

CHAPTER 39

STATE BOARD OF PHARMACY

Authority

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

Source and Effective Date

R.2005 d.25, effective December 10, 2004
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Chapter Expiration Date

Chapter 39, State Board of Pharmacy, expires on December 10, 2009.

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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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

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: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. GENERAL PROVISIONS

- 13:39-1.1 Purpose and scope
- 13:39-1.2 Definitions
- 13:39-1.3 Fee schedule
- 13:39-1.4 Payment of penalties
- 13:39-1.5 Opportunity to be heard

SUBCHAPTER 2. LICENSURE REQUIREMENTS

- 13:39-2.1 Examinations; score
- 13:39-2.2 Education requirements
- 13:39-2.3 Application for examinations
- 13:39-2.4 Age requirement
- 13:39-2.5 Proof of character
- 13:39-2.6 Criminal history background check
- 13:39-2.7 Proof of identity of applicant
- 13:39-2.8 Alleged violations of Pharmacy Act
- 13:39-2.9 Applicants educated in a foreign country
- 13:39-2.10 Authorization to practice; display of license
- 13:39-2.11 Replacement license
- 13:39-2.12 Change of name
- 13:39-2.13 Change of address of record; service of process
- 13:39-2.14 Verification of licensure
- 13:39-2.15 Reproduction of initial license prohibited
- 13:39-2.16 Biennial license renewal; administrative suspension
- 13:39-2.17 Reinstatement from administrative and disciplinary license suspensions
- 13:39-2.18 Inactive licensure
- 13:39-2.19 Steering prohibited
- 13:39-2.20 Responsibilities of pharmacists

SUBCHAPTER 3. LICENSURE BY RECIPROCITY

- 13:39-3.1 Limitation of reciprocal licensure
- 13:39-3.2 Requirements for reciprocal licensure of pharmacist currently licensed in another jurisdiction
- 13:39-3.3 Proof of character
- 13:39-3.4 Proof of identity of applicant
- 13:39-3.5 Alleged violations of the Pharmacy Act
- 13:39-3.6 Criminal history background check
- 13:39-3.7 Multistate Jurisprudence Pharmacy Examination

SUBCHAPTER 3A. CONTINUING EDUCATION

- 13:39-3A.1 Continuing education credit hour requirements
- 13:39-3A.2 Criteria for continuing education credit
- 13:39-3A.3 Continuing education credit hour calculations
- 13:39-3A.4 Continuing education credit hour reporting procedure
- 13:39-3A.5 Waiver of continuing education requirements
- 13:39-3A.6 Responsibilities of continuing education sponsors
- 13:39-3A.7 Monitoring of continuing education programs or courses

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

- 13:39-4.1 New pharmacies; eligibility and application
- 13:39-4.2 Issuance of permits
- 13:39-4.3 Display of permits
- 13:39-4.4 Death of owner or partner
- 13:39-4.5 Change of ownership
- 13:39-4.6 Change of corporate officers or stockholders of a publicly traded corporation
- 13:39-4.7 Change of location; remodeling of premises
- 13:39-4.8 Discontinued pharmacies
- 13:39-4.9 Availability of records upon termination of business
- 13:39-4.10 Business hours; unauthorized closing
- 13:39-4.11 Replacement permit
- 13:39-4.12 Change of name
- 13:39-4.13 Reproduction of permits
- 13:39-4.14 Permitting of pharmacy department
- 13:39-4.15 Permits; specialized permits
- 13:39-4.16 Steering prohibited
- 13:39-4.17 Responsibilities of permit holders
- 13:39-4.18 Procedures for centralized prescription handling

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

- 13:39-5.1 Purpose and scope
- 13:39-5.2 Pharmacy access and egress
- 13:39-5.3 Pharmacy signs
- 13:39-5.4 Spatial requirement of pharmacy prescription area
- 13:39-5.5 Prescription counter
- 13:39-5.6 Prescription area sink
- 13:39-5.7 Storage and adequate stock
- 13:39-5.8 Minimum equipment and facilities
- 13:39-5.9 Cleanliness, orderliness and sanitation
- 13:39-5.10 Television in prescription area prohibited
- 13:39-5.11 Prescription balances, scales, weights and automatic counting devices
- 13:39-5.12 Restriction on storage of prescription legend drugs and controlled dangerous substances

