Name: Froedtert Health Vendor Sales Representative Access and Credentialing Policy

Last Review Date: 05/27/2022

Next Review Date: 05/27/2025

Policy Number: FH-SC.003

Origination Date: 10/01/2009

Purpose:

Monitor and control Vendor Sales Representative access and credentialing at all Froedtert Health facilities.

This policy establishes:

1. Requirements to monitor and control Vendor Sales Representatives access at all Froedtert Health owned, leased, and operated sites.
2. Standards for efficient, and safe interactions between our Vendor community and our Froedtert Health staff.
3. Definitions for ownership and accountability related to managing Vendor access to Froedtert Health.
4. Clear guidelines for the use of the Vendor Credentialing System (VCS) at Froedtert Health

The inconsistent application of Vendor management processes across Froedtert Health facilities can lead to possible liability concerns, compliance, integrity, and fairness issues. Healthcare industry accrediting organizations require contracted labor and services in accredited facilities to be managed just as the facility would manage direct employees, including verification of all relevant human resource information. Further, such accrediting organizations through their standards require accredited facilities to manage safety and security risks, including the identification, as appropriate, of all patients, staff and other people at the facility.

Definitions:

1. **Vendor Sales Representative**: Refers to personnel who represent a company or companies in any patient care area or sale/market any patient care supplies, equipment or services to Froedtert Health. Vendor Sales Representatives include all categories of supplies, services and equipment (e.g. medical-surgical, pharmaceuticals, laboratory, information technology, capital equipment, office products, etc.).
2. **Contract Labor and Collaborative Partners**: Refers to individuals contracted either directly or indirectly through a Vendor by Froedtert Health to perform a specific job duty or task (e.g., consulting, training, project work, service, maintenance, etc.) on a routine and regular basis in any patient care areas accredited by an accrediting or standard organization. This would include

contracted collaborative partners that work with Froedtert Health staff in areas of medical research, scientific advancement and protocol development. Contract Labor and Collaborative Partners are not subject to this policy as stated in Exception D & E below if certain conditions are met. If those conditions are not met, it is the intent of this policy that Contract Labor and Collaborative Partners will generally fall within the definition of a Vendor Sales Representative and will be subject to this policy.

3. **Patient Care Area**: Any area within any Froedtert Health facilities where it would be normal that patients be present. This would include but not be limited to patient care and procedure rooms, waiting areas, patient elevators and walkways and provider offices.

4. **Vendor Credentialing System (VCS):** Any one of several platforms used to vet and approve vendors and their representatives. Froedtert currently uses GHX VendorMate and Contractor Compliance.

5. **Approved VCS App**: GHX VendorMate

Exceptions: The following individuals & groups are not subject to this policy unless they visit Froedtert facilities at least once per week. Such individuals would be classified as "regularly on site" and would need to comply with the rules laid out in this policy.

A. Individuals representing governmental or regulatory agencies, business audit services such as insurance or financial auditors; study monitors under a clinical trial agreement; clinical service agencies such as home health and/or hospice agencies; or guests participating in a tour that does not involve sales and marketing.

B. Executive/corporate management from companies visiting a Froedtert Health entity for purposes of a meeting as long as all of the following criteria are met:

    a. Any Vendor Sales Representative with responsibility for the Froedtert Health account in attendance has registered in the VCS;

    b. The meeting is for the primary purpose of a strategic alliance, new business development discussions or scientific exchange with key Froedtert Health physician/administrative leaders;

    c. The meeting is at the request or agreement of a member of the Froedtert Health administrative staff, physician, scientist or administrator and such Froedtert Health personnel accompany and participate in the meeting;

    d. The meeting is conducted in a conference room or private office, preferably in a non- patient care area.

C. Principals/employees of management consulting firms visiting a Froedtert Health entity for purposes of a meeting are exempt only for the first on site meeting, and any subsequent meetings in non-patient care areas.

