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Owner: David Carlson: Gvp Sourcing & Clin Inter Ofcr
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Departments:
Applicability: Providence Health & Services Systemwide

PSJH-REH-1004 Health Care Industry Representatives (HCIR) in Patient Care Areas

Executive Sponsor:	Venkat Bhamidipati, EVP, CFO, PSJH
Owner:	David Carlson, GVP Strategic Sourcing & Clinical Resource Integration, REHG
Contact Person:	Jennie Kim, Director, Supplier Relationship Management

Scope:

This policy applies to Providence St. Joseph Health and its family of organizations^[1] (collectively known as "PSJH") and their caregivers (employees), employees of partner organizations, volunteers and others who are in the direct control of PSJH (collectively referred to as workforce members). This is a management level policy, reviewed and recommended by the Policy Advisory Committee (PAC) to consider for approval by senior leadership, which includes vetting by Operational Leadership Council (OLC) and Executive Council (EC) with final approval by the President, Chief Executive Officer or appropriate delegate.

Purpose:

PSJH recognizes the need for a structured system within the patient care setting for education, training, and introduction of products, techniques, technology, and equipment to the patient care team. Health care industry representatives (HCIR), by virtue of their training, knowledge, and expertise, can provide technical and educational assistance to the patient care team, which facilitates the safe and effective use of products and technologies. Collaborating with HCIRs requires standard guidelines that clearly define the management of HCIRs and their activities within PSJH facilities, consistent with applicable laws, regulations, bylaws, and existing policies. The purpose of this policy is to supply guidelines to PSJH ministries, affiliated health care facilities, and members of the health care team regarding management of HCIRs; to ensure an optimal service, preserving a reasonable opportunity for HCIRs to conduct necessary business and patient care related activities as well as the patient's safety, right to privacy, and confidentiality.

Background:

In keeping with the philosophy and mission of PSJH, it is the policy of PSJH to collaborate with HCIRs to improve the health of the community, contain costs, and optimize the patient experience and safety. The presence of the HCIR during the procedure is not a substitute for any training of the patient care team that is essential to use of the products or services. The patient care team must have the theoretical understanding, knowledge, training, and skills that are necessary for use of the products or services prior to the procedure.

Definitions:

- HCIR:** Health Care Industry Representative, including any health care industry employee, agent, or representative whose responsibilities may include sales, customer service, clinical consultation, technical support, or repair/maintenance. Previous and current policies may define HCIR as "sales", "vendor", "manufacturer", "supplier", "rep", etc.
- PSJH:** Providence St. Joseph Health, its ministries, and all affiliates, including Covenant Health System, Swedish Health Services and Swedish Edmonds entities.
- Facility/Ministry:** Any PSJH location that provides health care services, and its staff.
- Patient care team:** The physicians, allied health professionals, nurses, technologists, and other facility staff whose primary role is providing therapeutic, diagnostic, or ancillary services to the patient.
- Patient care area:** Location or department where a patient is undergoing a procedure or diagnostic test, or receiving any therapeutic

treatments under the care of the patient care team.

6. **REH/REHG:** Resource, Engineering and Hospitality (Group), its staff or team members.

Policy Statement:

Department managers/directors at all facilities, including acute care hospitals, ambulatory surgery facilities, and office based operating room (OR) settings will establish and enforce this policy governing the presence of HCIRs. This and all other policies should comply with applicable state and federal laws and regulations and be consistent with the organization's existing policies. The following sections describe the responsibilities and expectations of the PSJH facilities and HCIRs.

Section	Title
1	Responsibilities of PSJH Facilities
2	Requirements and procedures for HCIRs to be present in the patient care setting
3	Conduct, role and limitations of the HCIR in PSJH facilities
4	Equipment and product management
5	Non-Compliance

Section 1

Responsibilities of PSJH Facilities

1. **Policy and Orientation:** The PSJH Standards/Code(s) of Conduct, this policy and other pertinent paperwork such as this policy, attestation forms and orientation material specific to the facility will be available through the online vendor management tool, such as GHX's "Vendormate".
2. **Registration and Badging:** PSJH facilities will utilize an online vendor management tool, to collect and review necessary credentialing data and documents.
3. **Introduction to Personnel:** Facility staff or health care provider will introduce the HCIR to all involved procedural staff where appropriate, such as during the "time out".
4. **Monitoring of HCIR:** The HCIR's activities should be monitored by the physician or clinician who is responsible for the patient (or at the physician's discretion, by a supporting health care professional, such as a Physician Assistant or nurse involved in the patient's care). The HCIR's presence and activities in the patient care setting should be recorded in the procedural records.
5. **Attire:** Facility will provide the HCIR with appropriate attire and means to comply with all policies (PSJH facilities are encouraged to utilize methods to clearly identify HCIRs, such as unique color caps or scrubs);
6. **Staff Training:** Facility will work with HCIR to provide the procedural staff with adequate and timely opportunities for any necessary training and in-services for new products and procedures.

Section 2

Requirements and procedures for HCIRs to be present in the patient care setting

1. **Registration and Identification:** Prior to entering any patient care settings, the HCIR must be registered with the vendor management tool used at the facility and must comply with the applicable credentialing requirements identified in that tool. Upon arrival of the HCIR, the facility should provide the HCIR time-limited approval and identification to be visibly worn at all times. The specific check-in and check-out process may vary depending on the facility. The HCIR must follow the check-in and check-out process of the facility they are entering.
2. **Orientation to PSJH:** The HCIR must acknowledge having read and understood the contents of the PSJH Standards/Codes of Conduct booklet (available in the vendor management tool). The HCIR must also complete any required facility/ departmental orientation prior to entering patient care settings.
3. **Credentials:** The HCIR must provide necessary credentials appropriate to the procedure and setting; and attestation/documentation of training on applicable procedures as defined in the vendor management tool including sterile/aseptic techniques, infection prevention and blood-borne pathogens, and OSHA safety standards.
4. **Confidentiality:** The HCIR must demonstrate understanding of HIPAA and sign the Confidentiality and Non-Disclosure Statement (HIPAA Statement). The HCIR must comply with all applicable federal and state laws and local and system PSJH policies that protect patient privacy and Protected Health Information (PHI), and the PHI section of the Code of Conduct.

5. **Health Screening:** The HCIR must comply with required immunizations and TB test, and upload required documentation into the vendor management tool.
6. **Appointment Required:** The HCIR visiting the facility for a specific patient procedure may be present only by appointment made a minimum of 24 hours prior to the procedure, and only at the request of the physician or applicable clinician at the time the procedure is scheduled. Emergency requests without appointment may only be requested by the physician or the nurse in charge. Facility access for other purposes also require an appointment accepted by the PSJH staff requesting the visit.
7. **Authorization:** The HCIR's presence in the patient care setting is authorized by the clinical director/ manager of the department and the physician or clinician who requested the HCIR's presence.
8. **Patient Rights and Consent:** Except in a life- or limb-threatening emergency, the patient's (or patient's designee's) acknowledgment of the presence and purpose of HCIR during the procedure should be documented.
9. **Product Testing:** For product testing situations, the HCIR will comply with all requirements as determined by REHG.
10. **Conflict of Interest:** Conflicts of interest between HCIRs and PSJH employees or physicians, or the appearance thereof, must be avoided. PSJH maintains a Conflict of Interest (COI) Policy applicable to the HCIR and the COI Policy's requirements are in addition to the requirements of this policy. When an actual, potential, or perceived conflict of interest occurs, it must be disclosed in writing to the Strategic Sourcing Manager and documented in their PSJH conflict of interest disclosure form as soon as reasonably possible. Actual, perceived or potential conflicts of interest may also be reported through the Integrity Hotline (1-888-294-8455) or Integrity Online.
11. **Eligibility:** PSJH will not do business with any company/supplier/vendor if it or any of its officers, directors, or employees is or becomes ineligible to participate in any federal health care program, or is or has been convicted of a criminal offense in relation to the provision of health care. Absent prior approval by PSJH REH, HCIRs may not access a PSJH facility if they have any criminal history or have had a license to provide health care services revoked or suspended by any State licensing authority. PSJH expects each company/supplier/vendor to assume full responsibility for taking all necessary steps to assure that its employees involved in providing goods and services to PSJH, directly or indirectly, have not been or are not currently excluded from participation in any federal program. (See PSJH-REH-1005 Excluded Individuals and Entities Checks - Vendors)
12. **Publicity:** HCIRs are not permitted to distribute advertising, press releases, or any other general public announcement regarding the use of their products or services in PSJH facilities or by PSJH physicians, employees, or other staff, without prior written authorization from PSJH.
13. **Parking:** HCIR must park it's vehicle in appropriate, designated locations as identified by the facility. Unattended vehicles will be towed at the owner's expense.

