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Owner Dawn Whiting:
Asst Dir
Pharmacy
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and Hospital
Authority (DHHA)
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Regulation of Pharmaceutical Industry Representatives

Policy

PURPOSE

To establish a clear and consistent set of rules governing all Pharmaceutical Industry Representatives (PIR) activities while conducting business with all subsets of Denver Health and Hospital Authority (DHHA).

SCOPE

DHHA – All locations and departments, including all facilities owned or leased for use by the Authority.

PIRs are responsible for adhering to the requirements below. DH staff are responsible for enforcing PIR requirements and reporting violations.

DEFINITIONS

ACCME Requirements: Procedures developed by the Accreditation Council for Continuing Medical Education, designed to prevent inappropriate commercial influence on continuing medical education programs.

AMCP Monograph: A clinical monograph for drug formulary review, prepared by a pharmaceutical company utilizing the standardized format of the Academy of Managed Care Pharmacy.

Drug : A chemical or other substance administered to a patient to diagnose or treat disease. For the

purposes of this policy, a biologic, as defined by the US Food and Drug Administration (FDA), is considered a drug. A medical device, as defined by the FDA, is not a considered a drug.

Pharmaceutical Industry Representatives (PIR) :

Manufacturers, services, and other vendors of pharmaceutical, medical device, medical supply, and medical testing companies, and their employees, representatives, agents, and vendors.

Denver Health and Hospital Authority (DHHA) :

Denver Health Medical Center, Ernest E. Moore Shock Trauma Center, Community Health Services including Family Health Centers and School-based Health Centers, Denver Public Health, Rocky Mountain Poison and Drug Safety, Denver CARES.

POLICY

- A. Pharmaceutical Industry Representatives (PIRs) may not conduct sales, marketing, or "educational" activities at DHHA facilities or via teleconferencing or electronic (email) communications.
- B. Exceptions to this policy must be approved in advance and in writing by one of the following:
 1. the Chief Executive Officer
 2. the Chief Medical Officer
 3. the Chief Ambulatory Officer
 4. the Administrative Director of Pharmacy Services
 5. the Chair of the Pharmacy and Therapeutics (P&T) Committee
- C. Exceptions to this policy are expected to be rare. Typical situations in which an exception may be appropriate include:
 1. Pharmaceutical company sponsorship of a Continuing Medical Education event, approved by DH and operating in accordance with ACCME requirements
 2. PIR's having appointments with DH personnel for a specific business purpose for formulary products only
- D. When on campus for business purposes, PIRs will display a name tag including company affiliation at all times
- E. Under no circumstances will sales or marketing activities be conducted in patient care areas or in the presence of patients or family members
- F. Under no circumstances may DH personnel share protected health information with PIRs, except for the narrow purposes of
 1. Enrolling a patient in a free or discounted drug program
 2. Complying with an audit of a free or discounted drug program
 3. Reporting a suspected drug-related adverse event
- G. Denver Health medical staff members and employees must interact with PIRs in accordance with the DHHA [Gifts and Interactions with Vendors](#) and [Conflicts of Interest](#) policies and

procedures.

- H. Patient education items and other clinical aids bearing drug company names and logos may not be used in patient care areas
 - 1. Exceptions may be granted by one of the persons listed in B.
- I. PIRs shall not participate in the formulary approval process, unless contacted by the formulary management pharmacist, the Administrative Director of Pharmacy Services, or the Chair of the Pharmacy and Therapeutics Committee
 - 1. PIRs shall not assist medical staff members in preparing requests for additions to the formulary
 - 2. PIRs may provide information to the P&T Committee in the form of an AMCP monograph
- J. If PIRs do not follow the applicable Green Security badging procedures, the PIR shall be redirected to a Green Security kiosk and a violation shall be reported to the Drug Policy and Formulary Management Clinical Pharmacist Specialist in Acute Pharmacy.

EXTERNAL REFERENCES

ACCME requirements: Available at www.accme.org (accessed 2/13/2020)

DHHA RELATED DOCUMENTS

[Medication Samples](#)

[Gifts and Interactions with Vendors](#)

[Conflicts of Interest](#)

[COI Questionnaire](#)

[Medical Device Industry Representatives](#)

ATTACHMENTS

None

Approval Signatures

Step Description	Approver	Date
	Nathalie Seoldo Hinman: Pharmacy Administrative Director Lic 20771	03/2023

Pharmacy and Therapeutics Committee	Gale Albrecht: Pharmacist Clinical Specialist	03/2023
	Vincent Fransua: Buyer Supervisor	03/2023
	Enid Wade: General Counsel	11/2022
	Connie Price: Chief Medical Officer	11/2022
	Thomas MacKenzie: Chief Quality Officer	10/2022
	Kathy Boyle: Chief Nursing Officer	10/2022
	Sandra Shumaker: Director of Hospital Compliance	09/2022
Formatting Review	Brooke Tidball: Administrative Assistant	09/2022
	Dawn Whiting: Assistant Pharmacy Director	09/2022

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