

Policies of the University of North Texas Health Science Center	Chapter 14 – UNT Health
14.301 Proper management of sample medications in the office setting	

Policy Statement. Sample medications shall be obtained, dispensed, maintained, stored and secured in compliance with institutional policies/procedures and applicable federal, state and local laws.

PURPOSE:

To obtain and dispense sample drugs in compliance with applicable laws and guidelines.

To maintain the integrity of sample drugs through proper handling, storage and security.

Application of Policy.

All faculty and staff, including UNTHSC QM Committee and Sub-Committees,
Departmental QM Committees, Pharmacy, QM Office.

Definitions.

1. Sample – A prescription drug which is prepackaged by the original manufacturer, provided to the physician at no cost by the manufacturer, and is either marked as a sample on the original container or is included in the physician's records as a sample.

Procedures and Responsibilities.

Procedure / Duty

Responsible
Party

1. Include all of the following components on all forms submitted by physicians when obtaining sample drugs.
 - a. the name, address, professional designation and signature of the provider making the request
 - b. the identity and quantity of the requested sample drug
 - c. the name of the manufacturer of the requested sample drug
 - d. the date of the request

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Personnel

According to Section 158.002 (Provision of Free Samples) of the Texas Medical Practice Act, a physician may supply a pharmaceutical sample to a patient free of charge if, in the physician's opinion, it is advantageous to the patient, in adhering to a course of treatment prescribed by the physician, to receive the sample.

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| 2. A pharmaceutical sample provided under this section must be:

a. provided to the physician without cost from the manufacturer, delivered at no cost, directly or indirectly to the patient.

b. prepackaged by the original manufacturer and not be repackaged.

c. marked on the immediate container to indicate that is a sample or recorded in records that indicate that it is a sample | Licensed
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| 3. Records shall be accessible as provided under state and federal law. | Licensed
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| 4. All state and federal labeling and recordkeeping requirements shall be followed and documented. | Licensed
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| 5. All invoices shall be kept for purchases, receiving orders, or documentation for acquired sample drugs on file for two (2) years from the date of acquisition. | Licensed
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| 6. The criteria used for obtaining sample medications are specific to each clinic's scope of service. | Licensed
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| 7. After receiving a written or verbal order from the physician, physician assistant (PA) or nurse practitioners (NP) should obtain the sample medication from the drug room and check the label CAREFULLY to make sure that the correct drug was chosen. | Licensed
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| 8. Check patient's medical record for allergies or ask patient about allergies. | Licensed
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| 9. Sign out the drug on the Sample Medication Sign-in Sheet. Include the following:

a. date

b. drug | Licensed
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- c. amount of drug
- d. lot number
- e. expiration date
- f. patient name
- g. signature of person dispensing drug/provider prescribing drug

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| <p>10. Affix a label to ALL sample drugs prior to dispensing to a patient and include the following:</p> <ul style="list-style-type: none"> a. date of delivery b. name and strength of drug c. directions for use d. name and address of the physician e. name of the patient | <p>Licensed Healthcare Providers, Clinic Personnel</p> |
| <p>11. The physician, PA, or NP should provide and document instructions to the patient regarding the medication including the purpose and possible side effects as well as the correct dosage, route, and frequency of administration.</p> | <p>Licensed Healthcare Providers, Clinic Personnel</p> |
| <p>12. Maintaining and Storing Sample Drugs</p> <p>Maintain the Sample Medication Sign-in sheet for two (2) years for tracking purposes.</p> | <p>Licensed Healthcare Providers, Clinic Personnel</p> |
| <p>13. Return sample drugs that are outdated or unusable to the Pharmacy with appropriate paperwork. Maintain records of outdated or unusable sample drugs for two (2) years from date of disposal.</p> | <p>Licensed Healthcare Providers, Clinic Personnel</p> |
| <p>14. Store sample drugs in an area that is secured by a locking device and is accessible only to appropriate staff.</p> | <p>Licensed Healthcare Providers, Clinic Personnel</p> |
| <p>15. Inspect sample drugs (monthly) to detect outdated or unusable drug.</p> | <p>Licensed Healthcare Providers, Clinic Personnel</p> |

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| 16. Maintain a sample medication sign out sheet, and ALWAYS record samples given to patients so as to allow for the recall of previously dispensed drugs if needed. | Licensed
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| 17. Document sample drugs on:
1) the patient's medical record and
2) Sample Medication Sign-in sheet. | Licensed
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References and Cross-references. Federal Public Law 100293, Prescription Drug Marketing Act of 1987 (commonly referred to as the Dingle Bill) under Section 5, requires that a physician can only obtain pharmaceuticals after the physician has made a request in writing on a form, as specified in the law, and signed by the physician.

Section 158.002 (Provision of Free Samples) of the Texas Medical Practice Act

Forms and Tools.

Sample Medication Sign-in Sheet

Approved: October 2009

Effective: October 2009

Revised: