

CentraCare Health (CCH) adopts the following policy/procedure for:	
St. Cloud Hospital	CCH - Monticello
CCH – Long Prairie	CCH - Paynesville
CCH – Melrose	CCH – Sauk Centre
(include only the entities for which the policy/procedure applies)	

Original: 5/2003 Minor Review: 07/15; 10/16 Full Review: 05/09; 06/13
Responsible Person: Director, Supply Chain & Support Services
Approving Committee/Board: CentraCare Health Executive Council
Category: Operations
Cross Reference: Medication Samples Storage and Distribution in Hospital Clinics or Hospital Outpatient Areas Policy
Type: Policy

I. PURPOSE:

To establish evidence-based principles and clear expectations regarding access, identification, and activities of vendors within CentraCare Health facilities.

To support the establishment of working relationships that benefits our patients, physicians, and staff and respects the resources of our vendors.

To enhance safe, high-quality patient care via criteria and evidence-based decisions.

To prevent unnecessary release of confidential information and ensure vendors exposed to confidential information commit in writing to respect and protect the information.

To uphold high ethical standards and encourage responsible use of health care dollars by refraining from acceptance of non-value added items and activities.

II. POLICY:

It is CentraCare Health policy to regulate, monitor and manage vendor representative access to activities within health facilities to maintain a secure environment for our patients, visitors, employees, volunteers and physicians; to promote productive use of time; and to promote efficient and safe product selection and utilization.

It is the policy of CentraCare Health to avoid conflicts of interest and the appearance of conflicts of interest, in the provision of care and the conduct of all business by CentraCare Health. Recognizing that significant dollars are devoted to marketing activities by pharmaceutical, equipment and supply vendors and result in higher overall health care expenses for our patients. CentraCare Health employees and physicians must refrain from accepting gifts of any sort from vendors, including food, office products, travel and any other items not directly contributing to the provision of care to our patients.

All vendor representatives entering and/or doing business with any CentraCare Health individual or department will adhere to the following guidelines regarding vendor interactions.

This policy also establishes guidelines for interactions with industry for physicians, other providers and employees of CentraCare Health in order to prevent conflicts of interest and maintain appropriate working relationships between industry and health care providers that deliver real benefits in the form of improved health care for patients and communities.

Interactions with industry occur in a variety of contexts, such as on-site training on newly purchased products, clinical trials for the development of new products, and support of continuing medical education. Many aspects of these interactions are positive and important for furthering the objectives of CentraCare Health. However, these interactions must be ethical and cannot create conflicts of interest or the appearance of such conflicts that could endanger or be perceived to endanger patient safety; data integrity; educational program integrity; or the reputation of physicians, employees or the institution.

III. DEFINITIONS

- A. Vendor: a vendor shall be defined as any individual, organization, or organization representative which sells or may potentially sell products and/or services for use in the course of CentraCare Health operations.
- B. Conflict of interest: situations in which reasonable observers could conclude that the moral and/or professional standards of the provider or employee's role could be compromised. Financial conflicts of interest occur when providers or employees are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.

IV. GUIDELINES

A. Qualification for access

- 1. Vendor representatives are required to complete the appropriate Class 1 or Class 2 category requirements prior to conducting business with CentraCare Health – see Appendix A
- 2. No vendor representatives will be seen by CentraCare Health staff on CentraCare Health facility premises without a pre-scheduled appointment or other specific invitation by a CentraCare Health representative.
- 3. All vendors, prior to visiting a CentraCare Health facility, must register with RepTrax and meet requirements and conditions including:
 - a. Review and sign confidentiality statement;
 - b. Document evidence of specified immunizations;
 - c. Provide evidence of annual influenza vaccination,**
 - d. Review and commit to Vendor Access policy;
 - e. Document evidence of appropriate training and competency as required by specific departments served;
 - f. Provide evidence that vendor represented is not on the Medicare sanction list.
- 4. Frequency, duration and purpose of vendor representatives' presence within our facilities are to be determined by department directors/clinic administrators or their designee.

B. Facility access: immediately upon entry to CentraCare Health facilities, vendor representatives are to check in at one of the designated locations and check out upon departure. Representatives calling on the CentraCare Heart & Vascular Center or SCH Surgery Department may check in at those locations.

