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Policy No:	2 MED 209	Effective Date: 07/01/04

## OBJECTIVE

To establish a procedure for Pharmaceutical Representative activities in the Detroit Medical Center.

## SCOPE

All healthcare professionals involved in the medication process and pharmaceutical representatives conducting business within a DMC site.

## DEFINITIONS

Pharmaceutical Representatives (PRs) include salespersons, representatives, or other employees of drug manufacturers drug distributors, suppliers and drug wholesalers, nutritional product manufactures or drug infusion equipment manufacturers intended for use or purchase by the DMC.

## POLICY

PRs serve as sources of information for their products and provide assistance in the purchase, inventory and use of pharmaceuticals. The Detroit Medical Center recognizes the importance of quality, cost-effective products in providing patient care, and desires a cooperative relationship with our vendors and their representatives. All PRs calling on hospitals in the Detroit Medical Center, regardless of appointment, must have a Vendor Pass or badge. PRs are allowed in the hospital pharmacy and in medical and nursing staff offices by appointment only. Patient care areas are specifically restricted. DMC-affiliated clinics may choose to adopt this policy. Consult with the individual clinic.

## PROVISIONS

- PRs must register prior to conducting business at that specific hospital (Appendix A). Registration must be repeated each time a new representative is assigned or important information changes occur (e.g. telephone/pager number, mergers, acquisitions, changes in supervision or on a business card). At the time of registration, representatives will be given a copy of this policy and asked to provide pertinent information related to their company, its products, and preferred method of communication. Copies of the Disclosure Statement (Appendix B) will also be provided at this time.
- All PRs should register at the Information/Lobby Desk at the site where they are conducting business. Additional registration is required at some site and is as follows:
  - CHM – Information/Lobby Desk
  - DRH – Information/Lobby Desk AND Department of Pharmacy
  - HUH/HWH/TCH/RIM - Information/Lobby Desk AND Department of Pharmacy
  - HVSH – Information/Lobby Desk AND Materials Management
  - MIOSH – Information/Lobby Desk
  - SGH – Information/Lobby Desk AND Department of Pharmacy
- Appointment does not permit "carte blanche" access to other areas/hospital personnel and/or does not permit visits for an extended length of time. In general, patient care areas are specifically restricted unless authorized in advance and in writing by the pharmacy director. In the case of a structured preceptorship, access to patient care areas are permitted only through prior approval by the site administrator or designee. Patient care areas include inpatient units, the emergency department, the operating room, clinics, anesthesia, procedure rooms, radiology rooms, etc. In the case of a structured preceptorship, the representative must have a signed hospital-approved waiver of liability and patients must be asked for their consent prior to a representative attending rounds in their presence.
- Preceptorships must adhere to the guidelines as defined by the DMC P&T Committee, and be approved by the each site's MUC Committee (Appendix C).
- Upon arrival of EVERY visit at EVERY site, PRs are required to register as detailed above. The secretary or designee will issue a badge only if there is a prearranged appointment/meeting (including grand rounds) and upon signing in the departmental log (Appendix D). PRs must wear the badge in a visible manner at all times and are required to return the badge to the location at which they registered upon departure from the facility. The PR, after signing out, will leave the hospital premises. If a secretary is not available in the department upon arrival or departure, the representative will leave a signed, timed, and dated business card when signing in and again when signing out.

