CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1, 45:14-47, 45:14-48a.(4), 45:14-61, and 45:14-62.

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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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by Reciprocity, was renamed Registered Pharmacist Requirements; and Subchapter 8, Pharmacy Training Sites, was repealed by R.2009 d.247, effective August 3, 2009.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.

Subchapter 13, Collaborative Practice, was adopted as new rules by R.2013 d.017, effective February 4, 2013. See: 44 N.J.R. 655(a), 45 N.J.R. 214(b).

Subchapter 11, Compounding in Retail and Institutional Pharmacies for Sterile and/or Non-Sterile Preparations, was renamed Compounding Sterile Preparations in Retail and Institutional Pharmacies; and Subchapter 11A, Compounding Non-Sterile Preparations in Retail and Institutional Pharmacies, was adopted as new rules by R.2013 d.084, effective June 3, 2013. See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).

CHAPTER TABLE OF CONTENTS

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.

5. Only pharmacists and interns or externs under immediate personal supervision provide professional consultation with patients and physicians;

6. Only pharmacists, interns or externs accept telephone prescriptions and only pharmacists, interns or externs, or pharmacy technicians consistent with the requirements of N.J.A.C. 13:39-6.6(b), accept renewal authorizations;

7. No misbranded, deteriorated, adulterated, improperly stored or outdated drugs or any drugs marked "sample" or with any like designation or meaning are dispensed or present in the active stock in the pharmacy;

8. The prescription area is maintained in an orderly and sanitary manner; and

9. The pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with acceptable professional standards and comply with all Federal and State 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 pharmacist-in-charge for references to pharmacist-in-charge.
Amended by R.2004 d.380, effective October 4, 2004.
See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).
In (e), deleted existing 8, recodified former 9 to 14 as 8 to 13.
Recodified from N.J.A.C. 13:39-3.18 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-6.2, Prescription prepared, compounded or dispensed by pharmacy externs or interns, recodified to N.J.A.C. 13:39-6.5.
Amended by R.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
Rewrote (f)4.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Registered pharmacist-in-charge". Deleted "registered" preceding "pharmacist-in-charge" throughout; in (a), substituted "whose license is" for "licensed and"; in (b), the introductory paragraph of (c) and in (e), deleted "registered" preceding "pharmacist"; in the introductory paragraph of (c), inserted ", except as provided in (c)1 below"; added (c)1; in (d) and (e), deleted "or other Board-licensed establishment" following "pharmacy"; rewrote (f)1; and in (f)9, inserted "provide pharmaceutical services in accordance with acceptable professional standards and".
Administrative change.
See: 43 N.J.R. 1204(b).

13:39-6.3 Identification tag

All personnel working in the pharmacy, except personnel engaging in the compounding of sterile preparations consistent with the requirements of N.J.A.C. 13:39-11, shall wear an identification tag, which shall include at least the person's first name, first initial of their last name and job title. The identification tag of any employee in training shall reflect the status of the employee as a trainee.

Repealed by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Section was "Sale of controlled dangerous substances and prescription legend drugs by other than a registered pharmacist in a Board-licensed establishment".
New Rule, R.1998 d.166, effective April 6, 1998.
See: 29 N.J.R. 5051(a), 30 N.J.R. 1297(b).
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section.
Amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
Inserted the final sentence.
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.

13:39-6.4 Meal or restroom breaks

(a) A sole pharmacist on duty may take restroom breaks and 30-minute meal breaks while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

2. The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:

i. The receipt of new written prescriptions; and

ii. The dispensing of prescription medications which have been checked by the pharmacist; and

3. A sign shall be posted in the prescription dispensing area stating "Pharmacist on break, but available for emergencies and counseling."

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-6.4, Direct supervision of dispensing and compounding, repealed.
Amended by R.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
Section was "Meal breaks". In the introductory paragraph of (a), substituted "restroom breaks and" for the first occurrence of "a" and substituted "meal breaks" for "meal break"; in the introductory paragraph of (a)2, inserted "restroom or" and substituted "breaks, provided a pharmacy employee remains present in the pharmacy," for "break"; and in (a)3, substituted "prescription dispensing area" for "pharmacy" and deleted "meal" preceding "break".

13:39-6.5 Prescription handling by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.18, consistent with the requirements of this chapter. On or after April 5, 2011, all steps performed by a pharmacy technician, intern or extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

Recodified from N.J.A.C. 13:39-6.2 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-6.5 Restriction on display of prescription legend drugs and, recodified to N.J.A.C. 13:39-5.12.

