Authorized Signatories Policy.
15. Requests for evaluation of new products similarly must be initiated by clinicians and requires approval through the New Product/Trial Request Process via PARTE.
   a. Products and equipment undergoing an evaluation require a contract vetted by the Supply Chain Contracting Department and signed by authorized YNHH administration members specifying duration, use parameters, and any financial terms.
   b. Trials of pharmaceuticals are not permitted.
   c. Please refer to the YNHHS Contracts and Authorized Signatories Policy.
16. Vendor Representatives may not use inter-hospital phones, paging system, or inter-hospital mail systems.
17. Vendor Representatives are not permitted to provide funding, gifts, or meals for education in-services, whether on campus or off campus, unless specifically invited through a written request from the YNHHS Department's Administration to attend for the purpose of educating.

18. Vendor Representatives may not be present on any clinical site at any time without an appointment made with the Department's leadership.
19. Vendor Representatives may only be present in patient care areas for the purpose of staff education/support, repair/service of equipment, or for maintenance of consigned stock or instrument trays. Other approved appointments must be held in a location that does not require travel through a patient care area.

**B.** Violation of the Vendor Expectations and Oversight Policy

1. In the event that a member of the YNHHS staff observes a Vendor or Vendor Representative in violation of this policy, the staff member should immediately notify a department (i.e. Pharmacy) or a Corporate Supply Chain Management representative (Contact list available on the Materials Management intranet site at Clinical Materials Contact List).
2. YNHHS will investigate and determine appropriate disciplinary action based upon the severity, circumstances, and frequency of the violation. Such action will be communicated to all system hospitals, as needed. Examples of disciplinary action include:
    a. Verbal and/or written warning to the vendor representative and their supervisor.
    b. Restriction of all activity and service calls at any YNHHS location (3 months, 6 months, 1-year, or indefinite) depending on infraction and related factors.
    c. Violations of any representative of a given company may result in disciplinary action applicable to all representatives of that company.

**C.** Protocols Specific to Vendor Access to the Operating Rooms or Heart & Vascular-Interventional Radiology, and other Procedural Areas

1. Access, Conduct, and Attire
    a. Entering any Hospital Site – adhere to guidelines outlined in Procedures Section A of this document.
    b. Entering Perioperative Services or IR/CATH Procedural Areas/Departments at individual sites**:**
        i. Entering Procedural Areas: Vendors with printed ID Badge may only enter procedural areas if compliant with all Vendormate Credentialing requirements and specific sign in requirements, and if on site for legitimate business which includes in-room/suite procedure support, consignment inventory management or a confirmed appointment with a staff member physician or staff manager/supervisor.
        ii. Attire in Procedural Areas
            A. Vendors must wear only disposable RepScrubs issued from the vendor machines. All vendors must display Vendormate badge and RepScrubs badge. Scrub suits or cover-ups from any other facility or site are not permitted. RepScrub suits are issued for use in procedural areas and are not allowed to be used as street attire. RepScrubs may not be worn in any area outside the walls of the hospital including transportation between campuses or sites, food cart areas, garages, and parking lots. Vendors must wear specific site/department issued RepScrubs and head cover at all times

in procedure areas. The procedure for obtaining RepScrubs varies by site. Please address questions to site specific Managers.

B. In addition, as per Surgical Attire in Perioperative and Procedural Areas policy, all head and facial hair, including sideburns and hair at the nape of the neck, will be covered when in the semi-restricted and restricted areas of the surgical suite. A single-use mask will be worn in the procedural areas where there may be open sterile supplies. The mask must cover both the mouth and the nose. It must be secured in a manner that prevents venting. Disposable masks are not to be saved for future use by wearing around the neck or tucking in pockets. Remove and discard mask after use by handling only the ties. Powered-Air-Purifying-Respirators (spacesuits) will be used for total joint procedures and other cases deemed appropriate by the surgeon.

