

SUBJECT: Health Care Industry Representatives (HCIRs) Standards of Conduct and Vendor Credentialing	REFERENCE NUMBER: M.14-HSM-8072-0301
APPROVALS:	ORIGIN DATE: 10/2008
	REVISION NUMBER: 1
	REVISION DATE: 5/2013
	MOST RECENT REVIEW DATE: 5/2013

PURPOSE:

The purpose of this policy is to provide reasonable and consistent standards for Health Care Industry Representatives (HCIRs) who do business with Park Nicollet Health Services (PNHS) in order to promote patient safety and ethical business relationships. All HCIRs are expected to understand and abide by the standards established in this policy.

OWNER:

The Director, Supply Chain, and the Chief Compliance Officer of PNHS are the owners of this policy.

CONTACT/CONTENT EXPERT:

Director, Supply Chain

DEFINITIONS:

Accountable Personnel: Accountable Personnel refers to any Staff member who is a physician leader (service line chief, department chair, and site leader), vice-president, or designated director or supervisory personnel.

Entertainment: The word entertainment is defined in accordance with its usual and customary meaning, to mean something that entertains, such as a performance or show. It includes activities such as attending events, like a Twins or Vikings game, as well as participating in sporting events such as golf.

Gifts: Any money, real or personal property, a service, a loan, a forbearance or forgiveness or indebtedness, or a promise of future employment, that is given and received without the giver receiving consideration of equal or greater value in return. Gifts do not include Patient Education Materials, or free Samples, Supplies, or Equipment intended for use by PNHS patients. Examples of gifts include personal items such as iPads, iPods, or clothes; items for use in the workplace, whether branded or not, such as pens, notepads, or clocks; as well as food, beverages, transportation, lodging and entertainment.

Health Care Industry Representative (HCIR): HCIR refers to any individual representing any vendor, manufacturer, distributor, contractor, service company or any other organization that

sells or provides products or services to PNHS. HCIRs perform marketing activities, manage contract sales, generate other sales, provide quotes, demonstrate products, solve problems, advise clients on matters, or perform many other duties generally associated with their company. Examples of HCIRs may include, but are not limited to, marketing and sales roles, such as office product, technology hardware and software, business support services, pharmaceutical, medical supply or device sales.

Patient Care Areas (PCA): PCAs are any and all sites in any PNHS Facility in which patients and visitors may receive care, including but not limited to examination rooms, emergency centers, Urgent Care Clinics, hospital floors, procedure rooms, and laboratory and imaging areas, or in any area in which patients and visitors may traverse, assemble, wait, visit, or otherwise occupy space for any purpose, including but not limited to waiting rooms, lounges, and registration areas, with the exception of specific public areas, including cafeterias and entrance areas.

Patient Education Materials: Written or electronic materials necessary to educate the patient about a product, or solicit a patient's informed consent to use a product in connection with the patient's care.

PNHS Facilities: PNHS Facilities refers to all facilities owned or operated by PNHS, including Methodist Hospital, Park Nicollet Clinics, and Tria. Please note that the Check-In Process is currently only required of HCIRs when on site at Methodist Hospital.

Reprax: Reprax is the name of the program implemented by PNHS to help us ensure that our Health Care Industry Representatives (HCIRs) meet our standards for environmental health, privacy, safety, and quality. Reprax is the outside organization that handles the registration and review process for our HCIRs and also supplies the software program and temporary badges that our HCIRs will use.

Samples, Supplies or Equipment: Free product samples, supplies, or equipment provided by HCI that are not intended to be sold and are intended for patient use.

Staff: Staff refers to any PNHS employee, temporary employee, student or volunteer at any location, as well as independent health care practitioners on the PNHS medical staff while they are providing clinical, administrative, or other services in or on behalf of any Facility owned or operated by PNHS.

