System-wide Policy: Allina Supplier Access Policy

Reference #: SYS-SC-ASCM-006

Origination Date:				
Revised Date:				
Next Review Date:				
Effective Date:				

September 2007 August 2012 August 2014

Approval Date:

Approved By: Corporate Compliance

System-Wide Policy Ownership Group: System Policy Information Resource:

Supply Chain Management Director, Purchasing

Stakeholder Groups
Finance Council
Executive Leadership Team (ELT)
Supply Chain Management
Surgery Departments
Cardiology & Vascular Departments
Interventional Radiology Departments

SCOPE:

Sites, Facilities,	Departments,	People applicable to
Business Units	Divisions,	(Physicians, NP,
	Operational Areas	Administration,
		Contractors etc.)
System - Wide		

POLICY STATEMENT:

This Allina policy establishes system wide guidance governing the business relationships between Allina facility personnel and Health Care Industry Representatives. The policy is intended to outline appropriate activities and interactions between Allina employees and these representatives, including the review of product information, sales promotion, sponsorship of medical education, coordination of studies for new and existing products and technologies, and responses for procurement, or recall, of specific products, to meet regulatory guidelines and Allina policies.

It is the Allina Health policy that Health Care Industry Representatives, hereafter referred to as "HCIRs", may only have controlled access to medical care facilities and staff. This policy applies to all clinical and non-clinical areas of Allina. HCIRs are responsible for knowledge of and compliance with this policy. Allina staff are

responsible for reporting non-compliant conduct to Supply Chain Management and/or hospital Security.

DEFINITIONS:

- A. Allina Facilities owned or operated by Allina Health
- B. Allina staff any employee of Allina Health and any physician or healthcare provider caring for patients at Allina
- C. Health Care Industry Representatives (HCIR) Professionals that represent a company or companies to healthcare clients, including physicians, nurses, buyers, purchasing agents, and general users of the company's products. Representatives can generate sales, demonstrate products, solve problems, advise clients on matters, quote prices, or many other duties associated with representing their company.
 - Non-Clinical Health Care Industry Representatives HCIRs that do not primarily serve in clinical support roles. These HCIRs' visits are sales related and do not provide technical assistance, do not operate equipment, and generally do not enter patient care areas.
 - Clinical Health Care Industry Representatives HCIRs that primarily serve clinical support roles. These HCIRs often provide technical assistance or operate equipment. Their roles may require them to work in patient care areas, and/or offer assistance to or consult with patient care staff.
- D. Independent Contractors Individuals working at Allina who meet the criteria establishing them as Independent Contractors (see Human Resources Policy 801)
- E. Patient Care-Related Services It is acknowledged that a limited number of HCIRs may be specifically requested by Allina staff pursuant to a Allina Health policy, to be involved with provision of hands-on patient care via:
 - a) Conducting approved staff or physician training,
 - b) Consulting with staff or physicians concerning a specific patient,
 - c) Programming and/or calibrating an implantable device, or
 - d) Repair or maintenance of medical equipment by trained technicians.

PROCEDURES:

1. HCIRs must adhere to Allina supplier access registration requirements which include signing in and out of Reptrax at each visit, wearing Allina issued name badges at all times in addition to their employer issued photo identification badge. HCIR access is limited to the areas indicated at check in, as stated on the Name Badge. HCIRs can complete Allina's registration process on-line through Allina's vendor credentialing service; Reptrax. Registration must be completed prior to scheduling any appointments, visits, cases, or work at the Allina facility. Contact Allina Supply Chain Management for information. http://www.allinahealth.org/ahs/aboutallina.nsf/page/supplier. HCIRs will

be allowed admittance only ONE time without proper registration as described above and will be denied entry into the facility for any subsequent attempts until registration is completed.

