CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1 and 45:14-47.

Source and Effective Date

R.2010 d.090, effective May 17, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 39, State Board of Pharmacy, expires on May 17, 2017. See: 43 N.J.R. 1203(a).

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was adopted 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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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).

Subchapter 12, Nuclear Pharmacies, was recodified from Subchapter 11 by R.1994 d.476, effective September 19, 1994. See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

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: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Subchapter 10, Automated Medication Systems, was adopted as R.2000 d.28, effective January 18, 2000. See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

Subchapter 3A, Continuing Education, was adopted as R.2003 d.130, effective March 17, 2003. See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Chapter 39, State Board of Pharmacy, was readopted as R.2005 d.25, effective December 10, 2004. See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Subchapter 2, Licensure Requirements, was renamed Requirements for Initial Licensure; Subchapter 2A, Requirements for Reciprocal Licensure, was adopted in part as new rules and recodified in part from Subchapter 3, Licensure by Reciprocity; Subchapter 3, Licensure by Reciprocity, was renamed Registered Pharmacist Requirements; and Subchapter 8, Pharmacy Training Sites, was repealed by R.2009 d.247, effective August 3, 2009. See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Chapter 39, State Board of Pharmacy, was readopted as R.2010 d.090, effective May 17, 2010. As a part of R.2010 d.090, Subchapter 3, Registered Pharmacist Requirements, was renamed Pharmacist Requirements; and Subchapter 6, Registered Pharmacist-in-Charge; Pharmacy Personnel, was renamed Pharmacist-in-Charge; Pharmacy Personnel, effective June 21, 2010. 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 New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all pharmacies; pharmacists; applicants for permits, licensure or registration; interns; externs; pharmacy technicians; 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).
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "pharmacy technicians" for "supportive personnel" preceding "and anyone within the jurisdiction".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Rewrote the section.

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 or registrant. "Address of record" may be a licensee's or registrant's home, business or mailing address, but shall not be a post office box unless the licensee or registrant also provides another address which includes a street, city, state and zip code.

"Board" means the New Jersey State Board of Pharmacy.

"Compounding" means the preparation, mixing, assembling, packaging and labeling of a drug or device as the result of a practitioner's prescription or initiative based on the relationship of the practitioner or patient with the pharmacist in the course of professional practice or for the purpose of, or incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

"Dispense or dispensing" means the procedure entailing the interpretation of a practitioner's prescription or medication order for a drug, biological or device, and, pursuant to that order, the proper selection, measuring, compounding, labeling and packaging in a proper container for the subsequent administration to, or use by, a patient. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medication" means:

1. Articles recognized in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

3. Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and

4. Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

"Immediate personal supervision" means that the pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, the finished label and the accuracy and appropriateness of the actions of pharmacy technicians, interns and externs.

"Legend drug or device" means any drug or device that:

1. Bears, at a minimum, the symbol "Rx only" or words of similar import; and/or

2. Requires a prescription or order by a practitioner.

"Pharmaceutical services" means all services provided by a pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labeling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counseling on the proper and safe use of drugs and medications.

"Pharmacist" means an individual holding an active license to engage in the practice of pharmacy in this State.

"Pharmacy" means a location permitted by the Board to engage in the practice of pharmacy in this State.

"Pharmacy technician" means an individual registered with the Board and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.15. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs and/or devices in the course of professional practice.

"Prescription" means a lawful order of a practitioner for a drug, device or diagnostic agent for a specific patient.

"Professional judgment" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the practitioner.

Amended 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).
Inserted "Address of record"; in "Legend drug or device", rewrote 1; rewrote "Licensed practitioner"; and in "Registered pharmacist" or "pharmacist", substituted a reference to licenses for a reference to certificates, and substituted a reference to the current license renewal period for a reference to the current registration period.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote "Address of record", added "Immediate personal supervision" and "Pharmacy technician", deleted "Direct supervision" and "Supportive personnel".
Amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
In definition "Address of record", inserted "or registrant" twice and inserted "or registrant's"; and in definition "Pharmacy technician", updated the N.J.A.C. reference.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote definition "Prescription".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Deleted definitions "Authorized prescriber", "Licensed practitioner" and " 'Registered pharmacist' or 'pharmacist' "; rewrote definitions "Compounding", "Dispense or dispensing", "Immediate personal supervision" and "Pharmacy technician"; substituted definition "Drug or medication" for definition "Drug or medicine"; added definitions "Pharmacist", "Pharmacy" and "Practitioner"; in paragraph 2 of definition "Legend drug or service" substituted "a practitioner" for "an authorized prescriber"; in definition "Pharmaceutical services", deleted "registered" preceding "pharmacist", and substituted "labeling" for "labelling" and "counseling" for "counselling"; and in definition "Professional judgment", substituted "practitioner" for "prescriber".

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i.	Application for licensure	125.00.
ii.	Verification of licensure	25.00.
iii.	Application for reciprocity	125.00.
iv.	Application for reinstatement	
	(1) Disciplinary suspension	225.00.
	(2) Administrative suspension	225.00.
v.	Initial licensure fee	
	(1) If paid during the first year of a biennial renewal period	140.00.
	(2) If paid during the second year of a biennial renewal period	70.00.
vi.	Biennial license renewal	140.00.
vii.	Replacement biennial license	25.00.
viii.	Inactive license renewal	(To be determined by future rulemaking)
ix.	Late renewal fee	100.00.
x.	Replacement of initial wall license	40.00.
xi.	Continuing education review fee	10.00.
xii.	Continuing education program or course: sponsor review fee	50.00.

2. For in-State pharmacies as follows:

i.	Pharmacy permits	
	(1) Application for permit	275.00.
	(2) Annual permit renewal	175.00.
	(3) Change of ownership/name	275.00.
	(4) Change of location	275.00.
ii.	Replacement of annual permit	25.00.
iii.	Late renewal fee	100.00.
iv.	Verification of permit	25.00.

clear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

13:39-12.4 Minimum requirements for space, equipment, supplies, and library

(a) Each nuclear pharmacy must meet the following requirements for space:

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for non-radioactive drugs;

2. Hot lab and storage area shall be a minimum of 120 square feet; and

3. The compounding and dispensing area shall be a minimum of 300 square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

1. Dose calibrator;

2. Refrigerator;

3. Drawing station;

4. Well scintillation counter;

5. Microscope;

6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;

7. Radiation survey equipment of the appropriate type and calibration to detect quantities of radioactive materials as prescribed in the appropriate radioactive material licenses; and

8. Other equipment deemed necessary for radiopharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

(c) Each nuclear pharmacy shall have on the premises the following, up-to-date reference books:

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. State statutes and rules relating to pharmacy;

3. State and Federal regulations governing the use of applicable radioactive materials; and

4. Text relating to the practice of nuclear pharmacy and radiation safety.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (c), rewrote the introductory paragraph and 1.

13:39-12.5 Quality control

The holder of a nuclear pharmacy permit shall be responsible for the radioactive quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biological and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in humans and other animals, including internal test assessment and authentication of product history.