



**Children's
Hospital
of The King's
Daughters**

VENDOR ACCESS POLICY AND PROGRAM



Children's Hospital of The Kings Daughters
601 Children's Lane
Norfolk, VA 23507
757-668-9476

(Revised – February 2019)

Table of Contents

About CHKD.....	4
Our Mission, Vision and Values.....	4
Our Mission.....	4
Our Vision.....	5
Our Values.....	5
CHKD’s Vendor Program	6
Purpose	6
Policy.....	6
Scope.....	6
I. Overview of the Registration Process	7
24-Hour Vendor Identification Badge.....	7
II. Registration Support.....	8
Vendor Program Administrator	8
Credentialing and Badging Requirements	9
III. CHKD Policies and Procedures	10
Conflict of Interest	10
Corporate Compliance Program, Deficit Reduction Act (DRA) of 2005 and False Claims Act	10
HIPAA and Patient Confidentiality	10
Confidentiality of Business and other Proprietary Information	10
Conduct & Interactions with CHKD Associates and Medical Staff.....	10
Audio/Video Taping, Digital and Still Photography.....	11
IV. Vendor Identification Badges.....	12
Vendor Photo Identification Badges	12
24-Hour Vendor Identification Badges	12
Badge Display.....	12
Lost Badges	12
V. Vendor Sign-In-Out Procedure	13
Representatives and Vendors.....	13
Visitation Rules	13
VI. General Facility Access and Standards.....	15
Tobacco-Free Campus.....	15
Badge Sign-In and Sign-Out Process	15
Scheduled Appointments.....	15
Accompanying Guests.....	15
Access to Patient Care Areas	15
Temporary Electronic Door Access	15
Access to Common Areas of the Hospital.....	16
Parking	16

Use of Cell Phones and Hospital Equipment.....	16
VII. Supply Chain/Purchasing Policies	17
Supply Chain Strategy	17
Supply Chain Strategy – Goals of Service.....	17
General Supply Chain /Purchasing Guidelines.....	17
Use of Purchase Order	17
Group Purchasing Membership	17
Standard Payment Terms.....	17
Non-Pharmaceutical Samples and Trials.....	17
New Product Introductions.....	18
Clinical Equipment Trials.....	18
Removal of Product	18
Product Recalls.....	18
VIII. Gifts and Meals Provided to Associates.....	19
IX. HIPAA/Patient Confidentiality.....	20
Confidentiality of Information	20
X. Compliance	21
Reporting	21
XI. Vendor Representatives in Restricted Patient Care Areas	22
General Standards.....	22
XII. Required Documentation & Competencies	23
XIII. Operating Room Standards	24
AORN Position Statement.....	25
Position Statement	25
Role of the Health Care Industry Representative	25
Rationale	26
XV. Pharmaceutical Manufacturer Representatives Conduct Policy	28
XVI. Fire Safety	29
XVII. Infection Prevention Guidelines	30
Wellness.....	30
Bloodborne Pathogens	30
Standard Precautions.....	30
Hand Washing	30
Blood Spills	31
Contaminated Sharps and Linens	31
XV111. Non-Compliance	32
CHKD Vendor Code of Conduct.....	33
Confidentiality Statement	34
Vendor Gift Disclosure Form.....	36

About CHKD

CHKD Health System offers a network of comprehensive pediatric services in more than 40 locations that stretch from Williamsburg to Elizabeth City, North Carolina. On the outpatient side, we offer primary care, diagnostic services, urgent care, emergency care, rehabilitative therapies, day surgery and care in more than 30 pediatric subspecialties. Inpatient care is offered at Children's Hospital of The King's Daughters, Virginia's only comprehensive freestanding pediatric hospital.

The King's Daughters, a women's service organization that has worked to improve the well-being of children in our region for more than a century, established Children's Hospital of The King's Daughters in 1961.

Today, CHKD is a 206-bed teaching hospital with special units for neonatal and pediatric intensive care, cancer care, acute inpatient rehabilitation, medical and surgical care, and transitional care. As a freestanding, full-service children's hospital, every inch of our facility and all members of our medical team are devoted exclusively to the needs of young people, and our patients benefit from the full range of pediatric specialists and support services available only at freestanding children's hospitals.

Our Mission, Vision and Values

Our mission and vision set the standard for our values. In order to succeed with our strategic planning, and as a recognized leader in children's healthcare, these values are necessary to achieve our goals. All of us are responsible for making those goals happen.

Our Mission

In leading the region in the provision of children's healthcare services, Children's Hospital of The King's Daughters Health System (CHKDHS) will:

- Deliver excellence in quality and service as we continually measure and improve our outcomes;
- Evolve and enhance services in response to the needs of children and the advancement of science;
- Educate the next generation of leaders in children's health;
- Be the healthcare employer of choice; and
- Collaborate with others to attain our vision.

Our Vision

CHKDHS will lead the region as the preferred provider of quality children's health services.

Our Values

- Excellence in Quality of Care and Service
- Teamwork and Communication
- Honesty and Integrity
- Personal Responsibility and Stewardship of Resources
- Creativity and Innovation

CHKD's Vendor Program

Purpose: The purpose of this program is to provide a safe environment for all patients, visitors and staff by monitoring Hospital access and sales activities associated with the selling of goods, services or equipment to CHKD. It is important to regulate the presence, engagement and movement of vendor representatives, contractor personnel and visitors on CHKD premises to provide a secure environment that protects the efficiency and integrity of physicians, other healthcare providers and employees; supports patient safety, privacy and family-centered care; and maintains the integrity of the procurement process.

Policy: All vendor representatives and contractors doing business at a CHKD patient care facility will comply with the established access requirements and policies associated with providing products, services or equipment. Any product, service or equipment brought into a CHKD facility not meeting these requirements will be considered a no-charge trial to CHKD for which there will be no remuneration. Badges are not transferable and can be used only by the representative to whom they are issued.

Scope: This policy applies to any vendor representative and contractor providing educational support, service, products, and/or equipment to any CHKD patient care facility. This policy does not apply to temporary clinical or physician staff, volunteers, or visitors.

- All vendors **must** have scheduled appointments. Cold calls will not be accepted. Vendor Representatives arriving at CHKD without an appointment will be turned away.

I. Overview of the Registration Process

NOTE: All vendors and their representatives currently serving CHKD are to complete an online certification process, managed by Green Security, in order to continue their business relationship with CHKD.

