

Froedtert Health

Supplier / Sales Representative Access and Privileges Policy

Applicable Facilities:	Froedtert Health, Inc. (All sites)
Effective Date:	December 1, 2011
Revision Date:	November 22, 2013

Purpose:

This policy establishes requirements for Supplier/Sales Representatives (as defined below) at all Froedtert Health sites relating to access, interaction and business transactions.

Froedtert Health recognizes that Supplier/Sales Representatives, by virtue of education, training, and expertise often serve as a resource for physicians, researchers and allied-health staff through the sharing of product information, technical information, and the provision of education and training.

The intent of this policy is not to interfere or create a barrier to the collaborative relationships that have been developed over the years with suppliers. Such relationships have been and continue to be important to the advancement of clinical practice, education and research. Froedtert Health considers the continuation of these relationships essential to ensure access to scientific and technological innovations. However, Froedtert Health also has an obligation to appropriately manage access of Supplier/Sales Representatives to Froedtert Health staff and patients.

The inconsistent application of supplier 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:

Contract Labor and Collaborative Partners: Refers to individuals contracted either directly or indirectly through a supplier 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 B 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 Supplier/Sales Representative and will be subject to this policy.

Supplier/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 (including, but not limited to, all consulting and administrative staff, physicians, scientists, students, administrators, nurses, pharmacists, contracting managers, buyers or purchasing agents and general users of the company's product). Supplier/Sales Representatives include all categories of supplies, services and equipment (e.g. medical-surgical, pharmaceuticals, laboratory, information technology, capital equipment, office products, etc.). Such representatives can generate sales, demonstrate products, solve problems, advise clients of matters, quote prices, or conduct other duties generally associated with representing their company.

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.

Exceptions: All individuals/groups listed as exceptions to this policy are not subject to this policy, if certain conditions are met as defined below.

Exception 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 are not required to register as a Supplier/Sales Representative or obtain a RepTrax issued identification (ID) badge for each visit. Each Froedtert Health facility may establish other registration requirements for those individuals listed as an exception (e.g. insurance/medical assessment personnel).

Exception B: Contract Labor and Collaborative Partners are an exception to this policy where a written agreement exists with the company providing the Contract Labor and Collaborative Partners specifying the level of credentialing necessary in order to meet accrediting organization's standards and adhere to Froedtert Health's Business Code of Conduct. Contract Labor and Collaborative Partner representatives are issued a longer term badge than those associated with infrequent or periodic visits to a Froedtert Health entity and are subject to this policy.

Exception C: Executive/corporate management from companies visiting a Froedtert Health entity for purposes of a meeting are not required to register or obtain a RepTrax identification (ID) badge as long as all of the following criteria are met:

1. Any Supplier/Sales Representative with responsibility for the Froedtert Health account in attendance has registered;
2. 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;

3. 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 with accompany and participate in the meeting;
4. The meeting is conducted in a conference room or private office, preferably in a non-patient care area.

Exception D: Principals/employees of management consulting firms visiting a Froedtert Health entity for purposes of a meeting are not required to register or obtain a RepTrax issued identification (ID) badge. If a subsequent engagement occurs and is conducted in an accredited patient care area, than all on-site employees of the consulting firm must register and obtain a RepTrax issued (ID) badge unless another exception applies.

Policy Statements:

Froedtert Health, Inc. will develop processes for supplier/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.

Procedure Statements:

Program Administration & Registration Process:

Each Froedtert Health facility will do the following:

Action	Definition / Clarification
1) Be designated as the “Supplier/Sales Representative Access Program Administrator” responsible for administering a Supplier/Sales Representative Access and Privileges process. The Program Administrator will partner with appropriate clinical and other departments to develop and administer specific procedures to insure appropriate access management.	Further, designate responsible personnel (e.g., surgical services, Clinic / Department location, Procurement office, etc.) as key check-in points for Supplier/Sales Representatives and issuance of supplier badges if not obtained in advance via the web-based vendor registration system.
2) Require all Supplier/Sales Representatives to complete a registration process prior to a site visit and provide an annual update to the registration information. The Program Administrator is responsible for communicating to relevant Froedtert Health staff and departments any issues that are identified in the registration process.	As part of the registration process, the Supplier/Sales Representative will present all relevant contact information and reasonable documentation as evidence of their competencies, training and qualifications in their company’s products, general hospital safety training, orientation, patient confidentiality, immunization records, conflict of interest form, background checks and business ethics. In some cases, a statement of attestation from the Supplier/Sales Representative’s Company will be sufficient.

