

MAINEGENERAL HEALTH

FUNCTIONAL AREA: Medication Management

POLICY #: MM-07

EFFECTIVE: 01/98

REVIEWED/REVISED: 01/00, 01/12, 07/00, 08/02, 10/03, 05/04, 06/06, 01/08, 01/10, 01/14, 12/15, 08/18, 11/18

TOPIC: Drug Samples and Prescription Assistance Program (PAP) Medications

AUTHORIZATION:

Chief Medical Officer, MGH

Chief Nursing Officer & CEO Community Care

Director, Pharmacy

Chair, Pharmacy & Therapeutics Committee

I. PURPOSE: To establish procedures for control, distribution, and dispensing of drug samples and prescription assistance program medications received, stored, and dispensed in outpatient practices for MaineGeneral Medical Center patients.

II. POLICY:

1. Samples

MaineGeneral Medical Center strongly discourages the use of drug samples. Instead, MaineGeneral Medical Center endorses the use of manufacturer vouchers which are handed to the patient with a prescription for discounted/free prescriptions at a retail pharmacy. If vouchers are not available, the Pharmacy Department acting under guidelines established by the Pharmacy and Therapeutics Committee is responsible for overseeing the use of drug samples. The following are guidelines established by the Pharmacy and Therapeutics Committee.

- A. Only medical staff members (physicians, physician assistants, and nurse practitioners) and clinical support staff (RN, MA, LPN) are authorized to sign for drug samples. If a shipment arrives boxed, a Patient Service Representative (PSR) may sign for it and hand it off to a clinical support staff member.
- B. Drug samples approved by the Pharmacy and Therapeutics Committee as Formulary Drugs will be allowed for use at MGMC affiliated physician practices.
- C. Non-formulary drug samples must be reviewed by the Pharmacy and Therapeutics Committee. A temporary trial period of up to 3 months may be granted by the Director of Pharmacy or designee until the request for non-formulary samples can be reviewed at the next scheduled Pharmacy and Therapeutics Committee meeting.
- D. Samples will be stored in a secure locked area with access restricted to authorized personnel as indicated in MM-04 Attachment 1.
- E. Pharmaceutical Representatives will not be allowed access to sample storage areas for any reason.

- F. Only a medical staff member or pharmacist (with a patient prescription) may dispense samples to the patient.
- G. Any sample given to a patient will be noted in the Patient's Medical Record.
- H. Receipt and Dispensing of all requested samples will be documented on the Drug Sample Receipt and Dispensing Log. The following information will be documented on receipt of the drug samples: receipt date, drug, strength, quantity, lot number, expiration date, and balance on hand. When dispensing, the patient's full name, drug, strength, quantity dispensed, lot number, expiration date and final balance will be recorded on the log. All areas that store sample medications must keep a perpetual inventory. See Attachment 1.
- I. Records of sample distribution will be retained in patient care areas for a minimum of one year.
- J. Drug sample storage and appropriate record keeping will be reviewed as part of the periodic unit medication inspection by the Director of the Pharmacy or designee.
- K. In the event of a drug recall, the Pharmacy Director or designee will review the receipt and distribution logs to assure that the stocked samples are not affected. In the event that they are affected, the samples will be quarantined and returned to the manufacturer as directed.
- L. In the event of a drug recall for safety reasons, the Pharmacy Director or designee will review the receipt and distribution logs to assure that the received and dispensed samples are not affected. Patients who may have received any affected samples will be informed of the recall.
- M. New non-formulary drug samples will require a physician request form (Attachment 2). This form will need to be completed and sent to the Director of Pharmacy so that temporary approval may be granted.
- N. When dispensing samples to patients for at home administration, the samples will be labeled with the patient name, patient date of birth, drug name, strength, directions for use, route of administration, indication, quantity, cautionary statements (if applicable), expiration date, office name & phone number, medical staff member's name, initials, and date).

2. Prescription Assistance Program Medications

MaineGeneral Medical Center supports the utilization of prescription assistance programs to supply medications free of charge to patients who meet the specific prescription assistance eligibility requirements. Patients will be guided through the application process.