Based on the scope of products and services marketed to CHKD, a vendor will be classified into one of three categories. The vendor's base of business, product offerings, access to patient areas, and other qualifying criteria will be used to establish the category. There are certification requirements specific to each category; these requirements are consistent with standards set forth by the following:

- A. Health Insurance Portability & Accountability Act of 1996 (HIPAA)
- B. Association of periOperative Registered Nurses' (AORN) Standards for Health Care Industry Representatives in Operating Rooms
- C. DNV
- D. CHKD Policies and Procedures

All vendors who plan to visit any of the CHKD facilities must register as a vendor with CHKD. An annual registration fee will apply to each representative of your company.

A Federal Tax Identification Number (FEIN) is required to complete the initial company registration. Individual representatives will need to register and submit additional credentialing requirements that are determined based on a risk profile criteria assigned by CHKD.

There are three classifications of individuals governed by this program, each of which have different credentialing and badging requirements (see chart on page 9).

- **(Level 2A) Vendors and Sales Representatives - Do not require access to patient care areas**
- **(Level 2B) Vendors and Sales Representatives – Requiring Limited Access to Patient Care Areas**
- **(Level 3) Any Vendor Requiring Access to Restricted Patient Care Areas**

24-Hour Vendor Identification Badge

24-hour badges will be issued for representatives needing access to a CHKD facility, two or fewer times annually. Authorization by a CHKD department manager is required to enter patient care areas with a 24-hour badge

II Registration Support

For Green Security registration or technical support questions, please contact Green Security at 866-750-3373 or support@greensecurityllc.com.

Vendor Program Administrator

For questions regarding the Vendor Access Program, you may contact one of the CHKD Vendor Program Administrators. They support the program by;

- Managing CHKD's corporate vendor database
- Providing Vendor Access Program Packets to any new vendor representative.
- Communicating infractions of vendor policy to the representative and their employer.
- Communicating any infraction involving a breach of patient confidentiality to the Corporate Compliance and HIPAA Privacy Officer.

You may contact;

For Vendors, Consultants, Sales Representatives

Maria Priester
Administrative Assistant, Supply Chain
Children's Hospital of The King's Daughters
905 Redgate Ave 2nd Floor
Norfolk, VA 23507
757-668-9476
marialuz.priester@chkd.org

Credentialing and Badging Requirements



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CREDENTIALS	DESCRIPTION OF REQUIREMENTS	Level 2A* Non-Patient Care Areas	Level 2B** Limited Patient Care Areas	Level 3*** Restricted Access Patient Care Areas
VENDOR AND COMPANY INFORMATION				
Background Check	A national "criminal" background check and sex offender check will be performed by Green Security annually. A valid driver's license is needed to run these checks. We will not accept an attestation letter from your company.	Provided by Green Security	Provided by Green Security	Provided by Green Security
Government Watch List (OIG, EPLS, \$ Medicaid)	A national government watch list check. Green Security checks to ensure that you and your company are not on any government watch lists.	Provided by Green Security	Provided by Green Security	Provided by Green Security
IMMUNIZATION & SCREENING CREDENTIALS				
Employee Drug Test (5 Panel)	Proof of a negative 5 or 10 panel drug test. A letter from your company or actual drug test results are acceptable. Please ensure your social security number has been censored out or your documentation will be declined	X	X	X
Tuberculosis Skin Test (PPD)	TB test with negative results, chest x-ray dated within one year with no signs of active TB, or latest chest x-ray with no signs of active TB accompanied by physician questionnaire/letter is required. Test documentation expires annually, as does physician questionnaire/letters if applicable	X	X	X
Influenza	Annual test and physician documentation expires annually	X	X	X
Measles, Mumps & Rubella (MMR)	Two doses of MMR vaccine or a blood titer test indicating immunity to Mumps, Measles and Rubella are required. Vaccination documentation will not expire once requirement is met.		X	X
Varicella	Two doses of the varicella vaccine or blood titer results indicating your immunity to varicella. Vaccination documentation will not expire once requirement is met.		X	X
TRAINING/COMPETENCY CREDENTIALS				
General Expectations & Hospital Safety	Acknowledgement of the following CHKD policies; Vendor Policy C5416, Non-Patient Care Contact, CHKD Vendor Policy and Access Procedure, CHKD Communicable Disease Form	X		
General Expectations & Hospital Safety	Acknowledgement of the following CHKD policies; Vendor Policy C5416, Potential and Direct Patient Care Contact, CHKD Vendor Policy and Access Procedure, CHKD Communicable Disease Form		X	X
Product and Services Training	A list or description of product and/or service training you have received from your company. Please provide a certificate of training or a letter on letterhead signed by your manager or superior.		X	X
Documentation and Competencies	Provide documentation of training/education and demonstrated competency in the following areas; Aseptic Principles and Infection Control, Blood borne Pathogens, Sterile Techniques, Product Complaints and Medical Device Reporting (MDR) & Patient Rights, Confidentiality and HIPPA			X
CONTRACTOR/COMPETENCY CREDENTIALS				
In-service & Procedures	Acknowledgement of the following CHKD Policies; Contractor Guidelines, Contractor Guidelines Off-Site, Emergency Codes	X		

Revised - 01/07/2019

Level 2A - General Contractors, Vendors and Representatives that do not require access to Patient Care Areas

Level 2B - Vendors and Representatives requiring limited access to Patient Care Areas

Level 3 - Vendors and Representatives requiring access to Restricted Patient Care Areas

* Non-Patient Care Areas - Examples include but are not limited to Accounting, Administration, Human Resources, Information Services, Marketing, Security and Supply Chain.

** Patient Care Areas - Examples include but are not limited to General Nursing Units, Pharmacy, Physical Therapy, Pulmonary, Radiology, Rehab Medicine, Respiratory and the Sterile Processing Department.

*** Restricted Patient Care Areas - Examples include but are not limited to Inpatient and Outpatient Perioperative Units, Cath Lab, Emergency Department, Neonatal Intensive Care Units, Pediatric Intensive Care Units

III CHKD Policies and Procedures

Regardless of classification, all vendors must acknowledge and abide by the following principles and policies to conduct business with CHKD:

- A. **Conflict of Interest.** (CHKD Policy Number C5410) Vendors must provide a full disclosure about any conflicts of interest that exist.

- B. **Corporate Compliance Program, Deficit Reduction Act (DRA) of 2005, and False Claims Act.** (CHKD Policy Numbers C5411 & C5423) Vendor acknowledges and abides by CHKD's Compliance Program and agrees to disseminate to its associates information about the Compliance Program and DRA Provisions – and require its associates to abide by the same.