Amended by R.2009 d.293, effective October 5, 2009.
See: 41 N.J.R. 1637(a), 41 N.J.R. 3840(a).
Section was "Prescription prepared or compounded by pharmacy externs, interns or pharmacy technicians". Rewrote the section.
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.

13:39-6.6 Pharmacy technician registration and pharmacy technician applicants

(a) A person wishing to be registered with the Board as a pharmacy technician shall:

1. Be 18 years of age or older;

2. Possess a high school diploma or its equivalent;

3. Submit a certification attesting to the fact that he or she is proficient in written and spoken English;

4. Apply to the Board for registration and submit the application fee set forth in N.J.A.C. 13:39-1.3;

5. Submit his or her name, address and fingerprints for purposes of a criminal history background check pursuant to N.J.S.A. 45:1-28 et seq., (P.L. 2002, c. 104) to determine whether criminal history record information exists which may disqualify the applicant from being registered by the Board; and

6. Submit, as part of the application for registration, evidence of good moral character which is an ongoing requirement for registration, and evidence that he or she:

i. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice as a pharmacy technician with reasonable skill and safety. For purposes of this section, the term "presently" means at the time of application or any time within the previous 365 days;

ii. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;

iii. Has not been convicted of violating any law relating to the practice of pharmacy;

iv. Has not been convicted of a crime involving moral turpitude; and

v. Has not had his or her authority to engage in the activity regulated by the Board suspended or revoked as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which determined the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

(b) By March 2, 2008, a pharmacy shall only employ a person registered with the Board as a pharmacy technician pursuant to (a) above, or a pharmacy technician applicant, consistent with (c) below, to perform pharmacy technician functions.

(c) By March 2, 2008, any person who is hired as a pharmacy technician who is not registered with the Board shall be designated a pharmacy technician applicant. A person may only be considered a pharmacy technician applicant one time and only for a maximum of 180 consecutive days. During the first 10 days of employment, the pharmacy technician applicant shall file an application with the Board to begin the pharmacy technician registration process. The applicant shall retain proof of filing the application until he or she receives his or her registration. If at the conclusion of the 180 day period, the pharmacy technician applicant has not completed the pharmacy technician registration process, consistent with (a) above, the applicant shall cease performing pharmacy technician functions in the pharmacy.

(d) All persons who are employed as pharmacy technicians on September 4, 2007 shall be registered with the Board by March 2, 2008. Such persons shall satisfy the requirements set forth in (a) above, except that such persons shall be exempt from satisfying the requirement established in (a)2 above. Such persons shall present proof of employment to the Board which establishes that they have been practicing as pharmacy technicians prior to September 4, 2007.

(e) If an applicant for registration as a pharmacy technician is being investigated for any alleged violation of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., or the pharmacy laws, rules or regulations of any other jurisdiction, the Board in its discretion may deny the applicant the opportunity to register as a pharmacy technician.

(f) A pharmacy shall not employ as a pharmacy technician applicant any person who was previously employed as a pharmacy technician applicant at a pharmacy in the State and who failed to complete the pharmacy technician registration process or any person who has been the subject of disciplinary action by the Board.

New Rule, R.2007 d.238, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
Former N.J.A.C. 13:39-6.6, Pharmacy technicians, recodified to N.J.A.C. 13:39-6.15.
Public Notice: Board of Pharmacy: Extension of Deadline for Registration as a Pharmacy Technician.
See: 40 N.J.R. 900(a), 7005(a).
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (e), updated the N.J.S.A. reference.

13:39-6.7 Authorization to practice as a pharmacy technician; display of registration

(a) An applicant for registration as a pharmacy technician who has successfully satisfied all Board requirements for registration and has been approved by the Board to be registered shall, upon payment of the initial registration fee set forth in N.J.A.C. 13:39-1.3, receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice as a pharmacy technician in the State of New Jersey until such time as an initial registration may be issued. The registrant shall maintain such authorization on his or her person at all times while engaging in the practice of pharmacy as a pharmacy technician until the initial registration is issued.

(b) Upon issuance, the current biennial renewal registration shall be conspicuously displayed in the registered pharmacy technician's principal place of employment.

(c) A registered pharmacy technician who is employed by more than one pharmacy in the State shall maintain the wallet-sized registration issued by the Board on his or her person when he or she is working at a location where his or her current biennial renewal registration is not on display.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (c), deleted "licensed" preceding the second occurrence of "pharmacy".