- 1. At the SCH main campus, vendor representatives are to enter the facility through one of the following approved entrances: North Entrance and South Entrance.
- 2. Upon entry, the representative is to use the provided kiosk to check in and print a vendor identification badge, and use the telephone to contact the person with whom they have an appointment to notify them of their arrival.
- 3. Badges may not be retained and used for subsequent vendor calls.

4. Vendors are to access only those areas necessary for sales/service calls per scheduled appointment. Access to other areas requires escort and authorization by a CentraCare Health employee.
 5. At no time is it permissible to loiter on CentraCare Health property for the purpose of distributing literature and/or informally contacting physicians or employees.
 6. Facility employees who encounter unidentified vendor representatives within the facility will direct them to the appropriate check-in locations at their site for check-in and issuance of photo ID badge.
 7. Failure to comply with required standards may result in loss of access to CentraCare facilities and staff.
- C. Vendor-paid services, food, gifts and samples
1. Any activities involving vendors, except those provided to large groups such as at conferences, are to be undertaken only at employee or CentraCare Health expense (such as lunches or golf outings.)
 2. Vendor-funded site visits to view equipment under consideration for purchase must be approved by the designated executive authority at each CCH entity, either on an individual visit basis or on a per-project basis (such as a major construction project). Because these visits can incur significant cost which may well be reflected in equipment purchase price, attendees are to be limited to those employees or physicians who are absolutely critical to the equipment evaluation and decision making.
 3. No gifts from vendors will be accepted, including promotional items such as pens or tablets, medical equipment such as stethoscopes or textbooks, or cash or cash equivalents such as gift certificates, coupons or vouchers.
 4. Perishable items received from a vendor may be donated to a local non-profit organization such as a hospitality house or food shelf.
 5. Discounts on personal purchases offered by vendors (e.g. cell phones, office supplies, movie tickets) are acceptable so long as they are offered to all CentraCare Health employees and publicized as such through the Human Resources Department.
 6. Medication sample distribution and management is addressed in the policy: Medication Samples – Storage and Distribution in Hospital Clinics or Hospital Outpatient Area
- D. Introduction of new supplies, drugs and equipment
1. New products and equipment must be introduced by contacting the CCH Contracting and Supply Chain Department. These will then be reviewed for possible approval by groups or individuals designated by CCH, such as the CentraCare Health Product Value Analysis Committee, clinic administrators, etc. Products are not to be introduced into any CCH facility without approval of CCH employees *officially* designated to do so. Vendors are responsible for determining who are authorized to receive product introduction requests.
 2. Payment will not be made for any products introduced without authorization.
 3. Product trials and implementations may require staff and physician in-services. The vendor may be required to provide multiple product in-services, possibly requiring all day, multiple day and/or multiple-site sessions.
- E. Vendor presentations, displays and information distribution
1. Vendor-sponsored educational programs are permitted with prior approval by authorized personnel.
 2. Educational presentations will be limited to products or services approved for use or evaluation by the CentraCare Product Value Analysis Committee.

3. Patient education materials may not be distributed to patients by vendors. Such material is to be distributed to others upon the request of nursing staff or physicians only.
- F. Guidelines related to vendor representative assistance within procedural areas
1. The vendor representative should be present only at the request of the operating surgeon.
 2. The vendor representative should be introduced to the entire surgical team and the purpose of the visit explained.
 3. The representative is to inform the appropriate CentraCare Health staff if instrumentation is required and if so, how and when it will be provided.
 4. Instrumentation to be used for the case must arrive within the CentraCare Health facility at least 12 hours in advance and must be accompanied by an all-inclusive check-in list.
- G. SOLICITATION OF VENDOR DONATIONS BY PHYSICIANS, OTHER PROVIDERS AND EMPLOYEES OF CENTRACARE HEALTH :
1. In no case should physicians, other providers or employees solicit vendors for monetary or non-monetary donations (e.g., funding for special events, conferences, CME, etc.).
- H. CONSEQUENCES OF FAILURE TO COMPLY WITH GUIDELINES:
1. Verbal warning.
 2. Letter to vendor representative and representative's supervisor, signed by the Care Center or department director and the Director of Supply Chain & Support Services.
 3. Suspension from facility for time period determined by CentraCare Health Supply Chain Management leadership and leadership of involved department(s).