- C. **HIPAA and Patient Confidentiality.** (CHKD Policy Numbers C3416 and C3403) The discussion, release, or use of any patient-related information viewed or overheard is prohibited for any purpose other than that which is related to job assignments and in compliance with patient privacy laws.

- D. **Confidentiality of Business and Other Proprietary Information.** Any type of information generated in connection with CHKD's operations must not be accessed, downloaded, discussed, used, or disclosed for any purpose other than to conduct business with, or on behalf of CHKD. Agreement to not improperly disclose confidential information continues after termination of the vendor business partnership.

- E. **Conduct & Interactions with CHKD Associates & Medical Staff.** When in facilities and interacting with Hospital associates and Medical Staff, **Vendor** understands and agrees that:
 - 1. Conversations with staff in patient care areas should be minimal, must be professional and case related only. No socializing.
 - 2. All patient education materials must be reviewed by the Hospital's Clinical Education Department prior to their use.
 - 3. Surgical Suites are to be entered only at the request of, and as directed by, the clinical staff and/or physician(s). The vendor cannot change or touch any equipment, carts, or sterile equipment. The vendor must follow the instructions of the Circulating Nurse at all times.

4. Standards governing introduction of new products and the removal of expired or recalled products are abided by as a condition of doing business with CHKD.
5. Policy for providing gifts, meals, and education to CHKD associates and Medical Staff must be followed (See Section VIII).
6. Items and services provided to and accepted from CHKD will not exceed those that are reasonable and necessary for ethical business purposes. The amount paid to, or payable by, CHKD will be at a fair market value amount.

F. Audio/Video Taping, Digital and Still Photography. (CHKD Policy Number C3300.3)

Compliance with the above standards shall extend to the Vendor Representative's Company, co-workers, agents, and subcontractors.

IV Vendor Identification Badges

CHKD approved identification badges are to be worn by vendor representatives at all times while in CHKD patient care facilities.

Vendor identification badges will consist of two categories:

Vendor Photo Identification Badge

Green Security will issue a photo identification badge to vendor representatives who have met the necessary requirements. Vendor badges will display the company name, vendor representative's name, vendor representative's picture, clearance level and vendor representative's identification number in the form of a barcode. These badges are required to access any CHKD patient care facility.

24-Hour Vendor Identification Badge

24-hour vendor badges will be available in Security. Vendor representatives needing a 24-hour badge will be required to log in prior to receiving a badge and log out at the close of business. The 24-Hour vendor badge will serve as a pass for the time period of the scheduled appointment or work requirement, not to exceed 24 hours. If a representative requests a 24-hour badge more than three times annually, they will be required to fulfill all the requirements for a vendor identification badge. Authorization by a CHKD manager is required to access patient care areas with a 24-hour badge. A "Confidentiality Statement" must be completed at time of sign-in at facility security desk.

Vendor identification badges are not transferrable. At no time may a representative allow the use of his/her badge by another individual. To do so will result in the loss of access to any CHKD facility.

Badge Display

Vendor identification badges must be prominently displayed by the representative, with the photo visible and, above the waist, and will be worn at all times while in a patient care facility.

Lost Badges

Lost badges must be reported to the Vendor Program Administrator within 24 hours. If this occurs outside of normal business hours, hospital security should be notified. Green Security will replace lost badges for a fee of \$19.99 for standard badges and \$29.99 for RFID Badges.

V Vendor Sign-In-Out Procedure

Representatives and Vendors

Appointments are required for all visits to CHKD facilities, except for product/device recalls, emergency deliveries, routing pre-arranged visits for deliveries, and on-site contract project work. **Unscheduled appointments and drop-in visits are not permitted.**

All vendors entering CHKD facilities will be required to sign-in and sign-out when entering and exiting the facility.

Some CHKD restricted areas, i.e. Pharmacy and Perioperative areas may require additional sign-in/sign-out procedures. Please check with the department you are visiting to confirm any additional requirements.

During normal business hours (8:00AM – 4:30PM Monday-Friday), sign in will be required at the Supply Chain Department located at 905 Redgate Ave. Norfolk VA 23507 located on the 2nd floor. After hours and weekends, vendors may sign in using a kiosk that will be located in the main lobby of the hospital.

During normal business hours, appointments will be verified by Supply Chain personnel. If an appointment or approval cannot be verified, access will not be permitted.

Vendors may use the kiosk in the main lobby to check out.

Visitation Rules

Visitation to a CHKD facility is by invitation only and will require a scheduled appointment. Under no circumstances will a vendor representative be permitted to visit CHKD staff without a scheduled appointment.

All vendor representatives are required to check-in and check-out of the site on completion of business. See sign-in/sign-out procedure.

After checking in, vendor representatives are authorized to visit only the areas designated by their badge and only those departments where they have a scheduled appointment. Vendor representatives may be present in common areas of the facilities; however, initiating unsolicited contact with clinicians or other employees is prohibited. At the completion of the scheduled appointment, vendor representatives are expected to leave the facility.

Vendor identification badges are not transferable. At no time may a representative allow

the use of his/her badge by another individual. To do so will result in the loss of access to any CHKD facility.

Vendor representatives are prohibited from access to confidential patient or product information unless it has been authorized as part of the information needed to complete their project. Only vendor representatives with appropriate clearance (Yellow or Blue Badge) may visit patient care areas and only when an appointment has been scheduled.

Vendor representatives are required to wear a CHKD or Green Security issued Vendor Identification Badge at all times while in a CHKD facility.

Vendor identification badges do not grant permission to provide direct patient care or indicate that CHKD or its facilities have approved the representative to provide such care. Only individuals who have met all applicable CHKD facility requirements regarding credentialing, clinical privileges and/or other qualifications are permitted to provide direct patient care. Vendor representatives who are present while patient care is being rendered must always follow the direction, when given, of the attending physician or other CHKD clinician involved in the procedure.

Vendor representatives are prohibited from displaying company information or advertisements without prior permission from the appropriate facility leadership, i.e., the Director of Supply Chain or Pharmacy.

Vendor representatives are not permitted to park in areas designated for patients. Representatives must park in designated visitor parking areas and pay the appropriate parking fees. Some facilities may have additional parking restrictions, which the representative should observe. Vehicles parked in unauthorized areas will be towed at the driver's expense.

VI General Facility Access and Standards

Vendors may enter CHKD facilities for the purpose of conducting business only when the following conditions are met:

A. Tobacco-Free Campus

CHKD is a tobacco-free campus. No tobacco product use of any kind will be permitted inside or outside of any CHKD property.