Section 3

Conduct, role and limitations of the HCIR in PSJH facilities

1. **Role of HCIR:** The HCIR's role is to provide essential technical training and assistance related to the specific product(s), service, or technology being used on a specific patient within a defined time period as determined by the health care professional. The role will be specifically re-defined for each patient encounter.
2. **No Direct Patient Care:** The HCIR may not engage in the practice of medicine or surgery, nursing, or any other medical decision making process. This includes suggesting alternative or unplanned usage of the product or technology that could constitute departure from standard of care or FDA approval of the product ("off-label").
3. **Services Allowed:** The HCIR may be involved in remote operation, inspection, service, calibration or manipulation of medical products to the physician's and manufacturer's specifications under the physician's supervision and within the limitations of FDA approval. The HCIR may not scrub in the procedure other than for training, preparation, or other limited activities directly pertaining to their device or product that requires sterility.
4. **Training:** The HCIR must provide all necessary education and training related to the scheduled procedure for the patient care team ideally a minimum of 24 hours prior to the procedure.
5. **Defined Visitation Purpose:** The HCIR's visit is specific to the individual patient and procedure on that day or other non-procedural purpose for which visit is scheduled; the HCIR may not use the opportunity of an approved procedural visit to introduce any unplanned product or technology that has not been previously approved.
6. **Access Limitations:** HCIR may not remain in facility any longer than is necessary for the procedure(s) scheduled or approved business. The HCIR's presence is strictly limited to the area he/she has approved access. HCIR may not enter any other patient care areas or "wander" around the facility.
7. **Promotional Activities and Solicitation:** PSJH strictly prohibits HCIRs from soliciting any health care provider or facility staff, or leaving promotional materials in public or patient care areas within the facility without prior approval by PSJH REH member.

8. **Displaying of product or promotional materials** without prior approval in public areas such as lobbies, cafeteria, elevators, and parking lot is also prohibited.
9. **Conduct Within the Patient Care Area:** The HCIR's conduct and attire should be professional and appropriate for the patient care environment. Attire should include a method of clearly identifying HCIR as NOT a member of the medical/nursing staff (e.g. unique color scrubs/hat, badge color, etc.). The HCIR may not enter the patient care area until prepping and draping is complete, where applicable, unless the HCIR's presence is required for the prepping and/or draping. The HCIR should be introduced to the entire OR/procedural team and purpose of visit clearly explained by the physician. The "time-out" or procedural pause should include acknowledgement of the HCIR.
10. **Non-essential Items:** The HCIR may not bring any non-essential objects (such as bags, cases, personal items) into the procedural area. The facility should provide cleaning materials to clean or wipe down any essential outside items prior to entry into sterile areas.
11. **Recorded Media:** Photographs, video, or audio recordings by the HCIR is strictly forbidden. (PSJH-RIS-801.11 Acceptable Use)
12. **Business Representation:** The HCIR may not knowingly misrepresent information, such as contract details, cost of product/services, utilization by other facilities/physicians, status in local or national trials, FDA status, details of competing products, or outcomes data.
13. **Contracts:** PSJH has established contract standards for a wide variety of products and services. Non-standard products and services in competition with these contracts may not be promoted by HCIRs without prior approval by PSJH Strategic Sourcing staff. Only the PSJH Strategic Sourcing Manager is authorized to sign contracts on behalf of PSJH. HCIRs or other company/supplier representatives may not attempt to arrange or sign contracts with any other PSJH employee, physician or department. HCIRs may not divulge contract-specific information with anyone without prior approval by PSJH Strategic Sourcing.
14. **Request for Information/Proposal/Quote (RFI/RFP/RFQ):** Participating suppliers responding to an request will enter a "Quiet Period" which means that no supplier employee, representative or agent, including HCIR, together may have verbal or written (including text messages) communications with any PSJH Caregiver (employee) or Provider (physician) regarding the request. Should a Caregiver or Provider contact Supplier Personnel/HCIR verbally or in writing (including text messaging) regarding contracting or the request, the Supplier Personnel/HCIR must direct the Caregiver or Provider to the PSJH Strategic Sourcing Manager responsible for the request. The Supplier Personnel/HCIR must not discuss the request and must inform the PSJH Strategic Sourcing Manager of the Caregiver or Provider contact. Communications regarding the request may only take place directly with the PSJH Strategic Sourcing Manager. The request is a PSJH internal process and any external interference (e.g. participation in internal decision making, conference calls, retaining or sharing any internal information you become aware of) is in direct violation of the "Quiet Period" and will result in the Supplier being disqualified from the request process.
15. **Timely Invoice Submission:** HCIRs billing for items provided for use during a procedure are required to present a properly completed company sales order no-later than 24 hours upon completion of the case. If the procedure is completed on a Friday or the day preceding a holiday, 24 hours is then defined as one business day. The sales order must be signed by the case RN or designee of PSJH and include procedure date, physician name, patient name, item catalog number(s), description(s) of the item(s), quantity used- including any wasted item(s), and per item pricing. The sales order is to be submitted to an authorized PSJH personnel, as indicated by the facility. Failure to provide a complete and timely sales order may cause PSJH to consider the items a donation from the supplier and no payment will be provided.
16. **The HCIR may not bring gifts or food/meals** into the facility other than that allowed by the Standards/Codes of Conduct. Cash, cash equivalents, or any gifts which could be perceived as intended to influence a PSJH staff or physician's decision or judgment are never permitted. Contact PSJH System Integrity or your regional compliance office if you have a question regarding this section. Individual facilities may have more restrictive gift standards. Workforce members will follow the more restrictive standard.

