DENVER HEALTH
Level One Care For ALL

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Regulation of Pharmaceutical Industry Representatives and Medication Samples

Document Type: Policy

CONTENTS

PURPOSE

To ensure the safety of patients, visitors, and staff, to protect patient confidentiality, to promote staff efficiency and integrity, to avoid disruption of care, and to ensure patient privacy and confidentiality.

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

To establish methodology for the receipt, storage, labeling, dispensing and disposal of medication samples at all DH practice sites.

POLICY

DH shall avoid conflict of interest through the regulation of Pharmaceutical Industry Representatives & Medication Samples.

DEFINITIONS

A. *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.

B. *Denver Health and Hospital Authority (DH)*:
Denver Health Medical Center, Rocky Mountain Regional Trauma Center, Community Health Services including Family Health Centers and School-based Health Centers, Public Health, Rocky Mountain Poison and Drug Center, DenverCARES.

RESPONSIBILITY

A. PIRs are responsible for adhering to the requirements below.

B. DH staff are responsible for enforcing PIR requirements and reporting violations (e.g., if the applicable REPTrax badging procedures have not been followed, the representative shall be redirected to a REPTrax kiosk and a violation shall be reported).

C. The Director of Service or his/her specific named designee, such as a Clinic Director is responsibility for proper receipt, recording, storage, and dispensing (which includes labeling and disposal) of sample medications. The DOS or designee will be responsible for assuring that all sample drugs are checked regularly for proper storage, expiration dating, documentation and dispensing records.

METHODOLOGY

A. Vendor Requirements:
  1. Professionalism:
    a. It is the responsibility of any pharmaceutical representative to conduct business in a professional and courteous manner.
    b. Vendor personnel are expressly prohibited from utilizing the DH patient parking garages which has been established for the sole use of DH patients.
  2. Appointment Required:
    a. PIRs shall only meet with those individuals with whom they have a scheduled appointment.
    b. Consideration for appointment approval will include:
      1. Because interacting with vendor personnel in an appropriate manner requires specific skills in discerning valid evidence from promotional messages, vendor representatives are prohibited from detailing medical students or other health care trainees except in the presence of a supervising preceptor.
      2. Pharmacy and Therapeutics (P&T) Committee representatives shall not be lobbied and are strictly prohibited from utilizing materials for presentation.

3. PIRs may provide pharmacoeconomic data only to the DH P&T Committee via PDL as per Federal guidelines in the Food and Drug Modernization Act . Under no circumstances should any financial information be provided to physicians.
4. Related support personnel (e.g., clinical microbiology staff, laboratory staff) shall not be lobbied to expand the testing or reporting of test results (e.g. antimicrobial susceptibility, genotype testing).
5. Promotion (detailing) of drugs is restricted to drugs on the DH formulary and in accordance with any formulary restrictions.
6. Promotion (detailing) of a drug by multiple representatives on the same visit is discouraged.

