

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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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

“Board” means the New Jersey State Board of Pharmacy.

“Compounding” means the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber’s prescription or medication order, including, but not limited to prescription compounding, and intravenous admixture preparation.

“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.

“Direct supervision” means that the registered pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing of drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

“Dispense or dispensing” means the procedure entailing the interpretation of an authorized prescriber’s prescription order for a drug or device, and pursuant to that order, the proper selection, measuring, labeling, and packing in a proper container. The act of dispensing shall include all necessary consultation by the pharmacist.

“Drug or medicine” 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.

“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 an authorized prescriber.

“Licensed practitioner” means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, nurse practitioner/clinical nurse specialist or physician assis-

tant, or other health care practitioner licensed or approved to write prescriptions intended for the treatment or prevention of disease, as set forth in N.J.S.A. 45:14-14.

“Pharmaceutical services” means all services provided by a registered pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labelling, 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 counselling on the proper and safe use of drugs and medications.

“Prescription” means any order for drugs and related items as defined in N.J.S.A. 45:14-14.

“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 prescriber.

“Registered pharmacist” or “pharmacist” means a person whose license is in good standing for the current license renewal period.

“Supportive personnel” means those persons who perform pharmaceutical functions under the direct supervision of a registered pharmacist. Interns and externs are specifically excluded from this definition.

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.

13:39-1.3 Fee schedule

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

1. For pharmacists as follows:
 - i. Application for registration \$125.00.
 - ii. Examination: \$50.00 plus the cost of the North American Pharmacist Licensure Examination (NAPLEX).
 - (1) Multistate Jurisprudence Pharmacy Examination (MJPE) 60.00.
 - iii. Reciprocal fee 125.00.
 - iv. Reinstatement of licensure 225.00.
plus application fee.
 - 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. Transfer of grades 125.00.
 - ix. Late renewal fee 100.00.

x.	Replacement wall license	40.00.
xi.	Continuing education review fee	10.00.
xii.	Continuing education program: provider review fee	50.00.
xiii.	Yearly fee for distribution of minutes and agenda	60.00.
2.	For pharmacies as follows:	
i.	Pharmacy permits	
(1)	Application for permit	275.00.
(2)	Annual renewal	175.00.
(3)	Change of ownership	275.00.
(4)	Change of location	275.00.
ii.	Replacement permit certificate	25.00.
iii.	Replacement wall permit	25.00.
iv.	Late renewal fee	100.00.

Amended by R.1993 d.414, effective August 16, 1993.

See: 25 N.J.R. 1666(a), 25 N.J.R. 3839(a).

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)1, rewrote ii, substituted a reference to licensure fees for a reference to registration fees in the introductory paragraph of v, substituted a reference to license renewal for a reference to registration in vi, substituted a reference to biennial licenses for a reference to registration certificates in vii, and substituted a reference to licenses for a reference to certificates in x.

13:39-1.4 Payment of penalties

(a) Any penalties levied by the Board must be paid within 30 calendar days of the receipt of a penalty letter or final order of the Board unless otherwise prescribed by statute or terms of a final order.

(b) Failure to comply with this rule will result in action by the Board according to the provisions of N.J.S.A. 45:1-24.

13:39-1.5 Hearings

(a) Any time the Board seeks to impose a disciplinary sanction upon a licensee, the licensee may request a hearing.

(b) Any hearings held shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

SUBCHAPTER 2. APPLICANT QUALIFICATIONS AND EXAMINATIONS REQUIREMENTS

13:39-2.1 Examinations; grades

(a) The examination for licensure by the Board shall be the North American Pharmacist Licensure Examination (NAPLEX). An applicant shall attain a passing grade of not less than 75. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) The applicant shall also pass the Multistate Jurisprudence Pharmacy Examination (MJPE). A passing grade of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(c) If the applicant should fail either the NAPLEX or the MJPE three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the field examination(s).

Recodified from N.J.A.C. 13:39-2.10 and amended by R.1999 d.214, effective July 19, 1999.

