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Pharmacist
Clinical Specialist
Document Area Pharmacy
Applicability Denver Health
and Hospital
Authority (DHHA)
Document Types Policy

Medication Samples

Policy

PURPOSE

To establish the appropriate use of medication samples (including grant provided medication samples and covered medical supply samples) and methodology for the receipt, storage, labeling, dispensing and disposal at all Denver Health and Hospital Authority (DHHA) practice sites.

SCOPE

- A. DHHA – All locations and departments, including all facilities owned or leased for use by the Authority.
- B. This policy applies to medications, including grant provided medications and biologics. This policy also applies to covered medical supply samples which fall under covered pharmacy benefits. A separate policy exists for management of medical device samples and is overseen by the Product Evaluation Committee.
- C. DHHA shall avoid conflict of interest through the regulation of Pharmaceutical Industry Representatives (PIR) and Medication Sample use. PIRs are responsible for adhering to the requirements below.
 - 1. DHHA staff are responsible for enforcing PIR requirements and reporting violations. Violations can include 1) 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 2) unauthorized communications to DHHA staff regarding non-formulary medications, and/or 3) conducting sales, marketing, or educational activities at DHHA facilities or via electronic means.
 - 2. Please see the Regulation of Pharmaceutical Industry Representatives policy for further detail.
- D. The Director of Service (DOS) or his/her specific named designee, such as a Clinic Director is responsible for proper receipt, recording, storage, and dispensing (which includes labeling and disposal) of requested samples. The DOS or designee will be responsible for assuring that all sample medications, grant provided medications, and approved covered medical supply samples are checked regularly for proper storage, expiration dating, documentation, and dispensing records.

DEFINITIONS

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, 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.

Medication: 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 medication. A medical device, as defined by the FDA, is not a considered a medication.

Covered medical supplies: Medical supplies which are traditionally dispensed at pharmacies and fall under covered pharmacy benefits. This includes diabetic testing supplies (glucose monitoring kits, readers, sensors, test strips, lancets, pen needles), insulin syringes, and spacers if requested to be utilized as samples.

POLICY

- A. Samples of medications or covered medical supply samples which fall under a pharmacy benefit may not be accepted for patient or employee use at any DHHA facility prior to review and approval by the Pharmacy and Therapeutics (P&T) Committee. This policy includes both formulary and non-formulary medications.
- B. The use of samples is discouraged at DHHA because the medications/covered medical supplies which samples are requested for generally cost more than similar medications and/or do not provide enough clinical benefit to account for the increased cost to the patient and to DHHA if the sample is continued beyond the initial sample timeframe. In the outpatient setting, it is recommended to take advantage of Patient Assistance Programs as opposed to utilizing medication samples to help the patient with long term medication access. Additionally, all medications including samples must follow all Joint Commission and State Board of Pharmacy requirements (storage, labeling, dispensing, documentation, etc) which will be the responsibility of the DOS or his/her designee and can have legal ramifications if not properly adhered to.
 - 1. Exceptions to utilizing medication and covered medical supply samples must be evaluated on a case-by-case basis by the P&T Committee and are expected to be rare. An example of a sample request that may be approved is a medication that is donated by a private organization or via grant funding, not by a pharmaceutical company.
 - 2. Any medication which has not been on the market for >18 months will not be considered for use as a sample. The purpose of this rule is to allow time for data about real-world effectiveness and safety, as well as role in therapy as data becomes available.
 - 3. Utilizing medication or covered medical supply samples for the purpose of a trial to show a benefit to DHHA is not recommended or appropriate. These "trials" are not rigorous enough to show superiority compared to current practice or well designed clinical studies. In addition, these trials are susceptible to bias and confounding. It is inappropriate for pharmaceutical companies to utilize non-study "real-world" provision of samples to support efforts to gain market share within institutions.
- C. To be considered for approval by the P&T Committee, the following criteria for sample medications or sample covered medical supplies must be met:
 - 1. Request for approval and a detailed plan for use of a specific sample medication or covered medical supply sample in a designated location must be submitted to the P&T Committee in

- writing on the "Request to Receive Sample Medication (or covered medical supply samples)" form (Attachment A) by the involved DOS.
2. Presentation of information to P&T Committee is required by DOS or his/her designee, explaining why the sample is needed, how its use will be controlled and monitored, and how all applicable regulatory standards and legal requirements will be met.
 3. The DOS/designee will be notified by a P&T Committee Representative of the P&T Committee's decision.
 - a. If the request is approved, the DOS/designee will be authorized to implement their plan to receive and dispense the sample medication or covered medical supply sample.
- D. If the P&T Committee approves the use of a specific sample medication or covered medical supply, the DOS/designee will be responsible for the following:
1. Assuring that approved plan is implemented and carried out as written.
 2. Storing and dispensing the sample in a manner that is compliant with the procedures outlined below.
 3. Informing the P&T Committee of any changes in the manner in which the sample is handled.
- E. Medication dispensing to ambulatory patients must occur from the requesting DOS and/or designee and cannot be dispensed from an outpatient pharmacy, per the Federal Prescription Drug Marketing Act.
1. The dispensing practitioner is responsible for complying with all dispensing requirements, including labeling, as specified in State and Federal regulations.
 - a. Prior to receiving or dispensing a sample, a request for use of the specific sample medication or supply must be reviewed and approved by the P&T Committee.
- F. For sample medications/covered medical supplies approved for use by the P&T Committee:
1. A record must be maintained to document receipt and disposition of each dose of the sample medication or dispense of the covered medical supplies.
 2. All samples 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.
 3. The prescribing and dispensing of sample medications or covered medical supply samples must be documented in the patient's medical record in the same manner as any prescribed medication.
 4. Patients must be provided comparable written medication information as provided to patients who have their medications dispensed by a DHHA pharmacy.
 5. The P&T Committee may request follow up reporting on patient usage, record keeping, adherence to implementation policy, or other factors in order to ensure appropriate use and patient safety.
- G. Sample medications/covered medical supplies 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.
1. The presence of unapproved samples will be reported to the Chief Medical Officer, the appropriate DOS, and the Chair of the P&T Committee.
- H. The DOS and/or designee are responsible for disposing of samples which are expired or no longer needed in any DHHA location. Pharmacy can be contacted if needed for direction on how to dispose of medications properly.
- I. In the event of a medication recall, the DOS/designee is responsible for identifying and removing any affected sample medications/covered medical supplies from DHHA facilities.

EXTERNAL REFERENCES

- A. Poison Prevention Packaging Act PPPA (PL 91-601), December 30, 1970; Available at: <http://www.cpsc.gov//PageFiles/107555/01-pppa.pdf> (accessed May 16, 2016).
- B. CRS 12-42.5: Pharmacists, Pharmacy Business, and Pharmaceuticals. <https://www.colorado.gov/pacific/sites/default/files/atoms/files/Pharmacists%2C%20Pharmacy%20Business%2C%20and%20Pharmaceuticals%20Practice%20Act.pdf> (accessed February 1, 2021)
- C. 21 CFR Part 203: Prescription Drug Marketing. http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr203_02.html (Accessed February 1, 2021)
- D. CPMG 7356.022: Enforcement of the Drug Sample Distribution Requirements of the Prescription Drug Marketing Act (PDMA). <https://www.fda.gov/media/85415/download> (Accessed February 1, 2021)

RELATED DHHA DOCUMENTS

[Regulation of Pharmaceutical Industry Representatives](#)

ATTACHMENTS

Attachment A - Request to Receive Sample Medication (or covered medical supply samples) at Denver Health, 02/2021

Attachment B - Medication Dispensing to Ambulatory Patients, 02/2021



Attachments

[Attachment A: Request to Receive Sample Medication \(or covered medical supply samples\) at Denver Health](#)

[Attachment B: Medication Dispensing to Ambulatory Patients](#)

Approval Signatures

| Step Description | Approver | Date |
|-------------------------------------|--|---------|
| Pharmacy and Therapeutics Committee | Nathalie Seoldo Hinman: Pharmacy Administrative Director Lic 20771 | 03/2021 |
| | Gale Albrecht: Pharmacist Clinical Specialist | 03/2021 |
| | Debra Gardner: Assistant Chief Nursing Officer | 03/2021 |
| Formatting Review | Scott Hoye: General Counsel | 03/2021 |
| | Brooke Sullivan: Administrative Assistant | 03/2021 |
| | Gale Albrecht: Pharmacist Clinical Specialist | 03/2021 |