3. Drug Sample Authorization Required:
   Drug samples, either formulary or non-formulary, shall not be solicited or accepted at any area of DH without prior approval from the P&T Committee.
4. Educational Material Authorization Required:
   a. A copy of all materials intended for posting or display on patient care areas (e.g., charts, educational posters) must receive approval from the P&T Steering Committee.
   b. The P&T Steering Committee reserves the right to prohibit the posting of material found to contain incorrect information, information contrary to DH policy or information determined to be promotional in nature.
5. Conflict of Interest (Prohibited Materials & Meals):
   a. Items with product or manufacturer logos that are not intended for educational purposes (i.e., pads, pens, coffee mugs, etc.) may not be distributed, used or displayed. Educational items such as wall charts or educational brochures may be used, provided they have been reviewed and approved by the P&T Committee as described above.
   b. Flyers or posters promoting continuing education activities may not be posted in any DH facility.
   c. Any type of inducement or incentive to use a specific drug is strictly prohibited. No PIR may violate the DH Conflict of Interest policy by providing drug samples, gifts, on-site meals or promotional materials to DH employees or in support of any DH conference or meeting. Participation in the Medication Assistance Program is, however, beneficial to patients and DH and continued support for this program is encouraged.
   d. 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 policies contained in Chapter 21 - Sponsored Programs and Research.
   e. 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's policy is to retain the ability to publish results and to declare relationship in all consent forms in accordance with policies contained in Chapter 21 - Sponsored Programs and Research.
6. Appointment Registration Required:
   a. PIRs must be registered and approved in advance and shall check in at one of the REPTrax registration kiosks on the day of arrival.
      1. PIRs must acknowledge receipt of and agree to abide by this policy in REPTrax before they can complete their check-in process and print their REPTrax badge.
      2. Refer to REPTrax for credentialing requirements.
   b. Available kiosk locations for registration are located on the main DH campus and include the Medical Center Information Desk, Purchasing Department Front Desk, and in the Main Lobby of Administration.
      1. In the event of registration equipment failure, another available location shall be utilized.
      2. PIRs that have an appointment at a DH facility other than where a REPTrax kiosk is located, must first visit the DH Main campus to check-in at a kiosk before they travel to the DH facility for their appointment.
   c. At the end of the appointment, the SVR must sign-out at a REPTrax kiosk to document their departure from DHHA.
7. Appointment Badge Required:
   a. All vendor personnel must be in possession of a photo identification badge while in any DH facility.
   b. A date-specific REPTrax badge must be issued from a kiosk and displayed unobstructed along with a photo identification badge if not present on REPTrax badge. All 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.
   c. Vendor personnel who are not in possession of a current badge will not be allowed access to enter DH facilities.
8. Authorized and Unauthorized Areas:
   a. To protect patient confidentiality as required by state and federal law and to avoid disruptions in patient care, PIRs are prohibited from all patient care areas or from areas where there is access to patient information, including conferences where patient information is presented or discussed.
   b. Meetings with vendor representatives may be conducted in private offices, but not in physician lounges or in public areas.
   c. Vendor personnel must enter through the main entrances. No entry is allowed through the Emergency Department entrances, if applicable.
9. Unauthorized Activities:
   a. Promotion (detailing) of drugs is restricted to drugs on the DH formulary and in accordance with any formulary restrictions. Any presentation of information about a drug, including "educational" presentations, is covered under this policy.
      1. The representative shall list in REPTRAX all medications and products that he/she will discuss, detail, or promote during this visit. The representative shall not discuss, detail, or promote any product that was not listed in REPTRAX.
      2. If a representative is asked to discuss a medication or that is not on the DH formulary, he/she must decline to detail or discuss the medication/indication, but may direct the inquiry to his/her company's medical affairs office.
   b. Promotion (detailing) of drugs is restricted to uses approved by the Food and Drug Administration. Furthermore, when a drug has a DH limitation or restriction, promotion (detailing) of that drug is limited to that limitation or restriction. "Off label" detailing is strictly prohibited.
   c. Vendor representatives are not allowed to discuss or request specific patient information.
   d. 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 representative's privileges.
   e. Pharmaceutical and other vendors 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.
   f. Vendor representatives may not access any departmental mailboxes to distribute information of any kind. Information must be mailed or given to a departmental representative, only at their request, for distribution.
10. Enforcement:
    a. While it is recognized that the vast majority of vendor representatives will not knowingly violate this policy, occasions may arise when the policy is not followed. In these situations, disciplinary action may be necessary.
    b. As noted above, the dissemination of false or misleading information will be grounds for immediate and permanent suspension of privileges at DH.

c. For other violations, a progressive discipline approach will be employed.
    1. With the first infraction, a letter of reprimand from the Chair of the P&T Committee or designee will be sent to the PIR. A copy of the letter will also be provided to the appropriate DH department director, the hospital CEO, and the representative's immediate supervisor.
    2. A second infraction will result in the loss of hospital privileges for a period of six months.
    3. A third infraction will result in the representative being permanently barred from conducting business at DH.
d. Vendor personnel who have lost hospital privileges and are found conducting business on DH premises may be subject to ticket and fine under Colorado Statute.