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

Rewrote the section. Former N.J.A.C. 13:39-2.1, Education requirements, recodified to N.J.A.C. 13:39-2.2.

13:39-2.2 Education requirements

(a) An applicant for the NAPLEX and MJPE examinations shall have been duly granted or have fully completed all the requirements for graduation of a minimum five-year pharmacy course leading to a degree of Bachelor of Science in pharmacy or Doctor of Pharmacy given in a school or college of pharmacy accredited by the American Council of Pharmaceutical Education (ACPE).

(b) Before being admitted to the examination, either a transcript of the applicant's record or a certificate by the registrar of the school or college of pharmacy attended must be supplied stating that the applicant has either graduated or has completed all of the requirements for graduation. If the transcript or certificate does not state that the applicant has graduated or has completed all the graduation requirements, the Board may require other forms of proof to be supplied by the applicant.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-2.1 and 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), substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.2, Application to be filed, recodified to N.J.A.C. 13:39-2.3.

13:39-2.3 Application to be filed

An applicant for the NAPLEX and MJPE examinations shall file an application for such examination at least 30-days prior to the date of the examination unless the 30 day requirement is waived by the Board because of extenuating circumstances. The required fees as prescribed in N.J.A.C. 13:39-1.3 shall also be submitted.

Amended by R.1990 d.551, effective November 19, 1990.

See: 22 N.J.R. 2395(b), 22 N.J.R. 3499(b).

Changed filing deadline from 60 to 30 days.

Recodified from N.J.A.C. 13:39-2.2 and amended by R.1999 d.214, effective July 19, 1999.

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

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.3, Birth certificate, repealed.

13:39-2.4 (Reserved)

Recodified from N.J.A.C. 13:39-2.3 and repealed by R.1999 d.214, effective July 19, 1999.

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

N.J.A.C. 13:39-2.3 was "Birth certificate".

Amended by R.1999 d.214, effective July 19, 1999.

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

Substituted a reference to licensure for a reference to registration in the first sentence, and changed N.J.A.C. reference at the end.

13:39-3.11 Foreign graduates

(a) Any pharmacist applicant with a degree from a country where the primary language is other than English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has been certified within two years of applying for licensure in the State by the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy.

(b) Any pharmacist applicant with a degree from a country other than the United States, where the primary language is English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(c) A request for waiver of the FPGEC certificate shall delineate good cause for the waiver request. The Board may, after due consideration and within its own discretion, waive the TOEFL examination and the Test of Spoken English (TSE) examination components of the FPGEC certification process.

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).

Rewrote the section.

13:39-3.12 Physical and mental competence of reciprocal licensees

(a) An applicant for reciprocal licensure shall be physically and mentally able to perform all duties normally required of a registered pharmacist.

(b) The Board, at its discretion, may require proof of the applicant's physical and mental competence to practice pharmacy in this State.

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).

In (a), substituted a reference to licensure for a reference to registration.

13:39-3.13 Preliminary application

A preliminary application obtained from the Board for reciprocal licensure shall be submitted to the National Association of Boards of Pharmacy.

Amended by R.1999 d.214, effective July 19, 1999.

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

Substituted a reference to licensure for a reference to registration.

13:39-3.14 Multistate Jurisprudence Pharmacy Examination: reciprocal licensure

(a) An applicant for reciprocal licensure shall pass the Multistate Jurisprudence Pharmacy Examination. A passing grade of not less than 75 shall be attained. If an applicant fails the examination, he or she will be required to repeat the examination.

(b) If the applicant for reciprocal licensure fails the examination three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the law examination.

Amended by R.1999 d.214, effective July 19, 1999.

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

Rewrote the section.

13:39-3.15 Biennial license renewal

(a) Every registered pharmacist, on or before April 30 of each odd-numbered year, shall renew his or her license through the payment of a license renewal fee as prescribed by N.J.A.C. 13:39-1.3 and the filing of a renewal application.

(b) The renewal application shall list the name, home address, original license number, places and hours of employment, continuing education credits, and other information as requested.

