

CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:14-1 et seq.

Source and Effective Date

R.1999 d.214, effective June 16, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Executive Order No. 66(1978) Expiration Date

Chapter 39, State Board of Pharmacy, expires on June 16, 2004.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was filed and became effective prior to September 1, 1969.

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989. See: 20 N.J.R. 1648(a), 21 N.J.R. 1712(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1994 d.351, effective June 16, 1994. See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b), 26 N.J.R. 3878(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1999 d.214, effective June 16, 1999. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14-1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, supportive personnel and anyone within the jurisdiction of the Board of Pharmacy.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Case Notes

Violations of N.J.A.C. 13:39-8.14(b)2, 10 and 13 found as controlled substances records were improperly kept, misbranded drugs were in pharmacy and drugs were improperly stored, respectively; penalties (also cited as N.J.A.C. 13:39-8.12). *New Jersey State Bd. of Pharmacy v. Yanuzzi*, 4 N.J.A.R. 489 (1981).

13:39-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Address of record" means an address designated by a licensee which is part of the public record and which may be disclosed upon request. "Address of record" may be a licensee's home, business or mailing address, but shall not be a post office box.

"Authorized prescriber" means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

13:39-9.24 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39-7.3 through 7.7.

(c) The space provided for the institutional pharmacy shall be in accord with the size of the facility and the scope and complexity of the pharmaceutical services.

Recodified from 13:39-9.15 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39-9.25 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The registered pharmacist-in-charge shall be responsible for all the medications in the facility, that is, the drugs in the pharmacy service area, drugs in transit, and the drugs in the patient care areas.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the United States Pharmacopoeia/National Formulary.

5. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities must be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. Patient records shall be kept confidential.

Recodified from 13:39-9.16 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a)3, substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge.

13:39-9.26 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions. The equipment shall be sufficient to process drugs required by the facility.

Recodified from 13:39-9.17 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted a reference to biologicals.

13:39-9.27 Institutional decentralized pharmacies

(a) Institutional decentralized pharmacies, that is, "satellite pharmacies", means areas within the health care institution other than the original institutional permit location, where the preparation, dispensing, and compounding of medications are performed. Medication shall not be dispensed without a pharmacist present.

(b) Institutions utilizing or desiring to utilize institutional decentralized pharmacies shall file a remodeling application to the Board to conduct a decentralized pharmacy.

(c) Institutional decentralized pharmacies will be subject to normal Board inspections.

(d) The minimum equipment requirement for an institutional decentralized pharmacy shall be the following:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. Patient profile record system;

3. Properly safeguarded storage place if necessary for Schedule II controlled dangerous substances if not dispersed;

4. A refrigerator if necessary for the exclusive storage of biologicals and other medicinal products requiring refrigeration;

5. Labels; and

6. A sink with hot and cold running water exclusive of restroom facilities shall be easily accessible to institutional decentralized pharmacy personnel.

Recodified from 13:39-9.18 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote (d)1.

SUBCHAPTER 10. (RESERVED)**SUBCHAPTER 11. STERILE ADMIXTURE SERVICES IN RETAIL AND INSTITUTIONAL PHARMACIES****13:39-11.1 Purpose and scope**

This subchapter shall apply to all retail and institutional pharmacies which, on or after June 15, 1998, compound and dispense sterile admixture products.

Amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section.

13:39-11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

“Class 100 air quality conditions” means conditions in which the air particle count is no greater than a total of 100 particles of 0.5 micrometers and larger per cubic foot of air.

“Class 1,000 air quality conditions” means conditions in which the air particle count is no greater than a total of 1,000 particles of 0.5 micrometers and larger per cubic foot of air.

“Class 10,000 air quality conditions” means conditions in which the air particle count is no greater than a total of 10,000 particles of 0.5 micrometers and larger per cubic foot of air.

“Clean room” means an enclosed space in which the concentration of airborne particles is controlled and there are one or more “clean zones.”

“Clean zone” means a defined space in which the concentration of airborne particles is controlled to meet a specified airborne-particulate cleanliness class.

“Controlled environment” means a designated area for sterile product preparation.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).