POLICY:

All HCIRs conducting business with PNHS Staff will adhere to the standards identified in this policy in order to ensure the safety of PNHS patients, and promote ethical relationships between HCIRs and PNHS Staff. PNHS Staff will understand the standards contained in this policy and report non-compliance to the Director, Supply Chain. An HCIR's failure to abide by these standards could result in termination of business relationships with PNHS, prohibition of conducting future business with PNHS, and a ban on access to PNHS Facilities.

PROCESS:

A. Standards of Conduct

1. Gifts Prohibited

HCIRs are prohibited from offering or providing any Gifts to PNHS Staff. This includes a prohibition against offering or providing free food to PNHS Staff.

- a. HCIRs are not prohibited from providing PNHS Staff with Patient Education Materials. However, such materials must be provided directly to PNHS Staff and may not be displayed or left in any location in PNHS Facilities. Unless specifically agreed to in writing, acceptance of Patient Education Materials by PNHS Staff does not obligate PNHS to distribute such materials to patients.
- b. HCIRs are not prohibited from providing PNHS Staff with free Samples, Supplies or Equipment intended for use by PNHS patients. However, use of such items is limited by PNHS policy, as may be changed from time to time. Unless specifically agreed to in writing, acceptance of free Samples, Supplies or Equipment does not obligate PNHS to distribute such items to patients.

2. Access to PNHS Staff and PNHS Facilities

HCIRs may not visit PNHS Staff in any PNHS Facility without an invitation from PNHS Staff. Invitation is defined as a verifiable written or oral agreement or arrangement, defined mutually, for HCIRs to have personal or group setting access to any PNHS Staff. Specific departments may provide additional requirements for accessing PNHS Staff, and such requirements must be followed by HCIRs.

3. HCIR Conduct in PNHS Facilities in General

- a. PNHS internal communication resources, such as corporate group e-mails, voice-mails, or other distribution lists, shall not be provided to or used by HCIRs to contact PNHS Staff, but HCIRs can contact *individual* clinicians and Accountable Personnel in accordance with the policies of PNHS.
- b. HCIRs shall not use any PNHS equipment, including but not limited to phones, computers, and office equipment such as copiers and printers, and materials such as stationery and office supplies, unless Accountable Personnel give permission and are physically present during such use.
- c. HCIRs shall not use PNHS paging systems to locate any PNHS Staff.
- d. PNHS reserves the right to limit parking for HCIRs.
- e. HCIRs are prohibited from access to and use of the Arneson Methodist Hospital Library or any other PNHS library facilities, unless specifically granted by Accountable Personnel and accompanied by such personnel.
- f. HCIRs are prohibited from attending any and all PNHS medical or surgical meetings or conferences in which patient-specific material is presented or discussed without an invitation by Accountable Personnel also in attendance at that meeting. Advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during or after the educational activity. HCIRs shall not engage in sales or promotional activities while in the educational activity.
- g. HCIRs shall leave PNHS Facilities promptly after conducting business.

4. HCIR Conduct in Patient Care Areas

- a. HCIRs are prohibited from entering a PCA without authorization by Accountable Personnel. Other PNHS Staff are not authorized to permit access to PCAs.
- b. HCIRs are prohibited from engaging in product detailing, selling, marketing, promotion, or other product-related business in any PCA.
- c. HCIRs shall not use cell phones in any PCA at any PNHS Facilities.
- d. HCIRs working in or have access to Operating Rooms, patient procedural areas, and other patient care areas must have advance verifiable appointments for their attendance and work, arranged through the appropriate Accountable Personnel.
- e. HCIRs shall only have limited locations and work space in any Operating Room or procedural area as verified and defined by PNHS Accountable Personnel.
- f. HCIRs must sign in and out for each visit to the Operating Room or procedure area, using standard procedures established for visiting HCIRs. HCIRs may also text “out” to 53856 if they’re set up with Mobile Device Services through Reprax. This functionality is only available for checking out.
- g. HCIRs must observe strict privacy and confidentiality rules around patient identifiers of any kind in patient care areas. No written or electronic information, materials, objects, devices, labels, or other items with patient information on them or belonging to patients shall be removed from these settings.
- h. HCIRs shall only touch, use, or operate products, materials, devices, and machines for which they are authorized and currently representing.
- i. HCIRs are prohibited from touching patients or any instrumentation, devices, equipment, products, or materials (e.g. pacemakers, catheters, prostheses, surgical equipment or devices) in any way connected to a patient except those patients using materials for which the HCIR is responsible.
- j. Authorized HCIRs may calibrate a pacemaker, implantable cardioverter defibrillator, and other devices for which they are specifically contracted to do so. Authorized HCIRs with special training and meeting industry requirements may perform remote calibration, if authorized by PNHS Accountable Personnel.