(c) The renewal application shall be signed by the applicant.

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).

In (a), substituted a reference to licenses for a reference to certificates of registration, and substituted a reference to license renewal fees for a reference to registration renewal fees; and in (b), substituted a reference to license numbers for a reference to certificate of registration numbers, and deleted "by the Board" at the end.

13:39-3.16 Duplicate renewal license

If a renewal license is lost or destroyed, a duplicate renewal license may be obtained upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3. Proof of the applicant's identity and proof of loss or destruction of the applicant's renewal license originally issued must be submitted.

Amended by R.1999 d.214, effective July 19, 1999.

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

Substituted references to licenses for references to certificates of registration throughout.

13:39-3.17 Reinstatement in good standing

(a) If a registered pharmacist permits his or her license to lapse for a period of less than five years through a failure to renew his or her license, the license may be brought into good standing through payment as per N.J.A.C. 13:39-1.3(a)iv and vi of the reinstatement fee, the current and lapsed renewal fee(s) and any outstanding penalties and

upon submission of proof of identity and the filing of an application to be obtained from the Board. An applicant for reinstatement shall also submit proof of satisfaction of continuing education requirements as provided in N.J.S.A. 45:14-11.11.

(b) If the license has lapsed for a period of five years or longer, the applicant for such reinstatement must pass the Multistate Jurisprudence Pharmacy Examination. The applicant shall also submit payment as per N.J.A.C. 13:39-1.3(a)1iv and vi of the reinstatement fee and the current renewal fee and proof of identity along with an application to be obtained from the Board. An applicant for reinstatement shall also submit proof of satisfaction of continuing education requirements as provided in N.J.S.A. 45:14-11.11.

(c) Every applicant for reinstatement must submit evidence of satisfactory completion of the continuing education requirements which are 15 credits per year up to a maximum of five years or 75 credits.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote (a) and (b).

13:39-3.18 Registered pharmacist-in-charge

(a) A registered pharmacist shall not assume the responsibilities of a registered pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously.

(b) There shall not be more than one registered pharmacist-in-charge of any one pharmacy or pharmacy department.

(c) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, the incoming registered pharmacist-in-charge shall take an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5.

(d) Whenever a registered pharmacist assumes the duties of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, he or she shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(e) A registered pharmacist-in-charge shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to ensure the fulfilling of the following responsibilities:

1. Employment and supervising personnel in a prescription department or pharmacy department;
2. Maintaining accurate records of all prescription medication received and dispensed;
3. Ensuring that medication dispensed conforms with the prescription received;

4. Maintaining the security of the prescription area and its contents, which includes the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription area while the pharmacist is temporarily absent but within the premises;

5. Ensuring that only pharmacists and interns or externs under direct supervision provide professional consultation with patients and physicians;

6. Ensuring that only pharmacists, interns or externs accept telephone prescriptions and renewal authorizations;

7. Ensuring that all dispensed medication is properly labeled;

8. Ensuring the use of prescription labels naming the registered pharmacist-in-charge;

9. Ensuring the posting of the name of the registered pharmacist-in-charge on the entrance to the pharmacy or pharmacy department in such a way as to be visible to the public;

10. Prohibiting the presence of misbranded, deteriorated or outdated drugs in the active stock in the pharmacy;

11. Operating the prescription area in an orderly and sanitary manner;

12. Ensuring the dispensing of all medication generally prescribed to patients in the trading area of the licensed premises or as required by the speciality for which the pharmacy holds a permit;

13. Notifying the Board in writing within 30 days when his or her duties as registered pharmacist-in-charge terminate at a specific location; and

14. Ensuring compliance with all statutes, rules and regulations governing the practice 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.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (c) through (e), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge.

SUBCHAPTER 4. PHARMACY PERMITS

13:39-4.1 Issuance of permits

All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

13:39-4.2 Display of permits

A permit issued by the Board for the operation of a pharmacy or other licensed establishment shall be conspicuously displayed.