D. Contract Labor and Collaborative Partners when a written agreement exists specifying the level of credentialing necessary in order to meet accrediting organization's standards and adhere to Froedtert Health's Code of Business Conduct. Contract Labor and Collaborative Partner representatives may be issued a long term badge and managed through the Contractor Compliance system, Froedtert Security, & Froedtert HR practices.

E. Representatives from contracted vendors that do not have regular contact with patients or patient equipment such as delivery services, couriers, and facility maintenance staff unless they are regularly on site. If representatives from these contracted vendors do have regular contact with patients or regular access to patient care areas, they will be considered Contract Labor or a Collaborative Partner as defined in Exception D.

Policy:

Froedtert Health will develop processes for Vendor Sales Representative access and privileges that comply with the following requirements: Minimize disruption to the clinical practice, establish and maintain product and equipment quality, and promote standardization through compliance with contractual commitments.

A. Vendor Sales Representatives will be expected to follow a prescribed set of guidelines for conducting business with Froedtert Health. Failure to follow our guidelines will result in an inability to visit our facilities when acting in a sales capacity.

B. Staff of Froedtert Health facilities will help monitor sales visits and behavior by sales personnel. Staff will report Vendor Sales Representatives who have failed to follow our prescribed process and guidelines to the Supply Chain Department, so that appropriate follow up and/or corrective action can be taken.

Procedure:

1. Supply Chain will partner with Security, HR, Occupational Health, Infection Prevention, Facilities Management, and other appropriate departments to ensure appropriate access management.

2. Supply Chain will designate responsible personnel & locations through the organization as check-in points for Vendor Sales Representatives and issuance of Vendor badges.

3. Representatives will not be allowed in any Froedtert facility or site without a valid pre-scheduled appointment. "Drop-ins" and "cold calls" are not welcome.

4. Sales and service representatives will be required to check-in, obtain a ID Badge, and check-out upon completion of their visit(s). Vendors may use the VCS kiosks around the organization, or an app-based check in process as detailed below.

5. Credential requirements will be determined by the following departments: Supply Chain, Infection Control, Risk Management, Safety & Security, and Occupational Health & Wellness.

6. As part of the registration process, the Vendor Sales Representative will present all required information including but not limited to:

    a. A valid photo ID

    b. Reasonable documentation of relevant competencies, training and/or qualifications

    c. General safety training

    d. Patient confidentiality

    e. Immunization records

    f. Conflict of interest forms

    g. Background checks

7. All Vendors that may have access to Personal Health Information ("PHI") as defined by HIPAA must have a current Business Associate Agreement (BAA) on file, or have signed a Froedtert Health Confidentiality agreement as deemed appropriate.

8. Vendor Sales Representatives will also be required to confirm receipt and understanding of relevant documents, policies and procedures.

9. Vendor Sales Representatives who will be visiting or working within a patient care area as a technical advisor, the following additional requirements to protect the health and safety of staff, patients and others are followed:

    a. Written proof of the Vendor Sales Representative's current status pertaining to COVID-19 Vaccination TB testing, hepatitis vaccination, MMR (measles, mumps, and rubella) vaccination and chicken pox vaccination.

    b. Documented evidence of training and competencies on the following topics: infection control and aseptic practices, blood-borne pathogens, patient rights, confidentiality, HIPAA, informed patient consent, product compliance and medical system, device, product, procedure or service they will be delivering and/or operating.

    c. Comprehensive processes to govern the admission and presence of Vendor Sales Representatives in any operating rooms and/or procedural areas. This will include the ability to clearly identify any Vendor Sales Representatives in such procedural areas.

10. Vendor Sales Representative's services to physicians and clinical staff providers during surgical, interventional and diagnostic procedures will be restricted to observation and verbal consultation only.

11. Persons acting in a sales capacity will be required to visibly display an authorized sales pass prior to conducting business.

