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| <b>Title: Ambulatory Clinic – Samples</b>   | <b>Procedure</b> |
| <b>Patient Age Group:</b> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> All Ages <input type="checkbox"/> Newborns <input type="checkbox"/> Pediatric <input type="checkbox"/> Adult |                  |

**DESCRIPTION/OVERVIEW**

This document establishes procedures to control medication samples and ensure compliance with NM Board of Pharmacy Rules and Regulations.

**REFERENCES**

- New Mexico Board of Pharmacy:
- UNM Hospitals Vendor Access Procedure
- UNMH Ambulatory Clinic Dispensing Policy

**AREAS OF RESPONSIBILITY**

- Ambulatory Clinics with an active Class A or B license from NM Board of Pharmacy or on-site clinics may dispense or administer samples. Ambulatory Clinics with an active Class C license may only procure samples for administration in the clinic. Clinics are responsible for implementation and coordination of this procedure.
- Pharmacy Administration has authority to approve exceptions or any discretionary modification to the procedure to follow federal and state rules and regulations.

**PROCEDURE**

1. It is the intention of the UNM-HSC that ambulatory services to be allowed to procure samples for dispensing, distribution or administration to their patients for the following reasons:
  - 1.1. To give the patient a trial of medication for tolerance and effectiveness prior to prescribing the medication to the patient.
  - 1.2. To assist a patient in using a particular medication to cover the time needed for prior authorization for insurance purposes.
  - 1.3. To assist in community/state programs providing medication samples for specific patient populations (examples being but not limited to: sexual abuse clinic, smoking cessation medications for high risk patients).
2. Other special needs for sample dispensing or non-formulary samples must be discussed and approved by Clinical Director of Pharmacy or P&T Committee.
3. Consultant Pharmacist must be notified of a decision to stock samples by any ambulatory services within the UNM Health Sciences Center.
4. Prior to dispensing samples, the physician or healthcare provider responsible for procuring the samples of the clinic must attend a mandatory in-service from the consultant pharmacist that outlines in detail the responsibilities of dispensing drug samples.
5. Pharmaceutical representatives must follow all UNM Hospitals Vendor Access Procedure
6. No person shall sell, trade, barter or exchange, or offer to sell, trade, barter or exchange any pharmaceutical products samples. By definition, samples mean a drug, which is not intended to be sold and is intended to promote the sale of the drug.

7. Employees who are not licensed to prescribe drugs will not acquire, accept, or distribute drug samples for their own use or the use of others at UNMHSC. Drug samples in the possession of employees obtained outside UNMHSC must be appropriately labeled as required by the State Board of Pharmacy.
8. Drug samples for the personal use of individual physicians may be kept temporarily in physicians' offices.\* However, self-treatment with drug samples should follow precisely the labeling and medical record requirements defined by federal and state regulations.
9. The dispensing of medication samples requires a patient-physician relationship documented in the patient chart. The Consultant Pharmacist must review 5% of all patient's charts that have received dispensed samples.
10. Providers will be responsible for all drug sample procedures, which are subject to all record keeping, storage, patient counseling and labeling requirements for prescriptions drug use as defined by applicable state and federal legal laws and UNMH Ambulatory Clinic Dispensing Policy
11. All samples receipt must be signed and dated when received and kept on file for 3 years.
12. Drug samples within UNMHSC not meeting the above guidelines will be seized and disposed of according to state and federal regulations. Pharmaceutical companies responsible for violations of the drug sample policy will be contacted through administrative channels to prevent recurrences. Clinics may be denied dispensing sample privileges for violation of this policy. Representatives may be denied access to UNM-HSC for violation of this policy.

*\* Physicians who accept drug samples for the treatment of themselves or their families might consider the AMA Council on Ethical and Judicial Affairs. The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance, and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion 8.19, \* "Self-Treatment or Treatment of Immediate Family Members." It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.*

## **DEFINITIONS**

**Dispensing Unit** – container or containers of a drug entity, either repackaged or manufacture's original container(s), containing a quantity suitable for the prescribed treatment or condition.

**Distribute** – delivery of a dispensing unit by a licensed practitioner to a patient of the clinic by means other than dispensing.

## **SUMMARY OF CHANGES**

Samples may be delivered to clinic

Vendor access procedure language added (5).

Dispensing procedure language added.

AMA Update (\*)

Replaces “Ambulatory Clinic – Drug Sample”, (11/2003).

## **RESOURCES/TRAINING**

| <b>Resource/Dept</b>                              | <b>Internet/Link</b>  |
|---|---|
| Ambulatory Pharmacy Policy & Procedure Update     | Learning Central – Clinical Education   |
| Cynthia Lujan RPh, Pharm D, Consultant Pharmacist | Office: 272-4899 Pgr: 951-1895 <a href="mailto:cllujan@salud.unm.edu">cllujan@salud.unm.edu</a> |

## DOCUMENT APPROVAL & TRACKING

| Item                            | Contact   | Date            | Approval |
|---------------------------------|---|-----------------|----------|
| <b>Owner</b>                    | Cynthia Lujan, PharmD – Ambulatory Service Consultant Pharmacist  |                 |          |
| <b>Consultant(s)</b>            | William Long PharmD, MBA – Director of Pharmacy Operations<br>Louis Achusim BS, PharmD, MS – Executive Director of Pharmacy |                 |          |
| <b>Committee(s)</b>             | Medical Safety Committee<br>Clinical Operations PP&G Committee<br>Nursing Practice Council                                  |                 | Y        |
| <b>Nursing Officer</b>          | Sheena Ferguson, , Chief Nursing Officer  |                 | Y        |
| <b>Medical Director/Officer</b> | David Pitcher, MD   |                 | Y        |
| <b>Official Approver</b>        | Erin Doles, Administrator, Professional & Support Services  |                 | Y        |
| <b>Official Signature</b>       |   | Date: 7/21/2009 |          |
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| <b>Issue Date</b>               | Clinical Operations Policy Coordinator  | 7/24/2009       |          |

## ATTACHMENTS

None