13:39-6.8 Replacement of technician registration

A replacement initial registration or renewal registration shall be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the initial registration or renewal registration, or upon return of the damaged initial registration or renewal registration to the Board.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.9 Technician change of name

If a registered pharmacy technician legally changes the name under which he or she has been practicing as a pharmacy technician, the pharmacy technician shall notify the Board within 30 days of such change. The registered pharmacy technician shall submit original proof of the change of name or a certified copy of the court order or marriage certificate which shall be retained by the Board. When a replacement registration is issued, the initial registration shall be returned for cancellation and the pharmacy technician shall remit the required fee as prescribed in N.J.A.C. 13:39-1.3.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.10 Technician change of address of record; service of process

(a) A registered pharmacy technician shall notify the Board in writing of any change in his or her address of record within 30 days of such change.

(b) Failure to notify the Board of any change in a registered pharmacy technician's address of record pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1-21(h) and N.J.A.C. 13:45C-1.3, and the imposition of penalties set forth in N.J.S.A. 45:1-25.

(c) Service of any administrative complaint or other Board-initiated process at a registered pharmacy technician's address of record shall be deemed adequate notice for the purposes of N.J.A.C. 1:1-7.1 and the commencement of any disciplinary proceedings.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.11 Verification of technician registration

A verification that the registration of a pharmacy technician is in good standing shall be supplied by the Board upon written request and upon payment of the fee set forth in N.J.A.C. 13:39-1.3.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.12 Reproduction of technician registration prohibited

The initial registration, biennial registration or wallet-sized registration issued by the Board to any pharmacy technician shall not be reprinted, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, except as provided in N.J.A.C. 13:39-6.8.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.13 Biennial technician registration renewal; administrative suspension

(a) A pharmacy technician shall renew his or her registration for a period of two years from the last expiration date. The pharmacy technician shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:39-1.3, prior to the date of registration expiration. A pharmacy technician who submits a renewal application within 30 days following the date of registration expiration shall submit the renewal fee, as well as the late fee set forth in N.J.A.C. 13:39-1.3. A pharmacy technician who fails to submit a renewal application within 30 days of registration expiration shall have his or her registration suspended without a hearing. Such suspension shall be deemed an administrative suspension.

(b) A pharmacy technician who continues to perform the functions of a pharmacy technician with a suspended registration shall be deemed to be engaging in unauthorized practice as a pharmacy technician and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(c) The Board shall send a notice of renewal to each pharmacy technician, at least 60 days prior to the expiration of his or her registration. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalty or fines shall apply to the pharmacy technician for any unauthorized practice during the period following the registration expiration, not to exceed the number of days short of 60 before the renewal was issued.

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.14 Reinstatement from administrative and disciplinary suspensions of a pharmacy technician's registration

(a) A pharmacy technician who has had his or her registration administratively suspended pursuant to N.J.A.C. 13:39-6.13 may apply to the Board for reinstatement following the date of registration expiration. A pharmacy technician applying for reinstatement shall submit:

1. A reinstatement application, including an affidavit of employment listing each job held during the period of registration suspension, including the names, addresses, and telephone numbers of each employer;

2. All past due renewal fees set forth in N.J.A.C. 13:39-1.3;

3. A reinstatement fee set forth in N.J.A.C. 13:39-1.3; and

4. Any outstanding penalties imposed by the Board.

(b) A pharmacy technician who has had his or her registration suspended pursuant to disciplinary action taken by the Board may apply to the Board for reinstatement of his or her registration at the conclusion of the suspension period. A pharmacy technician applying for reinstatement from a disciplinary suspension shall submit:

1. A renewal application, including an affidavit of employment listing each job held during the period of registration suspension, including the names, addresses, and telephone numbers of each employer;

2. A reinstatement fee set forth in N.J.A.C. 13:39-1.3;

3. The applicable renewal fee(s) set forth in N.J.A.C. 13:39-1.3; and

4. Evidence of having met all conditions imposed by the Board pursuant to the disciplinary and/or reinstatement order(s).

New Rule, R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

13:39-6.15 Pharmacy technician duties and pharmacist-technician ratios

(a) In addition to externs and interns, only pharmacy technicians and pharmacy technician applicants may assist the pharmacist in performing the following tasks:

1. Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

2. Data entry;

3. Label preparation;

4. The counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system; and

5. Accepting authorization from a patient for a prescription refill, or from a practitioner or his or her agent for a prescription renewal, provided that the prescription remains unchanged, consistent with (a)5i below:

i. The pharmacy technician or pharmacy technician applicant shall identify himself or herself as a pharmacy technician when accepting authorization from a practitioner or his or her agent. For purposes of this section, "prescription refill" means the dispensing of medications pursuant to a practitioner's authorization provided on the original prescription. For purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refills remaining.

