

MEDICATION SAMPLES

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PURPOSE:

This policy outlines the criteria and procedures for safe use of medication samples at Stevenson Memorial Hospital.

PREAMBLE:

Accreditation Canada specifies that sample medications are subject to the same medication management processes as other types of medications. This policy is consistent with the recommendations of the Institute for Safe Medication Practices (ISMP), the College of Physicians and Surgeons of Ontario (CPSO), the Ontario College of Pharmacists (OCP), and the College of Nurses of Ontario (CNO).

DEFINITIONS:

Sample Medication: A medication that has been approved for use by Health Canada and is provided free of charge by a pharmaceutical manufacturer’s representative to a prescribing Healthcare Practitioner for the purpose of evaluation in individual patients outside of a clinical drug trial and to initiate therapy.

POLICY STATEMENT:

Procurement and provision of medication samples is discouraged in the hospital. Although medication samples may be helpful in providing patient care, their use can increase the risk that patients will receive improperly labelled, misidentified, expired, or undocumented drugs. This in turn can lead to lack of screening for drug interactions, potential duplicate therapy, or contraindicated drug therapy that expose the patient to adverse events. Additionally, use of medication samples circumvents the Stevenson Memorial Hospital Formulary system and process.

Inpatient Areas:

1. Medication samples are NOT allowed to be procured, stored, distributed, or dispensed to patients for inpatient use.
2. Patients may supply their own Health Canada approved medication received as samples from their prescriber for use during their hospital stay if the medication is non-formulary, is not available from Pharmacy, and meets the criteria outlined in the hospital’s Patient Own Medication policy.

Outpatient Areas/Ambulatory Clinics

3. Medication sample distribution to outpatients is discouraged but may occur if such will serve:
 - To initiate therapy pending the filling of the prescription in a community pharmacy
 - To evaluate the clinical performance of the medication and the patient response prior to issuing a prescription
 - As part of a patient education program (e.g. Insulin for Diabetic Education Centre)
 - To ensure adequate treatment where the normal means of obtaining medications would result in excessive financial burden or other hardship to the patient
 - As part of a compassionate supply program
4. Any outpatient area that accepts or dispenses samples must have prior approval from the Manager of Pharmacy, Pharmacy & Therapeutics Committee, and Medical Advisory Committee. The storage area must be inspected by the Pharmacy Department for appropriateness.
5. The Pharmacy Department will inspect and audit records in all sample storage areas.
6. Each area or clinic dispensing samples must have assigned personnel to receive supply and maintain the medication samples inventory including checking for expired products.
7. Medication samples may only be dispensed by practitioners who have dispensing within their scope of practice (e.g. physicians, nurse practitioners, nurses and pharmacists) and upon a valid order from a prescriber.
8. Dispensing of medication samples by non-pharmacists must meet the same standards of dispensing that a pharmacist must meet and must follow the appropriate discipline's College policies and standards. Dispensing must comply with all relevant legislation for dispensing of drugs, including proper storage, labeling, patient education, and retention of records.
9. The dispensing practitioner must provide patient education on proper usage, potential risks and side effects, and any follow-up that is required.

All Patient Care Areas

10. Sample medications will NOT be
 - Narcotic, Controlled Drug, or Targeted Substances
 - Used by staff or staff family members for personal use
11. Only medications relevant to the prescriber's practice may be provided as samples.
12. The distribution of medication samples by prescribers will not involve any form of material gain for the prescriber or for the practice with which they are associated.
13. The appropriateness of therapy will be assured by the prescriber or healthcare professional dispensing the sample medications in terms of screening for drug interactions, duplicate therapy, patient allergies and contraindications.

RESPONSIBLE STAFF:

Physicians, nurses, nurse practitioners

PROCEDURAL STEPS:

Documentation:

1. The following must be documented on the Sample Medication Log Sheet (Appendix A):

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- Receipt of samples from suppliers including date, sample medication name, strength, quantity, lot number, expiry date, manufacturer name, name and signature of receiving healthcare professional
 - Destruction of samples when expired
 - Dispensing for each time dispensed including date provided, sample medication name, strength, quantity, lot number, expiry date, prescriber name, name of practitioner dispensing
2. There must be one Sample Medication log per medication dosage form/strength. Multiple strengths of the same medication must have individual log sheets.
 3. The prescriber/dispensing healthcare practitioner will document in the patient record the following information: date, sample medication name and strength, quantity, instructions for the use of the drug, and the fact that education was provided to the patient.

Labeling

1. Sample medications dispensed to patients must be labeled with the following information:
 - Hospital name, address and telephone number
 - Patient Name
 - Date of dispensing
 - Name and strength of medication
 - Directions for use including dose, route, and frequency (e.g. Take one tablet three times daily)
 - Quantity dispensed
 - Prescriber's name and designation
2. Pharmacy will provide preprinted labels that can be filled in with the required information to facilitate labeling of sample medications.

Storage

1. All medication samples must be stored in a designated locked room or cabinet. Storage conditions must maintain product integrity (e.g. refrigerated or room temperature).
2. Designated staff will check regularly, at a minimum every 3 months, for expiry dates. Screening is documented on the log sheets and the quantity of expired drugs removed noted.
3. Expired or damaged sample medications will be disposed of in hospital-provided Pharmaceutical Waste containers.

REFERENCES:

1. College of Physicians and Surgeons. Dispensing Drugs. Revised Dec 2022. [CPSO - Dispensing Drugs](#)
2. College of Physicians and Surgeons. Prescribing Drugs. Revised Dec 2019. [CPSO - Prescribing Drugs](#)
3. College of Nurses of Ontario. Practice Standard – Nurse Practitioner. Revised Dec 2023. [41038_strdrnec.pdf \(cno.org\)](#)

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4. College of Nurses of Ontario. Medication Samples.
[Medication samples \(cno.org\)](https://www.cno.org/medication-samples)
5. College of Nurses of Ontario. Practice Standard. Scope of Practice. July 2023
[Scope of Practice \(cno.org\)](https://www.cno.org/scope-of-practice)
6. Southlake Regional Health Centre. Policy – Medication Samples. Nov 2023.
7. Ontario College of Pharmacists. Practice Policies & Guidelines: Distribution of Medication Samples.
[Distribution of Medication Samples - OCPIInfo.com](https://www.ocpi.com/distribution-of-medication-samples)
8. Government of Ontario, Drug and Pharmacies Regulation Act. Revised May 2023.
[Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H.4 \(ontario.ca\)](https://www.ontario.ca/laws/statutes/90/h4)

RELATED DOCUMENTS:

SMH Policy 11183: Formulary Management
SMH Policy PHM006: Patient Own Medications (POM)

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