- 2. All interactions with Allina staff by HCIRs must adhere to Allina's Corporate Compliance policies and guidelines.
- 3. In order to minimize the potential for disruption of patient care activities, appointments are required during normal hospital business hours and must be made and confirmed in advance of visiting any Allina facility. HCIRs supporting neuro, orthopedic, spine, or cardiovascular implants may be exempted from this requirement as it is assumed their services will be required by the hospital on a regular basis. HCIRs that are exempt from scheduling appointments will be notified by hospital management of their exempt status.
- 4. Allina staff can only meet with HCIRs if an approved appointment has been scheduled. Meetings with HCIRs are to be conducted by Allina staff in their respective offices or designated areas only. Loitering in Allina corridors and other areas in an attempt to facilitate a non-scheduled meeting with an Allina staff member is prohibited.
- 5. HCIRs are prohibited from conducting business, inclusive of the selling or marketing of products or services, in nursing units, patient care areas, nurse lounges, physician lounges, or any public areas such as cafeterias, lobbies or mailrooms. HCIRs may not enter a nursing unit or patient care area except as permitted in #11 below. Additionally:
 - a) HCIRs will not demonstrate any supplies, equipment or pharmaceuticals to staff or physicians without approval by Supply Chain and the department manager.
 - b) HCIRs will not demonstrate or promote any device which is used to package drugs for patient administration, without proper coordination through Supply Chain Management <u>and</u> Pharmacy Services.
 - c) All supplies and implants must be approved through the Allina New Product Review process. Allina will compensate the supplier \$1 for products that are not approved through this process and may initiate disciplinary action as noted below under **Enforcement and Disciplinary Action.**
 - d) The facility may develop a list of individual staff or departments that do not wish to be called upon by HCIRs. HCIRs are not allowed to make appointments with these individuals or departments.
- 6. HCIRs may not use the Allina network, office equipment, computers, or telephones not available to the general public.
- 7. HCIRs may not use the overhead public address paging system to locate any Allina staff member.
- 8. The facility may designate parking restrictions for HCIRs. HCIRs will pay for parking at the same schedule as patients and visitors.
- 9. HCIRs must enter Allina facilities wearing street clothes and change into facility issued scrubs to perform job functions requiring this attire. HCIRs wearing non-facility issued scrubs may be asked to leave the facility.

- 10. HCIRs must respect the privacy and confidentiality of patients, families, and staff in accordance with HIPAA requirements at all times. In respect to patient privacy:
 - a) HCIR access to patient care areas is not permitted except as outlined in #11.
 - b) HCIRs are not allowed to attend medical care facility conferences where patient specific materials are discussed or presented.
- 11. Patient Care-Related Services may only be provided upon compliance with the below criteria and must, at all times, be conducted under the supervision, direction and responsibility of a licensed Allina Health healthcare professional or physician.
 - a) HCIRs must be accompanied by Allina staff while in patient care areas.
 - b) Only HCIRs providing Patient Care-Related Services may enter into patient care areas within Allina for business purposes and then, only by appointment and preapproval. HCIRs shall complete the authorized business task, immediately leave the area, and return to registration. HCIRs are not authorized to enter employee or physician lounges or proceed into other offices or areas.
 - c) Presence of HCIRs providing Patient Care-Related Services in the OR must be requested by a physician and preapproved by the OR Administrator or designee. HCIRs are limited to the specific case they have been requested to attend and are not to circulate to any other patient care areas.
 - d) HCIRs are required to confirm with staff regarding the patient's Informed Consent to verify that they have not initialed "no observers and/or students" before entering procedure rooms.
 - e) HCIRs are prohibited from providing services as an active participant in patient care. They may provide consultative services for the use, care, demonstration, handling, and maintenance of their products or services. HCIRs are not to "scrub" or be involved in the sterile field, such as opening sterile products. They are not to have any patient contact.
 - f) HCIRs are not allowed to operate any equipment used in a procedure or program/calibrate programmable devices unless under the direction of the attending physician. These devices include but are not limited to: pacemakers, internal cardiac defibrillators, nerve stimulators and lasers.
 - g) HCIRs must attest to receiving the required training, education & health clearance prior to entering patient care areas.
- 12. HCIRs must supply American Association of Tissue Banks AATB certification and U.S. Food & Drug Administration FDA registration documents to Supply Chain prior to introducing tissue and biologic products at Allina. All products must meet the requirements as outlined in the Allina Tissue Purchasing Policy.

