Service Area: Supply Chain Management	**YALE NEW HAVEN HEALTH POLICY & PROCEDURES**
Title: YNHHS Vendor Visitation Policy	
Date Approved: 10/18/2018, 02/13/2020	**Approved by:** System Operating Committee (SOC)
Date Effective: 02/17/2020	**Date Reviewed/Revised:** 07/31/2013; 09/18/2017; 11/28/2017; 8/14/2018; 9/12/2018, 12/11/2019
Distribution: MCN Policy Manager and YNHHS Internet Page	**System Policy Type (I or II):** Type I
Supersedes: YNHH Vendor Visitation Policy V-2. Bridgeport Hospital Vendor Visitation Policy Greenwich Hospital Vendor Visitation Policy, Gifts & Business Courtesies from Vendors Guidelines, Gifts & Gratuities Policy, Vendor Access to the Operating Rooms or Heart & Vascular, IR/Cath Lab Procedural Areas, Pharmaceutical Company Representatives and Medical Liaison Visitation Policy, On Site Review by External Agency Representatives, Vendor Liaison Post Hospital Care Provider	

PURPOSE

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" , to enhance patient care, quality and safety, ensure confidentiality of information and cost effective procurement that complies 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 and other providers including, but not limited to, Northeast Medical Group and each of their subsidiary entities.

POLICY

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

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

Vendor Representative(s – Any representative such as, sales person, 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.

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

REPSCRUBS – Disposable scrub distribution system utilized by onsite vendor representatives to conform to O.R. attire policy.

PROCEDURES

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Section I: General Vendor Visitation Procedures

A. Vendor representatives, PCRs 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 Sections I, II, III, and IV of this document. Pharmaceutical representatives are additionally required to adhere to the YNHHS Pharmaceutical Vendor Policy (Section V).

B. All Vendor representatives wishing to conduct business at YNNHS facilities must do so

through the designated Supply Chain Management Department credentialing service (Vendormate) and another System department (such as Pharmacy Department, Food Services, Facilities/Construction, OR and IR/Cath Lab).

C. Vendors who have been authorized as YNHHS business partners by Corporate Supply Chain and one 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 breach of this policy.

D. Vendor Representatives are individuals who market products and services to YNHHS facilities. All Vendor representatives must be fully registered and signed in to the VendorMate vendor management system upon each visit to the hospital. Representatives are not allowed to conduct business at YNHHS without full registration in the VendorMate System. When fully registered and upon signing into the system upon each visit, the Vendor representative will then be allowed to print a vendor badge with photo ID, that must be worn visibly on a part of the clothing located above the waist. 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 Procurement Coordinator or other Supply Chain Management personnel.

E. Vendor Representatives must read and acknowledge understanding and compliance with all policies, guidelines and documentation requirements in Vendormate Credentialing in order to be issued the Vendormate Credentialing ID. If non-compliant with any requirements, vendor 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 health screening or other requirements needed to remain compliant. If vendor is still not compliant, the Vendormate Credentialing sticker will not print. Vendor may not enter any site or department in this circumstance and must satisfactorily correct the deficiency. Entering any site or department without a Vendormate Credentialing ID sticker is a serious violation of policy and will result in vendor suspension from further business at any YNHHS site, or other action as appropriate.

F. Upon Vendormate registration, the Vendor Representative must read and acknowledge acceptance of the YNHHS PCR guidelines initially and annually thereafter.

    1. 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.

G. Vendor visits are by advanced appointment only. No "Cold Calls" allowed.

H. 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 are compliant and are active in Vendormate Credentialing which includes being update to date with vaccinations per YNHHS Policies.

I. Vendors should not enter the hospital if they have a cold, the flu or symptoms of an infection such as fever, rash, cough, sore throat, nausea, vomiting or diarrhea.

J. Loitering is not permitted in any area of the hospital.

K. Vendors are not allowed to park or unload at patient entrances.

L. Vendors should maintain a patient and patient family focus when onsite and adhere to the YNHHS Code of Conduct.

M. 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 product fairs/demonstrations, OR or other procedural area technical support, in-service programs, or service / repair work.

N. All new technology and new product requests must be initiated by clinicians or other hospital or university staff, and are subject to evaluation by the appropriate YNHHS committee based upon clinical need and evidence, contract terms and conditions, financial and reimbursement implications, and operational and inventory impact.

O. Requests for Trials of new products similarly must be initiated by clinicians or other hospital staff and requires approval through the New Product/Trial Request Process via Epic. Trials of pharmaceuticals are not permitted.