C. It is the expectation that vendors covering multiple cases simultaneously be conscious of traffic within rooms and minimize exits and returns. This means that coordination of implant needs should be generated via phone whenever possible, eliminating additional traffic within the Operating Room.

c. Vendor Role within Procedural Areas

i. Criteria for Vendor's Presence in Procedural Areas:

A. Provision of a consigned item required for a procedure
B. Surgeon requested procedural support of new product or technology
C. Education of staff on a new product or new technology
D. Equipment repair or maintenance
E. Maintenance of instrument trays or consigned inventory

ii. Vendors are forbidden to scrub and/or to participate in patient care/contact including personally operating, using, or manipulating any equipment (vendor or hospital owned) at any time, in any way. The only exceptions are for ICD/Pacemaker programmers, Neuro-monitoring/DBS equipment, navigation equipment, laser equipment, or blood collection devices approved by the Tissue & Transfusion Safety Officer or Blood Bank Director.

iii. Any requested product or implant provided by the vendor must be handed off to the circulator nurse for verification and documentation into patient record if required. The vendor representative is prohibited from engaging in product verification or delivery of any product or implant to the sterile field.

iv. Vendors serve only as equipment and product resources and are only permitted to offer technical advice to the team regarding their company's equipment or products. Discussions regarding alternative products distract medical staff and can detract from patient care and are thereby prohibited.

v. Vendor visits require appointments with departmental approval. Sales visits are not permitted.

2. Evaluation of New Product (Non-Formulary)

a. No new product or non-formulary supply, instrument, or equipment is to be used in procedural areas at any time without advance review and written approval. This includes any item that is new, updated/upgraded, not currently used and/or not yet

approved for use at the respective YNHHS site. Please check with Value Analysis to ensure product is approved and on formulary.

b. Supplies/Instruments
    i. Supply/Instrument New Product use is not permitted without a Physician request and prior authorization by site-specific Supply Chain Management at least two (2) business days in advance.
    ii. Non-compliance is a violation of policy and will result in vendor suspension from future business at any YNHHS site.
    iii. Vendors will **not** be paid for unapproved items.
    iv. Instrumentation/ implants must be delivered to the site-specific SPD 24 hours prior to surgery for onsite sterilization. Vendors should provide enough instrumentation to support case volume in one (1) day without the need for re-sterilization. Instrument sets must be checked and removed from the hospital within 24 hours after use.
    v. To maintain and document an appropriate chain of custody, any Bone or Tissue, including components, products **CANNOT** be provided directly to YNHHS clinicians to bring to procedural areas. These products must be shipped into the hospital on a Purchase Order and **cannot** be hand carried into procedural areas.
    vi. Vendor requesting to have implants/supplies consigned at the hospital must have these items reviewed and approved by Clinical Materials Management (CMM). Vendor must provide a list that includes the system name, product description, manufacturer # and quantity that will be signed by both parties. If they are to be kept in a bin, it must be hospital appropriate. Bins must be stacked neatly and labeled with the contents so it can be matched against the agreed list of consigned items. All changes to the consignment list must be reviewed and approved by CMM.
    vii. Implants and related instruments brought in on a case-specific basis should come in 24 hours before the case and be removed within 24 hours after the case. Bins need to be labeled with the name of surgeon and YNNH site, date and time of surgery, and patient initials. Bins must be stacked neatly. Cardboard boxes are not allowed in the OR.
    viii. Vendors are not permitted to relocate inventory within the system or externally without express permission from YNHHS leadership.
c. Equipment-Specific Expectations
    i. Equipment evaluation or use is not permitted without a Physician request and written authorization by a site manager at least five (5) business days in advance. New equipment evaluation requests must be initiated by clinicians and are subject to evaluation and endorsement by the appropriate YNHHS committee, which will be determined based upon clinical need and supporting evidence, contract terms and conditions, financial and reimbursement implications, and operational and inventory impact.
    ii. Use of Capital/Clinical Equipment requires the additional completion of the Capital Equipment Trial/Loan Form including all required signatures by YNHHS administrative representatives, prior to delivering equipment to any YNHHS site. For any agreement to be considered binding, CSC Contracting

departments will review/create any equipment loan or evaluation contracts/agreements to ensure compliance with YNHHS and oversight agency standards. Short term use/evaluation of equipment requires coordination with the site-specific manager.

iii. Safety Inspection: The Clinical Engineering Department must inspect all approved electrical equipment prior to trial/use. Inspection stickers will be affixed by Clinical Engineering and any equipment without an updated inspection sticker may not be used in any procedural area.

iv. Please refer to the YNHHS Contracts and Authorized Signatories Policy for the signing of any contracts. Contracts signed inappropriately may be considered invalid.

d. Staff Training and Education

i. After appropriate authorization, vendor will provide any operationally or legislatively required education and training on equipment, supply or instrument operation and use. It should include but not be limited to, sufficient information regarding sterilization, decontamination, operation, function, safety precautions, and proper disposal of products, equipment, and devices as well as latex allergy implications. Such training shall be documented and validated by the Vendor and OR Educator and maintained as appropriate.