12. Vendor Sales Representatives may only visit specific departments/areas where they have a confirmed appointment.

13. General ID Processes: Vendor Sales Representatives may use one of three different types of badges to access a Froedtert Health site: A VCS printed badge, a long term (aka “hard”) badge, or a digital badge.

    a. All types of badges will clearly identify the wearer as a Vendor (versus an employee or other Froedtert Health staff).

    b. All types of badges must be displayed above the waist

    c. VCS printed badges will only be valid for the day they are printed and will clearly display the date for which it is valid

    d. If Froedtert chooses, a long term “hard” badge may be issues to a vendor. All vendors who receive a long term badge must present a valid VendorMate registration at Security on a quarterly basis.

    e. Digital badges will be presented on a daily basis at the entrance point to a location. Vendors using digital badges for access must wear a badge identifying themselves and their company for the duration of their visit.

14. At all acute facilities VCS printed badges and up to date, long term badges may be used. Digital badges are not acceptable.

15. At non-acute facilities a Vendor Sales Representative may use all types of badges listed in #13 above.

16. Vendor Sales Representatives that have not checked-in and/or are not visibly displaying a valid ID or access approval will not be allowed into a Froedtert Health facility, and will be referred to the Froedtert Health Supply Chain Department.

17. All individuals serving in a sales capacity will be required to check-in and check-out of the Froedtert Health authorized Vendor Credentialing System (VCS).

    a. The web-based vendor credentialing system (VCS) will serve as a management tool to perform random audits, address program compliance and support tracking any potential risks or exposures, if ever needed. The system will track the date of the Vendor visit, the Vendor Sales Representative’s destination at the facility, a time of entry to the facility and other information as deemed necessary.

18. All Froedtert staff will communicate the existence and enforcement of the Vendor Sales Representative Access and Privileges Policy and requirements to materials management personnel, facility staff and to potential Vendors.

SURGERY DEPARTMENT SPECIFIC GUIDELINES:

When visiting any Froedtert Health, Inc. Surgery Department, you must have a pre authorized appointment (see Procedure #3 above) and comply with the following guidelines. Failure to comply will result in suspension or permanent revocation of your sales privileges at all Froedtert Health facilities.

1. Representatives will not be given access to the Surgery Schedule or Patient Scheduling. Representatives will also not procure information from a patient's chart.

2. While in the Surgery Department, representatives will not approach and/or solicit other physicians or attempt to attend procedures for which he/she has not previously been cleared.

3. Representatives will not use the Operating Room for sales calls. Samples will not be provided directly to staff, physicians or patients. All new products must follow the established Value Analysis practices of Froedtert Health.

4. Representatives found to be "counter-selling" our reprocessing efforts will be suspended for a period not less than 3 months.

5. All products presented for use in the Surgery Department must be FDA approved.

6. In the event a surgeon contacts a sales or manufacturing representative directly for a product(s) to be used in the Surgery Department, the sales or manufacturing representative will present the product(s) to the Surgery Buyer/Inventory Specialist upon entering the Surgery Department. List price and discounted pricing information is required. Froedtert Health, Inc. will not pay list price for any product utilized in the Surgery Department.

7. Contact the Supply Chain Department to initiate or modify a consignment program.

8. If a product(s) is brought into the Surgery Department without a purchase order being issued in advance, we will consider whatever is brought in a "donation."

9. Safety inspection of all electrical and battery operated equipment must be completed by the BioMed Department before being brought to the Surgery Department. BioMed requires a minimum of 48 hours (excluding weekends) to complete all safety testing.

10. Non-electrical equipment, instruments, instrument sets, and reusable items must be here no later than 48 hours before a scheduled procedure to assure they are processed correctly for our patients.

11. All sets currently not in inventory must be accompanied by an electronic file supplied to the appropriate Service Coordinator. This file should be in Microsoft Excel format. This file must include: Set Name; Instructions for use (IFU); Manufacturer name; Rep's name, phone number, and e-mail address; Catalog number; Order number; Item name; Quantity of each item; Price of each item; Packaging; Type (implant, instrument, consumable); and HCPCS Level II code (required for any implant). If there are multiple pans, Vendor

must indicate pan number and total number (i.e. Pan 1 of 3). Additionally, each pan must be itemized and, if layered, noted as to upper/middle/lower, and the sequence of items within the tray (i.e. left to right, bottom to top). Vendors may use the file template provided by the hospital, or one from their company, so long as it contains the required information.