(b) Pharmacy technicians and pharmacy technician applicants shall not:

1. Receive new verbal prescriptions;

2. Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

3. Verify dosage and directions;

4. Engage in prospective drug review;

5. Provide patient counseling;

6. Monitor prescription usage;

7. Override computer alerts without first notifying the pharmacist;

8. Transfer prescriptions from one pharmacy to another pharmacy; or

9. Violate patient confidentiality.

(c) A pharmacy shall require all pharmacy technicians and pharmacy technician applicants employed by the pharmacy to sign a patient confidentiality statement. Such statements shall be maintained on-site by the pharmacy.

(d) Except as provided in (e) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. The pharmacist shall provide immediate personal supervision, as defined in N.J.A.C. 13:39-1.2, of all pharmacy technicians he or she supervises. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio. A registered pharmacy technician or a pharmacy technician applicant who is receiving in-service training, which shall not exceed 210 days, shall be excluded from the 1 to 2 ratio during such training. A pharmacist shall not supervise more than two persons receiving in-service training at the same time.

(e) A pharmacy that employs a pharmacist to pharmacy technician ratio greater than 1:2 shall:

1. Establish written job descriptions, task protocols, and policies and procedures that pertain to the duties performed by the pharmacy technicians;

2. Ensure and document that all pharmacy technicians who are working when the ratio exceeds 1:2 have:

i. Passed the Pharmacy Technician Certification Board's Pharmacy Technician Certification Examination and have fulfilled the requirements to maintain this status;

ii. Passed a Board-approved certification program and have fulfilled the requirements to maintain this status; or

iii. Completed a program that includes a testing component, which has been approved by the Board as satisfying the criteria set forth in (f) below. Completion of a program with a Board-approved testing component shall qualify the pharmacy technician to work only for the specific pharmacy and/or corporation for which the pharmacy technician was employed when the training was obtained. If the pharmacy technician becomes employed by another pharmacy and/or corporation, the pharmacy technician shall be required to complete the new employer's training program;

3. Ensure that all pharmacy technicians are knowledgeable in the established job descriptions, task protocols, and policies and procedures in the pharmacy setting in which the technicians are to perform their duties;

4. Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols and policies and procedures, nor involve any of the prohibited tasks in (b) above;

5. Ensure that all pharmacy technicians receive in-service training before the pharmacy technicians assume their responsibilities and maintain documentation thereof. A registered pharmacy technician or a pharmacy technician applicant who is receiving in-service training, which shall not exceed 210 days, shall be excluded from the 1 to 2 ratio during such training. A pharmacist shall not supervise more than two persons receiving in-service training at the same time;

6. Provide immediate personal supervision as defined in N.J.A.C. 13:39-1.2; and

7. Provide the Board, upon request, with a copy of the established job descriptions, task protocols, and policies and procedures for all pharmacy technician duties.

(f) If the pharmacist to pharmacy technician ratio exceeds 1:2, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians, which shall include the following:

1. Supervision by a pharmacist;

2. Confidentiality safeguards of patient information;

3. Minimum qualifications;

4. Documentation of in-service education and or ongoing training and demonstration of competency, specific to practice site and job function;

5. General duties and responsibilities of pharmacy technicians;

6. Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

7. All functions related to prescription processing;

8. All functions related to prescription legend drug and controlled substance ordering and inventory control;

9. Prescription refill and renewal authorization;

10. Procedures dealing with documentation and records required for controlled drug substance and prescription legend drugs;

11. Procedures dealing with medication errors, including classification of medication errors;

12. Pharmacy technician functions related to automated systems;

13. Functions that may not be performed by pharmacy technicians, including at a minimum those functions listed in (b) above; and

14. A form signed by the pharmacy technician which verifies that the manual has been reviewed by the technician.

(g) The pharmacist-in-charge shall review at least every two years and, if necessary, amend the policy and procedure manual. Documentation of the review shall be made available to the Board upon request.

(h) When pharmacy technicians and pharmacy technician applicants are engaged in any permitted activities, the pharmacist(s) shall be responsible for all the activities of the pharmacy technicians and the pharmacy technician applicants.