P. Vendor Representatives may not use inter-hospital phones, paging system or inter-hospital mail systems.

Q. Vendor Representatives are not permitted to attend or provide educational in-services at YNHHS unless specifically invited through a written request from the Department Administration.

R. Vendor Representatives may not be present in patient care areas at any time unless an appointment is made with a company technician, who is on hand to repair and/or educate staff on the use of equipment. Other approved appointments must be held in a location that does not require travel through a patient care area.

Section II: Violation of Vendor Policy

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 http://sp2010app1vp.ynhh.org:8000/SCM/Pages/Clinical-Materials-Management.aspx. YNHHS will investigate and, based upon the severity, circumstances, and frequency of the violation, shall determine appropriate disciplinary action. Such action will be communicated to all system hospitals, as needed. Examples include:

A. Verbal and/or written warning to the vendor representative and his/her supervisor.

B. Restriction of all activity and service calls at any YNHHS location (3 months, 6 months, 1-year, or indefinite) depending on infraction.

C. Violations of any representative of a given company may result in disciplinary action applicable to all representatives of that company.

Section III: Procedures Specific to Vendor Access to the Operating Rooms or Heart & Vascular-Interventional and Procedural Areas

This section of the policy documents expectations for vendors who conduct business with the Department of Perioperative Services and/or the Operating Rooms (OR) and Heart & Vascular Center (HVC) at any site within YNHHS. It addresses access, conduct and attire, identification, role of vendor representative in procedural areas, provision, marketing, trials and sales of equipment, supplies or instruments, and billing requirements. **These guidelines are in addition to Privacy, Compliance and Information Security Policies, the YNHHS Code of Conduct and Scrub Suits and Surgical Attire Policy and Procedure NC: S-6.**

A. **Access, Conduct and Attire**

1. Entering any Hospital Site – adhere to guidelines outlined in Section I of this document

2. Entering Perioperative Services or IR/CATH Procedural Areas/ Departments at individual sites**:**

- Entering Procedural Areas
  Vendors with or without a photo ID may only enter procedural areas if compliant with all Vendormate Credentialing requirements, if compliant with site 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, manager or other. Vendors who will regularly provide onsite in-room/ suite support, particularly during off-shifts and weekends, should request photo ID through the site specific Manager.

- Attire in Procedural Areas
  Vendors must wear only the specific site/ department issued scrubs. Scrub suits or cover-ups from any other facility or site are not permitted. Scrub suits are issued for use in procedural areas and are not allowed to be used as street attire.

  Scrubs 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 scrubs and head covers at all times. The procedure for obtaining scrubs varies by site. Please address questions to site specific Managers.

  For York Street and Saint Raphael Hospital locations, all Vendors who enter the restricted area of the surgical suite must wear REPSCRUBS that have been dispensed via the facility SCRUBPORT. The Vendor must have a Badge adhered to the REPSCRUBS that is current and not expired. Street clothes are NOT to be

worn under REPSCRUBS. Tee shirts, if worn, must be completely covered by REPSCRUBS. Leaving the building with the intent in returning to a sterile patient care area or department must access the SCRUBPORT for another REPSCRUBS. Not following hospital protocol can result in being removed and/or banned from the facility.

In addition, as per Scrub Suits and Surgical Attire Policy NC:S-6, 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.

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

3. Vendor Role within Procedural Areas

Vendors are forbidden to scrub and/or to participate in patient care or 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, TAVR, Neuro-monitoring/DBS equipment, navigation equipment, laser equipment or blood collection devices approved by the Tissue & Transfusion Safety Officer or Blood Bank Director.

Vendors who fall under the above exceptions will submit, through Vendormate, annual documentation of their competencies and qualifications on the products, equipment and/or services they provide in procedural areas.

A vendor present in procedural area may provide the requested product or implant to the circulator as requested or required; though at no time may a vendor be actively engaged with the verification or delivery of a sterile implant or supply to the sterile field.

Vendors serve only as equipment and product resources and are only permitted to offer technical advice to the team regarding their equipment or device.

B. **Delivery of Instrumentation and/or Implants Requirements (Formulary or Non-Formulary)**

1. 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 day without the need for re-sterilization. Instrument sets must be checked and removed from the hospital within 24 hours after use.

C. **Evaluation or Trial of New (Non-Formulary) Products**

No new or non-formulary supply, instrument or equipment is to be detailed, used or trialed 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 approved for use at the respective YNHHS site. Approval for a trial is valid for use in up to 5 cases unless the YNHHS Clinical Governance Committee CGC) authorizes additional trial uses/cases in writing. Corporate Supply Chain will monitor trial case usage to ensure compliance.