	<p>Supplier/Sales Representatives will present a valid photo ID (e.g., driver’s license) to be photocopied or uploaded into the registration system. This process may be facilitated by use of the RepTrax vendor system for registration and ongoing management.</p>
<p>3) Provide each Supplier/Sales Representative with an identification system or badge. This ID system or badge will clearly identify the wearer as a supplier (versus an employee or other Froedtert Health staff), so Supplier/Sales Representatives are not mistaken by visitors or patients as a patient care provider. The ID Badge should include a photograph of the Supplier/Sales Representative.</p>	<p>Supplier/Sales Representatives are required to display their RepTrax issued ID badge at all times when on the campus or in any Froedtert Health site. The ID system or badge will be date sensitive, so it will expire prior to a future scheduled supplier visit. Supplier/Sales Representatives assigned long-term to a specific procedural area for technical knowledge may be issued a monthly or an extended ID badge.</p>
<p>4) Partner with Departments to ensure that Supplier/Sales Representatives calling on Froedtert Health, Inc. register and obtain a Supplier/Sales Representative identification badge for each visit.</p>	<p>New Supplier/Sales Representatives or suppliers that currently do not have a contract with Froedtert Health may attend an initial meeting without registering or obtaining an identification badge in order to understand the requirements of the policy for future meetings.</p>
<p>5) Provide each Supplier/Sales Representative with an orientation and education material specific to their role to promote familiarity with the Froedtert Health policies and procedures.</p>	<p>Information related to the following topics will be included in standardized orientation module (some variation by site may exist due to site-differences):</p> <ul style="list-style-type: none"> • Supplier/Sales Representative Access and Privileges Policy • Code of Conduct for Supplier/Sales Representatives (Appendix I to this policy) • Patient confidentiality, Health Insurance Portability Accountability Act (HIPAA) and Business Associate Agreement • Provider Product Standardization Program • New product introduction processes • Business ethics and code of conduct expectations • Organizational business standard • Product recall and alerts process • Proper use of wireless communication devices on site • Froedtert Health Code of Business Conduct

	<ul style="list-style-type: none"> • Other topics deemed appropriate by the Froedtert Health Supply Chain, Pharmacy, or Nutrition Departments.
6) Utilize the web-based vendor registration system (RepTrax) that records the visits of each Supplier/Sales Representative to a Froedtert Health facility.	The web-based vendor management system (RepTrax) 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 supplier visit, the purpose of the visit, the Supplier/Sales Representative's destination at the facility, a time of entry to the facility and other information as deemed necessary.
7) Communicate the existence and enforcement of the Supplier/Sales Representative Access and Privileges Policy and requirements to materials management personnel, facility staff and to potential suppliers.	
8) Partner with Departments to ensure that, if, the Supplier/Sales Representatives 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:	<ul style="list-style-type: none"> • Written proof of the Supplier/Sales Representative's current status pertaining to TB testing, hepatitis vaccination, MMR (measles, mumps, and rubella) vaccination and chicken pox vaccination. • 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. • Comprehensive processes to govern the admission and presence of Supplier/Sales Representatives in any operating rooms and/or procedural areas. This will include the ability to clearly identify any Supplier/Sales Representatives in such procedural areas. • Supplier/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.
9) Create a Supplier/Sales Representative Profile Database to be utilized to validate the representative status	If the Supplier/Sales Representatives have not previously registered, the completion of a Reptrax account/registration form will be required before an ID system or badge is provided. All Froedtert Health personnel contacted by a Supplier/Sales Representative shall inquire as to whether they have followed proper site visit procedures (i.e., registered and has a RepTrax issued ID badge). If the answer is negative, the Supplier/Sales Representative shall be instructed by staff as to the proper procedure to be followed and refer the Supplier/Sales Representative to complete the registration process.
10) Ensure that all suppliers that may have access to Personal Health Information (“PHI”) as defined by HIPAA have a current Business Associate Agreement (BAA) on file, or have signed a Froedtert Health Confidentiality agreement as deemed appropriate.	