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.1997 d.502, effective December 1, 1997.
See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).
Added (d) through (f).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (f), substituted a reference to supervising registered pharmacists for a reference to a registered pharmacists-in-charge.
Recodified from N.J.A.C. 13:39-6.7 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-6.6, Foreign prescriptions, repealed.
Recodified from N.J.A.C. 13:39-6.6 and amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
Section was "Pharmacy technicians". Rewrote the introductory paragraph of (a); in (b), inserted "and pharmacy technician applicants" and inserted the second sentence; in the introductory paragraph of (c), inserted "and pharmacy technician applicants"; added new (d); recodified former (d) through (g) as (e) through (h); rewrote (e) and (f); deleted former (h); and in (i), inserted "and pharmacy technician applicants" and "and the pharmacy technician applicants".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (a), deleted "registered" preceding "pharmacist"; in (a)3, deleted "and" from the end; in (a)4, substituted "; and" for a period at the end; recodified the first sentence of former (b) as (a)5; in (b)5, substituted "Accepting" for "Pharmacy technicians and pharmacy technician applicants may accept", "practitioner" for "physician" and ", consistent with (a)5i below:" for a period at the end; recodified the second through fourth sentences of former (b) as (a)5i; in (a)5i, substituted "practitioner" for "physician" and "practitioner's" for " prescriber's"; recodified (c) through (i) as (b) through (h); in (d), substituted "(e)" for "(f)"; in the introductory paragraph of (e), deleted "registered" preceding "pharmacist"; in (e)2iii, substituted "that" for the first occurrence of "which" and "(f)" for "(g)" and inserted a comma following "component"; in (e)4 and (f)13, substituted "(b)" for "(c)"; in (e)4, deleted a comma following "protocols"; in (f), inserted a comma following "technicians"; in (g), substituted "pharmacist-in-charge" for "pharmacist in charge"; and in (h), deleted "registered" preceding "pharmacist(s)".

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.1 Valid prescriptions

(a) A pharmacist shall only fill a prescription issued by a practitioner licensed to issue prescriptions in New Jersey and practicing in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14-55 and N.J.A.C. 13:45A-27, except as provided in N.J.A.C. 13:39-7.10 and 7.11.

(b) A pharmacist shall fill a prescription issued by a practitioner authorized to issue prescriptions in another state, territory or possession of the United States, including prescriptions issued at facilities within or outside of New Jersey that are regulated by the United States Department of Veterans Affairs and/or the Department of Defense. Such prescriptions shall be filled pursuant to New Jersey law. Such prescriptions shall not be required to be issued on a New Jersey Uniform Prescription Blank.

(c) Prescriptions, other than those listed in (a) and (b) above, shall not be filled by a pharmacy in New Jersey.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-7.1, Retail pharmacy access and egress, recodified to N.J.A.C. 13:39-5.2.
Amended by R.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
In (a), deleted "written" preceding the first occurrence of "prescription" and inserted "by a practitioner licensed to write prescriptions" and "and practicing in New Jersey"; and rewrote (b).
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Valid prescriptions; out-of-State prescriptions". In (a), substituted "issue" for "write" and updated the N.J.S.A. reference; and in (b), substituted "practitioner authorized to issue" for "prescriber licensed to write".

13:39-7.2 Lack of information on original prescription

(a) If a practitioner fails to include on the original prescription any information that he or she is required to include pursuant to rules governing the practitioner's professional practice, including New Jersey Uniform Prescription Blanks rules set forth at N.J.A.C. 13:45A-27, the pharmacist shall obtain such information.

1. If the practitioner has failed to include directions for use and the practitioner cannot be contacted, the pharmacist shall indicate on the prescription label the words "use as directed" or "as ordered by the physician" or similar words to the same effect.

(b) All information required for a valid prescription shall be recorded on the prescription, or in the patient profile record system maintained pursuant to N.J.A.C. 13:39-7.19, or in the pharmacy's other manual or electronic files.

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).
Recodified from N.J.A.C. 13:39-5.2 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Undesignated (a) and deleted (b). Former N.J.A.C. 13:39-7.2, Retail pharmacy signs, recodified to N.J.A.C. 13:39-5.3.
Repeal and New Rule, R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Lack of directions on original prescription".

13:39-7.3 Authorization for renewal of prescriptions; new prescriptions

(a) A prescription for medication or devices, which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the practitioner or the practitioner's authorized agent, and the prescription may not be filled or refilled after one year from the date the original prescription was issued. A pharmacist obtaining authorization from a practitioner's authorized agent shall document the name and title of the agent.

1. Prescriptions marked "PRN" or other letters or words meaning refill as needed shall not be renewed

beyond one year past the date the original prescription was issued.

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the practitioner.

(c) Prescription information obtained from a practitioner shall be documented at the time of receipt as a new prescription in hard copy form or by direct entry into the electronic prescription records system.

