



Origination: 10/2009
Last Approved: 10/2015
Last Revised: 10/2015
Next Review: 10/2018
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Policy Area: Purchasing
References:

Medical Device Industry Representatives

Document Type: Policy

PURPOSE

This procedure provides clear and consistent standards for Medical Device Industry Representatives' activities when conducting business with Denver Health and Hospital Authority (DH) ensuring the safety of patients, visitors and staff; to protect patient confidentiality; to promote staff efficiency; and to afford clinicians access to the latest technological advances following a systematic clinical and financial review.

SCOPE

- A. MDIRs: Responsible for understanding their obligations and adhering to all requirements defined in this procedure.
- B. Denver Health:
 - 1. Staff involved with MDIRs shall be responsible for monitoring MDIR compliance with this procedure and reporting violations.
 - 2. Sponsored Programs and Research
 - 3. Purchasing
 - 4. Pharmacy and Therapeutics (P&T) Committee
 - 5. Materials Management
 - 6. BioMedical Engineering Department
 - 7. Products Committees

DEFINITIONS

- A. *Medical Device Industry Representatives (MDIR)*: Manufacturers, services, and other vendors of medical devices, medical supply, and medical testing companies, and their employees, representatives, agents, and vendors. MDIR does not include consultants, construction workers or temporary labor.

PROCEDURES

A. MDIR Requirements / Professionalism:

1. MDIRs shall conduct business with DH in a professional and courteous manner.
2. MDIRs are expressly prohibited from utilizing DH patient parking garages; these are for the sole use of DH patients.

B. Conflict of Interest (Prohibited Materials and Meals):

1. Any type of inducement or incentive to use a specific medical device is strictly prohibited.
2. MDIRs shall comply with DH's Conflict of Interest policy.
3. Promotional materials are not to be displayed or distributed in any DH facility, to any DH employee or at any DH conference or meeting.
4. Examples of prohibited items include but are not limited to:
 - a. Gifts
 - b. On-site meals
 - c. Items with product or manufacturer logos that are not intended for educational purposes (i.e. paper pads, pens, coffee mugs, etc.).
 - d. Flyers or posters promoting continuing education activities.
5. Philanthropic gifts to the institution (in the form of contributions, endowments, capital contributions, or educational grants) which support DH's mission are appropriate, in most instances, and must be submitted through the appropriate channels in accordance with Sponsored Programs and Research policies.
6. All research supported by companies must have a scientific merit, must contribute relevant information and must be submitted by a Director of Service to the Grants Committee. DH is to retain the ability to publish results and to declare relationship in all consent forms in accordance with Sponsored Programs and Research policies.
7. This procedure complements, but does not replace, other DH policies that govern conflicts of interest. In the event of any inconsistencies between this procedure and other applicable policies, the policy or procedure that is more restrictive shall apply.

C. Scheduled Appointments / Visits:

1. MDIR visits must be approved in advance. Walk-ins will not be seen.
2. Requests to visit DH must be made through an authorized Purchasing Supervisor (PS).
 - a. The PS evaluates the purpose of the meeting and items to be presented.
 - b. The PS will contact the department and hospital staff to set an appointment for a meeting with the MDIR.
3. Scheduled appointments are restricted to the MDIR and identified DH department / staff. Access is limited to the unit the MDIR is authorized to visit.
4. Promotion or detailing of supplies is restricted to those companies / products listed on the DH supply formulary or to those receiving pre-authorization from the PS.

D. REPTRax Registration and Badge Requirements:

1. MDIR check-in process:
 - a. Properly register and check-in at a REPTRax registration kiosk on the day of the scheduled visit.
 - b. Meet all credentialing requirements as defined by REPTRax.
 - c. Acknowledge receipt of and agree to abide by this procedure in REPTRax prior to completing the check-in process and printing a REPTRax badge.
2. Appointment REPTRax Badge Required:
 - a. All MDIRs must be in possession of a photo identification badge while in any DH facility
 - b. A date-specific REPTRax badge will be issued from a kiosk and must be displayed unobstructed along with a photo identification badge, if not present on REPTRax badge.
 - c. Day-pass REPTRax and photo identification badges must be worn prominently on the lapel or above the waist at all times when present in any DH facility except during direct transit to a REPTRax kiosk.
 - d. MDIR personnel not in possession of a current REPTRax badge will not be allowed to enter DH facilities.
 - e. REPTRax kiosk locations for registration are available at the main DH campus:
 - i. Medical Center Information Desk,
 - ii. Purchasing Department Front Desk, and
 - iii. Main Lobby of Administration.
 - f. In the event of registration equipment failure, MDIRs are required to access another REPTRax kiosk.
3. DH facilities without a REPTRax kiosk: Prior to a scheduled appointment the MDIR is required to go to DH's Main Campus to check-in at a REPTRax kiosk.
4. Sign-out: At the end of an appointment the MDIR must sign-out at a REPTRax kiosk to document their departure from DH.
5. MDIR does not include consultants, construction workers or temporary labor. Contract labor working on campus for a defined period of time can be issued a badge from Human Resources with the appropriate departmental signatures and shall check in at one of the REPTRax registration kiosks on the day of arrival.

E. Authorized and Unauthorized Areas:

1. To protect patient confidentiality as required by state and federal law and to avoid disruptions in patient care, MDIRs are prohibited from all patient care areas and from areas where there is access to patient information, including conferences where patient information is presented or discussed except in the case of clinical staff training in the use of approved new or trial products or at the specific request and supervision of the attending physician.
2. Meetings with MDIRs may be conducted in private offices, but not in physician lounges or in public areas.

F. Unauthorized Activities:

1. Promotion (detailing) of medical devices is restricted to devices on the DH formulary and in accordance with any formulary restrictions. Any presentation of information about a device, including "educational" presentations, is covered under this procedure.

