

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 722.000: DISPENSING PROCEDURES FOR PHARMACISTS

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722.001: Purpose

The purpose of 105 CMR 722.001 is to describe procedures which pharmacists must follow when dispensing drug products in accordance with St. 1976, c. 470 and the regulations promulgated thereunder.

722.002: Citation

105 CMR 722.000 shall be known as 105 CMR 722.000: *Dispensing Procedures for Pharmacists*.

722.010: Scope and Application

105 CMR 722.000 establishes the rules and regulations which a pharmacist must follow to be in accordance with St. 1976, c. 470, when dispensing drug products.

722.020: Definitions

The terms used herein shall have the meaning set forth below. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1, and not defined herein shall have the meanings set forth therein when used in 105 CMR 722.000, unless the context clearly requires a different interpretation.

Commissioner means the Commissioner of the Massachusetts Department of Public Health.

Discharge Patient. For the purpose of 105 CMR 722.000 only, a discharge patient is a person who has been released from an inpatient hospital bed and is no longer registered as a hospital patient.

Drug Product means a product which contains an active drug ingredient and is in a dosage form *e.g.* tablet, capsule, or solution, generally, but not necessarily in combination with other substances included in the manufacturing process. An active drug ingredient is that portion of drug product intended to produce a therapeutic effect.

Drug Purchaser means any individual or third-party payor purchasing prescribed drugs on behalf of himself or others.

Emergency Room Patient. For the purposes of 105 CMR 722.000 only, an emergency room patient is a person registered at a hospital for the purpose of receiving emergency services or treatment and who departs from the hospital immediately after receiving such emergency services or treatment.

Generic Name means a non-proprietary (common) name used to identify a drug product as listed by the United States Adopted Names Council and the United States Pharmacopeia in the *USAN/USP Dictionary of Drug Names*.

722.020: continued

Hospital Employees. Employees of the hospital shall include persons currently on the payroll of the hospital and their spouse and dependents living in the same household, medical staff members, volunteers, students and/or individuals contracted for employment by the hospital.

Hospital Inpatient. For the purposes of 105 CMR 722.000 only, a hospital inpatient is a person formally admitted to a hospital bed for the purpose of receiving services or treatment and who remains in the hospital at least overnight. A person is considered a hospital inpatient if, after formal admission as an inpatient, such person is later discharged for medical reason or is transferred to another hospital before such person has occasion to occupy a hospital bed overnight.

Hospital Outpatient. For the purposes of 105 CMR 722.000 only, a hospital outpatient is a person formally registered on the hospital records as an outpatient and who is currently receiving services or treatments at a clinic of the hospital (*e.g.*, asthma clinic, arthritis clinic, radiation therapy clinic, *etc.*). Patients who are seen at a doctor's private office within or without the hospital shall not be deemed to be hospital outpatients.

Hospital Pharmacy means a hospital's central, satellite or branch pharmacy.

Hospital Premises means, for the purposes of 105 CMR 722.000 only, the buildings and contiguous grounds of a hospital.

Hospital-based Skilled Nursing Facility means, for the purposes of 105 CMR 722.000 only, a long-term care facility or unit thereof that is an integral and subordinate part of the hospital, is operated with other departments of the hospital under common governance and professional supervision such that the skilled nursing facility and the hospital are subject to the bylaws and operating decisions of a common governing board, is fully integrated with all other services of the hospital, and is financially integrated with the hospital.

Interchange means the exchange of a less expensive reasonably available drug product selected from the *Massachusetts List of Interchangeable Drugs* for a prescribed brand name drug product.

Interchangeable Drug Product means a product containing a drug in the same amounts of the same active ingredients in the same dosage form as other drug products with the same generic or chemical name.

Less Expensive means that the charge to the drug purchaser in the pharmacy where the sale takes place must be less for the interchanged drug product, whether brand name or generic, than the selling price for the prescribed drug product on the day of purchase.

Medical Emergency is a situation which requires immediate drug therapy for a patient in order to alleviate severe pain or avert disability or loss of life.

Pharmacist means any pharmacist registered in the Commonwealth to dispense controlled substances, and including any other person authorized to dispense controlled substances under the supervision of a pharmacist registered in the Commonwealth. Any pharmacist who fills a prescription is responsible for complying with all requirements of M.G.L. c. 112, § 12D, 105 CMR 720.000 *et seq.*, 721.000 *et seq.*, 722.000 *et seq.*, and all subsequent amendments whether or not that pharmacist orders drugs for the pharmacy.

Reasonably Available Drug Product means any interchangeable drug product which appears on the *Massachusetts List of Interchangeable Drugs* as long as that product is sold through interstate commerce and is obtainable by a pharmacist within a time period of 72 hours or less.

722.040: Medical Emergencies

In a medical emergency the pharmacist may fill a prescription marked "no substitution" by dispensing a less expensive interchangeable drug product as allowed by the *Massachusetts List of Interchangeable Drugs* if the particular brand is not in stock; similarly, the pharmacist may fill a prescription not marked "no substitution" in a medical emergency by dispensing the brand name product as written if he has no less expensive interchangeable drug product in stock to be dispensed.

In such instances, the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and the person purchasing the drug product must indicate acceptance of this deviation from the law by legibly writing his or her signature on the prescription. All such prescriptions shall be clearly identifiable and available for review by officials empowered to enforce the laws of the Commonwealth.