Section 4

Equipment and product management

1. **HCIR-delivered Instruments:** The HCIR is wholly responsible for ensuring that HCIR-delivered instrument sets are complete and correctly assembled/disassembled upon arrival and departure. The HCIR is responsible for ensuring that an adequate number of products and instrument sets are available for each procedure. Count sheets, when required, should be provided. If no count sheets are provided, the facility will not be responsible for the cost of any item missing after the procedure. PSJH follows the Association for the Advancement of Medical Instrumentation (AAMI) guidelines that require no loaded tray should be heavier than **25 pounds**, including the weight of the tray itself; based on the manual lifting standard proposed by the National Institute for Occupational Safety and Health (NIOSH). All HCIR-delivered instrument sets must be removed within 24 hours of completion of the procedure, unless it will be used again within that time period. Specific requirements for handling HCIR-delivered instruments may vary by facility.
2. **Instrument Tracking Management Solution:** PSJH may utilize an instrument tracking management solution (such as Settrax) to coordinate, receive and manage HCIR-delivered instruments. HCIR will register with designated instrument tracking management solution and comply with all required processes and policies identified through designated instrument tray management tool.

3. **Sterilization and High Level Disinfection (HLD):** Sterilization/HLD of instruments or other items will be performed by the facility per protocol, as needed. Any items requiring sterilization/HLD must be delivered to the facility at least 24 hours prior to the scheduled procedure, or as directed by the facility. The HCIR is responsible for providing any special cleaning, disinfection, disassembly, and sterilization/HLD instructions that meet the minimum manufacturer's recommendations, when necessary. The HCIR must also provide the vendor's procedure for sterilization/HLD, when applicable, such as for pre-sterilized items.
4. **Product Handling and Documentation:** The HCIR must collaborate with circulating nurse or other members of the patient care team to assist in proper documentation of product information, checking expiration dates, integrity of packaging, etc. The HCIR may not open sterile packaging or dispense sterile items onto the procedural field.
5. **Power Compatibility/Safety:** Equipment requiring power will be inspected and approved by biomedical staff prior to usage.
6. **Facility Equipment:** The HCIR may not use, adjust, alter, remove, or operate any equipment in the patient care area, other than that which he/she brought into the area or is owned/serviced by his/her company.
7. **Medical Product/Device Storage:** Storing product(s) and/or device(s) at any PSJH facility is strictly reserved for PSJH usage.
8. **Samples:** The HCIR may not leave product "samples" in the facility without the prior approval of Strategic Sourcing. All delivered samples must be approved and documented with a valid "no charge" purchase order.

Section 5

Non-compliance

1. **Policy Non-compliance and Disruptive Behavior:** Non-compliance with any PSJH policies and any behavior that disrupts the facility's business or patient care, or that affects patient or staff safety, will be investigated and will result in immediate restriction from all facilities during the investigation. If the non-compliance or disruptive behavior is confirmed, the HCIR may be subject to verbal/written warning, initiating the dispute resolution process under the Vendor Agreement, HCIR removal from the facility, limitation or restriction of future access by HCIR and/or all other HCIRs from that supplier/company, notation in the vendor management tool profile, and/or distribution to other PSJH facilities. Access limitations issued by one PSJH facility will be applied to all PSJH facilities. All decisions are final at the time communicated and are at the sole discretion of PSJH.
2. **Fraud, Waste, and Abuse:** PSJH will investigate and take appropriate action, which may include reporting to the appropriate government and/or law enforcement agency, pursuing civil action or pressing criminal charges, for all allegations of fraud, waste, and/or abuse. Please refer to the Code of Conduct for details. The policy prohibits retaliation against any PSJH workforce member for reporting a concern in good faith.
3. **No Responsibility:** Non-compliance with any PSJH policies may result in the facility assuming no responsibility for payment for products used, lost, or damaged, and may lead to restrictions of the HCIR's activities at all PSJH facilities.
4. **Patient Care Team Authority:** Any member of the patient care team may request that the HCIR leave the patient care area at any time for any reason, and the HCIR must comply with such request.
5. **Contact Person:** Any questions regarding this policy and all HCIR management procedures, including access to the facility, should be addressed to the REH Operations Manager/Supervisor responsible for the facility.

