

Supplier/Sales Representative Access and Privileges Policy

Applicable Facilities:	Mayo Clinic and Mayo Health System Sites
Effective Date:	March 1, 2008
Revision Date:	N/A

Purpose:

This policy establishes management requirements for Supplier/Sales Representatives (as defined below) at all Mayo Clinic and Mayo Health System (“Mayo”) facilities relating to access, interaction, and business transactions.

Mayo 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.

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

The inconsistent application of supplier management processes across Mayo facilities can lead to possible liability concerns, compliance, integrity, and fairness issues. Health care 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 a Mayo facility to perform a specific job duty or task (e.g., consulting, training, project work, service and maintenance, etc.) on a routine and regular basis in any patient care areas accredited by an accrediting or standards organization. This would include contracted collaborative partners that work with Mayo 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 Mayo staff, (including, but not limited to, all consulting and administrative voting 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 on matters, quote prices, or conduct other duties generally associated with representing their company.

Patient Care Area: Any area within any Mayo 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 supplier identification (ID) badge for each visit. Each Mayo 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 Mayo Clinic's Code of Conduct and Integrity Program. Contract Labor and Collaborative Partners' representatives are issued a longer term badge than those associated with infrequent or periodic visits to a Mayo entity and subject to this policy.

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

1. Any Supplier/Sales Representative with responsibility for the Mayo 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 Mayo physician/administrative leaders;
3. The meeting is at the request or agreement of a member of the Mayo consulting or administrative voting staff, physician, scientist or administrator and such Mayo personnel will accompany and participate in the meeting and has the approval of a division or department chair;

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 Mayo entity for purposes of a meeting are not required to register or obtain a Supplier/Sales Representative identification (ID) badge. If a subsequent engagement occurs and is conducted in an accredited patient care area, then all on-site employees of the consulting firm must register and obtain an identification (ID) badge unless another exception applies.

Policy Statements:

It is the policy of Mayo Clinic that each Mayo Clinic and Mayo Health System facility 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 local Mayo facility Supply Chain/Materials Management Department **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 locations, 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.

<p>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 Mayo staff and departments any issues that are identified in the registration process.</p>	<p>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 record, 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. 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 a web-based 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 Mayo staff), so Supplier/Sales Representatives are not mistaken by visitors, or patients as a patient care provider.</p>	<p>Supplier/Sales Representatives are required to display this ID system or badge at all times when on the campus, or in any of the Mayo Clinic or Mayo Health System buildings. 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 the Mayo Clinic or Mayo Health System facility 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 Mayo 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>It is recommended that Suppliers/Sales Representatives meet with the appropriate Sourcing and Contracting Manager to understand Mayo's contracting strategy.</p>
<p>5. Provide each Supplier/Sales Representative with an orientation and education materials specific to their</p>	<p>Information related to the following topics will be included in a 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

<p>role to promote familiarity with the Mayo Clinic policies and procedures.</p>	<p>Privileges Policy</p> <ul style="list-style-type: none"> ◆ 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 standards ◆ Product recall process ◆ Proper use of wireless communication devices on site ◆ Mayo Code of Conduct and Integrity Program ◆ Other topics deemed appropriate to the Mayo Clinic or Mayo Health System site.
<p>6. Utilize the web-based vendor registration system that records the visits of each Supplier/Sales Representative to a Mayo Clinic or Mayo Health System facility.</p>	<p>The web-based vendor management system 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.</p>
<p>7. Communicate the existence and enforcement of the Supplies/Sales Representative Access and Privileges Policy and requirements to materials management personnel, facility staff and to potential suppliers.</p>	
<p>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</p>	<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

<p>followed:</p>	<p>or service they will be delivering and/or operating.</p> <ul style="list-style-type: none"> ◆ 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.
<p>9. Create a Supplier/Sales Representative Profile Database to be utilized to validate the representative status.</p>	<p>If the Supplier/Sales Representatives have not previously registered, the completion of a registration form will be required before an ID system or badge is provided. All Mayo Clinic and Mayo Health System 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 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.</p>
<p>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.</p>	

Enforcement:

This Supplier/Sales Representative Access and Privileges Policy is administered through the local Supply Chain/Materials Management operations in partnership, collaboration, and cooperation with department/division leadership, administration and all Mayo staff and students. Comments, questions, and violations are to be directed to the Supply Chain /Materials Management Department at each Mayo site. The Supply Chain/Materials Management Department will work with the Supply Expense Coordinating Committee, Medical-Industry Relations Committee, and the Office of Compliance related to the enforcement of this policy, as necessary.

