1. **Purpose**

1.1. To protect the privacy and safety of our patients and ensure that we provide the highest quality service possible.

1.2. To minimize interruption of patient care and staff productivity.

1.3. To ensure that all McLaren Health Care (MHC) subsidiaries conduct all business with Vendors with the highest ethical standards intended to protect patient confidentiality, and ensure appropriate and cost-effective use of medical devices, supplies, service and equipment and pharmaceuticals.

1.4. To require Vendors that conduct business with MHC subsidiaries to complete a certification process and act in accordance with all established MHC policies and guidelines.

2. **Scope**

2.1 Applies to all Vendors who are selling a product and/or service including those that provide medical devices, supplies, pharmaceuticals, service, and equipment. Admittance to any of the locations to any of the MHC subsidiaries by a Vendor is a privilege, not a right.

2.2 Applies to MHC and its subsidiaries. All employees, physicians, residents, and trainees are required to adhere to this policy. It is the responsibilities of MHC subsidiaries to ensure that Vendors and staff are knowledgeable and compliant with this policy.

2.3 Applies to all Vendors, including those involved in patient care procedures where their presence may be necessary in an advisory capacity.

2.4 Applies to Vendors providing training or in-service on supplies or equipment as it relates to their presence in procedural areas.
3. Definitions

3.1. Vendors are any representative of a distributor, manufacturer, or any other company, who visits for the purpose of soliciting, marketing, or distributing products or information regarding the use of medical devices, supplies, services, pharmaceuticals, and equipment.

3.1.1. This does not apply to service relationships that require an on-site presence as a condition of providing the contracted service. Such services must be documented by a written contract. (Examples include but are not limited to IT Service Providers, Food Service Management, Construction Management Providers, Auditors, Attorneys, Contractors/Repair Service Providers, etc.).

3.2. MHC Pharmacy policies include drug use guidelines, formularies, and utilization management initiative approved by MHC.

3.3. Vendor Certification is the process to qualify a Vendor who wants to come onsite a MHC subsidiary. The certification and educational process will include but not be limited to MHC policies and procedures, privacy regulations, conflict of interest and HIPAA requirements. Vendor will acknowledge the understanding of MHC policies which must be completed as part of this process.

3.4. Staff is defined as all employees, managers, directors, administrators and employed physicians.

3.5. Service is defined as purchased services or repair service to facilities or equipment.

3.6. Patient care areas are defined as areas or departments where patients are present and/or PHI may be present. Examples of patient care areas include operating rooms, pharmacy, sterile processing, etc.

4. Policy

4.1. Vendors that interact with MHC are required to comply with all applicable MHC patient care, privacy, pharmacy guidelines, health requirements, research integrity, HIPAA, Code of Conduct requirements, and follow the practice procedure requirements of this policy.

4.2. Vendors who visit any McLaren subsidiary more than 4 times per year are required to register and complete the certification process before visiting MHC subsidiaries.

4.3. It is the responsibility of the MHC subsidiaries to ensure that Vendors and staff are knowledgeable and compliant with these guidelines.

4.4. Staff members are required to uphold the highest professional standards in interactions with all Vendors.

4.5. Enforcement of this policy and ongoing monitoring is the responsibility of all staff.
4.6. Staff is required to report all violations of this policy to their Department Head and Supply Chain.

4.7. Violators of this policy will be subject to the following disciplinary action (also listed in Section 5.10 Compliance and Disciplinary Action):

4.7.1. **1st Offense**: Vendor representative will be given a written warning. And the Vendor Representative leadership will be notified.

4.7.2. **2nd Offense (for the same type of violation)**: Vendor Representative will be suspended from visiting all McLaren facilities, and the Vendor will be asked to provide a new Representative to service McLaren’s needs.

4.7.3. Depending on the severity of the violation, at MHC’s sole discretion a Vendor Representative may be suspended after the first offense.

5. Procedure

5.1. General Guidance

5.1.1. Vendors are only permitted to visit MHC subsidiaries by an approved appointment set up through MHC’s Vendor Credentialing system. Employees and physicians are under no obligation to grant appointment requests. Vendors cannot drop in without an approved appointment.

5.1.2. If the Vendor is visiting more than 4 times per year, they must go through the credentialing process.

5.1.3. Request for appointments must be made by calling ahead prior to the requested day and creating an appointment request in MHC’s Vendor Credentialing system. Product or service to be discussed must be identified at the time the appointment is made.