Guiding Principles:

PSJH Standards/Codes of Conduct

Additional policies referenced throughout this document:

PSJH-GOV-208 Conflicts of Interest Policy

PSJH-REH-1005 Excluded Individuals and Entities Checks

Vendor Badging Policy

PSJH Privacy and Security Policies (including Confidentiality)

Attachments:

PSJH-REH-1004A HCIR in Patient Care Areas - COVID-19 Addendum

Applicability

^[1] For purposes of this policy, "Affiliates" is defined as any entity that is wholly owned or controlled by Providence St. Joseph Health

(PSJH), Providence Health & Services, St. Joseph Health System, Western HealthConnect, Covenant Health Network, Inc., or is jointly owned or controlled by PSJH or its Affiliates and bears the Providence, Swedish Health Services, Swedish Edmonds, St. Joseph Health, Covenant Health Network, Covenant Health, Kadlec Regional Medical Center, or PacMed Clinics name (includes Medical Groups, Hospice, Home Health, etc.).

Attachments

[PSJH-REH-1004 HCIR in Patient Care Areas - COVID 19 Addendum - FINAL 5 26 20.pdf](#)

Approval Signatures

Approver	Date
Cynthia Johnston	04/2019
David Carlson	04/2019
Jennie Kim	04/2019

Applicability

AK - Providence Alaska MC, AK - Providence Kodiak Island MC, AK - Providence Seward MC, AK - Providence Valdez MC, CA - Mission Hospital Laguna Beach, CA - Mission Hospital Mission Viejo, CA - Petaluma Valley Hospital, CA - Providence Cedars-Sinai Tarzana MC, CA - Providence Holy Cross MC, CA - Providence LCM MC San Pedro, CA - Providence LCM MC Torrance, CA - Providence Saint John's Health Center, CA - Providence Saint Joseph MC, Burbank, CA - Queen of the Valley Medical Center, CA - Redwood Memorial Hospital, CA - Santa Rosa Memorial Hospital, CA - St. Joseph Hospital - Eureka, CA - St. Joseph Hospital Orange County, CA - St. Jude Medical Center, CA - St. Mary Medical Center Apple Valley, MT - Providence St. Joseph MC, Polson, MT - St. Patrick Hospital, OR - Clinical Support Staff (CSS), OR - Connections, OR - Credena Health (CH), OR - Home Health (HH), OR - Home Medical Equipment (HME), OR - Home Services, OR - Home Services Pharmacy (HSRx), OR - Hospice (HO), OR - Providence Ctr for Medically Fragile Children, OR - Providence Hood River Memorial Hospital, OR - Providence Medford MC, OR - Providence Medical Group, OR - Providence Medical Group, OR - Providence Milwaukie Hospital, OR - Providence Newberg MC, OR - Providence Portland MC, OR - Providence Seaside Hospital, OR - Providence St. Vincent MC, OR - Providence Willamette Falls MC, Providence Home and Community Care, Providence St. Joseph Health, Providence and Kadlec Express Care, Swedish Medical Center - Ballard Campus, Swedish Medical Center - Cherry Hill Campus, Swedish Medical Center - Edmonds Campus, Swedish Medical Center - First Hill Campus, Swedish Medical Center - Issaquah Campus, TX - Covenant Children's Hospital, TX - Covenant Hospital Levelland, TX - Covenant Hospital Plainview, TX - Covenant Medical Center, TX - Covenant Specialty Hospital, WA - Kadlec Regional Medical Center, WA - NWR Providence Medical Group, WA - Providence Centralia Hospital, WA - Providence Holy Family Hospital, WA - Providence Mount Carmel Hospital, WA - Providence Physician Services, WA - Providence Regional MC Everett, WA - Providence Sacred Heart MC, WA - Providence St. Joseph's Hospital, WA - Providence St. Mary MC, WA - Providence St. Peter Hospital, WA - Providence Surgery Center, Pacific Campus, WA - SWR Providence Medical Group