B. Credentialing Requirements

Non-Clinical and Clinical HCIRs conducting business with PNHS are required to register within 60 days following an initial contact or visit to a PNHS Facility and thereafter, annually through the approved PNHS HCIR web-based registration company (Reprax –www.reprax.com). Attachment A provides a flowchart that describes the HCIR Enrollment Process and the Check In Process required of Non-Clinical and Clinical HCIRs.

Non-Clinical and Clinical HCIRs will be required to follow a Check In Process when visiting PNHS Staff at Methodist Hospital. There are five check in locations:

- Safety and Security Office, 1st floor between Methodist and Meadowbrook
- Cath Lab, HVC, 2nd floor
- Methodist Pharmacy
- Operating Room, Methodist 2nd floor

- Lab, E315, Meadowbrook

Instructions for individuals staffing the check in locations at Methodist Hospital is available from Supply Chain Administration.

A Quick Reference Guide for PNHS staff regarding the credentialing process is provided in Attachment B.

HCIR Categories

If there is a question as to the correct category of a particular HCIR, the Director of Supply Chain may be consulted to determine the appropriate category.

1. Administrative

HCIRs in this category do not serve in clinical support roles. It is unlikely that HCIRs in this category would ever access patient care areas, and any contact with patients would be incidental. Examples of HCIRs in this category include repair personnel (gas, electric, plumbing), maintenance personnel, construction workers and business consultants such as accountants, attorneys, employee benefit consultants, and other finance, strategy, and business consultants.

HCIRs in this category are not normally required to register with Reprax, unless Accountable Personnel require that they register as a non-clinical HCIR. Even if not required to register in Reprax, companies employing such HCIRs must ensure that their employees and agents understand and abide by the Standards of Conduct described above. In addition, if HCIRs in this category are provided with uniforms or nametags by their companies, such uniforms or nametags should be worn while providing services in a PNHS Facility.

2. Non-Clinical

HCIRs in this category provide some technical assistance and might enter patient care areas, but have no direct involvement in patient procedures. HCIRs in this category must register with Reprax and complete the Registration Requirements identified in Attachment C.

3. Clinical

HCIRs in this category often work in patient care areas. HCIRs in this category must register with Reprax and complete the Registration Requirements identified in Attachment C.

RELATED DOCUMENTS

[Gifts and Entertainment \(A.68-HSM-8201-0899\)](#)

[Conflicts of Interest \(A.77-HSM-8201-0804\)](#)

[Product Review \(M.15-HSM-8072-0301\)](#)

[Loaner Instrumentation and Implants Receiving and Retrieval JJ.15-MH-7030-0209](#)

[Consulting, Speaking, and Other Relationships between Staff and the Health Care Industry \(A.63-HSM-8201-0908\)](#)