5.1.4. Should unanticipated patient care requirements arise, the appointment may need to be rescheduled. The Vendor will respect the decision to cancel and reschedule at another time.

5.1.5. Vendors will be required to check in and check out at the designated check in and check out area(s) at the respective subsidiary.

5.1.6. Vendors must obtain an identification badge through MHC’s Vendor Credentialing system to be allowed on site. The badge must be clearly displayed at all times during the visit. Badges must be obtained through MHC’s Vendor Credentialing System upon completion of registration. Badges will be used to check in and out of appointments.

5.1.7. Vendors can bring associates with them. If the associate has not registered to be certified (see section 5.2 Certification process), he/she must sign in and receive a temporary Vendor Guest paper badge. If the associate is visiting more than 4 times per year, he/she must get
registered through MHC’s Vendor Credentialing system. Vendors must not solicit procedure or patient volumes or competitive cost information from MHC staff or physicians. This information may only be shared with a Vendor with the approval of Supply Chain Management.

5.1.8. Staff and physicians may not share pricing, internal reports, communications, agendas, minutes, or other documents intended for internal distribution with Vendors.

5.1.9. Pricing comparisons are frequently misleading since the ultimate cost of supplies is dependent on many factors, including contracted discounts and rebates. Therefore, only pricing/cost information that has been approved by Supply Chain Management and/or Pharmacy may be discussed and only upon the request of the administrative or clinical department leader. No contracts under any circumstances may be given to or signed by staff.

5.1.10. MHC reserves the right to limit the number and duration of time a Vendor can visit an MHC subsidiary.

5.2. Vendor Credentialing Process:

5.2.1. Vendors are granted access to MHC locations as a privilege not a right.

5.2.2. Vendors interested in visiting an MHC subsidiary must be knowledgeable to all applicable MHC policies and requirements including those addressing privacy and confidentiality. Vendors who will visit more than 4 times per year are required to successfully complete a certification process through MHC’s Vendor Credentialing system prior to scheduling any appointments.

5.2.3. The Vendor may be required to pay a non-refundable annual fee to be credentialed through MHC’s Vendor Credentialing system to cover the cost of providing the education, certification and associated ongoing compliance monitoring. The annual fee (if required) cannot be waived.

5.2.4. Certification will be conducted online through MHC’s Vendor Credentialing system’s website.

5.2.5. The Vendor will be required to confirm that they have reviewed and agree to comply with the policies therein.

5.2.6. Once the Vendor Credentialing process has been successfully completed, a photo identification badge will be shipped to the Vendor. The Vendor is required to check in and out at the designated scanning station with their identification badge, provided the Vendor has a scheduled appointment.

5.2.7. Vendors must be recertified on an annual basis and pay the annual fee.

5.2.8. Vendors will have online access through MHC’s Vendor Credentialing system to all applicable Supply Chain Management and other MHC policies.

5.2.9 The following actions will occur if a Vendor submits a positive drug screening result for ANY drug:
5.2.9.1 McLaren Supply Chain Manager will contact the company to notify them of the Vendor’s positive drug screen and will ask to determine if the Vendor is eligible to a re-test.

5.2.9.2 If the company would like the Vendor to re-test, a temporary replacement Vendor will be asked to fill in until the re-test results come back.

5.2.9.3 If the re-test results are negative, the original Vendor can resume his/her relationship and visitation with McLaren. If the re-tests results are still positive, a new Vendor will be asked to take the original Vendor’s place.

5.2.10 Vendors are subject to random drug screening requests from McLaren Health Care at the Vendor’s expense.

5.3. Patient Care Procedure Area Requirements:

5.3.1. Vendors who are allowed in patient care areas (A “patient care area” may be defined as any area in any department where a patient or potential patient is under the care of an MHC employee) during procedures with the consent of the patient, physician, and the manager in charge to protect patient privacy and safety Vendors must adhere to the following criteria:

5.3.1.1. As part of the Vendor Credentialing process, Vendors must provide a letter of competency from their employer that states that the Vendor has had the qualified training to supervise procedures utilizing the described company equipment/tools and/or the ability to train others in the use of their product.