Non-compliance or non-support of this policy or the rules outlined in Appendix I by a Mayo staff may result in disciplinary action.

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

- **First Infraction:**

The Chair or Director of Materials Management or designees will meet with the Supplier/Sales Representative to review 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 Mayo facilities indefinitely, with formal notification to the representative's supervisor. The suspension will be enforced for a minimum of two years.

As a final option, Mayo may terminate an agreement and convert to an appropriate, competitive, and acceptable product. Grievances may be filed with the Supply Expense Coordinating Committee, the Medical Industry-Relations Committee, or the Office of Compliance.

Approved by:	<p>Materials Management Operations Oversight Committee</p> <p>- Approved by MMOOC – 11-30-06</p> <p>Mayo Pharmaceutical Formulary Committee – Reviewed/Endorsed</p> <p>Supply Expense Coordinating Committee</p> <p>-Approved by SECC 12-20-06</p> <p>Clinical Practice Quality Oversight Committee – Reviewed and forwarded to Accreditation Liaison</p> <p>– Endorsed 12-26-06</p> <p>Clinical Practice Committees and CPAG</p> <p>- Approved by MCS CPC – 10-31-06</p> <p>- Approved by MCR CPC Ex. Committee – 01-25-07</p>
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	<ul style="list-style-type: none"> - Reviewed by the MCR CPC Equipment Subcommittee – 01-25-07 - Approved by MCJ CPC – Approved - Clinical Practice Advisory Group – 02-(12-14)-07 Mayo Health System Administrator’s Group – Approved 01-24-07 Conflict of Interest Committee – Reviewed/Referred to the Medical-Industry Relations Committee - Approved 12-08-06 Rochester Administrative Committee – 01-16-07; 03-27-07; 5-29-07 – Approved; 10-02-07 – Final Approval MCJ Pharmacy and Therapeutics Committee – 03-06-07 Pharmacy Leadership Group – 03-28-07 MCJ Administrative Council – 03-14-07 Mayo Clinic IT Executive Committee – 01-30-07 Mayo Clinic IT Committee – 02-06-07 Compliance Committee 11-14-06 Three Shields Coordinating Committee – 02-01-07; 07-11-07; 10-04-07 Mayo Health System Medical Directors – 02-21-07 MHS Management Committee – 02-26-07 Mayo Health System Board – 03-14-07 Mayo Clinic Rochester Research Committee – 04-16-08 Research Administrators Meeting -04-25-07 Mayo Clinic Jacksonville Research Committee –08-28-07 Mayo Clinic Scottsdale Research Committee - 07-16-07 MCR Executive Board – 10-11-07 MCS Finance Committee – 07-10-07 MCJ Executive Board - 06-20-07 Board of Governors – 12-03-07
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Date of Last Review:	December 3, 2007
Next Scheduled Review Date:	December 3, 2009
Contact Person(s):	Chair, Mayo Clinic Supply Chain Management
Resources:	NA
Related References:	Mayo Clinic and Mayo Health System Supplier/Sales Representative Access and Privileges Policy Mayo Clinic Code of Conduct and Integrity Program

APPENDIX I

CODE OF CONDUCT FOR SUPPLIER/SALES REPRESENTATIVES

RULES

Purpose: Mayo Clinic and Mayo Health System (“Mayo”) staff, business partners, and their representatives are responsible for familiarizing themselves with the Mayo Clinic Code of Conduct and Integrity Program and in adhering to the standards and rules of ethical business conduct. Mayo expects a shared commitment with vendors to work together with integrity within the framework outlined in this specific policy.

Supplier/Sales Representatives will comply with federal, state, and local laws as a basis of all business interactions.

It is considered a privilege for a Supplier/Sales Representative to have access to Mayo staff and resources; this privilege may be revoked at any time at the sole discretion of Mayo Clinic or a Mayo Health System facility. Failure to comply with these requirements will result in the administration of the appropriate action detailed in the Enforcement Section in the Policy. Mayo facilities may have supplemental policies to the following requirements.