SUBCHAPTER 6. REGISTERED PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

- 13:39-6.1 Purpose and scope
- 13:39-6.2 Registered pharmacist-in-charge
- 13:39-6.3 Identification tag
- 13:39-6.4 Meal breaks
- 13:39-6.5 Prescription prepared or compounded by pharmacy externs, interns or pharmacy technicians
- 13:39-6.6 Pharmacy technicians

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

- 13:39-7.1 Valid prescriptions; out-of-State prescriptions
- 13:39-7.2 Lack of directions on original prescription
- 13:39-7.3 Authorization for renewal of prescriptions
- 13:39-7.4 Emergency dispensing
- 13:39-7.5 Approval of FDA necessary
- 13:39-7.6 Record of pharmacist filling prescription
- 13:39-7.7 Copies of prescriptions
- 13:39-7.8 Transfer of prescriptions between pharmacies
- 13:39-7.9 Filing and storage of controlled substance prescriptions
- 13:39-7.10 Prescriptions transmitted by facsimile
- 13:39-7.11 Electronically transmitted prescriptions
- 13:39-7.12 Labeling
- 13:39-7.13 Professional judgment in dispensing drugs
- 13:39-7.14 Advertising and sale of prescription drugs
- 13:39-7.15 Restriction on sale of Schedule V over-the-counter controlled substances
- 13:39-7.16 Return of prescription medication
- 13:39-7.17 Disposal of unwanted drugs
- 13:39-7.18 Outdated drugs or drugs marked "sample"
- 13:39-7.19 Patient profile record system

SUBCHAPTER 8. PHARMACY TRAINING SITES

- 13:39-8.1 Definitions
- 13:39-8.2 Preceptor application procedures; responsibilities
- 13:39-8.3 Pharmacy training site requirements
- 13:39-8.4 Internship and externship practical experience
- 13:39-8.5 Change in intern status
- 13:39-8.6 through 13:39-8.7 (Reserved)

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

- 13:39-9.1 Purpose and scope
- 13:39-9.2 Definitions
- 13:39-9.3 Licensure of institutional pharmacies
- 13:39-9.4 Contract pharmaceutical services; institutional permit required
- 13:39-9.5 Advisory committees
- 13:39-9.6 Pharmacy and Therapeutics Committee; applicability; policies and procedures
- 13:39-9.7 Institutional pharmacy staff
- 13:39-9.8 Control of health care pharmaceutical services; responsibilities of the registered pharmacist-in-charge of the provider pharmacy
- 13:39-9.9 Pharmaceutical services
- 13:39-9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances
- 13:39-9.11 Drug disbursement; written orders; outpatient prescriptions
- 13:39-9.12 Drug disbursement; oral orders
- 13:39-9.13 Monitoring of patient drug therapy
- 13:39-9.14 Medication not dispensed in finished form
- 13:39-9.15 Drug labeling
- 13:39-9.16 Use of patient's own medication
- 13:39-9.17 Drug-dispensing devices
- 13:39-9.18 Disposal of unused medications
- 13:39-9.19 Records and reports
- 13:39-9.20 Drug information and education
- 13:39-9.21 After hours access to the institutional pharmacy
- 13:39-9.22 Pharmacy facilities; space
- 13:39-9.23 Storage and security
- 13:39-9.24 Equipment
- 13:39-9.25 Institutional decentralized pharmacies
- 13:39-9.26 Valid medication orders; out-of-State medication orders
- 13:39-9.27 Prescriptions and medication orders transmitted by technological devices in an institution

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

- 13:39-10.1 Purpose and scope

- 13:39-10.2 "Automated medication system" definition
- 13:39-10.3 Authority to use automated medication system
- 13:39-10.4 Written policies and procedures of operation
- 13:39-10.5 Personnel training requirements
- 13:39-10.6 Written program for quality assurance
- 13:39-10.7 Written plan for recovery
- 13:39-10.8 Written program for preventative maintenance of automated medication system