ATTACHMENTS

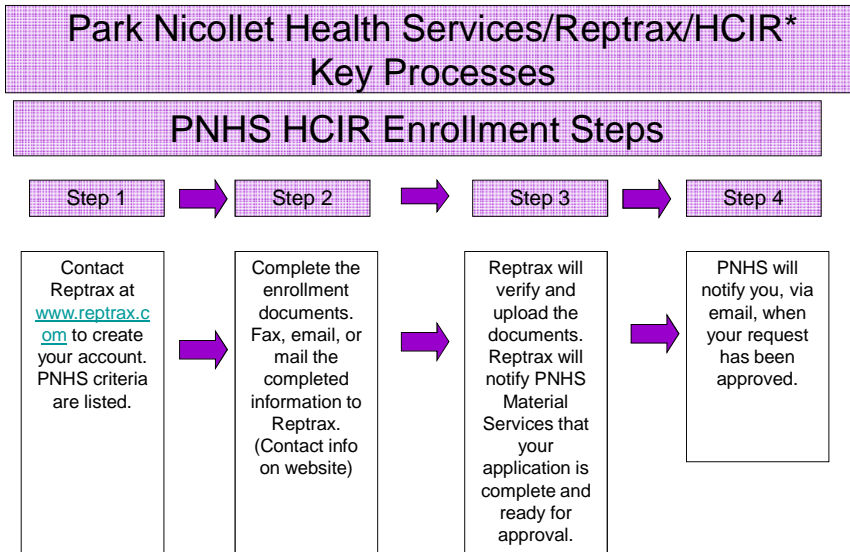
Attachment A – PNHS/Reprax/HCIR Key Processes

Attachment B - Quick Reference Guide Regarding Vendor Credentialing
Attachment C - PNHS HCIR Requirements

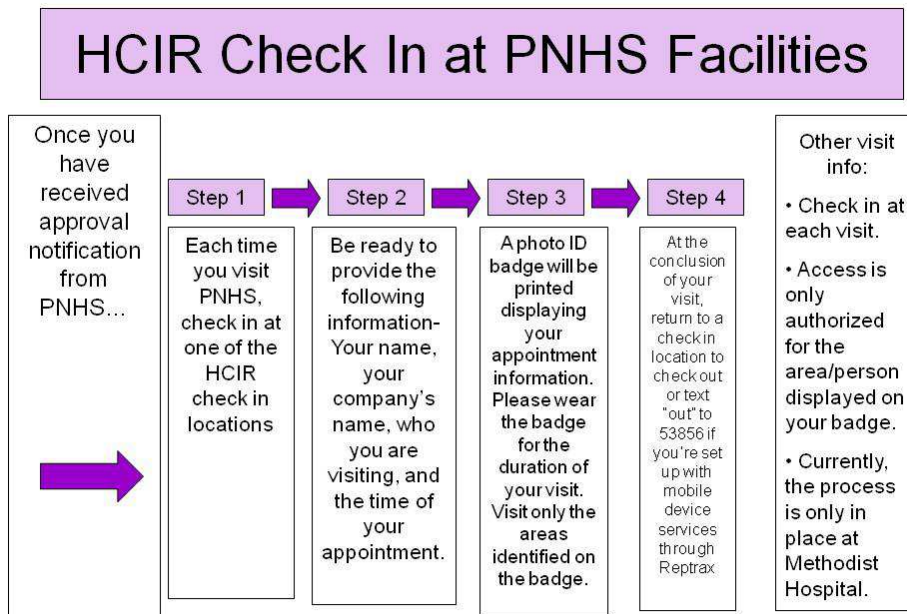
COMMITTEE APPROVAL
Corporate Compliance Committee

NOTE: This policy replaces Health Care Industry Representative (HCIR) Relationships M.14-HSM-8072-0301.

Attachment A



*Health Care Industry Representative

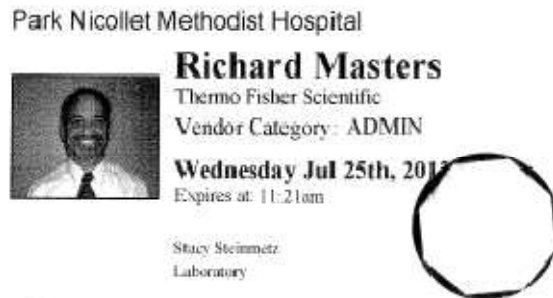


Attachment B – Quick Reference Guide Regarding Vendor Credentialing

Q #1: What do the Reprax badges look like?