3. Product Addition to Inventory
   a. In circumstances where a new product is requested by a Physician for ongoing use, the New Technology Review process must be followed.
      i. Vendors **cannot** complete or submit a New Product Request Form.
      ii. Vendor should provide product information as requested by physician, the Value Analysis team, CSC Contracting department, and/or site management.
4. Billing and Other Guidelines
   a. Vendors must provide invoices within 48 hours after use. Failure to do so may result in non-payment.
   b. Automated Bill only Vendors: only items with Lawson numbers will be reimbursed. All items without a Lawson number must be reviewed and approved prior to use or will not be reimbursed.
5. Monitoring and Compliance
   a. In addition to Materials Management staff, Physicians, Patient Service Managers, Circulating Nurses and/or Scrub Technicians will also monitor Vendors in the procedural areas according to the above guidelines.
   b. Non-compliance with any aspect of this policy will be reported to Materials Management and will result in restricted or suspended access and written report to manufacturer/vendor.
6. Questions/Contacts
   a. As noted throughout this policy, there are circumstances requiring contact with site-specific department management to include the OR, Heart and Vascular (IR/CATH) and Sterile Processing areas. It is the responsibility of the vendor to identify and contact these individuals as appropriate. Questions can be directed to any of the Clinical Materials Management team.

7. Supplier Corrective Action Request (SCAR) Process
    a. It is the policy of YNHHS that the SCAR process is initiated by the team/department who identified the compliance issues or poor customer service from our vendors. Corporate Supply Chain will review the complaint and may further investigate surrounding circumstances to make recommendations on further processing. Once the process is initiated, Strategic Sourcing is responsible for preparing the necessary documentation based on Procedures, Section C.9., and finally the SCAR documents will be issued to the vendor by Corporate Compliance.
8. SCAR Procedures
    a. SCAR Process Initiation
        i. The team or department who identifies the anomaly regarding vendor compliance to our internal policies and procedures, or lack of adequate customer service, will enter the SCAR request in Smartsheet using the following link: https://app.smartsheet.com/b/form/25713ba488bc47ddac8b65cea5b11a8d
        ii. All mandatory fields must be completed and supporting documentation provided, either in the description field of the form, or by attaching documents/files to the SCAR Smartsheet form.
    b. SCAR Process Documentation Preparation
        i. Strategic Sourcing will prepare the SCAR documentation using the standard template, and using the information provided in Procedures, Section B of this policy.
        ii. After the documentation has been completed, Strategic Sourcing will send any egregious issues to Corporate Compliance who will complete the investigation as warranted.
        iii. If a disciplinary action is required, Strategic Sourcing will make the necessary changes in Vendormate to restrict the vendor from YNHHS facilities.
    c. SCAR Process Distribution
        i. Corporate Supply Chain will review the documentation provided and distribute to the vendor point of contact. From this point onwards, any communication between YNHHS and the vendor regarding the SCAR will be responsibility of Corporate Supply Chain.
    d. Criteria for Corrective and Disciplinary Action
        i. The following table delineates some examples of criteria that will be used when determining disciplinary actions if a vendor has failed to adhere to YNHHS policies, or when the level of service provided is not as expected. Actual disciplinary action applied may be modified based on severity or repetition of infraction, or other factors, and ultimately is at the discernment of the relevant department and Corporate Supply Chain.

| **Policy Violation or Service Quality Issues** | **Disciplinary Action (first offense)** |
|---|---|
| Failure to comply with the Gifts and Gratuity policy of Interactions with Vendor Policy | 90-day suspension |
| Failure to comply with the Vendor Visitation Policy | 30-day suspension |
| Failure to comply with the Vendor Bill Only Process | Written Warning, non-payment |

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| Failure to comply with the Standards of Professional Behavior | 30-day suspension |
| Event which affected patient care (e.g., arrived late for support to a scheduled case, brought in an expired implant to a case, delivering vendor trays <24hrs before the case, etc.) | 30-day suspension |
| Repeat Violation | 90-day suspension |
| Theft or Fraud | Permanent Suspension |

ii. If a vendor representative is going to be suspended from doing business at YNHHS:
   A. Corporate Supply Chain must work with the vendor to ensure case coverage and support will be available after the suspension.
   B. Clinical Leadership of the site where this vendor conducts business will be notified ahead of the suspension.

e. SCAR Appeals Committee
   i. If a vendor appeals a SCAR, the situation will be escalated to the SCAR Appeals Committee, which includes the following members:
      A. VP of Supply Chain
      B. VP of Periop Services
      C. VP of Corporate Compliance
   ii. The SCAR Appeals Committee will take into consideration all the evidence that was collected during the investigation of the incident and will determine if the SCAR stands as initially issued, or if any changes are required.