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6. Appointments with senior medical staff are to be arranged through medical or departmental secretaries, or other means, in advance. The pharmacy department may contact departmental secretaries or other individuals to inform them of the arrival of a PR. After registering in the pharmacy and obtaining a badge, the PR will proceed to the medical department for the scheduled appointment.
7. Appointments with pharmacy administrative and clinical staff are arranged through the departmental secretary and/or manager/clinician in advance.
8. In general, the hospital paging system is for use by employees only and should not be used by PRs. A hospital telephone may be used to page an employee in a non-patient care area as long as it does not disrupt hospital business/operation. An employee may be paged via the public telephones by the PR if previously authorized by the employee.
9. DMC personnel will notify Security if representatives are observed in the hospital without a badge or appointment. Representatives without a prearranged appointment and badge will be requested to leave the premises.
10. Drug information personnel are integral to providing high quality, cost-effective care to patients of the DMC. Objective, unbiased drug information is a goal. This is normally best obtained from colleague physicians, pharmacists and other practitioners responsible for providing patient care in a therapeutically sound, fiscally responsible manner. The Drug Information Center will obtain and disseminate information on new formulary agents to practitioners in the DMC.
11. PRs may provide food and refreshments for CME, ACPE, or other departmental pre-approved educational formats for the DMC. Educational programs must be in compliance with WSU CME policy, and consistent with system CME/ACPE policy. Programs that exclusively utilize marketing information provided by the PR are not permitted. A PR may provide a brief (< 5 minutes) synopsis of a product, however, **the PR may not be the sole source of information for an educational program.** Entertainment programs/activities will not be permitted on hospital premises. Provision of meals/refreshments without an educational program/component is prohibited.
12. PRs must disclose to the Department of Pharmacy Services, all planned educational and promotional activities during which hospital staff (including, but not limited to, medical residents, interns, nurses, CRNAs, and physician assistants) will be present. The Disclosure Form (Appendix B) must be completed and submitted to the Department of Pharmacy Services prior to the event. A member of the Department of Pharmacy Services or Pharmacy and Therapeutics Committee may attend the event.
13. The DMC hospital formulary is determined by the Pharmacy and Therapeutics Committee and the formulary system is used for all drugs administered to patients in DMC hospitals. Attending medical staff and pharmacist staff may request a drug to be considered for formulary inclusion by personally completing a Formulary Addition Request Form. Only drugs approved for inclusion in the formulary may be stocked by the hospital pharmacies. Drugs that have been reviewed and denied formulary status may not be sampled or further promoted by drug company representatives in DMC hospitals. Drugs made available as "free goods" must be on the formulary and approved for use and distributed via pharmacy. At no time is a pharmaceutical representative allowed to deliver these types of medications directly to another department.
14. Formulary and non-formulary medications provided at no charge to the DMC for a "trial" basis is prohibited. Any formal request to study pharmaceuticals as part of a research protocol must gain IRB approval prior to any consideration by the P&T Committee.
15. Sample medications are not permitted in inpatient areas. Sample medications are permitted in outpatient areas according to the DMC policy on samples.
16. PRs must only promote formulary drugs within designated DMC guidelines or restrictions. Any distribution or sharing of promotional material that does not specifically adhere to DMC guidelines/restrictions is prohibited. Drug company representatives may not distribute or leave drug product literature in patient waiting or lobby areas.

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17. Promotion of non-formulary drugs in a group setting (e.g., morning report, prior to grand rounds, etc.) is prohibited. The PR must disclose the formulary status/DMC approval of any drug or indication when discussing any product with an individual on a one-to-one basis. A discussion of non-formulary drugs and indications outside of DMC guidelines with clinicians is only permitted in the clinician's office.
18. PRs with suggestions to maintain or improve the quality of care in a fiscally responsible manner are encouraged to meet with pharmacy administration or drug information personnel for evaluation of potential applicability at the DMC.
19. Infractions of this policy are reported to the site Director of Pharmacy where the infraction occurred and to the Executive Director of Pharmacy Services who serves as Secretary, DMC Pharmacy and Therapeutics Committee.
20. PRs who violate this policy, who provide false or misleading information, or in any way conduct themselves in a manner that is considered to be contrary to acceptable ethical standards or the interests of the DMC will have restrictions placed on their activities at the DMC. This may include having the representative reassigned or banning the involved representative(s) of the company from all DMC sites for a specified time. Depending on the severity of the infraction, the DMC may "ban" all representatives of a given pharmaceutical company. Should the company or PR continue to violate policies, the DMC reserves the right to change its business relationship with that company in such a manner as to prevent the violation from being repeated.

**APPENDICES**

Appendix A - Pharmaceutical Representative Registration Form

Appendix B - Disclosure Form: Pharmaceutical Company Sponsored Education/Promotion

Appendix C - Preceptorship Guidelines

Appendix D - Departmental Log of Pharmaceutical Representative Visits

**ADMINISTRATIVE RESPONSIBILITY**  
Pharmacy and Therapeutics Committee

**APPROVAL SIGNATURE(S)**

\_\_\_\_\_  
Chairperson, DMC P&T Committee

\_\_\_\_\_  
Date

\_\_\_\_\_  
Executive Director, DMC Pharmacy Services

Review Date:  
May, 2007

Supercedes:  
May 2004