A: The badge:

- Has the HCIR's picture, name of company, name of HCIR and date
- Is good for 12 hours – after 12 hours, the word “STOP” bleeds through
- Has a place for an appointment time and with whom



Q #2: What if I see an HCIR in my area without a badge?

A: Ask them to stop at an HCIR check in site for a badge. If they have not yet registered with Reprax, someone in the check in site will be able to provide them with information on how to get registered.

Q #3: What if I see an HCIR in my area with a badge showing “STOP” on it.

A: This means the badge has expired. The badges are designed to expire in 12 hours. “STOP” bleeds through 12 hours after the badge has been issued. If you see an HCIR with an expired badge, ask them to stop back at the HCIR check in site for a new badge.

Q #4: Will the Reprax system provide access reports for PN managers and other interested individuals?

A: Yes, reports can be generated detailing the access activities of HCIR's.

Q# 5: Why do non-clinical HCIRs (vendors) need to register with Reprax? They often don't have any patient contact.

A: The Reprax process provides a streamlined way for us to track access by non-clinical HCIRs and to make sure they are adequately identified with name badges and have checked in when visiting our Facilities. Through the services they provide to PNHS, non-clinical HCIRs still can impact and affect the level of care provided to patients. Although many non-clinical HCIRs will not directly access patient care areas at PNHS Facilities, it still is very important for them to have knowledge of and comply with the critical organizational policies that guide and govern supply chain activities for HCIRs.

- Q# 6: Do all repair personnel (gas, electric, plumbing) and contractor personnel (construction workers, painters) need to register with Reprax? What about the office product personnel who assemble office furniture in our Facilities?**
- A:** These types of personnel would be considered Administrative HCIRs and do not need to register with Reprax. The type of work and services they provide, although critical to PNHS as a whole, do not pertain to sales of supplies or services that are used to support daily operations and patient care levels. Their services focus primarily on maintenance of our physical Facilities, or providing business or consulting services to PNHS.
- Q# 7: Do medical equipment repair personnel have to register with Reprax?**
- A:** Yes, they would be considered non-clinical HCIRs and are subject to the criteria PNHS requires of non-clinical HCIRs.
- Q# 8: If an HCIR is regularly at the Methodist Campus as part of a clinical team (for example, a clinical consultant who assists in the orthopedic or cardiovascular areas on a daily basis) do they have to check in and pick up a temporary badge every time they come to Methodist?**
- A:** We want to make sure that non-PNHS personnel such as this who work with patients are properly identified, and we want to be able to monitor the frequency of their visits, so we expect them to check in each time. They are considered Clinical HCIRs and must Check In upon arrival at Methodist Hospital.
- Q# 9 Some HCIRs, such as waste disposal or paper shredding vendors, or carpet delivery vendors are in and out multiple time in a week, and may not consistently send the same person to do the job. Are they required to register with Reprax, and do they have to check in each time they visit the PNHS Methodist campus and pick up a badge?**
- A:** These contractors are considered Administrative HCIRs, so they are not required to register with Reprax, but if their company issues them a badge or a uniform with their name on it, we ask that they wear such identification while working in PNHS. Check with the Director, Supply Chain if you have a question about a specific vendor.
- Q #10: Do office machine/computer repair personnel (such as the copy machine repair person or computer installation person) have to register with Reprax, check in and pick up a temporary badge every time they visit the PNHS Methodist Campus?**
- A:** These contractors are considered Administrative HCIRs, so they are not required to register with Reprax, but if their company issues them a badge or a uniform with their name on it, we ask that they wear such identification while working in PNHS. Check with the Director, Supply Chain if you have a question about a specific vendor.
- Q #11: Sometimes medical professionals from nursing homes or similar Facilities come to PNHS to evaluate patients who may transfer to their Facility. Are they required to register with Reprax?**

A: These medical professionals are not considered HCIRs, so they are not subject to the Reprax registration requirement. However, such medical professionals should make an appointment with Care Integration. If this is not happening, contact the Director, Care Integration, Social Services for assistance.