- a. The representative shall list in REPTRax all products that he/she will discuss, detail, or promote during this visit.
 - b. The representative shall not discuss, detail, or promote any product that was not listed in REPTRax.
 - c. If a representative is asked to discuss a device that is not on the DH formulary, he/she must decline to detail or discuss the product.
2. Promotion (detailing) of devices is restricted to those approved by the Food and Drug Administration. Furthermore, when a device has a DH limitation or restriction, promotion (detailing) of that device is limited to that limitation or restriction. "Off label" detailing is strictly prohibited.
 3. Vendor representatives are not allowed to discuss or request specific patient information.
 4. All information presented by vendor representatives must be accurate. Provision of inaccurate or misleading statements will result in an immediate and permanent suspension of the MDIRs privileges.
 5. MDIRs may not, under any circumstances, leave promotional materials intended for patient care areas. Direct-to-consumer marketing (i.e. from a representative directly to a patient) is strictly prohibited.
 6. Use of departmental mailboxes for distribution of information of any kind is prohibited. If requested, information must be mailed or given directly to a DH department representative for distribution.
 7. MDIR shall not have direct patient contact with any DH patient except as provided for in section IV, E.
 8. The MDIR must read and agree to the confidentiality agreement maintained in REPTRax.
 9. MDIRs in the role of technology subject matter experts:
 - a. DH and the company represented by the MDIR must have a current agreement in place before the MDIR will be allowed access to a DH Operating Room or other clinical procedural area.
 - b. The MDIR will be under direct supervision of the attending physician involved in the case or procedure.
 - c. MDIRs shall observe DH dress code and change into DH scrub clothing before entering the Operating Room or other clinical procedural area.
 - d. Are prohibited from direct patient communication and contact.
 - e. Are not allowed to function as a circulating nurse or technician (e.g. opening sterile supplies).

G. Compliance / Enforcement / Recourse:

1. While it is recognized that the vast majority of MDIRs will not knowingly violate this procedure, occasions may arise when a violation does occur. In these situations, disciplinary action may be necessary including documentation of the policy violation in the MDIR's REPTRax personnel file.
2. Immediate and permanent suspension: Dissemination of false or misleading information will be grounds for immediate and permanent suspension of privileges at DH.
3. Other violations - a progressive discipline approach will be employed.
 - a. First infraction: A letter of reprimand from the Chair of the Products Committee or designee will be sent to the MDIR. A copy of the letter will also be provided to the appropriate DH department director, DH's Chief Executive Officer, and the MDIR's immediate supervisor.

- b. Second infraction: Loss of hospital privileges for a period of six months.
- c. Third infraction: The MDIR will be permanently barred from conducting business at DH.

H. Sample Products and Trial Evaluations Requirements:

1. The Product Evaluation Committee reviews and approves all samples of medical devices to be considered for patient use at DH. This includes both formulary and non-formulary devices.
2. To be considered by the Products Committee, the following criteria must be met:
 - a. Request for use of a new medical device in a designated location must be submitted to the Products Committee in writing on the "New Product Request" form (Attachment A).
 - b. Any medical device that includes a pharmaceutical or requires compounding must be reviewed by the Pharmaceutical and Therapeutics Committee (P&T) prior to review by the Product Evaluation Committee. This will ensure the agents are included in the institutional drug formulary and the dispensing process is consistent with the requirements of DH policy "Regulation of Pharmaceutical Industry Representatives and Medication Samples".
 - c. Presentation of information to the Products Committee is required by the requestor explaining why the new product is needed, how it will be used and what impact it will have on patient outcomes, quality and safety.
 - d. The Products Committee will review the request along with a cost / benefit analysis prepared by Purchasing and will notify the requestor of their decision.
 - e. If the request is approved, a corresponding in-service and implementation plan and an inventory impact plan will be put in place.

I. Criteria for loaner or trial evaluations of medical equipment:

1. Medical devices brought in on loan or for trial evaluation must be preapproved by a PS and approved by the appropriate federal agency governing that product (i.e., FDA, etc.). If this is unavailable, the Institutional Review Board must be contacted and approval granted prior to the product entering the institution. (Reference DH policy "Conducting Clinical Trials".) Medical devices not having FDA approval must be part of a federal grant proposal.
2. Consigned instrumentation and implants for loaner or trial evaluation must adhere to DH Procedure, "Management of Loaner and Consignment Instruments and Implants".
3. All new, loaner or trial evaluation medical equipment must be inspected by the Biomedical Engineering Department prior to being used for patient care.
4. Training must be provided to staff on all shifts prior to equipment being used in a DH facility. MDIR may only present content that has been previously discussed and approved. Training must be documented according to current hospital policy.
5. Supplies related to the equipment must be approved under these same guidelines.

RELATED DH POLICIES AND GUIDELINES

- A. Management of Loaner and Consignment Instruments and Implants
- B. Regulation of Pharmaceutical Industry Representatives and Medication Samples
- C. Conducting Clinical Trials
- D. Conflict of Commitment and Conflict of Interest

- E. Medical Staff Office Documents
 - 1. Physician Conflicts of Interest Policy
- F. Human Resources Principles/ Practices
 - 1. Employee Relations, Conflicts of Interest
 - 2. Employee Relations, Personal Appearance/ Dress Code

ATTACHMENTS

- A. Attachment A- New Product Request Form
- B. Attachment B- New Product Trial Evaluation Form

Attachments:

-  [A.Attachment A- New Product Request Form](#)
-  [B.Attachment B- New Product Trial Evaluation Form](#)

| | Committee | Approver | Date |
|--|-----------|--|---------|
| | | Colette Morris: Program Manager of Document Management | 11/2015 |

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