

105 CMR 722.000: DISPENSING PROCEDURES FOR CLINIC AND HOSPITAL PHARMACIES

Section

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722.001: Purpose

The purpose of 105 CMR 722.001 is to describe procedures which clinic and hospital pharmacies must follow when dispensing drug products in accordance with M.G.L. c. 94C.

722.020: Definitions

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

Clinic. An entity licensed by the Department of Public Health as a clinic, as defined in M.G.L. c. 111, § 52.

Clinic Employee. Persons currently on payroll or medical staff members of the clinic, system or accountable care organization, and their spouses and dependents living in the same household; clinic volunteers; students working at the clinic, or individuals contracted for employment by the clinic, system or accountable care organization.

Clinic Patient. A person formally registered as a patient who is receiving services or treatment at the clinic.

Clinic Pharmacy. A pharmacy that is not registered as a retail drug business pursuant to M.G.L. c. 112, § 39 and which is maintained and operated by the clinic.

Commissioner. 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. 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. 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.

Hospital. An entity licensed by the Department of Public Health as a hospital, as defined in M.G.L. c. 111, § 52.

Hospital Employees. Persons currently on the payroll or medical staff members of the hospital, system, or accountable care organization and their spouse and dependents living in the same household; volunteers at the hospital, students working at the hospital or individuals contracted for employment by the hospital, system or accountable care organization.

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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. A hospital's central, satellite or branch pharmacy.

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

Hospital-based Skilled Nursing Facility. 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.

Less Expensive. 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.

Pharmacist. 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: *List of Interchangeable Drug Products*, 721.000: *Standards for Prescription Format and Security in Massachusetts* and 722.000, whether or not that pharmacist orders drugs for the pharmacy.

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 14 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.

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(C) Notwithstanding 105 CMR 722.090(B), in the case of drugs which 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) through (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.

722.091: Clinic Pharmacies

(A) A clinic pharmacy may fill medication orders written by clinic practitioners for immediate administration, or prescriptions for current clinic patients and employees in accordance with employee health policies, pursuant to the prescription of a clinic practitioner legally authorized to issue prescriptions.

(B) A clinic may not dispense controlled substances, other than for immediate administration, unless it has pharmacy services listed on its health facility license or is authorized to do so by to M.G.L c. 94C, § 9(e).

722.095: Waivers

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

- (1) compliance would cause undue hardship to the facility;
- (2) the facility is in substantial compliance with the spirit of the requirement;
- (3) the facility's non-compliance does not jeopardize the health or safety of its patients and does not limit the facility's capacity to give adequate care; and
- (4) the facility provides to the Commissioner or his or her designee written documentation supporting its request for a waiver.

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 and c. 112, § 12D.