VI. REFERENCES:

- A. "Restricted Vendor Access," in *Health Care Advisory Board IC Best Practice Index*. Available at: http://www.advisory.com/members/download.asp?file=52769_26_14_08-03-2005_0.pdf&contentid=52769&collectionid=1266&program=14
- B. "Code of Ethics on Interactions with Health Care Professionals," adopted by Advanced Medical Technology Association, September 3, 2003. Available at: [Code of Ethics](#)
- C. "AORN position statement: the role of the health care industry representative in the perioperative/invasive procedure setting," in *Standards, Recommended Practices and Guidelines* (Denver: AORN, Inc, 2006) 261-263. Available at: http://www.aorn.org/PracticeResources/AORNPositionStatements/Position_HealthCareRepresentative/
- D. "American College of Surgeons' Statement on health care industry representatives in the operating room," in *Bulletin of the American College of Surgeons*, Vol. 85, No. 5, May 2000. Available at: [American College of Surgeons American College of Surgeons Statement on Health Care Industry Representatives in the Operating Room](#)
- E. "Report of the AAMC task force on industry funding of medical education to the AAMC Executive council," Available at: [Association of American Medical Colleges report on industry funding.pdf](#)

- F. "Managing visits from pharmaceutical sales representatives," in *IMSP Medication Safety Alert*, Volume 13, Issue 10, May 22, 2008. Available at: [Managing visits from pharmaceutical sales representatives](#)
- G. "Management guidelines for vendor access," in *Strategic Marketplace Initiative*, August 2006. Available at: <http://www.smisupplychain.com/tools/download/SMIVendorAccessGuideline.doc>
- H. "Materials managers must lead when tightening controls," in *Materials Management in Health Care*, September 2007, p. 40-42.
- I. "Addendum II: Council on ethical and judicial affairs clarification on gifts to physicians from industry (E-8.061)." Available at: [AMA \(Gifts to Phys CME\) Opinion E-8.061: clarifying addendum](#)
- J. "Sales rep background checks increasingly get outsourced," in *Materials Management in Health Care*, November 2007, p. 40-41.
- K. "Thanks, but no thanks," in *Minnesota Medicine*, April 2008, also available at [Thanks, but no thanks](#).
- L. "Characteristics of recipients of free prescription drug samples: a nationally representative analysis," in *American Journal of Public Health*, February 2008, Vol. 98, No. 2, pp 284-289.
- M. "Health industry practices that create conflicts of interest," in *JAMA*, January 25, 2006; 295: 429 - 433, also available at [JAMA -- Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers, January 25, 2006, Brennan et al. 295 \(4\): 429](#)
- N. "A social science perspective on gifts to physicians from industry," in *JAMA*, 2003;290:252-255, also available at [JAMA -- A Social Science Perspective on Gifts to Physicians From Industry, July 9, 2003, Dana and Loewenstein 290 \(2\): 252](#)
- O. "Undue influence?" in *Health Leaders*, May 2008, pp14-16.

Disclaimer: The policies and procedures posted on CentraNet are for internal use only. They may not be copied by independent companies or organizations that have access to CentraNet, as CentraCare Health cannot guarantee the relevance of these documents to external entities.

Appendix A



CentraCare Health Vendor Certification Process

Vendor representatives are required to meet requirements in the appropriate Class 1 or Class 2 category prior to conducting business within CentraCare Health.

The vendor representative should receive notification on the outcome of the certification request within two weeks if the certification submission is complete.

Vendor representatives will be required to review and comply with any and all revisions to these requirements as may be necessary from time to time. Reprax will notify vendors of revisions with appropriate notice.

Vendor Certification Requirements

Definition of Classification Level 1 – Non-Clinical Vendor Representatives

Vendor representatives that do not primarily serve in clinical support roles. These vendor representatives do not provide technical assistance, do not operate equipment, do not generally enter patient care areas, and do not provide assistance or consult with patient care staff.