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. 13:39-5.3 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-7.3, Spatial requirement of a retail pharmacy prescription area, recodified to N.J.A.C. 13:39-5.4.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Authorization for renewal of prescriptions". In the introductory paragraph of (a) and in (a)1, substituted "the" for "of" preceding "original" and inserted "was issued" ; in the introductory paragraph of (a), inserted a comma following "devices", inserted "filled or", inserted the last sentence, and substituted "practitioner or the practitioner's authorized agent" for "prescriber"; rewrote (b) and added (c).

13:39-7.4 Emergency dispensing

(a) Except as provided in (b) below, in the absence of a current, valid prescription, a pharmacist may dispense an emergency supply (no more than a 72-hour quantity) of a chronic maintenance drug or device if, in his or her professional judgment, refusal would endanger the health or welfare of the patient, provided the following conditions are satisfied:

1. The pharmacist first ascertains to the best of his or her ability, by direct communication with the patient or caregiver, that such a medication or device was prescribed for that patient by order of a practitioner. The pharmacist shall require the patient or caregiver to provide suitable identification. Such communication shall be documented in the patient profile record system maintained pursuant to N.J.A.C. 13:39-7.19 or in the pharmacy's other manual or electronic files; and

2. The pharmacist documents the dispensing of the emergency supply in the prescription record system.

(b) A pharmacist may dispense an emergency supply of a Schedule II controlled dangerous substance in the absence of a current, valid prescription upon receipt of oral authorization from a practitioner as provided under Federal law pursuant to 21 CFR 1306.11, consistent with the requirements of N.J.A.C. 13:45H-7.8.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-7.4, Prescription counter, recodified to N.J.A.C. 13:39-5.5.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (a), substituted "Except as provided in (b) below, in" for "In" and deleted "(except controlled dangerous substances)" following "drug"; in (a)1, substituted "practitioner" for "licensed practitioner; and" and inserted the second and third sentences; rewrote (a)2; and added (b).
Administrative change.
See: 43 N.J.R. 1204(b).

13:39-7.5 Approval of FDA necessary

(a) No drug or medicine other than a compounded prescription order shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration approval, where required.

(b) The storage, labeling and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy participating in experimental research shall comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46, Protection of Human Subjects of Research, incorporated by reference herein, as amended and supplemented and with the New Jersey Department of Health and Senior Services' Policy on the Protection of Human Research Subjects, incorporated by reference herein, as amended and supplemented, and which is available at http://www.state.nj.us/health/irb/policies.shtml.

Recodified from N.J.A.C. 13:39-5.4 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (a) and added (b). Former N.J.A.C. 13:39-7.5, Prescription area sink, recodified to N.J.A.C. 13:39-5.6.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Rewrote (b).

13:39-7.6 Required records and documents

(a) On or after April 5, 2011, a pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of each step of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each component function(s) is performed.

(b) Computer systems employed for audit trail documentation shall be designed to identify and document the unique and secure identifier for all pharmacists, pharmacy technicians, interns and externs who utilize the system. Computer systems that automatically generate the unique and secure user identifier of a pharmacist, pharmacy technician, intern or extern without requiring an entry by the responsible party are prohibited.

(c) Appropriate documentation identifying the unique and secure user identifier of all pharmacists, pharmacy technicians, interns and externs employed by the pharmacy shall be maintained by the pharmacy for a period of not less than five years after the last date of employment. If a pharmacy utilizes a manual system, appropriate documentation identifying the handwritten initials with the handwritten signature and printed name of all pharmacists, pharmacy technicians, interns and externs employed by the pharmacy shall be maintained for a period of not less than five years after the last date of employment. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure.

(d) All audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(e) Notwithstanding the requirements of (d) above, a pharmacy shall maintain prescription records for controlled dangerous substances as required by Federal law consistent with the provisions of 21 CFR 1304.04.

Amended by R.1991 d.355, effective July 15, 1991.
See: 22 N.J.R. 1866(b), 23 N.J.R. 2161(a).
Added new (d) through (f).
Redesignated existing (d)-(g) as (g)-(j).
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. 13:39-5.6 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-7.6, Storage and adequate stock, recodified to N.J.A.C. 13:39-5.7.
Amended by R.2009 d.293, effective October 5, 2009.
See: 41 N.J.R. 1637(a), 41 N.J.R. 3840(a).
Section was "Record of pharmacist filling prescription". Rewrote the section.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Added (e).

13:39-7.7 Copies of prescriptions and/or patient profile

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions and/or patient profile. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY."