B. Badge Sign-in and Sign-out Process

The Hospital's main entrance is open 24 hours and serves as the primary entrance for vendors and other visitors. The vendor is to complete the check-in and badge process in the Supply Chain offices located on the 2nd floor at 905 Redgate Ave Norfolk VA 23507 Monday through Friday, 8:00 AM to 4:30 PM. At the end of each visit, the vendor is to check-out at the self-service kiosk located in the main lobby. If vendor access is required during off hours or on weekends or holidays, the kiosk in the main lobby should be used for both the sign-in and sign-out process.

C. Scheduled Appointments

Vendors must have a scheduled appointment and must limit his/her business-related activities at CHKD to the scheduled appointment(s). Under no circumstances will cold calls (visits without previously-scheduled appointments) be allowed. Drop-in visits to departments other than the appointment are not permitted.

D. Accompanying Guests

Vendors agree to escort any guests accompanying the vendor who are not registered with the vendor program. The guest(s) shall obtain a temporary badge from the Supply Chain Department located on the 2nd floor at 905 Redgate Ave., Norfolk Va. 23507. Guests may be able to obtain a temporary badge no more than three visits, at which point the Hospital will require guest to register with the vendor program.

E. Access to Patient Care Areas

Vendors are not allowed to enter patient care areas of the Hospital without specific permission from a director or manager of that department. Vendors must also be registered at the appropriate level to enter patient care areas. While in patient care areas, the vendor should be accompanied by a CHKD associate and must follow any internal policies of the respective department.

F. Temporary Electronic Door Access

In the event a vendor's scheduled appointment requires the vendor to access

areas of the Hospital requiring electronic badge access, the vendor will need to be escorted to these areas by Hospital personnel. The vendor may contact CHKD's Supply Chain Department or Security Department, to request a temporary electronic badge. The vendor must leave their drivers license with the department assigning the temporary badge, as a means of Hospital ensuring badge is returned to Hospital by the end of vendor's visit.

G. Access to Common Areas of Hospital

Excluding appointments, a vendor may spend **up to one hour** in the Hospital's cafeteria, snack bar, lobby, and corridors. However, the vendor is **prohibited** from approaching physicians or CHKD associates in these areas, as well as in elevators or patient care areas, for the purpose of conducting business discussions.

H. Parking

Vendors may park in the visitor parking garage located off Olney Road and Wagner Road

I. Use of Cell Phones and Hospital Equipment

Vendors must follow CHKD's Safe Environment, Use of Cellular Telephone Policy at all times. Cellular phones are not permitted in the following areas of the hospital – critical care areas, PICU, NICU, CVICU, OICU, PACU, OR, or any room in which a cardiac monitor or ventilator is in use. Furthermore, unauthorized audio and video recording, or photography, (including cellular camera phone photos) is prohibited at any time or in any hospital location, pursuant to CHKD's Audio/Video Taping, Digital and Still Photography Policy. Policies are available for review upon request. Use of CHKD equipment, such as telephones and computers, is prohibited unless the vendor is visiting the Hospital for the purpose of conducting training or the CHKD department grants permission to the vendor.

VII Supply Chain /Purchasing Policies

The Supply Chain / Purchasing Department for CHKD is located at 905 Redgate Ave, Norfolk VA 23507. This Department is open from 8:00 AM to 4:30 PM, Monday through Friday, and can be reached at 757-668-9476 to schedule appointments. It is mandatory that all visits to the Supply Chain Department be scheduled in advance; cold calls will not be accepted.

Supply Chain Strategy

In support of CHKD's "patient first" core philosophy, the supply chain strategy is to create an effective supply chain operating model that will produce sustainable cost reductions, support high customer service standards, consolidate the supply chain infrastructure and standardize business practices. Vendors are expected to be in compliance with all applicable laws and regulations.

Supply Chain Strategy – Goals of Service

1. Provide optimum support to our caregivers by providing them with timely accessibility of appropriate, clean, safe, user-friendly products, equipment, and services.
2. Have a clear understanding of and maximum influence over all elements of supply chain cost.
3. Maximize understanding of and support for current and emerging technology.
4. Work with trading partners to enhance each other's quality of service and cost profile.

General Supply Chain/Purchasing Guidelines

- A. Use of Purchase Order** - All purchasing-related transactions require an approved purchase order (including those for which there is not an exchange of funds) – in order for the Accounts Payable Department to process payment.
- B. Group Purchasing Membership** - CHKD may share confidential information related to CHKD's vendor relationships with its Group Purchasing Organizations, currently Children's Hospital Association (CHA) and Vizient, and directly with members of CHA and Vizient. Volume purchases are to be reported to Vizient and CHA. Additional information is available by contacting the Purchasing Department.
- C. Standard Payment Terms** - Standard non-contracted payment terms are net 45 and shipments are FOB destination.
- D. Non-Pharmaceutical Samples & Products for Trial Use** - It is the policy

of CHKD that all new patient care products or substitute products will be evaluated for cost and quality CHKD's Value Analysis Committee. This committee will conduct a patient safety and product efficacy evaluation to ensure that there is a standardized review process before patient care products are recommended and purchased.

- E. New Product Introductions** – Vendors who wish to present new medical products, devices or equipment to Hospital personnel must be aware that prior to the evaluation or purchase, the appropriate Value Analysis Team must review and approve all items that introduce either new technology or significant change to existing technology to the organization.

This policy applies to all medical devices, disposable products and clinical equipment (approved by the Food and Drug Administration (FDA) or not), including any items that have been approved for use by the Institutional Review Board (IRB). Vendor Reps are responsible for scheduling an appointment with Supply Chain to introduce new products before these products can be discussed with physicians or CHKD Medical Staff. The product must be left with Supply Chain for review and evaluation by Value Analysis Committee. CHKD assumes no responsibility for supplies or equipment left by vendors in the organization for the purpose of evaluation. It is the responsibility of the vendor, to deliver, install, and remove the equipment or supplies upon completion of the evaluation.

- F. Clinical Equipment Trials** - Clinical equipment may only be accepted by CHKD with a no charge purchase order and must go directly to Biomedical Engineering Department prior to the trial. Vendors performing maintenance service on medical equipment must deliver a customer-signed service report to the Purchasing or Biomedical Engineering Department upon completion of the service.

- G. Removal of Product** - Vendors may not remove any supply, product, and equipment without verbal or written authorization by the Supply Chain Department.

- H. Product Recalls** – Vendors are required to notify the Supply Chain Department regarding product recalls. Such notification is to include identification of the product (including affected lot numbers and quantities), the reason for the recall, and a copy of the recall or FDA information.