- 13. All electrical equipment brought in by HCIRs must be checked by the hospital's biomed staff in the Clinical Equipment Services Department prior to bringing equipment into patient care areas.
- 14. Requests for clinical trial products will be managed through Allina's Investigational Review Board and Sponsored Projects departments.
- 15. All contract, pricing agreement and consignments must signed by a designated Allina Health Supply Chain agent. Agreements, consignment agreements or contracts signed by a non-authorized Allina Health agent will be considered non-binding.
- 16. Any modifications to consignment inventories shall be requested using a Consignment Amendment form and each form executed by both parties.
- 17. Allina shall perform periodic audits with the Supplier and reconcile all discrepancies resulting from each audit within 30 days of the date the inventory was recorded. Audit must be pre-scheduled and conducted during regular business hours only. Specific Allina departments may have additional requirements such as dates & times these audits may be conducted.
- 18. HCIRs are prohibited from using personal communication devices in Allina procedural areas unless accessing information requested by the clinical they are assisting.

Facility Departments & All Facility Employees

- 1. Allina staff should meet with HCIRs only if it has been preapproved by the hospital department manager or Supply Chain Management and they have a scheduled appointment.
- 2. All Allina staff members are responsible for identifying noncompliant or suspicious behavior by the HCIR and immediately reporting the infraction to their manager or facility security. Following notification to manager or security, complete the Allina Health Supplier Representative Incident Report and email to VendorAccess@allina.com

Enforcement and Disciplinary Action

- In exchange for access at Allina Health, HCIRs are required to abide by this Policy. Violations, including but not limited to, harassment of patients, staff members, or associates, aggressive marketing behaviors, or any behavior deemed inappropriate by Allina for an acute care setting, are subject to disciplinary action for the individual and/or the supplier.
- 2. The length, type and severity of disciplinary action for any violation of this policy are at Allina Health's sole discretion. Unless alternative or more severe action is deemed warranted by Allina Health, violations of this policy will result in the following actions:
 - a) First Offense
 - A letter or email indicating the infraction will be sent to the HCIR and the entity they represent.

- The HCIR and their up-line manager will meet with department where the infraction occurred along with a member of Supply Chain Management.
- b) Second Offense
 - A letter indicating the subsequent infraction will be sent to the HCIR and the entity they represent.
 - Access in Reptrax will be revoked until a satisfactory resolution has been reached.
- c) Third Offense
 - All access to Allina Health, for the individual(s) may be suspended permanently.
- 3. Any violations of this policy may affect future vendor relations with Allina Health, at its sole discretion.

FORMS: Supplier Representative Incident Report

REFERENCES:

Related Regulation and Laws:

Alternate Search Terms:

Related Policies:

Related Folicies.					
Name of Policy	Content ID	Business Unit where Originated			
HR Policy AHC 801	~	Human Resources			
Ethical Relationships with Industry Policy Reference #: 402-01.43	192342	Compliance			
Allina New Product	303-26	Supply Chain			
Review Policy		Management			
Tissue Purchasing	SYS-SC-ASCM-003	Supply Chain			
Policy Reference		Management			

Policies Replacing:

Name of Policy	Content ID	Business Unit where Originated
Allina Supplier Access Policy	SYS-FIN-PC-303-12	Finance

Prepared at the direction, request and in furtherance of the purposes of a review organization and should not be shared outside of Allina Health or its Affiliates. Protected under Wis. Stat. 146.38 and Minn. Stat. 145.61 et seq.