Q: #12 **Are non-clinical HCIRs (who may occasionally work or spend time in patient care areas) subject to Reprax, and do they need to check in and get a name badge each time they visit PNHS Methodist? (Examples: process improvement consultants or information technology consultants.)**

A: These contractors are considered Administrative HCIRs, so they are not required to register with Reprax, but if their company issues them a badge or a uniform with their name on it, we ask that they wear such identification while working in PNHS. Check with the Director, Supply Chain if you have a question about a specific vendor.

Q: #13: **What are the requirements for service league personnel, such as the people who sell merchandise in our lobby areas under the auspices of the auxiliary?**

A: These personnel are not considered HCIRs, so they are not required to register with Reprax. However, we ask that they stop by the Information desk for a “Visitor” badge.

Q: #14 **Do trainees of HCIR companies need to register with Reprax and follow the check in process if they are accompanied by an HCIR who is registered with Reprax?**

A: Yes, trainees are required to register and badge when visiting the Methodist Hospital Campus.

Q: #15 **An HCIR has arrived with treats or giveaway items such as pens and notepads for the department. What do I do?**

A: Remind the HCIR of our policy entitled Health Care Industry Representatives (HCIRs) Standards of Conduct and Vendor Credentialing Policy which prohibits them from offering or providing Gifts to PNHS Staff.

Q: #16 **An HCIR is attempting to invoice PNHS for the Medical Device Tax under the Accountable Care Act. What should I do?**

A: Contact Contact Director, Supply Chain Management who will coordinate a response from the VP, Controller and Director, Supply Chain Management.

Attachment C – PNHS HCIR Requirements

Registration Requirements	Clinical Health Care Industry Representatives	Non Clinical Health Care Industry Representatives	Source	Update frequency
Digital photograph	Required	Required	Digital camera, etc.	Once
Criminal Background Check	Required	Required	Employer letter or form	Annually
PNHS Signed Confidentiality Statement	Required	Required	Park Nicollet Health Services through Reptrax	Annually
Proof of Liability Insurance	Required	Required	Employer letter or form	Annually ¹
Product Training completion certification	Required	Required	Employer letter or Training Facility Certificate	Annually
OR Protocol Training Competency	Required		Employer letter or form (2)	Annually ¹
OSHA Blood & Body Fluids (BBF) Training	Required		Employer letter or Training Facility Certificate (2)	per schedule
Baseline Tuberculin Skin Test	Required		Clinic documentation	per schedule
Hepatitis B Vaccination ⁽¹⁾	Required		Clinic documentation	per schedule
Influenza ⁽¹⁾	Required		Clinic documentation	per schedule
Varicella (Chickenpox)	Required		Clinic documentation	per schedule
Rubella (German measles)	Recommended		Clinic documentation	per schedule
Rubeola (Red measles)	Recommended		Clinic documentation	per schedule
Infectious Parotitis (Mumps)	Recommended		Clinic documentation	per schedule
PNHS Health Care Industry Representatives (HCIRs) Standards of Conduct and Vendor Credentialing Policy	Required	Required	Review & sign off	Annually ²
PNHS Product Review Policy	Required	Required	Review & sign off	Annually ²
Loaner Instrumentation and Implants Receiving and Retrieval	Required for OR reps only		Review & sign off	Annually ²
Code of Conduct Compliance Resource Manual Education for Agents and Contractors Concerning False Claims Liability, Anti-Retaliation Protections, and Detecting and Responding to Fraud, Waste and Abuse http://www.parknicollet.com/Legal/Ethics-Compliance	Required	Required	Review & sign off	Annually ²
Harassment and Offensive Behavior Policy	Required	Required	Review & sign off	Annually
(1) Categorical documentation (completed, denied, in process - include projected completion date) (2) Available on line – search on Medical Education (example = www.Healthstream.com)		Annually ¹ Annually ²	with renewal of registration with renewal of registration or as updated	