VIII Gifts and Meals Provided to Associates

- A.** It is the policy of CHKD that associates refrain from accepting any gifts, honoraria, and/or entertainment, as this may create the perception of, or an actual conflict of interest. Gifts include items such as sporting event tickets, gift certificates, and travel – even if the cost to the vendor is zero. Additionally, under no circumstances may a CHKD associate solicit a gift from a vendor whose products are billed to a Federal healthcare program.
- B.** CHKD associates may accept meals from vendors under the following circumstances:
 - 1. The meals are modest and infrequent in nature.
 - 2. The meals do not include spouses or guests of CHKD associate, unless there is a business-related reason for doing so.
 - 3. The meal is provided as part of a business meeting or sales call conducted at a CHKD facility to discuss product features/demonstrations, contracts, and sales terms.
 - 4. The meal is provided as part of a legitimate educational session focusing on a topic of interest to the invited CHKD associate. The value of the meal is modest; the venue is modest and conducive to learning; and the meal is subordinate in time and focus to the educational portion of the session.
 - 5. The meal is provided at a professional conference as part of a vendor-sponsored event.
 - 6. Business meals provided to a CHKD associate at an off-site location are acceptable when such meals are infrequent, modest in value, reasonable, at an appropriate location conducive to business discussions, and does not incur travel and lodging expense.
- C.** In-Service Training Sessions - All in-services must be on formulary items and must be approved by the department manager in advance of the training being conducted. Meals and gifts may be provided during these training sessions, in accordance with the guidelines in the section, entitled "Gifts and Meals Provided to Associates."

IX HIPAA / Patient Confidentiality

CHKD respects the privacy of its patients and requires that all who conduct business with CHKD share this commitment. HIPAA, the Health Insurance Portability and Accountability Act of 1996, enhanced the protection of a patient's privacy. HIPAA prohibits a vendor from reviewing the medical records of patients for the purpose of determining which patients may benefit from the vendor products or services.

All information regarding CHKD patients and their care will be held in strict confidence. This information will not be discussed with third parties or in public places.

HIPAA privacy standards require CHKD to regulate business associates. Therefore, most individuals or companies performing an activity or service for CHKD that involves the use or disclosure of individually identifiable health information must agree to enter into a Business Associate Agreement ("BAA") to ensure that each business associate protects protected health information (PHI). The BAA contains provisions that establish the permitted and required uses and disclosures for PHI. Furthermore, the BAA provides that the business associate may not use or further disclose the information other than as permitted by the contract or as required by law.

All contracts proposed by vendors should include appropriate HIPAA compliance provisions. In any event, the vendor must agree that any and all actions taken or authorized by the vendor regarding the transaction, goods, or services involving or relating to CHKD shall comply with all applicable laws pertaining to standards for electronic transactions, including those set forth in the Health Insurance Portability and Accountability Act of 1996, and all rules published thereunder. The vendor is also responsible for requiring all agents or subcontractors to comply with such applicable law. Upon the request of CHKD, the vendor will provide appropriate documentation of its agent's or subcontractor's compliance with such requirements.

Confidentiality of Information

In the course of interacting with CHKD, you may receive information about CHKD patients, associates, donors, and its financial or business operations. Some of this information may be considered "confidential" by law or by CHKD policies. Confidential information may exist in any form – e.g., written, oral, overheard, observed, or electronic. It is your responsibility to comply with CHKD policies by accessing only such information that you need to perform your job and in accordance with the law. Individuals receiving confidential information are prohibited from disclosing such information to friends, relatives, co-workers, patients, and others unless permitted by CHKD policies, applicable law, or as required to perform your assigned job duties. Confidential information must be protected while doing business with CHKD and after your business relationship ends. Violation of the confidentiality policy may subject you to adverse action, up to and including termination of your business relationship with CHKD, as well as civil or criminal penalties as applicable by law.

X Compliance

CHKD strives to maintain the highest level of ethics and compliance with state and federal healthcare laws in our patient care and business conduct. CHKD recognizes that errors can occur and it is our priority to investigate those issues to the fullest extent.

It is with this in mind that the CHKD has in place a centralized Corporate Compliance program. The program was developed and is operated in accordance with all applicable state and federal guidelines and laws. Our program focuses on the prevention of non-compliance and the investigation of any reported issues of possible fraud, waste or abuse at CHKD.

Reporting

CHKD customers, employees, contractors, vendors and volunteers have the ability to report concerns to the Corporate Compliance Department:

- Compliance Hotline: (877) 373-0128

Reporting allows parties to remain anonymous if necessary. There will be no retaliation against anyone reporting concerns, in good faith, to the Compliance Department.

For more information

Compliance Department Office: (757) 668-8776

If you are attempting to report a quality of care concern or a patient safety issue, please visit our [Patients Rights and Responsibilities](#) page.

XI Vendor Representatives in Restricted Patient Care Areas

A. General Standards

CHKD recognizes the need for education and introduction of new technology, procedures, and techniques to health care professionals in the peri-operative setting. At the same time, a patient's right to privacy and safety must be protected – particularly when a vendor is present during a surgical procedure. All vendors present in procedural areas must abide by the following general standards:

1. A vendor may observe a procedure **only** at the request of a physician performing the procedure and the permission of the patient.
2. If a new medical product is being used, the product **must** be approved by the Hospital's Supply Chain Department **before** the product can be introduced to the physician and/or other clinical staff and before the product can be used with a patient.
 - B. Vendor Reps are **not** permitted to:
 1. Scrub in;
 2. Assist with procedures (other than technical assistance in the form of verbal consultation);
 3. Open sterile products; or
 4. Have patient contact
 - C. Vendors or Technical Support Representatives with specialized training may perform remote calibration of their company's products – e.g., pacemakers and pain management devices – to the physician's specifications.
 - D. A Vendor's presence during a procedure is to be documented in the patient's medical record.
 - E. Sales calls with physicians are to be conducted in non-patient care areas only.

XII Required Documentation & Competencies

- A.** A vendor that is present in the operating room, catheterization lab, or other procedural patient care areas during a procedure are **REQUIRED** to maintain documentation of certain competencies, health status, and background checks on file with CHKD through Green Security.

- B.** The vendor must provide the following to the department manager documentation in advance of being granted access to a procedure:
 - 1. Educational training and/or certification of the products/services the vendor is authorized to perform;
 - 2. Competency assessments for the products/services provided: Evidence of the vendor's comprehension and retention of the training received;
 - 3. Documentation of Education/Training for the following areas:
 - a. Aseptic Principles and Infection Control
 - b. Bloodborne Pathogens
 - c. Sterile Techniques
 - d. Product Complaints and Medical Device Reporting (MDR) requirements
 - e. Product Recall Processes
 - f. Patient Rights, Confidentiality, and HIPAA

XIII Operating Room Standards

Purpose: To protect the rights and confidentiality of our surgical patients and to eliminate unauthorized solicitation by vendor's accessing the operating room.