5.3.1.2. Vendors that will access patient care areas need to provide documentation for the following, which complies with JCAHO standards:

5.3.1.3. TB - Tested within the last 12 months (PPD recommended)

5.3.1.4. Varicella (Chicken Pox) - 2 vaccinations or titer of demonstrating immunity

5.3.1.5. Measles - 2 vaccinations or titer demonstrating immunity

5.3.1.6. Mumps - 2 vaccinations or titer demonstrating immunity

5.3.1.7. Rubella - 2 vaccinations or titer demonstrating immunity

5.3.1.8. Tetanus-Diphtheria-Acellular Pertussis (TDAP vaccine only required for representatives visiting obstetrical and nursery units)

5.3.1.9. Vendors must be fully vaccinated against COVID-19 and adhere to any CDC requirements for masking.

5.3.2. Vendors will wear attire (e.g., scrubs or cap), designated by McLaren when in patient care areas.
5.4. Vendor Access:

5.4.1. Vendors must enter wearing their designated Vendor photo ID at all times while on MHC premises and check in and check out at the designated area(s) of the facility by scanning their badge. Badges must always be worn and clearly visible from the waist up.

5.4.1.1. Any Vendor who has not checked in and entered through the designated area will be considered in violation of the policy. Supply Chain Management will notify the rep to leave and will issue a written warning or suspension.

5.4.1.2. An exception may be made to certain contracted Vendors that are delivering supplies and equipment for clinical procedures. For example, Orthopedic Implants and Cardiac Rhythm Management devices.

5.4.1.3. These type of vendor representatives will only be allowed access to these departments for the sole purpose of delivering supplies and equipment for the clinical procedure. Any other sales related discussions would require the vendor representatives to register with MHC’s Vendor Credentialing system and have an approved appointment as shown in 5.1.1 General Guidance.

5.4.1.4. Vendors will be required to scan their vendor badge to properly sign out before leaving the facility.

5.4.1.5. Vendors that do not enter the building are not required to check in or wear a badge. I.e., Lawn Care Vendors.

5.4.1.6. Violation of this will result in disciplinary action shown in Section 5.10 Compliance and Disciplinary Action.

5.4.2. Vendors are prohibited from entering patient care areas within MHC subsidiaries including but not limited to the Emergency Department, Operating Room, Cardiac Interventional Areas, other interventional areas, patient care units, outpatient clinics, clinic staff rooms, and any staff or physician lounges.

5.4.2.1. An exception to this is when a Vendor is:

• Required for training on new equipment or devices already purchased by the MHC subsidiary (refer to 5.3).

• Operating Room and other clinical areas exceptions where Vendor's presence is required to assist physicians or necessary to develop competency with the device or equipment. These instances will be prescheduled as part of the OR boarding process and/or preapproved by the department Head.

5.4.3. Vendors shall only use those areas in the facility designated for visitor use.

5.5. Displays
5.5.1. Other than specifically allowed for in this section, Vendors are not permitted to display products or product information within any MHC subsidiary.

5.5.2. Vendors cannot place information in mailboxes of staff or post Supply Chain on bulletin boards within any MHC subsidiary.

5.5.3. Displays may be allowed adjacent to meeting rooms in conjunction with approved MHC CME courses, approved research symposia or other education activities if:

5.5.3.1. The course director approves having commercial displays.

5.5.3.2. Placement is not a condition of providing support.

5.5.3.3. Vendor does not engage in any sales activity within the area that the education is occurring.

5.5.3.4. Displays are consistent with policies endorsed by the Accreditation council for CME Standards for Commercial Support.

5.5.3.5. Pharmaceutical displays must be approved by the Director of Pharmacy and must be consistent with the subsidiary approved drug formulary.

5.5.4. Displays may be allowed in staff lounges for training if approved by the Department Head.

5.6. Promotional Activities:

5.6.1. Cash or other incentive programs are strictly prohibited at any MHC subsidiary.

5.6.2. Food and beverage items of any kind provided by a Vendor is strictly prohibited unless provided as part of an educational session.

5.6.3. Vendors are not permitted to distribute, post, or leave any type of unsolicited printed or handwritten material, advertisements, signs, or invitations at any MHC subsidiary.