Information to be Provided by Base Level 1 Vendor Representative at Registration with CentraCare Health:

- A. Review and signature of CCH Vendor Access Requirements
- B. Review and signature of CCH confidentiality and CCH safety requirements
- C. Evidence of the Vendor Representative’s competencies, training, and/or qualifications in:
 - a. Company’s products
 - b. General hospital safety training
 - c. Business ethics

A written statement from the company may serve as adequate documentation unless otherwise specified by CentraCare Health.

Definition of Classification Premium Level – Clinical Vendor Representatives

Vendor representatives that primarily serve in clinical support roles. These vendor representatives often provide technical assistance or operate equipment. Their role requires them to often work in patient care areas, and/or provide assistance to or consult with patient care staff.

Information to be Provided by Level 2 Vendor Representative at Registration with CentraCare Health:

- A. Review and signature of CCH Vendor Access Requirements
- B. Review and signature of CCH confidentiality and CCH safety requirements
- C. Written proof of vendor representative’s immunization status, for:
 - TB testing
 - Hepatitis vaccination/declination
 - MMR (measles, mumps, and Rubella) vaccination
 - Chicken Pox vaccination
 - DPT vaccination
- D. Documented evidence of training and competencies in the following topics:
 - Infection control including Blood Borne Pathogen training
 - Aseptic practices
 - Informed patient consent
 - Product complaints and medical device reporting (MDR) requirements
 - Company’s products, including the medical system, device, product, procedure, or service vendor representative will be delivering and/or operating.

CentraCare Health
Confidentiality and Safety Requirements for all CCH entities, including St. Cloud Hospital

Confidentiality Commitment

CentraCare Health (CCH) is committed to protecting the confidentiality and security of information. During the course of my duties or purpose at CCH, I may have access to proprietary or confidential information. I understand that all proprietary and protected health information (collectively PHI) must be maintained confidentially, and in a secure fashion.

I agree to follow all CCH policies and procedures governing the confidentiality and security of PHI in any form, including oral, fax, photographic, written, or electronic. I will regard both confidentiality and security as a duty and responsibility during my involvement with CCH as a vendor. I have completed HIPAA training.

I agree that I will not access, release, or share PHI, except as necessary to complete my duties or purpose at the CCH. I understand that I may not access any information on friends or family members unless a Release of Information form authorizes me to do so, or doing so is a necessary part of my job duties. I understand that I am not authorized to use or release PHI to anyone who is not part of the CCH workforce, or as provided in CCH policies and procedures, by contract with CCH, or as required by law.

I agree that I will use all reasonable means to protect the security of PHI in my control, and to prevent it from being accessed or released, except as permitted by law. I will use only the access privileges I have been authorized to use, and will not reveal any of my passwords or share access with others. I will take precautions to avoid inadvertently revealing PHI; for example, I will use workstations in a safe manner and will make reasonable efforts to prevent conversations from being overheard, including speaking in lowered tones and not discussing PHI in public areas. If my company's responsibilities include performing a service on patient data belonging to or in the custody of CCH, I understand that a HIPAA Business Associate Agreement (BAA) must be initiated with CCH prior to performance of such responsibilities.

I agree that when my affiliation, visitation or assignment with CCH ends, I will not take any PHI with me except as otherwise directed by contract or BAA, and I will not reveal any PHI that I had access to as a result of my duties at CCH. I will either return PHI to CCH or destroy it in a manner that renders it unreadable and unusable by anyone else.

I agree to report unauthorized use or disclosure of PHI, or security issues affecting systems that contain or give access to PHI, to Chief Privacy Officer, CentraCare Health, 1406 Sixth Avenue North, St. Cloud, MN 56303 or calling (320) 656-7066.

I understand that if I do not keep PHI confidential, or if I allow or participate in inappropriate disclosure or access to PHI, I will be subject to immediate disciplinary or corrective action, up to and including dismissal or loss of access privileges to CCH property and facilities. I understand that unauthorized access, use, or disclosure of PHI may also violate federal and state law, and may result in criminal and civil penalties.