For the purpose of this document, vendors are included in the group referred to as "non-medical advisors."

1. Non-medical advisors may be present in the operating room **only** with the advance approval/request of the physician and the patient. **No walk-ins will be permitted.**
2. Non-medical advisors must **first** follow the vendor sign-In-out procedure" prior to arriving in the Operating Room area.
3. When entering the Operating Room non-medical vendor advisors will:
 - a. Approach the Operating Room front desk.
 - b. Leave a business card that is to be given to the appropriate circulating or charge nurse.
 - c. Have their CHKD-issued badge displayed prominently at all times.
 - d. Be suitably attired, according to CHKD's Operating Room policies.
 - e. Leave personal belongings in a designated secure area.
 - f. Turn off cell phone. Cell phone use is not allowed anywhere in the Operating Room.**
 - g. Adhere to the CHKD standards of confidentiality and infection prevention.
 - h. Not be allowed to participate in the actual procedure or make any adjustments to equipment used during the cases.
 - i. Not be allowed to open sterile supplies and implants.
 - j. Enter the Operating Rooms through the scrub area.
 - k. Enter the Operating Room only after induction of anesthesia or unless invited by the Surgeon prior to induction of anesthesia.
 - l. Function under the direction of the Circulating Nurse and the Director of Surgical Services. Noncompliance to directions from either of the nurses could result in removal from the Operating Room.

XIV AORN Position Statement

The Role of the Health Care Industry Representative in the Perioperative/Invasive Procedure Setting

Position Statement

AORN acknowledges and values the role of the health care industry representative in perioperative settings. AORN believes a health care industry representative may be present during an operative or other invasive procedure under conditions prescribed by the health care organization and in compliance with accreditation requirements and local, state, and federal regulations. AORN believes that perioperative registered nurses (RNs), perioperative administrators, and health care industry representatives are all accountable to advocate for patient safety; workplace safety; and the patient's right to information, privacy, and confidentiality when a health care industry representative is present during an operative or other invasive procedure. The following precepts should be used to guide a multidisciplinary team in developing and periodically reviewing policies and procedures related to health care industry representatives in operating or invasive procedure settings.

Role of the Health Care Industry Representative

AORN believes that by virtue of their education, knowledge, and expertise, health care industry representatives have a valid, but restricted, role in the operative or other invasive procedure setting. Health care industry representatives hold a variety of positions (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel) in their own organizations. When permitted access to the operating or invasive procedure room, a representative is accountable to advocate for patient safety, workplace safety, and patient privacy and should abide by the following measures:

- Provide technical support in accordance with the health care organization's policies and procedures and local, state, and federal regulations.
- Conduct formal in-service programs or one-on-one instruction for the perioperative team to provide essential education, technical training, and assistance related to the device.
- Provide education for perioperative team members to be educated about new procedures, techniques, technology, and equipment before their use in an operative or other invasive procedure.
- Comply with a defined, restricted role that does not include performing actions as a part of the clinical team, participating in sterile field activities, or accepting requests to perform tasks outside of his or her approved role as outlined in the health care organization's policies and procedures.
- Present documentation to verify specialized education and the health care organization's approval if he or she will be performing calibration or

synchronization to adjust or program devices (eg, implanted electronic devices, radio-frequency devices, lasers) under the supervision of the physician.

- Comply with the health care organization's policies and procedures to obtain permission from the surgeon; to obtain authorization from the designated authority; obtain authorization in advance from the designated authority for persons from the representative's organization who will be accompanying an experienced health care representative for the purposes of orientation; to bring equipment and instruments for inspection or sterilization before use; and to wear proper identification, preferably a photo identification badge.
- Update documentation of TB test and vaccinations as required by the health care organization's policies and procedures and infection prevention personnel.
- Comply with the AdvaMed Code of Ethics on Interactions with Health Care Professionals.
- Comply with the health care organization's policies and procedures to complete orientation as a health care industry representative and requirements for ongoing education in the following areas:
 - relevant devices, equipment, or supplies specific to the procedure in which he or she will be involved;
 - patient rights and confidentiality requirements included in HIPAA;
 - expected attire in the perioperative invasive procedure area;
 - traffic patterns in the perioperative suite;
 - hand hygiene practices;
 - expected conduct related to aseptic principles and sterile techniques;
 - prevention of infectious disease transmission and exposure to bloodborne pathogens according to OSHA requirements;
 - occupational safety information (eg, biohazardous waste, electrical, radiation)
 - and other relevant safety protocols; and
 - fire safety and evacuation routes.

Rationale

Tragic incidents have drawn attention to the need for individual facility policies to address formal education for physicians, nurses, and other members of the perioperative team on the use of new medical devices before they are used for direct patient care. When clinicians use equipment with which they are unfamiliar, it may be hazardous to both patients and perioperative team members. Misuse of complex technology can cause injury to patients and even death. Incidents involving new technology and the presence of the health care industry representative in the perioperative setting have been highly publicized, especially when the end result is a patient's injury or death. Hospitals have been cited and fined for allowing the use of surgical equipment that is not approved by the hospital; not providing formal education to physicians, nurses, and other perioperative team members on the proper use of the equipment; and permitting an unauthorized person from a medical device company to participate in an invasive procedure.

Operating and invasive procedure rooms are among the most potentially hazardous of all

clinical environments and are subject to strict regulations, clinical practice guidelines, and standards of care to preserve patient safety. The primary responsibility of both the RN and the administrator in operative or other invasive procedure rooms is to ensure the safety and privacy of patients undergoing operative or other invasive procedures. When policies and procedures that address the role of the health care industry representative in the operating or invasive procedure room are implemented, RNs, administrators, and health care industry representatives can be consistent in advocating for patient safety and workplace safety; preventing health care-associated infections; and maintaining patients' rights to information, privacy, and confidentiality when health care industry representatives are present during operative or other invasive procedures.

Using a systematic method to provide perioperative team members with education, training, and instruction related to new technology, equipment, techniques, and procedures is essential for safe patient care. Health care industry representatives who possess the requisite education, knowledge, and expertise can play a vital role in providing technical assistance, instruction, and education to perioperative team members. When health care industry representatives provide technical support to the perioperative team for new technologies or devices, it can potentially decrease the time of the operative or other invasive procedure and facilitate the attainment of optimal patient outcomes.