SUBCHAPTER 11. COMPOUNDING IN RETAIL AND INSTITUTIONAL PHARMACIES FOR STERILE AND/OR NON-STERILE PREPARATIONS

- 13:39-11.1 Purpose and scope
- 13:39-11.2 Definitions
- 13:39-11.3 Sterile and non-sterile preparation services; environment
- 13:39-11.4 General requirement for compounded sterile preparations; pre-approval
- 13:39-11.5 Pharmacist in charge and permitholders' responsibilities
- 13:39-11.6 Pharmacy technicians, interns and externs; required supervision
- 13:39-11.7 Training requirements for compounding sterile preparations
- 13:39-11.8 Batch preparation
- 13:39-11.9 Documentation
- 13:39-11.10 Information required to appear on prescription label
- 13:39-11.11 Use by date of sterile preparation
- 13:39-11.12 Handling, packaging and delivery
- 13:39-11.13 Policy and procedure manual for compounded sterile preparations
- 13:39-11.14 Quality assurance program for compounded sterile preparations
- 13:39-11.15 Patient profile records for compounded sterile preparations
- 13:39-11.16 Controlled environment for compounded sterile preparations: use, access, location; temperature
- 13:39-11.17 Controlled environment for compounded sterile preparations: construction
- 13:39-11.18 Controlled environment for compounded sterile preparations: stocking, maintenance and supplies
- 13:39-11.19 Controlled environment for compounded sterile preparations: clean room
- 13:39-11.20 Controlled environment for compounded sterile preparations: anteroom
- 13:39-11.21 Vertical air laminar flow hoods for compounded sterile preparations
- 13:39-11.22 Laminar air flow hoods not in a clean room for compounded sterile preparations
- 13:39-11.23 Controlled environment for compounded sterile preparations: self-contained sterile glove boxes
- 13:39-11.24 Library references
- 13:39-11.25 Disposal of drugs and materials
- 13:39-11.26 Security
- 13:39-11.27 (Reserved)

SUBCHAPTER 12. NUCLEAR PHARMACIES

- 13:39-12.1 Definitions
- 13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service
- 13:39-12.3 General requirements for a nuclear pharmacist
- 13:39-12.4 Minimum requirements for space, equipment, supplies, and library
- 13:39-12.5 Quality control

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, 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".

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

"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.

"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.

"Immediate personal supervision" means that the registered 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.

"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 assistant, 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.

"Pharmacy technician" means an individual employed by a pharmacy whose responsibilities do not require professional judgment in the preparation and distribution of medications and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.6. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

“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.

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”.

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 (To be determined by future rulemaking)
- 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.
- 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 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.

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.

Amended by R.2003 d.130, effective March 17, 2003.
See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

In (a)xii, added “or course” and substituted “sponsor” for “provider”.

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.

13:39-1.4 Payment of penalties

(a) Any penalties levied by the Board shall be paid within 10 calendar days of the finalization 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 may result in action by the Board according to the provisions of N.J.S.A. 45:1-24.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-1.5 Opportunity to be heard

(a) Any time the Board seeks to impose a disciplinary sanction upon a licensee, the licensee may request an opportunity to be heard by the Board.

(b) When demonstrated facts are in dispute, a hearing 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.

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.

SUBCHAPTER 2. LICENSURE REQUIREMENTS

13:39-2.1 Examinations; score

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

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. 13:39-7.11 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-5.12 Restriction on storage of prescription legend drugs and controlled dangerous substances

Prescription legend drugs, devices and controlled dangerous substances shall not be stored in the pharmacy in such a manner that they can be accessible to the public.

Recodified from N.J.A.C. 13:39-6.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Substituted "stored" for "displayed" following "shall not be" and substituted "pharmacy" for "licensed establishment" preceding "in such a manner".

SUBCHAPTER 6. REGISTERED PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.1 Purpose and scope

The rules in this subchapter shall apply to all pharmacies and pharmacy departments in the State. For purposes of this subchapter, "pharmacy" means a retail pharmacy or a retail pharmacy department, an institutional pharmacy or a nuclear pharmacy.

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. 13:39-6.1, Professional judgment in dispensing drugs, recodified to N.J.A.C. 13:39-7.13.

13:39-6.2 Registered pharmacist-in-charge

(a) Every pharmacy shall name a pharmacist licensed and in good standing in New Jersey as the registered pharmacist-in-charge of the pharmacy. No pharmacy shall operate without a registered pharmacist-in-charge for longer than 30 days.

(b) Whenever the registered pharmacist-in-charge is absent from the pharmacy for more than 30 days, the registered pharmacist-in-charge and the permit holder shall notify the Board of the name of the registered pharmacist who shall act as the interim registered pharmacist-in-charge.

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

(d) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65-5.4 and 5.5.