**D.** Gifts, Gratuities and Business Courtesies

1. Vendor Representatives must adhere to the guidelines expressed in the Gifts & Gratuities policy and the Interactions with Vendors policy.
2. No YNHHS employee is to ask for or to receive anything of value from a vendor that could influence or be perceived as influencing the judgment of the employee in the execution of their duties. To this end, no gifts whatsoever, including meals, shall be requested of, or accepted from, vendors.
3. Vendors and YNHHS employees are asked to report any violations of this procedure to the YNHHS Office of Privacy and Corporate Compliance (OPCC).
   a. OPCC Contact Information:
      i. Phone: 203-688-8416
      ii. Email: Compliance@ynhh.org **or** Privacy@ynhh.org
      iii. Hotline: 1-888-688-7744 **or** www.ynhhscomplianceprogramhotline.com

**E.** Guidelines for Pharmaceutical Company Representatives

1. Pharmaceutical Company Representatives (PCRs) or Medical Liaisons (MLs) must adhere to Procedures, Section A (General Vendor Credentialing). In addition:
   a. The Formulary Integration Committee (FIC), Pharmacy and Therapeutics Committee (P&T), and its sub-committee members shall not be specifically targeted by PCRs or MLs regarding product information or Committee business items.
2. Disbursement of product Information

a. PCRs or MLs shall first inform the Department of Pharmacy Services of new drugs they wish to discuss at YNHHS.
    i. Information changes pertaining to medications on formulary (e.g., indications, dosage, routes of administration, formulations, etc.) shall be provided to the Department of Pharmacy Services prior to discussion with other YNHHS personnel.
b. All pharmaceutical detailing shall be within the context of the Formulary Integration Committee (FIC) approved criteria for restricted drugs.
    i. PCRs shall limit discussions of restricted drugs with those authorized to prescribe as noted in the Formulary Integration Committee (FIC) approved criteria and designated pharmacy staff.
c. At no time shall PCRs or MLs detail non-formulary drugs or indications not included in the YNHHS criteria or specific hospital criteria without approval from the Director of Pharmacy Services or their designee.
    i. Non-formulary categories include the following: drugs not yet reviewed by the Formulary Committee, drugs reviewed and denied addition, and off-criteria indications of restricted formulary drugs.
d. All information and materials distributed at YNHHS must be approved by the Director of Pharmacy Services or designee prior to distribution.
e. Patient-related education and teaching materials may be distributed at the request of the institution.
f. Product package inserts and peer-reviewed journal articles that are not company labeled may be distributed only when attached to the YNHHS Criteria for Use to highlight differences between FDA approved indications and YNHHS approved indications.
g. Promotional materials may not be left in any area of a YNHHS facility, including public areas.

3. Educational Activities
    a. PCRs or MLs may not post and YNHHS will not advertise industry-sponsored events that are not CME/CE accredited or fail to comply with the YNHHS or Yale School of Medicine Conflict of Interest Policy, Accreditation Council for Continuing Medical Education (ACCME), or Accreditation Council for Pharmacy Education (ACPE) standards.

**REFERENCES**

A. Clinical Materials Management Contact List - Clinical Materials Contact List
B. YNHHS Code of Conduct

**RELATED POLICIES**

Gifts & Gratuities
Interactions with Vendors
Surgical Attire in Perioperative and Procedural Areas
YNHHS Contracts and Authorized Signatories Policy

**POLICY HISTORY**

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|---|---|
| A. Policy Origin Date | 05/01/2011 |
| B. Supersedes | Vendor Visitation Policy V-2 (YNHH); Vendor Visitation Policy (BH); Vendor Visitation Policy, Gifts & Business Courtesies from Vendors Guidelines, Gifts & Gratuities Policy (GH); Vendor Access to the Operating Rooms or Heart & Vascular, IR/Cath Lab Procedural Areas; Pharmaceutical Company Representatives and Medical Liaison Visitation Policy |
| C. Approved with Revisions | 07/31/2013; 09/18/2017; 11/28/2017; 08/14/2018; 09/12/2018; 12/11/2019; 10/06/2023 |
| D. Approved without Revisions | N/A |