722.050: Oral Prescriptions

Upon receiving an oral prescription for a brand name drug product, a pharmacist shall in addition to the information the pharmacist now requests, ascertain whether or not the prescriber wishes "no substitution" to be marked on the prescription and record this information with all other required information on his/her prescription log.

722.060: Generic Prescriptions

Upon receiving a prescription for a generic name drug product with no manufacturer specified by the prescriber, the pharmacist may select, regardless of whether or not the prescriber has marked "no substitution" on the prescription, any legally marketed drug product whether or not it appears in the *Massachusetts List of Interchangeable Drugs*, in accordance with the prescriber's intent and the normal exercise of professional judgement.

722.070: Labeling

(A) When a less expensive generic drug product has been dispensed, the words "interchange" plus the generic name and manufacturer of the product shall appear on the label in the following manner:

"Interchange": (Generic name of less expensive drug product dispensed plus manufacturer)

(B) When a less expensive brand name drug product has been dispensed, the words "interchange" plus either the generic name and manufacturer of the product or the less expensive brand name dispensed shall appear on the label in the following manner:

"Interchange": (generic name of less expensive brand drug product plus manufacturer of brand name of less expensive drug product)

(C) In addition to the above, the brand name of the prescribed drug product may also appear on the label in the following manner:

"Interchange": (Name of less expensive generic drug product plus manufacturer or brand name drug product actually dispensed) *for* (brand name drug product prescribed)

(D) Abbreviations are permissible as long as they are understandable, *e.g.*, "IC" may be used for "Interchange" and manufacturer's names may be abbreviated as shown in the *Massachusetts List of Interchangeable Drugs*.

722.080: Out-Patient Pharmacies

A pharmacist employed by a health care facility as defined in 105 CMR 700.001, other than a hospital, and who provides outpatient pharmacy services must comply with M.G.L. c. 112, § 12D and regulations promulgated thereunder when filling prescriptions. In particular, no prescription shall be accepted as valid by such a pharmacist unless it is on a prescription form approved by the Department pursuant to M.G.L. c. 112, § 12D.

722.090: Hospital Pharmacies

(A) Hospital pharmacies may fill medication orders for hospital inpatients, prescriptions for hospital outpatients and employees, and medication orders or prescriptions for inpatients of a hospital-based skilled nursing facility or a long-term care facility that is solely owned by a hospital that meets the Federal criteria for a sole community hospital contained at 42 CFR § 412.92 and is located on the hospital premises. Patients of such a hospital-based skilled nursing facility or long-term care facility shall be considered hospital patients for the purposes of receiving pharmacy services.

(B) Notwithstanding the provisions of 105 CMR 722.090(A), hospital pharmacies and their satellites or branches may fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14 day supply of the prescribed medication.

(1) Prescriptions for emergency room patients and discharge patients may not be refilled by the hospital pharmacy.

(2) Drug products which are only available from the manufacturer in greater than fourteen day supplies may be dispensed in larger quantities for emergency room and discharge patients. The quantity dispensed, however, may not exceed the smallest quantity supplied by the manufacturer.

(C) Notwithstanding 105 CMR 722.090(B), in the case of rare and unusual drugs which generally are not available in a retail pharmacy, a hospital pharmacist may fill prescriptions for emergency room patients and discharge patients in the amount prescribed by the practitioner. The Department may establish a list of those drugs which may be obtained from a hospital pharmacy under 105 CMR 722.090(B).

(D) In filling prescriptions in accordance with 105 CMR 722.090(A), (B) and (C), no prescription shall be accepted as valid by a pharmacist unless it is on a prescription form approved by the Department pursuant to M.G.L. c. 112, § 12D.

(E) Whenever a practitioner indicates "no substitution" on a prescription form, a hospital pharmacy shall dispense the drug product prescribed by the practitioner. Whenever a practitioner does not indicate "no substitution" on a prescription form, a hospital pharmacy shall dispense a less expensive drug product as listed in the hospital's formulary. A drug listed on the hospital's formulary shall be presumed to be a less expensive drug product. The hospital's formulary is a continually revised compilation of pharmaceuticals to be dispensed in the hospital as determined by the medical staff of the hospital. The hospital formulary shall include only those drugs which have been found to be therapeutically equivalent by the federal Food and Drug Administration.

722.095: Waivers

(A) The Commissioner or the Commissioner's designee may waive any requirement imposed by 105 CMR 722.000 when:

(1) The Commissioner determines that there is an emergency or other situation of critical need that affects public health and safety;

(2) Waiver of a requirement will alleviate the emergency or other situation of critical need;

(3) Waiver of a requirement will not jeopardize the health or safety of patients; and

(4) The emergency is expected to be temporary in nature, except in the case of critical access hospital or other similarly situated facility.

(B) A registrant seeking a waiver must request the waiver in writing and must provide written documentation supporting its request.

(C) A waiver shall be time limited. At the end of the waiver term, the Commissioner may extend the term if it is determined that the requirements of 105 CMR 722.095(A) can still be met.

(D) A waiver may be accompanied by conditions with which the registrant must comply. Failure to comply with the conditions of a waiver may result in immediate termination of the waiver.

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722.100: Severability

The provisions of 105 CMR 722.000 are severable. If any provision shall be declared invalid by any court, such provision shall be null and void and such determination shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 722.000: M.G.L. c. 94, § 6; c. 112, § 12.

NON-TEXT PAGE