(e) Whenever a registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a

pharmacy or other Board-licensed establishment, the registered pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(f) A registered pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1. Adequate staffing is present to fulfill the needs of the pharmacy or pharmacy department;
2. Accurate records of all prescription medication received and dispensed are maintained;
3. Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed;
4. Security of the prescription area and its contents are maintained at all times, including 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 and the reporting of any thefts and/or diversions of controlled substances are reported upon discovery to the Office of Drug Control and the Drug Enforcement Administration pursuant to Federal and State requirements, consistent with the requirements of N.J.A.C. 8:65-2.5(d);
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 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 pharmacists-in-charge for references to pharmacists-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. 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.

13:39-6.3 Identification tag

All personnel working in the pharmacy shall wear an identification tag which shall include at least the person's first name and job title.

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.

13:39-6.4 Meal breaks

(a) A sole pharmacist on duty may take a 30-minute meal break 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 meal break 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 pharmacy stating "Pharmacist on meal 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.

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

A pharmacy intern, extern or technician may prepare or compound prescriptions only under the immediate personal supervision of a registered pharmacist of this State. The registered pharmacist shall be personally responsible for the accuracy and appropriateness of the filled prescription.

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.

13:39-6.6 Pharmacy technicians

(a) Pharmacy technicians may assist the registered 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; and

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.

(b) Pharmacy technicians may accept authorization from a patient for a prescription refill, or from a physician or his or her agent for a prescription renewal, provided that the prescription remains unchanged. For purposes of this section, "prescription refill" means the dispensing of medications pursuant to a prescriber'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.

(c) Pharmacy technicians 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.

(d) Except as provided in (e) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio.

(e) A pharmacy that wishes to employ a registered 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 technician;

2. Ensure and document that each pharmacy technician passes the National Pharmacy Technician Certification Examination and fulfills the requirements to maintain this status, or completes a program which includes a testing component and which has been approved by the Board as satisfying the criteria set forth in (f) below;

3. Ensure that each pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policies and procedures in the pharmacy setting in which the technician is to perform his or her 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 (c) above.

5. Ensure that each pharmacy technician receives in-service training before the pharmacy technician assumes his or her responsibilities and maintain documentation thereof;

6. Require and maintain on site a signed patient confidentiality statement from each technician;

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

8. 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 (c) 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) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all pharmacy technicians which it currently employs.

(i) When pharmacy technicians are engaged in any permitted activities, the registered pharmacist(s) shall be responsible for all the activities of the pharmacy technicians.

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 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.

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.1 Valid prescriptions; out-of-State prescriptions

(a) A pharmacist shall only fill a written prescription issued in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14-14.4 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 only fill a prescription issued by an authorized prescriber licensed to write prescriptions in the United States or any territory of the United States. Such prescriptions orders shall be filled pursuant to New Jersey law.

(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.

13:39-7.2 Lack of directions on original prescription

If the prescriber fails to include on the original prescription directions to the patient for use of the medication, the registered pharmacist shall make a documented attempt to contact the prescriber to obtain such directions. In cases where the prescriber cannot be contacted, the registered pharmacist shall indicate on the label the words "use as directed" or "as ordered by the physician" or similar words to the same effect.

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.

13:39-7.3 Authorization for renewal of 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 prescriber, and the prescription may not be refilled after one year from the date of original prescription.

1. Prescriptions marked "PRN" or other letters or words meaning refill as needed shall not be renewed beyond one year past the date of original prescription.

(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 prescriber as provided in N.J.S.A. 45:14-14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

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.

13:39-7.4 Emergency dispensing

(a) 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 (except controlled dangerous substances) 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 licensed practitioner; and

2. The pharmacist documents the communication and requires the patient or caregiver to provide suitable identification and sign a statement attesting to the need before dispensing.

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.

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 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, 45 C.F.R. Part 46, Protection of Human Subjects of Research; incorporated by reference herein, as amended and supplemented.

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.

13:39-7.6 Record of pharmacist filling prescription

(a) A registered pharmacist who fills or compounds a prescription or who supervises the filling or compounding of a prescription by an intern, extern, or pharmacy technician shall place his or her signature or readily identifiable initials or other personal identifier on the original prescription or in the electronic data processing system.

(b) A registered pharmacist who refills a prescription shall place his or her signature or readily identifiable initials or other personal identifier on the reverse side of the original prescription or in the electronic data processing system. Each time a prescription is refilled, the date of the refill and the amount dispensed shall also be recorded on the original prescription or in the electronic data processing system.