SURGERY DEPARTMENT GUIDELINES:

When visiting any Froedtert Health, Inc. Surgery Department, you **must** comply with the following. Failure to comply will result in suspension or permanent revocation of your sales privileges at all Froedtert Health facilities.

1. Representatives will not be allowed in the Surgery Department without a valid pre-scheduled appointment. “Drop-ins” and “cold calls” are not welcome. Representatives will be on time for all scheduled appointments.
2. All representatives must check-in at the RepTrax station, and display their sales pass on their clothing above their waist while conducting business. All representatives are required to check-out at the RepTrax station when their business has concluded. Representatives visiting our Surgery Departments must also have a downloaded picture of themselves in RepTrax, so that it prints on your sales pass.
3. All information in the RepTrax system must be kept current.
4. Representatives will not be given access to the Surgery Schedule or Patient Scheduling. Representatives will also not procure information from a patient’s chart.
5. 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.
6. Representatives will not use the Operating Room for sales calls. Samples will not be provided directly to staff, physicians or patients without the prior approval of the Service Coordinator(s)/Inventory Specialist(s).

7. Representatives found to be “counter-selling” our reprocessing efforts will be suspended for a period not less than 3 months.
8. All products presented for use in the Surgery Department must be FDA approved.
9. 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.
10. Contact the Supply Chain Purchasing Department to initiate or modify a consignment program.
11. 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.”
12. 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.
13. 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.
14. 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.
15. 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.
16. A Vendor Notification Form must accompany any items being brought into the facility and delivered to SPD.
17. 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.
18. 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.
19. 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.
20. Representatives will not be allowed to scrub for surgery, enter the sterile field, or have direct physical contact with our patients.

21. 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.
22. Representative(s) will comply with the Surgical Attire Policy of the institution.
23. 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, handwashing, etc.). No backpacks or other bags are to be brought into the Operating Room suites.

PHARMACY GUIDELINES:

Froedtert & The Medical College of Wisconsin Community Physicians have made the decision to move away from the use of pharmaceutical representatives for patient and staff education purposes. Our clinics and physicians will utilize the Froedtert Hospital, Community Memorial Hospital, and St. Joseph's Hospital pharmacy departments for any and all pharmaceutical education and information needs. We appreciate the resource pharmaceutical representatives have provided in the past, but respectfully request that all pharmaceutical representatives refrain from visiting our providers. If there are special circumstances or needs, we will reach out to pharmaceutical representatives by invitation.

Enforcement:

This Supplier/Sales Representative Access and Privileges Policy are 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 located at Woodland Prime 400, N74 W12501 Leatherwood Ct, Suite 301, Menomonee Falls WI 53051. The Supply Chain Department will work with the Froedtert Health Compliance Department and site specific Safety & Security Departments to ensure enforcement of this policy.

Non-compliance or non-support of this policy or the rules outlined in Appendix I by a Froedtert Health staff member may result in corrective action.

Non-compliance by Supplier/Sales Representative with Froedtert Health policies or the rules outlined in Appendix I will result in, but not be limited to, the following actions:

- **First Infraction:**
The Corporate Director of Purchasing or their designee will contact the Supplier/Sales Representative to review an incident and possible future actions if infractions continue.
- **Second Infraction:**
There will be a suspension of the Supplier/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.
- **Third Infraction:**
There will be a suspension of the Supplier/Sales Representative's access and privileges at all Froedtert Health facilities indefinitely, with formal notification to the representative's supervisor.

Froedtert Health reserves the right to suspend or permanently revoke any vendor 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.

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 & Pharmacy, or the Corporate Compliance Officer.

Vendors are prohibited from knowingly presenting or causing to be presented, claims for payment or approval which are false, fictitious or fraudulent. Vendor is required to promptly report any type of fraud or abuse involving a Froedtert Health employee directly to our Compliance Hotline at ph. 414-259-0220.

QUESTIONS/CONCERNS

Please direct questions or concerns regarding Froedtert Health's Supplier/Sales Representative Access and Privileges Policy to:

Froedtert Health, Inc.
Supply Chain Purchasing
400 Woodland Prime
N74 W12501 Leatherwood Ct Suite 301
Menomonee Falls WI 53051-4490
Ph. 414-777-1950
Fax. Ph. 414-777-1953

If you have a pharmacy related question or concern, please send an email to:

CMU@froedtert.com