(b) Presentation of a prescription marked "COPY—FOR INFORMATION ONLY" or a labeled prescription container shall be for information purposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last dispensing pharmacy to transfer the prescription pursuant to N.J.A.C. 13:39-7.8.

Amended by R.1997 d.502, effective December 1, 1997.
See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).
In (c), added "or electronic transfer"; and in (d), added the second sentence.
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), added the last sentence; and added (e).
Recodified from N.J.A.C. 13:39-5.5 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-7.7, Minimum equipment and facilities, recodified to N.J.A.C. 13:39-5.8.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Copies of prescriptions". In (a), inserted "and/or patient profile"; and in (b), inserted "prescription marked 'COPY—FOR INFORMATION ONLY' or a" and deleted "or a prescription marked 'COPY—FOR INFORMATION ONLY'" following the first occurrence of "container".

13:39-7.8 Transfer of prescriptions between pharmacies

(a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy shall immediately comply with the patient's request.

(b) Except as provided in (c) and (d) below, a prescription may be transferred between pharmacies, consistent with this section, for one year from the date the prescription was written, provided refills of the prescription are available.

(c) A prescription for a Schedule II controlled substances may not be transferred.

(d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies pursuant to N.J.A.C. 13:45H-7.14(h) and 7.18(d). A prescription for a Schedule III, IV or V controlled substance that has been transferred shall not be transferred a second time. This prohibition shall not apply to the transfer of such prescriptions between pharmacies engaged in central prescription handling pursuant to N.J.A.C. 13:39-4.18(e) and to pharmacies that

13:39-9.17 Drug-dispensing devices

(a) Where the use of a drug-dispensing device is approved as an integral part of the drug distribution system by the facility, the pharmacist-in-charge and the Pharmacy and Therapeutics Committee, the device may be used when the pharmacist is not on duty (absent during either the day or night), provided that any absence of the pharmacist does not exceed 24 hours, or when the pharmacist is on duty, provided that proper review of the use of the drug-dispensing device can be ascertained. The supervision of any drug dispensing device so utilized shall be the responsibility of the pharmacist-in-charge servicing the health care facility. The drug-dispensing device data shall be checked for accuracy every 24 hours by a pharmacist and so documented.

(b) Packaging and labeling of medication for drug-dispensing devices, when done by the pharmacy, shall be performed under the immediate personal supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed health care professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, practitioners, pharmacy technicians, interns and externs shall have access to the medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f) All medications withdrawn from a drug dispensing device require a medication order by an authorized practitioner. All such medication orders shall be checked by the pharmacist within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

(g) When there is no pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the pharmacist-in-charge who is responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

Recodified from 13:39-9.6 and 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.
Recodified from N.J.A.C. 13:39-9.14 and 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 "immediate personal" for "direct" preceding "supervisor of a pharmacist"; in (c) and (d), deleted "direct" preceding "supervision of a pharmacist"; in (e), substituted "technicians, interns and externs" for "supportive personnel" following "authorized prescribers or designated pharmacy"; deleted (h). Former N.J.A.C. 13:39-9.17, Drug information and education, recodified to N.J.A.C. 13:39-9.20.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), (e) and (g), deleted "registered" preceding "pharmacist-in-charge" throughout; in (b), substituted "by the pharmacy" for "in the facility"; in (c), inserted "health care" and substituted "practitioners," for "physicians, authorized prescribers or designated"; in (f), substituted "practitioner" for "prescriber"; and in (g), deleted "licensed" preceding "pharmacy".

13:39-9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, lot or control number, or expiration or use by date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2. If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed.

3. Any and all medication returned by out-patients of the facility shall not be redispensed.

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and co-signed and witnessed by a licensed nurse, physician or pharmacist, or where allowed by Department of Health and Senior Services rules an administrator of the health care facility, and disposed of by the health care facility according to its written protocol and consistent with all local, State and Federal laws and regulations.

Recodified from 13:39-9.6 and 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 registered pharmacists-in-charge for a reference to pharmacists-in-charge in the introductory paragraph, and rewrote 1 and 4.
Recodified from N.J.A.C. 13:39-9.15 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), inserted "lot or" following "drug source" and inserted "or use by" following "expiration" in 1 and rewrote 4. Former N.J.A.C. 13:39-9.18, After hours access to the institutional pharmacy, recodified to N.J.A.C. 13:39-9.21.

Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (a), deleted "registered" preceding "pharmacist-in-charge".