- A. Medical staff members (physician, physician assistants and nurse practitioner) and clinical support staff (RN, MA, LPN) are authorized to sign for prescription assistance medication shipments. If a shipment arrives boxed, a Patient Service Representative (PSR) may sign for it and hand it off to a clinical support staff member.

- B. Prescription Assistance Medications will be stored in a secure locked area with access restricted to authorized personnel as indicated in MM-04 Attachment 1.
- C. Only a medical staff member, physician assistant or pharmacist (with a patient prescription) may dispense Prescription Assistance Program medications to the patient.
- D. Any medication given to a patient will be noted in the Patient's Medical Record.
- E. Receipt and Dispensing of all patient assistance medications will be documented on the Prescription Assistance Program Medication Receipt and Dispensing Log.
- F. The following information will be documented on receipt of the medication: receipt date, receiving patient name, drug, strength, quantity per container, lot number, expiration date, and amount received.
- G. The following information will be documented on dispensing of the medication: the patient's full name, date of birth, drug, strength, quantity dispensed, lot number, expiration date and final balance. All areas that store patient assistance medications must complete the log. See Attachment 3.
- H. Records of prescription assistance program medication dispensing will be retained in patient care areas for a minimum of one year.
- I. Prescription Assistance Program medication storage and appropriate record keeping will be reviewed as part of the periodic unit medication inspection by the Director of the Pharmacy or designee.
- J. In the event of a drug recall, the Pharmacy Director or designee will review the receipt and distribution logs to assure that the prescription assistance program medications are not affected. In the event that they are affected, the medications will be quarantined and returned to the manufacturer as directed.
- K. In the event of a drug recall for safety reasons, the Pharmacy Director or designee will review the receipt and distribution logs to assure that the prescription assistance program medications are not affected. Patients who may have received an affected medication will be informed of the recall.
- L. When dispensing the prescription assistance program medications for at home administration, the medication containers need to be labeled. The medication will be labeled with the patient name, patient date of birth, drug name, strength, directions for use, route of administration, indication, quantity, cautionary statements (if applicable), expiration date, office name & phone number, medical staff name and initials, and date. CAUTION: when applying the labeling, do not obstruct the name of the medication and any other labeling information on the original packaging.
- M. The dispensed medications will be deducted from the receiving log.
- N. The medical staff member will review the label(s) for accuracy and initial it/them, ask the patient if they wish to be counseled, and dispense the medication(s) to the patient.

O. In case a prescription assistance program medication is not picked up within 90 days, direction regarding return or destruction of the medication will be obtained from the manufacturer by the clinical support staff and processed accordingly.

III. RESPONSIBILITY: The Pharmacy, Medical and Clinical Support Staff have joint responsibility for adherence to this policy.

IV. PROCEDURE: The procedure for the Prescription Assistance Program is maintained on the MGMP Practice Sharepoint Site and will be reviewed at least biannually in accordance with review schedule for this policy or as changes are needed.

V. POLICY ACCESSIBILITY:

- Original approved MaineGeneral Health Policies are maintained in Administration at the ACH.
- Entities of MaineGeneral Health maintain and file policies specific to their areas in a designated Administrative area of their own.
- Copies of MGH policies are filed in the Health Sciences Library of the Thayer Center for Health (TCH), Waterville.
- Employees can access policies via the MaineGeneral Connect site.

VI. POLICY APPLIES TO:

- MaineGeneral Medical Center
- MaineGeneral Rehabilitation & Long Term Care
- MaineGeneral Retirement Community
- MaineGeneral Community Care
- All

VII. CITATIONS/BEST PRACTICE REFERENCES: (N/A)

VIII. POLICY ATTACHMENTS:

- ATTACHMENT 1 – Drug Sample Receipt and Dispensing Log
- ATTACHMENT 2 – Non-Formulary Medication Sample Request Form
- ATTACHMENT 3 – Patient Assistance Medication Receipt and Dispensing Log