1. Supplies/Instruments

- Supply/ Instrument trials or use are not permitted absent a Physician request to site specific management and written authorization by same at least 2 business days in advance.

- Non-compliance is a serious violation of policy and will result in vendor suspension from future business at any YNHHS site. Vendors will not be paid for unapproved items.

- In order to maintain and document an appropriate chain of custody, Implants and Bone and Tissue or any other products **CANNOT** be provided directly to YNHHS clinicians to bring to procedural areas. These products must be shipped into the hospital on a PO and cannot be hand carried into procedural areas.

- Vendor requesting to have implants/supplies consigned at the hospital must have these items reviewed and approved by Clinical Materials Management. 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 we can match it against the agreed list of consigned items. All changes to the consignment list must be reviewed and approved by CMM.

- Implants brought in on a case specific basis should come in 24hours before the case and be removed within 24 hours after the case. Bins need to be labeled with the surgeon, system name, date and time of surgery and patient initials. Bins must be stacked neatly. Cardboard boxes are not allowed in the OR.

2. Equipment Specific Expectations

- Equipment trials or use are not permitted absent a Physician request and written authorization by a site manager at least 5 business days in advance.

- Use of Capital/ Clinical Equipment requires the additional completion of the Capital Equipment Trial/Loan Form including all required signatures, prior to delivering equipment to any YNHHS site. Any such circumstance requires contact and coordination with the site specific manager.

- 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 absent an updated inspection sticker may not be used in any procedural area.

- Safety Event Management and Medical Device Reporting: Whenever medical equipment is broken it will immediately be removed from service, tagged as broken and Clinical Engineering will be contacted. If a patient is harmed and a onetime use device was involved, the department manager will be notified and will sequester the device. A sequestered device (one that was suspected to have caused harm to a patient must not be sent to the manufacturer or disposed of but rather maintained by the department manager or by the Legal & Risk Services Department. Patient information and/or the device will not be provided to the manufacturer or their representatives.

3. Staff Training and Education

   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.

D. **Product Addition to Inventory**

In circumstances where a new product is requested by a Physician for ongoing use, the New Technology Review process must be followed.

1. Vendors **cannot** complete or submit a New Product Request Form.

2. Vendor should provide product information as requested by physician or site management.

E. **Billing and Other Guidelines**

1. Vendors must provide invoices within 48 hours after use. Failure to do so may result in non-payment.

2. 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.

F. **Monitoring and Compliance**

1. 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.

2. 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.

G. **Questions / Contacts**

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 contact the delivery network/site and department specific materials management personnel.

Section IV: Gifts, Gratuities and Business Courtesies

Vendor Representatives must adhere to the guidelines expressed in the YNHHS "Gifts, Gratuities, and Business Courtesies" Policy.

No YNHHS employee is to ask for or receive anything of value from a vendor that could influence or be perceived as influencing the judgment of the employee in the execution of his/her duties. To this end, no gifts whatsoever, including meals, shall be requested or accepted from vendors. Vendors and YNHHS employees are asked to report any violations of this procedure to the YNHHS Office of Privacy and Corporate Compliance.

YNHHS Office of Privacy and Corporate Compliance Contact Information:

Phone: (203) 688-8416
Email: Compliance@ynhh.org or Privacy@ynhh.org
Hotline: 1-888-688-7744

Section V: Guidelines for Pharmaceutical Company Representatives

General Code of Conduct for Pharmaceutical Company Representatives PCR)/Medical Liaisons (MLs)

A. PCRs or MLs must adhere to all policies outlined in **Section I: General Vendor Visitation Procedures**. In addition:

1. 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.

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.

1. Information changes pertaining to medications on formulary (i.e. 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.

    1. 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 Medical Liaisons 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 his/her designee.

    1. 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 the Medical Center, including public areas.

Educational Activities

A. PCRs or Medical Liaisons 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.

Section VIII: Vendor Liaison Post-Hospital Care Provider & DME Representative

A. GENERAL STATEMENT FOR PURPOSE:

To define guidelines, which direct activities of liaisons/representatives identified by Care Coordination from, but not limited to, from post-acute hospital, interim care facilities, homecare, infusion companies during on site hospital visits. When requested, DME may be delivered to the hospital for patient use upon discharge. DME representative will check with patients nursing staff before interacting with patient and/or family.

- Ensure that patient care and patient privacy are not compromised.
- Facilitate timely discharges to clinically appropriate settings.

- Maintain effective communication between Clinical Effectiveness staff and other YNHH staff members as needed or required.
- Effectively utilize the time of YNHH staff members and post hospital care liaisons/representatives.

B. GUIDELINES:

It is expected that the post hospital care facility liaison/representative and/or DME representative will only evaluate the patient for which the facility was invited to review and NOT attempt to solicit 'new' business. Sharing of post-acute services information may be accomplished through distributing information through the main office of the Department of Clinical Effectiveness.

C. ROLE/FUNCTION OF LIAISON:

a. **Definition:** The liaison acts as a resource to educate the patient and family regarding the services available at their represented facility/vendor services as invited by patient care team. The liaison participates in all components of the process to facilitate a smooth transition to the next level of care accomplished through active and timely communication with YNHH staff and pt/family.

b. The credential liaison functions in the following capacities in relation to: Skilled Nursing Facility, Acute Rehab Facility, or Long Term Hospital evaluations and transfers. Specific Homecare and Infusion Therapy Service personnel are also included.

   i. Assists care coordinator and patient care team in determining level of care patient will require as a post discharge patient.
   ii. Discusses facilities treatment philosophy and infrastructure of services with patient and family. Discusses expectations and limitations of homecare services prior to discharge. Explains ability to meet anticipated care needs with patient and family. Assures demographics and contact information is correct.
   iii. Gathers pertinent medical and financial information from medical record, patient care team, patient and family. The liaison will not make copies of the medical record.
   iv. Discusses and assists family with understanding of the financial resources needed to support transfer. When appropriate, obtains insurance authorization for services.
   v. **Communicates** status of referral assessments **to the care coordinator regarding** acceptance, barriers and expected determination of patient's admission or denial to facility.
   vi. Collaborates with medical team and family to identify potential barriers to affect a timely and safe transfer.
   vii. Facilitates a patient's clinically safe transfer to facility or home with hospital staff.

c. Determination of Hospice In-patient vs. Home Care Needs:

   i. Assists care coordinator and patient care team in determining level of care patient will require and services necessary to support patients home care needs.
   ii. In collaboration with members of the hospital team, discuss hospice philosophy and services that will be provided to the patient and family.

iii. Determine based on insurance, need, psychological state and hospice resources the level of care patient can receive from hospice agencies and collaborates with Care Coordinator regarding the arranging for these services and supplies.
iv. Identify barriers preventing implementation of plan.
v. Remains in constant communication with Care Coordinator related to the planning process and need for collaborative intervention.
vi. Anticipates care needs of the patient and offers suggestions to the medical team for possible emergency conditions and/or pain management.

D. ROLE/FUNCTION OF DME REPRESENTATIVE

a. Provides equipment requested.
b. Demonstrates use of equipment.
c. Provides information to patient regarding ongoing services.
d. Reports to care coordinator/nursing staff any problems encountered.
e. Provides family with contact number if problems occur with equipment.

E. PROCEDURE:

a. Representatives must sign in at the Case Management Office before going to patient care areas. The following information must be presented:
    i. Company/Agency identification
    ii. List of patients to be reviewed or visited
b. Chart reviews must be conducted at the appropriate nurses 'station, unless otherwise directed by the charge nurse. Due to limited space available on the nursing units, reviews should be completed as quickly as possible.
c. Admissions coordinators, home health agencies and DME representatives may review charts when a specific request for their services has occurred.
d. Patient/family interviews may be conducted following contact with the respective Case Manager or Social Worker prior to the interview. Staff in the Case Management office will assist in identifying these individuals for interviews.
e. Chart review and patient /family interviews for the purpose of soliciting referrals is prohibited.

REFERENCES

Clinical Materials Management Contact List
http://sp2010app1vp.ynhh.org:8000/SCM/Documents/CMM%20Contact%20List%202017.pdf

RELATED POLICIES/DOCUMENTS

YNHHS Code of Conduct

Scrub Suit and Surgical Attire Policy and Procedure NC: S-6
https://ynhh.ellucid.com/documents/view/6883

REPSCRUBS
www.repscrubs.com
If you have any questions or require help registering, please call (407) 547-2680 or email info@repscrubs.com

Document Information

Document Title

Vendor Visitation Policy

Document Description

To provide guidelines that give Vendor Representatives an opportunity 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), to enhance patient care quality and safety, respect for the confidentiality of information and to ensure a cost effective procurement system that complies with YNHHS contractual and ethical policies and standards while fostering an environment of fair competition with vendor access and control.

Approval Information

Approved On:	02/13/2020
Approved By:	System Operating Committee
Approval Expires:	02/13/2023
Approval Type:	Manual Entry
Document Location:	/ YNHHS - Supply Chain Management
Keywords:	Vendor Visitation; reps; representative; rep, SC: I - 001
Printed By:	Guest User
Standard References:	N/A
Note:	This copy will expire in 24 hours