Rules for Supplier/Sales Representative Access and Privileges

Action	Definition/Clarification
1. Each Supplier/Sales Representative should disclose to the Local Supply Chain / Materials Management Department during the registration process, whether any apparent or perceived conflict of interest may exist in their business relationship	Specifically, any family, personal, or financial relationships that may exist between the Supplier/Sales Representative and the Mayo entity, physicians, or other clinical or allied-health staff should be disclosed.

with the Mayo facility.	
2. Supplier/Sales Representatives are not permitted to enter any patient care areas without a scheduled appointment, registration, and an ID system / supplier badge. Access to patient care areas is strictly prohibited, unless authorized by clinical staff and accompanied by said clinical staff.	Supplier/Sales Representatives must wear above the waist an identification badge with their company and individual's name, as well as the Mayo Clinic or Mayo Health System ID system / badge clearly visible at all times while at any Mayo facility. Hours for appointments are consistent with the normal hours of operation for the Mayo Clinic and Mayo Health System facilities, unless otherwise requested by a department or employee.
3. Supplier/Sales Representatives should wear business attire for purposes of conducting visits.	Supplier/Sales Representatives may not wear any medically-related clothing or uniforms (e.g., scrubs, lab coats, etc.) unless in a procedural area requiring such clothing and it is provided by the Mayo Clinic or Mayo Health System for such visits.
4. Supplier/Sales Representatives will not call on students, residents, and fellows at Mayo Clinic or Mayo Health System unless invited by a member of the consulting or administrative voting staff for training/education purposes only.	While on site, Supplier/Sales Representatives must be registered and have an identification badge. The consulting and/or administrative voting staff member that invited the Supplier/Sales Representative is responsible for (must serve as a proctor) providing oversight of the Supplier/Sales Representative, students, residents, and fellows during their visit.
5. The unauthorized use of pagers to contact physicians and other allied-health professionals is not permitted. Contacts with physicians and other allied-health professionals for appointments or other business should be made through the individual secretary only, or through a previously approved arrangement with the appropriate Mayo staff.	
6. No open or standing invitations may be granted a Supplier/Sales Representative by any Mayo staff.	

7. Approaching any member of the consulting or administrative voting staff, physician, scientist, administrator, or allied-health staff personnel in any Mayo Clinic or Mayo Health System facility without an appointment is prohibited.	
8. Supplier/Sales Representatives may not bring into a procedural area, operating room or any Patient care area any device that has the capability to record or transmit audio and/or take photographic images.	Including, but not limited to: cameras, video recorders, cell phones, personal data assistants, etc.
9. The use of a Mayo Clinic or Mayo Health System staff or patient shuttle bus by Supplier/Sales Representatives is not permitted, unless a patient of a Mayo facility or accompanied by hosting Mayo staff.	
10. The use by Supplier/Sales Representatives of Mayo facility elevators specifically designated for use by Mayo Staff Only is not permitted unless accompanied by a hosting Mayo staff.	
11. The use of Mayo communications infrastructure (e.g. Mayo phones, Mayo computers) is not permitted unless authorized by hosting Mayo staff and if used to conduct Mayo business.	
12. The use of Mayo Clinic or Mayo Health System bulletin boards by Supplier/Sales Representatives is not permitted.	
13. The use of Mayo Clinic and Mayo Health System documents and promotional materials by Supplier/Sales Representatives is not permitted.	
14. Supplier/Sales Representatives may be solicited for grants to offset the cost of educational programs or modest refreshments in conjunction	Supplier/Sales Representatives should not provide food on or off Mayo campuses for division/departmental administrative meetings or areas,