B. Sample Requirements:
1. Samples of drugs may not be accepted for patient use at any DH Facility prior to review and approval by the P&T Committee. This policy includes both formulary and non-formulary drugs.
2. To be considered for approval by the P&T Committee, the following criteria for sample drugs must be met:
    a. Request for approval and a detailed plan for use of a specific sample drug in a designated location must be submitted to the P&T Committee in writing on the "Request to Receive Sample Drug or Patient Assistance Program Medication" form (Attachment A) by the involved Director of Service (DOS).
    b. Presentation of information to P&T Committee is required by DOS explaining why the sample drug is needed, how its use will be controlled and monitored, and how all applicable regulatory standards and legal requirements will be met.
    c. Review of the request will be made by P&T Committee.
    d. DOS will be notified by P&T Committee Representative of the P&T Committee's decision. If request is approved, DOS will be authorized to implement their plan to receive and dispense the sample drug.
3. If the P&T Committee approves the use of a specific sample drug, the DOS will be responsible for the following:
    a. Assuring that approved plan is implemented and carried out as written.
    b. Storage and dispensing of the sample drug is compliant with the procedures outlined below.
    c. Informing the P&T Committee of any changes in the manner in which the sample drug will be handled in the future.
4. Drug dispensing to ambulatory patients should occur from an outpatient pharmacy whenever possible. In situations where drug dispensing from an outpatient pharmacy is not possible (e.g., CHS Family Practice Sites), the dispensing practitioner is responsible for complying with all dispensing requirements, including labeling, as specified in State and Federal regulations.
5. Prior to receiving or dispensing a sample drug, a request for use of the specific sample drug must be reviewed and approved by the P&T Committee.
6. For sample drugs approved for use by the P&T Committee:
    a. A record must be maintained to document receipt and disposition of each dose of the sample drug.
    b. All sample drugs dispensed by a practitioner at any DH location must be packaged and labeled in accordance with state regulations governing the practice of pharmacy. See Attachment B for summary of the applicable regulations.
    c. The prescribing and dispensing of sample drugs must be documented in the patient's medical record in the same manner as any prescribed medications.
    d. Patients must be provided comparable written drug information as provided to patients who have their medications dispensed by a DH pharmacy.
7. Sample drugs that have not been approved by the P&T Committee, or that are not handled according to the procedures above, will be removed from the area if identified and reported to the P&T Committee. The Executive Committee of the Medical Staff will be notified of the breach of DH policy by the P&T Committee Chairperson.
8. The pharmacy should be notified of any drugs, including sample drugs, which are no longer needed or desired in any DH location. The drugs will be removed from the area and disposed of properly.
9. The pharmacy will notify the DOS or designee of a drug recall that may involve an approved sample drug. The DOS and pharmacy will coordinate efforts to review sample drug supplies and determine if the involved drug is stored in the clinic.

REFERENCES

A. Colorado statutes governing the practice of pharmacy: CRS 12-42.5-101, et seq., "Pharmacists, Pharmacy Businesses, and Pharmaceuticals", effective July 1, 2012. Available at: http://cdn.colorado.gov/cs/Satellite?blobcol=urldata&blobheadername1=Content-Disposition&blobheadername2=Content-Type&blobheadervalue1=inline%3B+filename%3D%22CRS+12+22+-+Pharmaceuticals+and+Pharmacists+Effective+2012.pdf%22&blobheadervalue2=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251851144954&ssbinary=true (accessed May 14, 2013).

B. Poison Prevention Packaging Act PPPA (PL 91-601), December 30, 1970; Available at: http://www.cpsc.gov//PageFiles/107555/01-pppa.pdf (accessed May 14, 2013).

ATTACHMENTS

Attachment A - Request to Receive Sample Drug at Denver Health, 05/2013.

Attachment B - Medication Dispensing to Ambulatory Patients, 05/2013.

Attachments:

A: Request to Receive Sample Drug at Denver Health
B: Medication Dispensing to Ambulatory Patients