

 The power to heal		Clinical Manual
Policy Name: Vendors		Policy #: A 140
Original Date: October 2009	Last Review Date: January 2020	Next Review Date: December 2020
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POLICY:

Staff respects the right of patients to privacy and confidentiality while under the care of the Wound Care Center (WCC) by providing directions and limitations for Vendors who frequent the WCC.

PURPOSE:

To provide guidelines for Vendor activities such as calling on staff and providers of the WCC, providing reimbursement advice, observing patient care and accessing patient records.

DEFINITIONS:

Vendor: Includes but is not limited to Sales Representatives, Pharmaceutical Representatives, and Equipment/Supply Representatives who deliver materials or supplies to the WCC and/or who provide technical expertise for staff and providers of the WCC.

PROCEDURE:

1. Vendors are not allowed to review or access patient’s medical records or other patient sensitive documents during their site visits to the WCC.
2. Information contained in the Healogics Inc. (HI) clinical database is considered protected health information (“PHI”) and is part of patients’ medical records.
 - 2.1. The HI wound database and reports generated from the HI wound database may only be viewed by Hospital and HI employees within their job responsibilities.
 - 2.2. Vendors may not in any way view, have access or obtain access to the HI wound database itself or any report generated from the database, with the exception of modules already loaded into the database system for each individual vendor.
 - 2.3. Failure to comply with this policy may result in disciplinary action, up to and including termination, and possible civil and criminal penalties.
3. Observation of care, treatment or services by a Vendor may be permitted after the provider’s consent and patient’s written authorization have been obtained and documented in the medical record.
4. A Vendor may not assist or perform any care, treatment or service for a WCC patient involving physical contact with the patient.

5. Photographs of a patient or patient's wounds by a vendor are prohibited unless allowed by hospital policy and the patient's written authorization is documented in the medical record.
6. All Vendors must have identification on their person that is clearly visible.
 - 6.1. The identification must indicate the Vendor's name as well as the company affiliation.
 - 6.2. The Program Director (PD) or Clinical Nurse Manager (CNM) shall verify the identity of the Vendor by viewing a valid driver's license or other government issued picture identification.
7. Vendor Responsibilities
 - 7.1. All Vendors must have approval from the CNM or PD to be present in the WCC.
 - 7.2. Vendors shall not meet with the WCC's medical director and/or panel providers without the consent of the PD.
 - 7.3. All Vendors must sign in upon arrival to the WCC and/or with the hospital, if required. Sign in must include time in and time out, name, company, and purpose of the visit. (See Form: A140F)
 - 7.4. Vendors may not wander in the WCC but must be accompanied at all times by the CNM or PD or their designee.
 - 7.5. Vendors must follow all instructions regarding infection control practices and fire safety.
 - 7.6. All new electrical equipment must be reviewed and approved by the hospital's clinical engineering/biomedical department before arrival to WCC.
 - 7.7. All new wound care supplies or products must be reviewed and approved by the hospital's materials management department before arrival to the WCC.
 - 7.8. Unauthorized selling or lobbying for a product shall be grounds for removal from the WCC.
 - 7.9. General observation for educational purposes of a Vendor will not be allowed except where permitted by Sections 14 and 15 of this policy.
 - 7.10. Vendors are prohibited from distributing their marketing materials at the WCC without the consent of the WCC's PD.
 - 7.11. Vendor biologic samples should not be used for patient care purposes in the clinic unless allowed by hospital policy.
8. Vendors shall not promote any off label use of their products during their site visits, in email communications or during phone conversations with WCC staff or panel providers.
 - 8.1. Exception: When ordered by a provider, a product may be used for an off label purpose when the Medicare Administrative Contractor (MAC) or Fiscal Intermediary (FI) for that area allows payment for the off label use
 - 8.2. WCC Program Director should contact their HI Revenue Cycle Manager if they have any questions regarding this off label use.
9. In the event a Vendor is promoting an off label use (not addressed by exception above), immediately notify the HI Legal Department or Compliance Department at compliance@healogics.com or by calling 800-379-9774 and asking for the Compliance Department.
10. All information provided by the Vendor must conform to the Medicare Local Coverage Determination (LCD) in place for the state or jurisdiction where the hospital is located. If the Medicare Administrative Contractor (MAC) or Fiscal Intermediary (FI) does not have

a formal LCD in their state or jurisdiction then the manufacturer's package insert or guidelines must be followed for appropriate use of the product or supply being used.