National organizations recommend that equipment be inspected and approved by the health care organization's service provider before use and that loaned instruments be sterilized by the receiving organization before use. AORN recommends that members of the perioperative team use equipment and supplies according to the manufacturer's instructions for use. Health care industry representatives play a key role in educating perioperative team members in the use of new and existing technologies, equipment, and supplies based on the manufacturer's instructions for use. Notifying perioperative leaders in advance and having the equipment or instruments inspected and processed before the time of education, demonstration, and use reduces the risk for delays and facilitates productivity.

XV Pharmaceutical Manufacturer Representatives Conduct Policy

Vendors presenting pharmaceuticals, intravenous solutions, tubing or any item marked "Federal law prohibits dispensing without a prescription" shall deal directly with the CHKD Pharmacy Department.

- A. Pharmaceutical vendors shall schedule appointments by contacting the Pharmacy Department Secretary at 757-668-7163.
- B. Pharmaceutical vendors **MAY NOT** enter patient care areas, e.g. the emergency department, surgical services, nursing stations, and anesthesia without authorization from the Pharmacy Department.
- C. No samples, legend or over-the-counter product may be left in this facility. Any educational or promotional programs for prescribing medications must be registered in the pharmacy prior to discussing with CHKD Staff.
- D. Only formulary approved medications may be presented on CHKD property unless approved by the pharmacy department. The formulary status of a medication may be determined by contacting the Pharmacy Department.
- E. Displays are not permitted in public areas. Funding for educational programs is encouraged. Speaker programs must be arranged through the pharmacy or Medical Education Departments.
- F. CHKD has a "closed" formulary system. Non-formulary medications are not available for use on patients in this facility. Requests for addition of items to the formulary must be initiated by a physician with privileges at this institution and reviewed by the Pharmacy and Therapeutics (P&T) Committee. The requesting physician must contact the Pharmacy directly and provide appropriate documentation for P&T Committee consideration.
- G. Violation of these policies by the Pharmaceutical Vendor will result in suspension of visiting privileges.

XVI Fire Safety

In the event you hear the fire alarm while conducting an appointment at CHKD, you should listen for an overhead paging announcement of "Facility Alert Fire (Location)". If the alarm is not near your location, no action is required, and you may continue what you were doing. However, **do not use the elevators during a fire**, use the stairs instead.

For your safety, and that of others, remember the word "**RACE**" as a reminder about the appropriate action to take. RACE is an acronym for Rescue, Alarm, Confine, and Extinguish/Evacuate.

- Rescue:** Rescue individuals who are in immediate danger.
- Alarm:** Pull the nearest fire alarm box by grabbing the center handle and pulling down until it stops. Release the handle and notify the closest CHKD associate.
- Confine:** Confine the heat and smoke by closing all doors and windows in the area of the fire, plus adjacent areas.
- Extinguish/Evacuate:** Use a fire extinguisher to put out the fire, if you feel comfortable doing so and if use of an extinguisher would be effective in eliminating or greatly reducing the fire. Otherwise, evacuate the area immediately, closing the door behind you.

To use a fire extinguisher, remember the word "PASS" to correctly use the device:

- P** Pull the pin
- A** Aim the nozzle at the base of the fire
- S** Squeeze the handles to release the extinguishing agent
- S** Move the extinguisher in a back-and-forth sweeping motion

XVII Infection Prevention Guidelines

To reduce the risk of transmitting pathogens, there are a few precautionary practices to employ:

A. Wellness:

Stay home if you are sick with something infectious. If you are not feeling well, for your own health and for consideration of others, we ask that you cancel your appointment and reschedule when you are feeling better.

B. Bloodborne Pathogens:

Bloodborne pathogens are microorganisms present in human blood and other potentially infectious materials. Examples of common illnesses spread by blood borne pathogens include Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV), and Malaria. Any body fluid with visible blood may be infectious.

These microorganisms can cause disease or death when transmitted from an infected person to another person. The transmission may occur when blood or body fluid from an infected person enters another person's body. For healthcare workers, this transmission may occur:

- through accidental puncture from contaminated needles, other sharps, or broken glass
- contact between mucous membranes and infected body fluids

C. Standard Precautions:

In 1996, the Centers for Disease Control issued "Standard Precautions" as recommendations for the protection against the transmission of blood borne diseases and other diseases when treating all patients. To protect yourself and others, always treat all blood, body fluids, secretions and excretions, non-intact skin and mucous membranes as if they are infected with bloodborne or other pathogens.

D. Handwashing:

Handwashing is one of the most important precautions for preventing the transmission of infections. A standard handwashing technique consists of: soap, a vigorous rubbing together of all surfaces of lathered hands for 10 – 15 seconds, thorough rinsing under a stream of water, thorough drying hands with a clean, disposable paper towel, turning off faucets with the paper towel, and disposing of the paper towel in a garbage receptacle.

Handwashing must occur:

- Before and after treatment with each patient
- Before donning gloves and after gloves are removed
- Immediately when accidental bare-handed contact with blood, body fluids, secretions and excretions, non-intact skin, mucous membranes, or infected equipment occurs.

E. Blood Spills:

To clean up blood spills, wear gloves, blot the blood with absorbent materials, use a disinfectant to clean the area of the spill, and discard the blood-soaked materials in a biohazard bag.

F. Contaminated Sharps and Linens:

Sharps: When handling sharps, always wear gloves. Do not recap the needles. Dispose of the used sharp in a needle box immediately after use.

Linens: When handling contaminated linens, always wear gloves, and handle the linens as little as possible. Place the soiled linens in a leak-proof bag if soaking is likely.

XVIII Non-Compliance

Vendor's failure to adhere to the regulations set forth in the Vendor Access Policy will result in the following:

- On the first infraction, the facility on-site department manager will address the situation with the Vendor; identify and clarify the policy to prevent further occurrences. This interaction will be documented and reported to the Vendor Access Program Administrator in a written memo or email.
- On the second infraction by the same vendor, an investigation will be conducted that may lead to a letter of reprimand from the CHKD manager of the affected department, i.e., pharmacy or supply chain. This letter will be sent to the vendor, as well as his/her employer.
- After the third infraction by the same representative, an investigation will be conducted that may lead to the surrender of the vendor's badge and permanent suspension of the vendor's privilege to access CHKD facilities. The vendor's employer will be notified of the infraction in writing. Hospital security may prevent access to vendors who are not in compliance with this policy.

Any violation of federal, state or other regulatory laws may lead to the termination of the contract or business relationship. CHKD may report these violations to the appropriate agency, which could lead to consequences under the appropriate law.