Accessing St. Cloud Hospital Departments and Staff

Prior to going into procedural areas or patient contact areas, you will need to be approved in Reptrax. Badges will not be issued to vendors after three unapproved visits.

Medical Device Failure Reporting

When a vendor representative is notified by a SCH staff member about a product failure, the representative will make timely arrangements to have the product returned for analysis and ensure that a report of the analysis is sent to SCH in a timely manner. In addition, if the product failure is deemed a patient safety issue by SCH, the representative will make arrangements with SCH to have the product replaced. The Medical Equipment Management subgroup of the Environmental Safety Committee reviews the report of failures and follow-up actions. A report is given to Patient Safety Committee and trends reported to Product Value Analysis Committee for appropriate follow-up.

Product Recalls

When a vendor representative becomes aware of a recall or alert on a product used by SCH facilities, she/he is to immediately contact SCH Contracting and Procurement with the following information:

- Product description
- Product number
- Lot number
- Vendors are required to notify the Surgery Director, Clinical Value Analysis Specialist, and the Surgery Materials Manager Coordinator about product recalls, including identification of the product, reason for the recall, and a copy of the recall or FDA information. Similar information about product situations must be provided to the same individuals listed above.

Products & Equipment

During the evaluation of products, information requested must be provided to SCH within (1) week of the request. Requests include but are not limited to latex content disclosure, references, cleaning if equipment is reusable, studies on the product, pricing, training and in servicing plans. This information is required prior to approval for trial or implementation. If product is implemented due to urgent patient need without this information, the information must still be provided within (1) week of request or the product will need to be reviewed again and decision made about continuing to use the product.

Product Introduction

The vendor cannot remove any supply, product, or equipment without authorization by Purchasing during visiting hours and by charge personnel after business hours. A product return document will be issued when returning equipment for tracking purposes.

In servicing and Training

In servicing and training for new products and equipment will be scheduled by hospital personnel with the vendor representative. It is expected that the representative will then be present for the scheduled in-services unless the Education Department or Clinical Value Analysis Specialist is notified and arrangements made. Failure to meet the agreed upon scheduled in-services could result in the product/equipment being delayed for implementation or trial and/or reevaluation of the decision to implement or trial the product/equipment. Trends with training issues will be reported to Product Value Analysis Committee.

In servicing and Training cont.

Clinical equipment can only be brought in with a no charge purchase order and must go directly to Biomedical Engineering prior to trial.

Codes/Safety

When a vendor representative is on site, one of the following codes may be announced. Information about codes, including the type and number that are called, is considered confidential information and should not be shared. An explanation of each is provided for your information and safety.

- | | |
|--|-----------------------------------|
| Code Red: Fire Alert | Code Blue: Cardiac arrest |
| Code Green: Behavioral control | Code Black: Tornado alert |
| Code Search: Bomb threat | Code Pink: Infant/child abduction |
| Code Orange: Disaster | Trauma Code: Medical alert in ETC |
| Dr. Quick: Quick physician response to PCW | |

Please ask SCH staff if you have any questions regarding appropriate actions when these codes are announced.

Conflict of Interest

Do you have any family, personal and financial relationships between you and any St. Cloud Hospital entity, physician and staff?

_____ Yes

_____ No

Vendor or vendor representative sanction

Have you or your company ever received notice of termination or been sanctioned, monitored (excluding random monitoring) or excluded from status as a supplier of service under the Medicare, Medicaid or any other federal or state government programs?

_____ Yes (if yes, explain below and contact Kris Peterson, Director of Supply Chain & Support Services to discuss next steps)

_____ No

Consequences of failure to abide by requirements:

St. Cloud Hospital will initiate a vendor representative performance review if this action is deemed necessary. The vendor representative’s supervisor will be notified when appropriate. The resulting action of this review may include any or all of the following:

1. Verbal warning
2. Letter to vendor representative and the representative’s supervisor.
3. Suspension from entering or doing business within St. Cloud Hospital for a period of time to be determined by the supply chain management

department and other involved department(s).

Denial of vendor certification:

Vendor representatives who fail to meet all certification requirements will be denied certification. St. Cloud Hospital reserves the right to deny certification to any vendor representative or revoke a previously issued vendor representative certification.