<p>with formal educational courses, meetings and presentations that are reviewed and accredited by an internal (e.g., Mayo Clinic School of Medicine CME), or external continuing education agency or approved by the Medical/Industry Relations Committee.</p>	<p>employee or student social events, staff planning sessions or retreats or any formal or informal internal meeting not accredited by an external entity or approved by the Medical/Industry Relations Committee. Supplier/Sales Representatives may not distribute food to any area, unit, or person on the Mayo campus in conjunction with a sales call or as part of marketing or promotional activities. A copy of Mayo Clinic's policy on industry-provided food can be found at: http://mayoweb.mayo.edu/man-pgripm/ir-fd.html</p>
<p>15. The confidentiality of patient medical or demographic information must be maintained and can only be accessed by authorized Mayo Clinic and Mayo Health System personnel.</p>	<p>Unauthorized access to patient information is strictly forbidden and will result in revocation of supplier access and privileges.</p>
<p>16. Supplier/Sales Representatives may not distribute promotional discount coupons, claim cards, or vouchers for prescription medications, samples, or other items to staff or patients in any Mayo Clinic or Mayo Health System facility.</p>	<p>Samples of prescription medications, claim cards, or vouchers are not permitted, unless approved through the Mayo entity's Clinical Practice Committee and Pharmacy operation.</p>
<p>17. Supplier/Sales Representatives from for-profit companies that sell supplies, services, or equipment to Mayo Clinic or Mayo Health System facility may not leave promotional or marketing items (e.g., pens, note pads, coffee cups, etc) with any Mayo Clinic physician or staff.</p>	<p>Supplier/Sales Representatives may only leave descriptive educational literature pertaining to the product or service offered by the supplier with Mayo staff for appropriate distribution. No unsolicited items or promotional materials are to be left in areas accessible to patients. Mayo staff are encouraged not to accept promotional or marketing items while in attendance at external meetings (e.g., vendor shows).</p>
<p>18. Mayo Clinic and Mayo Health System entities may occasionally host visitors from other healthcare organizations interested in reviewing/observing the use of a supply, technology (equipment) or</p>	<p>Such visits must be coordinated between the Mayo entity and the requesting healthcare organization. Supplier/Sales Representatives that accompany the visitors may not conduct any business on Mayo entity</p>

<p>service in clinical practice, research, or education.</p>	<p>property. The host Supplier/Sales Representative must be in compliance prior to the site visit. Guests will be required to attest to health status prior to visit if directly entering a patient care environment (e.g., surgery, cardiac cath lab, etc.)</p>
<p>19. Supplier/Sales Representatives must acknowledge that Mayo Clinic and Mayo Health System have entered into contractual agreements to establish and maintain product and equipment quality and promote standardization.</p>	<p>Compliance with these contractual commitments help improve overall patient care, supply chain efficiency and cost effectiveness. Therefore, Supplier/Sales Representatives must respect and support contractual commitments associated with the Mayo Clinic awarded suppliers for products and services over the entire term of the agreement.</p>
<p>20. Supplier/Sales Representatives of competing or non-awarded suppliers will be prohibited from counter detailing or promoting sales of their comparable products in areas or departments that have an existing contractual arrangement, both on campus and off campus, for a period of one year, if such action could undermine the terms and conditions of the existing contractual arrangement.</p>	<p>During this period, competing Supplier/Sales Representatives that have breakthrough technology (i.e., significant advancement in product performance, patient outcomes, or costs regarding specific products being supplied by a competitor via an existing contractual arrangement) must first disclose the technology to the applicable Mayo Clinic or Mayo Health System Supply Chain / Materials Management Department, or the Mayo Clinic Supply Chain Management contracting manager responsible for the product portfolio. Mayo Materials staff will work collaboratively with the impacted areas and within their respective supply processes to assure exposure of potential breakthrough technology to review in the impacted areas.</p>
<p>21. Supplier/Sales Representatives must follow Mayo Clinic and Mayo Health System processes for the introduction of new or innovative supplies, products, or equipment.</p>	<p>Failure to follow established processes for the introduction of new or innovative technology (including establishment of pricing, terms and conditions with the appropriate supply</p>

	<p>chain sourcing and contracting personnel) will result in payment of an amount to the closest functionally equivalent supply, product, or equipment under contract with Mayo at the sole discretion of the supply chain / materials management operation.</p>
<p>22. Supplier/Sales Representatives will not set up displays for promoting products or services in any Mayo Clinic or Mayo Health System facility without prior approval.</p>	<p>All displays will be limited to an enclosed institutional conference room or a designated area. Displays for products are permitted only for the awarded contractual supplies, services, or equipment. For example, only medications on the Mayo Pharmaceutical Formulary will be permitted for pharmaceutical display purposes. Displays including products outside of awarded contracts are permitted ONLY in conjunction with formal CME programs (e.g., CME programs awarded Category 1 credit) in order to meet standards that educational content is free from commercial bias (Accreditation Council for CME).</p>
<p>23. Supplier/Sales Representatives are required to obtain a purchase order for goods and services prior to delivery.</p>	<p>The purchase order is governed by the terms and conditions printed on the order and/or included in a contractual agreement between Mayo and the Supplier. <u>All</u> goods and services should be exchanged at fair market value pursuant to a purchase order or a contract. Suppliers are not to accept verbal orders This is a requirement for payment to occur.</p>