5.6.4. Vendor-sponsored raffles, lotteries, or contests, which result in gifts to the winner, are forbidden.

5.6.5. Promotion of drugs against established drug formularies are strictly prohibited. Vendors who discuss such agents will be suspended from visiting MHC subsidiaries pending review of the event. If the Vendor is found in violation of any policy, the ability to visit any MHC location will be suspended for a minimum of one month. Repeated and flagrant violations can result in indefinite suspension of privileges for the individual and, if necessary, the company.
5.6.5.1. Sample medications will not be accepted from Vendors unless the practice has received approval through the Special Cause Variation process.

5.6.6. Preprinted prescription pads from Vendors are not permitted at any MHC subsidiary.

5.7. Gifts/Grants

5.7.1. No personal gifts from Vendors of any kind are permitted at any MHC subsidiary or to any staff members.

5.7.2. Textbooks and items of educational value may be provided to the institution if approved by the department chair/director and consistent with Conflict-of-Interest policies.

5.7.2.1. The standards of Commercial Support of the Accreditation Council for CME address institutional responsibility, handling of funds, and reasonableness of payments, disclosure, and other issues.

5.7.3. Unrestricted educational grants should go through the Foundation.

5.7.4. If the subsidiary does not have a Foundation, the grant should go through the department head.

5.8. Donations and Solicitations:

5.8.1. Support of any physician or staff CME activities must be made through the Chair or Department Head and the Department of Graduate Medical Education.

5.8.2. Physicians may attend non-CME educational events during off-hours with the approval of the respective CEO.

5.8.3. Donations to MHC are to be coordinated through the respective subsidiary Foundation and Vendors should contact this area directly if they are interested in making a donation.

5.8.4. If the subsidiary does not have a Foundation, donations are to be coordinated through the respective Department Head.

5.8.5. MHC staff that would like to solicit donations from Vendors for any non-CME departmental activities, supplies, functions, events, fundraisers; equipment, etc. should contact their respective Foundation.

5.8.6. The Office of the Foundation will contact the Vendor and solicit the request on the behalf of the subsidiary.

5.9. Confidentiality:

5.9.1. Vendors shall not attend programs in which specific patients are discussed or when quality assurance or risk management issues are presented.
5.9.2. Preceptorship programs (programs for the education of Vendors) involving contact with, discussion of, or observation of individual patients, requires the advance consent of the patient and approval of the Department Head.

5.9.3. Any outside surgeon or physician brought in by a Vendor attending a clinical procedure will need to sign a confidentiality agreement and get the patient’s approval and the medical staff’s approval for the procedure.

5.10. Compliance and Disciplinary Action

5.10.1. Staff Responsibilities:

5.10.1.1. All staff is responsible for assuring that Vendors comply with this policy. Vendors in violation of this policy are to be immediately reported to the Department Head and Supply Chain Management. Supply Chain Management is responsible for contacting the Compliance Officer.

5.10.1.2. Security may request to inspect a vendor’s identification badge. Vendors without proper identification badges will be escorted to the appropriate area and given information regarding certification. Uncooperative Vendors or those in violation of policies will be escorted off premises.

5.10.1.3. The Compliance Officer and Supply Chain Management will investigate any reported violations of this policy.

5.10.1.4. Vendors who violate policies are subject to loss of visitation privileges at MHC subsidiaries. There will be no refunds of fees associated with Vendor credentialing.

5.10.1.5. The Compliance Officer and Supply Chain Management will report all Vendor disciplinary action to the Department Head and the Chief Executive Officer.

5.10.1.6. If a Vendor does not adhere to this policy; the following actions will be taken:

1st Offense: Vendor representative will be given a written warning and the Vendor leadership will be notified.

2nd Offense (for the same type of violation): Vendor representative will be suspended from visiting all McLaren facilities, and the Vendor will be asked to provide a new Representative to service McLaren. MHC reserves the right to suspend a Vendor for a first offense.

5.10.1.7. Staff found not to be in compliance with this policy will be reported to their supervisor for disciplinary action. Depending on the severity of the situations, discipline up to and including discharge may be warranted.

5.10.1.8. Non-employed physicians that are in violation of the policy will be reported to the
Department Chair and/or the Medical Executive Committee for suggested action.

David Bueby  
Corporate Vice President  
Supply Chain Management  

09/16/2022  
Date:  

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Supersedes Policy: Sales and Service Representatives and any and all Subsidiary Vendor Policy & Procedures