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the pharmacist-in-charge. On or after April 5, 2011, a pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in an audit trail. Audit trail documentation shall be generated at the time the component function(s) is performed. All audit trail and medication order information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) The pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39-7.19 and as follows:

1. The profile records for inpatients shall contain: the date of each entry; the name; sex; age or birthdate; location of the patient; the drug name, dose, route of administration and quantity dispensed; the reported diagnosis, allergies and chronic condition(s) of the patient.

2. All notations made on the inpatients' profile records by pharmacy technicians, interns and externs shall be verified and countersigned, either manually or electronically, by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored for five years following patient discharge. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall conform to the requirements set forth in N.J.A.C. 13:39-7.6.

(d) Records for receipt, use and final disposition of controlled dangerous substances shall be maintained by the institutional pharmacy in compliance with the requirements of Federal and State controlled dangerous substances laws and regulations. Nursing administration and audit records for controlled dangerous substances shall be available for review by the pharmacy.

(e) Records of the receipt, dispensing and disposal of investigational drugs shall be maintained by the institutional pharmacy in compliance with Federal and State laws and regulations.

(f) The pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee, where applicable, and are submitted to all appropriate State and local agencies consistent with State and local laws and regulations.

Recodified from 13:39-9.7 and 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) and (f), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; in (a), substituted a reference to statutes and regulations for a reference to laws; and in (f), deleted a former second sentence.
Recodified from N.J.A.C. 13:39-9.16 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (a), (b), (f). Former N.J.A.C. 13:39-9.19, Advisory committees, recodified to N.J.A.C. 13:39-9.5.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (a) and (c); in (b)1, deleted "the initials of the pharmacist performing the dispensing or supervising;" preceding "the reported", and inserted a comma following "diagnosis"; and in (b)3, deleted "immediately" preceding the last occurrence of "retrievable", and inserted "within one business day".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a) and (f), deleted "registered" preceding "pharmacist-in-charge".

13:39-9.20 Drug information and education

(a) The pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39-5.8.

(b) On each patient care unit, the pharmacist shall maintain the following:

"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, and the finished label.

"Internal test assessment" includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

"Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

"Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear 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).
Deleted "Direct supervision"; added "Immediate personal supervision".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In definition "Immediate personal supervision", deleted "registered" preceding the first occurrence of "pharmacist".

13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the immediate personal supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business. On or after April 5, 2011, nuclear pharmacies shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the radiopharmaceutical services, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in performing radiopharmaceutical services pursuant to this subchapter, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of the services performed shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each service is performed. Such documentation shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal United States Nuclear Regulatory Commission or its successor's requirements and the requirements established by the State of New Jersey Bureau of Radiation Protection. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy dispensing radioactive drugs may be exempted from the general space requirements for pharmacies.

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. The environment where the handling of radioactive materials takes place shall be properly ventilated so that

radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;

2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas; and

3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) The immediate outer container of a radioactive drug to be dispensed shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The radionuclide;

4. The chemical form;

5. The amount of radioactive material contained in millicuries or microcuries;

6. If a liquid, the volume in milliliters;

7. The requested calibration time for the radioactivity contained;

8. The name, address, and telephone number of the nuclear pharmacy;

9. The prescription number; and

10. The date and patient's name, if available.

(f) The immediate container shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The name of the radiopharmaceutical.

(g) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(h) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission or its successor. A nuclear pharmacy may furnish radiopharmaceuticals to these practitioners for patient use.

(i) Nuclear pharmacies shall comply with all applicable laws and regulations of Federal and State agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive rules pertaining to pharmacy permits for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(j) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(k) Prescription orders for delivery of radioactive drugs for use in the medical practice of a United States Nuclear Regulatory Commission licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(*l*) A qualified nuclear pharmacist shall have the authority to delegate to any qualified and properly trained person or persons, acting under his or her immediate personal supervision, any nuclear pharmacy act which a reasonable and prudent pharmacist would find is within the scope of sound pharmaceutical judgment to delegate. Such delegation may only occur if, in the professional opinion of the qualified nuclear pharmacist, the act may be properly and safely performed by the person to whom the pharmacy act is delegated. The delegated act may only be performed in its customary manner, not in violation of other statutes. The person to whom a nuclear pharmacy act is delegated shall not hold himself or herself out to the public as being authorized to practice pharmacy.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a) and (*l*), substituted "immediate personal" for "direct".
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (a).

13:39-12.3 General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall meet the following requirements:

1. He or she is a pharmacist licensed to practice in the State of New Jersey; and

2. He or she meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nu-