12. Sets are to be delivered to the Decontamination Area of the Sterile Processing Department (SPD). All sets will need to be sterilized upon arrival to our institution.

13. A Vendor Notification Form must accompany any items being brought into the facility and delivered to SPD.

14. Rep must be on site and readily available for those cases involving new sets or seldom used sets. Exclusions from this are by surgeon discretion only.

15. Once the set/tray has been used and has been decontaminated, it must be removed from the hospital within 48 hours, unless it will be used for a subsequent posted case.

16. Representatives will play no role in diagnosis and treatment of a patient. Representatives are to limit their comments and advice to the use and performance of the product(s), and will avoid making unsolicited statements or suggestions of alternative approaches.

17. Representatives will not be allowed to scrub for surgery, enter the sterile field, or have direct physical contact with our patients.

18. In the event of an emergency or code, representatives will be asked to leave immediately. Representatives must follow the direction provided by our Froedtert Health, Inc. employees at all times.

19. Representative(s) will comply with the Surgical Attire Policy of the institution.

20. Representatives are required to follow the direction of the Surgery Dept Circulating RN while in the Operating Room suite. Representatives must also adhere to universal precautions (wearing protective eyewear, hand washing, etc.). No backpacks or other bags are to be brought into the Operating Room suites.

PHARMACY GUIDELINES:

Froedtert & The Medical College of Wisconsin does not utilize pharmaceutical representatives for patient and staff education purposes or for presentation of pharmaceutical or disease state information at Pharmacy & Therapeutics (P&T) Committee or Subcommittee meetings. Our clinics, physicians, and P&T governance will utilize the Froedtert Health Pharmacy Department for any and all pharmaceutical education and information needs. For special circumstances or needs, pharmaceutical representatives will be contacted by invitation. All clinical information, health economics outcomes research data, utilization questions, or contracting matters must be routed through Froedtert Health's Center for Medication Utilization or Pharmacy Contracts and Purchasing Coordinator.

Enforcement:

This Vendor Sales Representative Access and Privileges Policy is administered through the Froedtert Health Supply Chain Department in partnership, collaboration and cooperation with Froedtert Health Executive Leadership, and all Froedtert Health staff and students. Comments, questions and violations are to be directed to the Supply Chain Department. The Supply Chain Department will work with the Froedtert Health Compliance Department and site specific Safety & Security Departments to ensure enforcement of this policy.

A. Non-compliance or non-support of this policy by a Froedtert Health staff member may result in corrective action.

B. Non-compliance by Vendor Sales Representative with Froedtert Health policies will result in, but not be limited to, the following actions:

C. First Infraction: A Supply Chain Director or their designee will contact the Vendor Sales Representative to review an incident and possible future actions if infractions continue.

D. Second Infraction: There will be a suspension of the Vendor Sales Representative's privileges at the facility for a period up to three months, with a formal notification to the representative's supervisor. Current business will be conducted by an alternative representative from the company.

E. Third Infraction: There will be a suspension of the Vendor Sales Representative's access and privileges at all Froedtert Health facilities indefinitely, with formal notification to the representative's supervisor.

F. Froedtert Health reserves the right to suspend or permanently revoke any Vendor Sales Representative's ability to call upon our health system if the circumstances have been determined to be of a serious nature. Violations of a serious nature may also result in an escalation of the suspension and/or revocation process.

G. As a final option, Froedtert Health may terminate an agreement and convert to an appropriate, competitive and acceptable product. Grievances may be filed with the VP of Supply Chain, the Chief Pharmacy Officer, or the Corporate Compliance Officer.

QUESTIONS/CONCERNS:

Please direct questions or concerns regarding Froedtert Health's Vendor Sales Representative Access and Privileges Policy to FH Supply Chain 262-532-5350

Pharmacy related questions or concerns, may be addressed to: CMU@froedtert.com

Related Policies: Corrective Action
Solicitation and Distribution

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