Any vendor permitting use of his/her identification badge by another individual will immediately have their identification badge withdrawn by CHKD supply chain management and will no longer have access to CHKD facilities.

Vendors who do not adhere to CHKD policies will be subject to remedial actions ranging from suspension to permanent dismissal of rights to conduct business with CHKD on behalf of their companies. Because CHKD does not want to hinder the delivery of patient care, the Vendor's company may assign another Vendor Representative to service CHKD during the suspension or permanent dismissal of the Vendor Representative violating CHKD's policies.

CHKD Vendor Code of Conduct

CHKD strives to exercise the highest standards of conduct in working with vendors. We expect that our vendors will also use these same high standards when conducting business with CHKD.

- Vendors will keep patient and business information confidential.
- No vendor will seek the attention or time of CHKD personnel without an appointment.
- Vendors will not request anyone other than a designated member of Supply Chain, Perioperative Services, Facilities or Pharmacy Departments to sign any type of purchasing agreement or contract. Agreements or contracts signed by a non-authorized CHKD agent will be considered non-binding. No agreement will be deemed valid until all CHKD contract conditions are met.
- All contract negotiations and interactions between CHKD and vendors/suppliers shall be conducted in a manner that avoids the violation of any law or regulation and the appearance of impropriety.
- Vendors will observe the general hours of operation of each facility. Access shall be limited to 8:00 AM to 5:00 PM unless other arrangements have been made through Supply Chain, Perioperative Services, Pharmacy Departments or other involved departments.
- Vendors will not demonstrate, on-site, any supplies, equipment or pharmaceuticals to staff without approval by that department manager.
- On each visit, vendors will be required to register upon arrival and sign out upon departure at a designated site(s) in each facility. (See Vendor Representative Sign-in/Sign-out Procedure in Vendor Information Packet) During the visit, representatives will be required to display the appropriate issued photo ID or 24-hour badge.
- Gifts or inducements of any kind are subject to the limitations of the CHKD Code of Conduct. Any violation could negatively impact future business. Violation of federal or state laws or other regulator agencies may result in CHKD reporting these violations to the appropriate agency.
- Vendors not compliant with CHKD Corporate and Hospital policies, procedures, including, Department Dress Code, Fire and Safety, etc. and Code of Business Conduct will lose their opportunity to access CHKD facilities.

Signature

Date

Print Name

Confidentiality Agreement

I, _____ **[PRINT INDIVIDUAL'S NAME]**, am requesting access to a facility of Children's Health System, Inc. and its subsidiaries and affiliates ("CHS") to observe patients/patient records during my observation experience or to gain access to certain patient care areas of CHS as an employee of a company providing goods or services to CHS. In conjunction with my requested access to a CHS facility, I agree to the following:

1. I understand that patient information is confidential and protected by state and federal laws and that no patient information is to be revealed to anyone outside of CHS without the written authorization of the patient/his parent/his legal guardian, or a subpoena, court order or federal/state statute.

2. I agree that under no circumstances will I reveal confidential patient information to anyone outside CHS. I understand that informational elements such as dates of service, patient name or initials, date of birth, any component of the patient's address other than state, phone numbers, medical record number, account number, etc. are considered patient identifiers and as such can not be revealed to anyone outside CHS. (Example: stating that you observed an ear tube placement procedure at CHKD on 1/12/19 is a BREACH in patient privacy).

3. I understand that within the facility patient information is shared for treatment, payment, and operations and then **only on a need to know basis**. Patient case discussion, consultations, examinations, and treatment are private and conducted discreetly.

4. While in a CHS facility, I agree:

- (a) not to share patient information with anyone not directly involved in the patient's care or treatment and then only under the direction of my sponsor.
- (b) not to discuss confidential information in areas where it may be overheard (elevators, halls and cafeteria).
- (c) not to access any patient information without specific direction by my sponsor.
- (d) not to attempt access to patient information for personal reasons.
- (e) to inform my sponsor of any personal relationships I may have with a patient or patient's family to whose information I may access. When possible, this notice is to be made prior to any significant access to the patient or his information.
- (f) if allowed access to computerized health information by my sponsor, to clear computer screens of patient information before leaving the screen.
- (g) to return any patient information given to me on paper to the professional staff member or employee who provided it to me or to dispose of it within the facility using a shred-it box.
- (h) not to store or transmit any patient information using a portable device or any other electronic means.
- (i) not to remove patient information in any form from the facility.
- (j) not to make any photographs, videos, voice recordings or any other reproduction in any media or of any nature whatsoever.

5. I understand that the federal government has defined through the HIPAA Privacy Rule

the appropriate uses and disclosures of individually identifiable health information (patient information). I further understand that the federal government could impose civil fines and/or criminal fines and/or imprisonment for inappropriate use of patient information and that **ANY PERSON** who knowingly uses, causes to be used, obtains, and/or discloses individually identifiable health information in violation of the Privacy Rule has committed a felony. Criminal offenses include those committed under false pretenses or committed with the intent to sell, transfer, or use protected health information for commercial advantage, personal gain, or malicious harm. Criminal penalties can result in up to \$250,000 in fines and/or 10 years in **PRISON**.

6. I understand that I am not permitted, and I will not attempt, to enter any area of a CHS facility prior to checking in at the designated CHS registration area and unless I am accompanied by a CHS designated escort. I understand that my failure to be accompanied by a CHS designated escort may result in my immediate expulsion from the CHS facility.

7. I understand that my failure to comply with any of the requirements set forth above may result in CHS excluding my access to all CHS facilities immediately and permanently.

8. I understand that my obligations and all terms and conditions of this Agreement apply during any period in which I am permitted access to a CHS facility and continue in full force and effect indefinitely thereafter.

Employer Guest Signature: _____ Date: _____

Name of Organization/Hospital/Institution/Company from which Employer Guest comes, as applicable: _____

Approved by:

Sponsor Signature: _____

Sponsor Name: _____

Sponsor Title: _____

Date: _____

Vendor Gift Disclosure Form

I, _____, an authorized representative of _____ (Vendor Name)

(Vendor), attest that during the time period _____ through _____,

Vendor provided only the gifts or other items of value described in this form to CHKD or any of its affiliates or any employees or representatives of such entities. Please note that any item or service provided under the express terms of a written contract between Vendor and CHKD or its affiliates need not be reported on this form.

None (check here) _____

The following gifts or other items of value (describe in reasonable detail, including date, to whom the gift/item of value was provided and approximate value):

The signature below represents our attestation that no gifts or other items of value other than those described above were provided during this reporting period.

Signature and Title

Date