(c) Initials and/or access code number(s) of the pharmacist responsible for the filled prescription shall be entered into the system each time a prescription is filled or refilled. Computer programs which automatically generate a pharmacist's initials without requiring a direct entry by the pharmacist responsible for the filled prescription at the time of dispensing are prohibited.

(d) Appropriate documentation identifying handwritten initials with the handwritten signature and printed name of the pharmacist shall be maintained by the pharmacy for a period of six years after the last date of employment.

(e) All prescription records, including original and refilled prescription data, and the number of refills authorized by the prescriber 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 immediately retrievable and readable.

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.

13:39-7.7 Copies of prescriptions

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions. 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 labeled prescription container or a prescription marked "COPY—FOR INFORMATION ONLY" 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.

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, consis-

tent with this section, one time only, pursuant to N.J.A.C. 8:65-7.14(h) and 7.18(d).

(e) A prescription may be transferred electronically by pharmacists between pharmacies for the purpose of refill dispensing consistent with the requirements in N.J.A.C. 13:39-7.11.

(f) A prescription may be transferred by telephone between pharmacies for the purpose of refill dispensing provided that:

1. The sending pharmacy invalidates the prescription on file as of the date the prescription is transferred and records on the back of the invalidated prescription order or in the electronic system the following:

i. That the prescription has been transferred and the date of transfer;

ii. The name of the pharmacy to which the prescription was transferred;

iii. The name or personal identifier of the pharmacist, intern or extern to whom the prescription was transferred; and

iv. The initials or personal identifier of the pharmacist, intern, or extern issuing the transferred prescription order;

2. The receiving pharmacy, upon receiving such prescription directly from another pharmacy, records the following:

i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;

ii. The name or personal identifier of the sending pharmacist, intern or extern ;

iii. All information constituting a prescription order, as well as the following:

(1) Date of issuance of original prescription;

(2) Date of original dispensing;

(3) Original number of refills authorized on original prescription;

(4) Complete refill record from original prescription;

(5) Number of valid refills remaining; and

3. The receiving pharmacist, intern, extern or technician informs the patient or caregiver that the original prescription has been cancelled at the sending pharmacy.

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. 13:39-7.8, Cleanliness, orderliness and sanitation, recodified to N.J.A.C. 13:39-5.9.

13:39-7.9 Filing and storage of controlled substance prescriptions

(a) Prescriptions for all controlled substances listed in Schedule II shall be maintained in a separate prescription file.

(b) Prescriptions for all controlled substances listed in Schedules III, IV and V shall be maintained in a separate prescription file for such controlled substances only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in schedule II or in the usual consecutively numbered prescription file for non-controlled substances.

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. 13:39-7.9, Television in prescription area prohibited, recodified to N.J.A.C. 13:39-5.10.

13:39-7.10 Prescriptions transmitted by facsimile

(a) A pharmacist may accept for dispensing a facsimile prescription, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription which is transmitted by a device which sends an exact image to the receiver.

(b) A pharmacist shall not fill a facsimile prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-14, or the prescribing practitioner's authorized agent.

(c) The facsimile machine used to receive prescriptions shall be located within the pharmacy prescription area.

(d) A facsimile prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-7.2(d), except that an NJPB shall not be required for the prescription.

(e) The facsimile transmission of the prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription;
2. The date and time of the prescription transmission;
3. The name, address, telephone number and facsimile number of the pharmacy; and
4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(f) A pharmacist shall seek verbal verification of a facsimile prescription from the prescribing practitioner whenever the pharmacist has reason to question the authenticity, accuracy or appropriateness of the prescription. A pharmacist may accept verbal verification regarding the authenticity or legibility of a facsimile prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill a facsimile prescription where there is a question regarding authenticity, accuracy or appropriateness if such verification is not provided.

(g) A pharmacist shall retain a printed copy of a facsimile prescription, or an electronic reproduction of the facsimile prescription that is readily retrievable and printable, for a minimum of five years pursuant to N.J.S.A. 45:14-15. The printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (h)1, 2 and 3 below.

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted by facsimile consistent with the requirements of this section. The facsimile prescription shall serve as the original written prescription.

(j) A pharmacist shall not enter into any agreement with a prescribing practitioner that requires that facsimile prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

New Rule, R.2003 d.373, effective September 15, 2003.

See: 34 N.J.R. 3064(a), 35 N.J.R. 4290(a).

Administrative correction.

Sec: 35 N.J.R. 4724(a).

Recodified from N.J.A.C. 13:39-5.8A by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).