11. Reimbursement Advice:
 - 11.1. Shall be provided by a member of the HI Revenue Cycle Department and not the Vendor
 - 11.2. If clarification on a local coverage determination (LCD) or appropriate use of a specific product or supply is needed, the HI Revenue Cycle Manager shall contact the respective reimbursement department of the Vendor or manufacturer of the product. At that time, appropriate guidance shall be provided to the WCC by the HI Revenue Cycle Manager.
 - 11.3. PDs and WCC staff shall only discuss their reimbursement questions with a member of the HI Revenue Cycle Department.
12. Hospitals maintain control of actual product and technology selection for use in their WCC.
 - 12.1. Due to the potential for issues such as perceived vendor bias, space availability, product tracking and monitoring, Healogics, Inc. discourages distributing products on consignment. Any decision to distribute by consignment must include the hospital's Risk Management, Compliance and Supply Chain/Materials Management leadership.
13. Vendors are responsible for arranging any education, in-services or product evaluations through the PD or CNM prior to the event.
14. Vendors may observe a patient encounter where Vendor's product is to be used if prior verbal consent is obtained from Center AVP, patient's treating provider, and any Healogics staff to be present at the encounter. The Center must also obtain written authorization from the patient prior to the Vendor entering the treatment room and according to the following procedure:
 - 14.1. Inform the patient about the educational purpose of Vendor observation.
 - 14.2. Provide the patient with Attachment A (HIPAA Authorization for Vendor Observation of Patient Care).
 - 14.3. If the patient authorizes the observation, input the signed authorization into the medical record or EMR as soon as possible.
 - 14.4. Follow process for Authorizations as noted in Healogics and hospital policy with respect to revocations.
15. During an authorized observation, Vendors may not:
 - 15.1. Promote an off-label use of their product(s).
 - 15.2. Engage in, assist, or perform any medical care, treatment or service.
 - 15.3. Have access to any patient PHI contained in the patient's medical record.
16. Vendors desiring to implement a program requiring involvement of the PD should ensure the program has been reviewed by Healogics Corporate Compliance office.

REFERENCES:

The Joint Commission, Comprehensive Accreditation Manual for Hospitals - IM.02.01.01 and 03

SUPERSEDES:

None

ATTACHMENTS/FORMS:

See Form: (A140F) Vendor Sign-In Log

Attachment A: HIPAA Authorization for Vendor Observation of Patient Care

VERSION HISTORY:

January 2020	Added section on observation of care by vendor and authorization form for patient to sign.
January 2019	Corrected titles of RCMs; Removed redundant language at 11.2; Added language regarding written authorizations for vendors to observe care of the patients
January 2017	Changed reference of Physician to Provider
January 2016	Deleted item number 12.2 referencing new technology. Deleted attachment A140b New Technology Assessment and Evaluation Request.
January 2015	Policies of Acelecare Wound Centers, Inc. and Healogics, Inc. merged into one policy. <ul style="list-style-type: none"> • For Healogics sites: Added item 12.3 regarding distribution of supplies via a consignment process; Changed to only WCC acronym • For Acelecare sites: New policy
July 2014	Revised language in procedure step 2.2 – Vendor may not view with exception of modules already loaded into the database system
September 2013	Corrected center acronym, added verbiage related to involvement of PD with vendor; grammatical error, added sign-in with hospital if required
September 2012	Policies of Diversified Clinical Services, Inc. and National Healing Corporation combined to create one policy for Healogics, Inc. Original Date revised to reflect earliest of the two policies. <ul style="list-style-type: none"> • For National Healing sites: This is a new policy. • For Diversified sites: Updated Compliance department contact information
September 2011	Removed DCS Product Review Committee, clarified vendor assistance, taking of photographs by vendor, sample usage and removed approved DCS vendor list in WCC, added exception to off label use, updated TJC and removed NIAHO references
September 2010	Added the use of the DCS Products Committee Review, clarified vendor access to patient records, clarified who can provide reimbursement advice, added hospital control of actual product selection, PD and CC identification of vendor, restriction of vendor distributing marketing materials without consent of PD, restriction of use of vendor samples and off label use of vendor products, added NIAHO reference
October 2009	New policy

HIPAA AUTHORIZATION FOR VENDOR OBSERVATION OF PATIENT CARE

You are not required to sign this form.

The purpose of this Authorization is to allow _____ (“Vendor”) to observe medical care provided to me by the wound care physicians and nursing staff in the Wound Care Center. The purpose of this observation is for the vendor representative to observe the vendor product in use. During this observation, the Vendor representative may become aware of the past, present, and future status of your medical condition and may photograph the use of their product.

Check all that apply:

- I authorize Healogics, Inc. and its affiliates (“Healogics”) to use or disclose spoken facts about my health or treatment in the presence of Vendor representative while obtaining medical treatment in the Wound Care Center.

- I authorize Vendor to photograph the use of their product during my treatment.

I understand that once my information is disclosed it may no longer be protected by federal privacy laws.

This Authorization is effective as of the date signed below and continues for as long as I am an active patient receiving wound care services at a Healogics-managed Wound Care Center. I may revoke this authorization at any time in writing, but if I do, it will not have effect on any actions taken prior to receiving the revocation. Revocation will be effective immediately upon receipt of written notice to the Healogics-managed Wound Care Center.

I know that I may refuse to sign this form. Not signing this form will not change the way my health care providers treat me or my eligibility for health benefits.

Patient Name (print): _____ Patient Signature: _____

Date: _____ Time: _____ a.m./p.m.

If patient cannot sign, patient's representative must sign below:

Representative Name: _____ Representative Signature: _____

Relationship to Patient: _____ Date: _____ Time: _____ a.m./p.m.

Office Use Only

Provider Signature: _____ Date: _____ Time: _____ a.m./p.m.